

**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
April 10-11, 2014
Atlanta, Georgia**

Meeting Summary Report

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Meeting Agenda

Healthcare Infection Control Practices Advisory Committee

April 10-11, 2014

Centers for Disease Control and Prevention

Tom Harkin Global Communications Center (Building 19, Auditorium B3)

1600 Clifton Road NE, Atlanta, GA

Thursday, April 10, 2014

Time	Topic	Purpose	Presider/Presenter
9:00	Welcome and Introductions	Information	Neil Fishman (HICPAC Chair) Jeff Hageman (CDC)
9:15	DHQP Healthcare-Associated Infection Updates	Information	Denise Cardo (CDC) Michael Bell (CDC)
9:45	Draft Guideline for Prevention of Surgical Site Infections: Status, summary of comments and next steps	Information	Jeff Hageman (CDC)
10:15	Draft SSI Guideline: Options for addressing "no recommendations"	Information Discussion	Mary Hayden (HICPAC)
11:00	Break		
11:20	Draft SSI Guideline: Reviewing the 1999 recommendations	Information Discussion	Jeff Hageman (CDC)
12:15	Lunch		
1:30	Draft SSI Guideline: Review of content-specific issues and proposed actions	Information Discussion	Sandra Berrios-Torres (CDC) TBD
3:15	Break		
3:35	Draft Healthcare Personnel Guideline for Infection Prevention: Section I Baseline Structure and Routine Practices	Information Discussion	David Kuhar (DHQP)
4:30	Public Comment		
4:45	Liaison/ <i>Ex officio</i> reports		
5:00	Adjourn		

Friday, April 11, 2014

Time	Topic	Purpose	Presider/Presenter
9:00	NHSN Update	Information Discussion	Dawn Sievert (CDC)
9:30	HICPAC Recommendations for Core Infection Prevention and Control Practices	Information Discussion	Gina Pugliese (HICPAC)
10:30	Break		
10:45	HICPAC Recommendations for Core Infection Prevention and Control Practices (cont.)	Information Discussion	Gina Pugliese (HICPAC)
11:15	Draft SSI Guideline: Day 1 follow-up and next steps	Information Discussion	TBD
11:30	Public Comment		
11:45	Summary and Wrap-Up		

List of Participants

Day 1: Thursday, April 10, 2014

HICPAC MEMBERS

Dr. Neil Fishman, Chair
Dr. Hilary Babcock
Ms. Ruth Carrico
Dr. Sheri Chernetsky Tejedor
Dr. Daniel Diekema
Dr. Mary Hayden

Ms. Lynn Janssen
Ms. Gina Pugliese
Dr. Selwyn Rogers
Dr. Tom Talbot
Dr. Michael Tapper
Dr. Deborah Yokoe

DESIGNATED FEDERAL OFFICIAL

Mr. Jeffrey Hageman, Deputy Chief, Prevention and Response Branch, DHQP

EX OFFICIO MEMBERS

Dr. William B. Baine, Agency for Healthcare Research
and Quality
Dr. David Henderson, National Institutes of Health

Dr. Stephen Kralovic, US Department of Veterans
Affairs
Dr. Daniel Schwartz, Centers for Medicare and
Medicaid Services

LIAISON MEMBERS

Ms. Kathleen Dunn, Public Health Agency of Canada
Ms. Janet Franck, DNV Healthcare
Dr. Michael Howell, Society of Critical Care Medicine
Ms. Jennifer Sears, National Association of County
and City Health Officials
Dr. Emily Lutterloh, Association of State and
Territorial Health Officials
Ms. Lisa McGiffert, Consumers Union
Dr. Silvia Munoz-Price, America's Essential Hospitals
Ms. Michael Anne Preas, Association of Professionals
of Infection Control and Epidemiology, Inc.

Dr. Mark Rupp, Society for Healthcare Epidemiology
of America
Dr. Mark Russi, American College of Occupational
and Environmental Medicine
Dr. Sanjay Saint, Society of Hospital Medicine
Dr. Robert Sawyer, Surgical Infection Society
Ms. Rachel Stricof, Council of State and Territorial
Epidemiologists
Ms. Margaret VanAmringe, the Joint Commission
Ms. Amber Wood, Association of periOperative
Registered Nurses

CDC REPRESENTATIVES

Ms. Kathy Allen-Bridson, CDC/DHQP
Dr. Matt Arduino, CDC/DHQP
Dr. Beth Bell, CDC/NCEZID
Dr. Michael Bell, CDC/DHQP
Dr. Sandra Berrios-Torres, CDC/DHQP
Dr. Denise Cardo, CDC/ DHQP
Dr. Nora Chea, CDC/DHQP
Dr. Ryan Fagan, CDC/DHQP
Dr. Carolyn Gould, DHQP/CDC
Dr. Rita Helfand, CDC/NCEZID
Ms. Liz Hoo CDC/OD/PPEO
Dr. Kara Jacobs Slifka, CDC/NCEZID/DFWED
Dr. Alison Laufer, CDC/DHQP

Mr. Paul Malpiedi, CDC/DHQP
Dr. Duc Nguyen, CDC/DHQP
Ms. Lyn Nguyen, CDC, NCEQID/ OD
Ms. Amanda Overholt, CDC/DHQP
Dr. Loria Pollack, DHQP/CDC
Dr. Melissa Schaefer, CD/DHQP
Dr. Issac See, CDC/DHQP
Mr. Jason Snow, DHQP/CDC
Ms. Erin Stone, CDC/DHQP
Dr. Nimalie Stone, CDC/DHQP
Ms. Monica Torres, CDC/DHQP
Ms. Michelle Wilson, CDC/ OCFO/ALFO

HHS REPRESENTATIVES

Dr. Dale Hu, OASH/HHS

Mr. Daniel Gallardo, OS/OASH/ HHS

MEMBERS OF THE PUBLIC

Ms. Kay Argroves, American Association of Nurse Anesthetists
Mr. Steve Brash, Self
Dr. Dale Bratzler, University of Oklahoma
Mr. Russ Castioni, 3M
Mr. Jan Creidenberg, CareFusion
Ms. Megan DiGiorgio, Gojo
Ms. Stephanie Dominguez, Applied Medical
Ms. Pam Falk, Piedmont Health
Mr. Hudson Garrett, PDI
Mr. Peter Graves, Irrisept
Mr. Husher Harris II, Avaris
Dr. Jeffrey Hammond, Ethicon
Ms. Lori Harmon, Society of Critical Care Medicine
Ms. Eve Humphreys, Society of Healthcare Epidemiologists of America

Ms. Danielle Hunt, Abt Associates
Ms. Nancy Klinger, 3M
Ms. Rachel Long, CareFusion
Mr. Robert Mahler, Ansell Healthcare
Mr. Renee Odehnal, Ethicon
Dr. Joseph Solomkin, University of Cincinnati
Ms. Michelle Stevens, 3M
Ms. Lisa Tomlinson, Association of Professionals of Infection Control and Epidemiology, Inc.
Ms. Carolyn Twomey, Irrimax
Dr. Chantay Walker, Ethicon
Mr. Thomas Weaver, Association of Professionals of Infection Control and Epidemiology, Inc.
Ms. Cindy Winfrey, PDI
Mr. Hugo Xi, CareFusion

Day 2: Friday, April 11, 2014

HICPAC MEMBERS

Dr. Neil Fishman, Chair
Dr. Hilary Babcock
Ms. Ruth Carrico
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Dr. Daniel Diekema
Dr. Mary Hayden

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Dr. Stephen Kralovic, Veterans Administration
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Dr. Emily Lutterloh, Association of State and Territorial Health Officials
Ms. Lisa McGiffert, Consumers Union
Dr. Silvia Munoz-Price, National Association of Public Hospitals and Health Systems
Ms. Michael Anne Preas, Association of Professionals of Infection Control and Epidemiology, Inc.

Dr. Mark Rupp, Society for Healthcare Epidemiology of America
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Ms. Amber Wood, Association of periOperative Registered Nurses

CDC REPRESENTATIVES

Dr. Michael Bell, CDC/DHQP
Dr. Denise Cardo, CDC/ DHQP
Dr. Scott Fridkin, CDC/DHQP
Mr. Jeremy Goodman, CDC/DHQP
Dr. Rita Helfand, CDC/NCEZID
Dr. L. Clifford McDonald, CDC/NCEZID

Ms. Amanda Overholt, CDC/DHQP
Dr. Issac See, CDC/DHQP
Dr. Melissa Schaefer, CD/DHQP
Ms. Elizabeth Skillen, CDC/DHQP
Ms. Erin Stone, CDC/DHQP
Dr. Nimalie Stone, CDC/DHQP

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Dr. Chantay Walker, Ethicon
Mr. Thomas Weaver, Association of Professionals of
Infection Control and Epidemiology, Inc.
Ms. Cindy Winfrey, PDI
Mr. Hugo Xi, CareFusion

Executive Summary

Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), the Centers for Disease Control and Prevention (CDC), and The Department of Health and Human Services (HHS) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on April 10-11, 2014 in Atlanta, Georgia. The Designated Federal Official (DFO) and Chair confirmed the presence of a quorum with voting members and *ex officio* members for HICPAC on both days of the meeting. HICPAC voting members disclosed their conflicts of interest for the public record on both days.

CDC presented updates on healthcare-associated infection (HAI) efforts within DHQP.

Much of the first day of the meeting was devoted to information and discussion related to the Draft Guideline for Prevention of Surgical Site Infections (SSI). CDC described the status of the draft, a summary of public comments received to date, and a review of the 1999 recommendations. HICPAC presented the workgroup's conclusions regarding options for addressing the "no recommendations" elements in the guideline. SSI Guideline authors presented HICPAC with a review of issues related to antimicrobial prophylaxis (AMP) raised by public comment and proposed actions to respond to them. SSI Guideline content-specific comments, clarifications, and proposed actions were also presented. Updates to the guideline literature reviews will be conducted. HICPAC discussion primarily focused on how to address the "no recommendation" elements and some of the elements included in the 1999 Guideline that were not carried forward in the update. An easily-revised, "living" table will be created and organized by category to include all of the questions in the guideline.

CDC also presented information on the Draft Healthcare Personnel Guideline for Infection Prevention, particularly on the first section, which serves as a general introduction. HICPAC indicated that the section will be useful for a range of healthcare personnel. Discussion also addressed additional topics to include in the document.

HICPAC stood adjourned from 5:10 pm on April 10 until 9:09 am on April 11.

CDC presented HICPAC with a high-level overview of proposed updates to NHSN, the timing of the releases, and additions and enhancements in them. Updates on proposed definitions, particularly CAUTI and CLABSI, will be provided during the next HICPAC meeting.

HICPAC presented an update on the workgroup recommendations for Core Infection Prevention and Control Practices. The workgroup will refine the recommendations based on the committee's input and present a final version for HICPAC approval.

HICPAC stood in recess at 11:34 am on April 11, 2014.

Department Of Health and Human Services

Centers for Disease Control and Prevention

National Center for Preparedness, Detection, and
Control of Infectious Diseases
Division of Healthcare Quality Promotion
Healthcare Infection Control Practices Advisory Committee
April 10-11, 2014
Atlanta, Georgia

Meeting Summary Report

The 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 April 10 and 11, 2014, at the Tom Harkin Global Communication Center (Building 19), Centers for Disease Control and Prevention, 1600 Clifton Road NE, Atlanta, Georgia.

Thursday, April 10, 2014

Welcome and Introductions

Jeffrey Hageman, MHS
Deputy Chief, Prevention and Response Branch, DHQP, NCEZID
Centers for Disease Control and Prevention
HICPAC Designated Federal Official

Neil Fishman, MD
HICPAC Chair

Mr. Jeff Hageman, HICPAC Designated Federal Official (DFO), called the meeting of HICPAC to order at 9:09 am. He welcomed three new HICPAC members: Ms. Lynn Janssen, Dr. Sheri Chernetsky Tejedor, and Dr. Hilary Babcock. One new member, Dr. Charlie Huskins, was unable to attend the meeting. Mr. Hageman asked HICPAC members to introduce themselves and disclose any conflicts of interest.

- Dr. Mary Hayden has conducted unfunded research for Sage Incorporated, which is providing product at no charge for facilities for a study with which she has been involved. She has been involved in a research project for which PDI, Inc. has provided product.
- Dr. Tom Talbot's spouse has received research funding from Sanofi Pasteur, MedImmune, and AstraZeneca for *Clostridium difficile* (*C. difficile*) vaccine and influenza vaccine research.

- Dr. Dan Diekema has received research funding from Pfizer and Forest Laboratories for antimicrobial resistance (AMR) surveillance. He has also received funding from bioMérieux, which produces diagnostic devices.
- Ms. Ruth Carrico has contributed to the development of education and a survey of practice sponsored by Abbott Diabetes Care focusing on practices involving blood glucose monitoring. She works with MedScape to develop content for healthcare providers regarding adult immunization improvement strategies.

Mr. Hageman confirmed that a quorum was present. Dr. Neil Fishman welcomed HICPAC voting members, new members, and liaisons.

DHQP Healthcare-Associated Infection Updates

Denise Cardo, MD

Director, DHQP, NCEZID

Centers for Disease Control and Prevention

CDC uses data from the National Healthcare Safety Network (NHSN) to move the field of healthcare-associated infection (HAI) prevention forward. DHQP uses NHSN data to monitor national progress of the HHS Action Plan. State reports are being generated. The next step is to create facility-level reports.

The Targeted Assessment for Prevention (TAP) reports focus not only on the Standardized Infection Ratio (SIR), but also on excess numbers of infections and other concerns, such as the types of units in a facility, device utilization ratios, and types of pathogens. This information is shared with Quality Improvement (QI) organizations, Hospital Engagement Networks (HENs), health departments, and the Agency for Healthcare Research and Quality's (AHRQ) Comprehensive Unit-based Safety Program (CUSP).

TAP reports promote prevention and help facilities fuel their prevention efforts. For example, the data may point to facilities that do not engage in sufficient prevention regarding catheter-associated urinary tract infections (CAUTI). The data collected regarding adherence to CAUTI prevention recommendations has helped DHQP formulate ways to better promote prevention. The NHSN data also indicate barriers to prevention so DHQP can determine whether the HICPAC-recommended interventions will work.

Over 4700 hospitals report CAUTI data. Based on the data, DHQP inferred that approximately 1000 of those hospitals would likely benefit from additional technical guidance and assistance. DHQP can link these hospitals with other groups that have CAUTI-related initiatives. Connections can be made between hospitals and groups for other types of infections, focusing on implementing proven strategies and using the NHSN data to assess whether those strategies are working.

The division published the *CDC Antibiotic Resistance (AR) Threat Report* in October 2013. The report included estimates of the burden of AR in the US. The report not only illuminates the problem of AR, but also provides guidance regarding potential strategies for moving forward. These strategies include detecting and tracking patterns of antibiotic resistance and use; responding to outbreaks involving antibiotic-resistant bacteria;

preventing infections from occurring and resistant bacteria from spreading within and across facilities; and discovering new antibiotics and new diagnostic tests for resistant bacteria.

The March 2014 *Vital Signs* focused on “Making Health Care Safer” and described key elements to promoting stewardship programs in all hospitals in the US. The elements were based on feedback gathered at HICPAC’s last meeting. The CDC Director requested a budget initiative of \$30 million for fiscal year (FY) 2015. The budget was included in the President’s proposed budget for 2015, which has not yet been approved. The initiative will address the following seven antibiotic-resistant threats: *C. difficile*, Carbapenem-Resistant Enterobacteriaceae (CRE), Multidrug-resistant (MDR) *Neisseria (N.) gonorrhoeae*, Extended-Spectrum Beta-Lactamase (ESBL), MDR *Salmonella*, Methicillin-resistant *Staphylococcus aureus* (MRSA), and MDR *Pseudomonas*.

The proposed activities in the initiative are to speed up and expand the “detect and protect” process through a group of five regional laboratories; promote regional collaborations between healthcare settings in communities to focus particularly on *C. difficile*, CRE, and other MDR pathogens; and implement stewardship programs in all hospitals. The goals of this initiative are more aggressive than the goals in the HHS Action Plan. These aggressive goals demonstrate how additional investment for implementation and tracking of the AR problem will lead to better prevention. The concept of this approach is rooted in experiences in the United Kingdom (UK), where stewardship was a critical element of prevention.

Michael Bell, MD
Deputy Director, DHQP, NCEZID
Centers for Disease Control and Prevention

CDC is making a major investment in advanced molecular detection and learning how these tools refine understanding of transmission, pathogenesis, and reservoirs for pathogens of interest. Of particular interest is “the human gut” for which 90% of the organisms have not been characterized and do not grow easily, but are likely to be very important. CDC has a new window into understanding the dynamics of that reservoir and how it responds to antimicrobials. CDC is also focusing on unintended consequences of the technology shift in advanced molecular detection. The new tools are exciting, but the agency needs to understand what will happen when culture-based diagnoses wane and tools that have been relied upon for surveillance are no longer available.

HICPAC Discussion:

The TAP reports are in a pilot phase and are not currently available to the public. Participating facilities sign informed consent forms that stipulate which groups have access to the information. DHQP hopes to include TAP reports in NHSN on a continuing basis. HICPAC encouraged CDC to make the TAP reports publicly available, which will spur changes and improvements in hospitals that are “falling behind.” Facilities may find it helpful to “drill down” to a more comparable comparison pool. For example, the TAP report could stratify information by categories such as “large hospital,” or “teaching hospital,” to allow for peer-level comparisons.

Draft Guideline for Prevention of SSI: Status, Summary of Public Comments, Next Steps

Jeffrey Hageman, MHS

Deputy Chief, Prevention and Response Branch, DHQP, NCEZID
HICPAC Designated Federal Official
Centers for Disease Control and Prevention

The Society for Healthcare Epidemiology of America (SHEA) is publishing a White Paper on the evolving landscape of HAIs in *Infection Control and Hospital Epidemiology (ICHE)*, focusing on areas for research and prevention. A number of recent changes in surveillance, reporting, and methodologies represent important opportunities to drive quality and to consider the impacts that guidelines and recommendations are having on infections. Prevention is progressing quickly, with a number of new technologies for detection and prevention and advances in the implementation of recommendations. Significant challenges remain regarding how to implement and maintain adherence to core practices.

The SHEA paper also addresses opportunities for research. Advances in study design have implications for the hierarchy of evidence that is considered in guideline development. The evidence base in infection control is immense and growing rapidly. Different stakeholders are becoming more involved in infection prevention as evidenced by the growth and diversity of viewpoints represented on HICPAC. Guidelines are needed in new settings where healthcare is delivered.

CDC has a long history of producing guidelines in many areas. There was no peer-reviewed evidence upon which to base recommendations when the first set of guidelines was published in 1975. These guidelines were a narrative of expert opinion augmented by helpful and practical information. With increasing focus on quality and surveillance today, there is additional scrutiny of guidelines and the development process. In 2011, the Institute of Medicine (IOM) released “Clinical Practice Guidelines We Can Trust,” a report on standards and clinical practice guidelines. The report includes eight key evolving standards for guidelines. The *Journal of the American Medical Association (JAMA)* noted recently that AHRQ is adopting the new IOM standards for inclusion and increasing the requirements for what they will recognize as a valuable clinical practice guideline with an emphasis on increasing rigor and transparency. The IOM report also focuses on disclosing competing interests and what they might constitute. *JAMA* also highlights that guidelines do not just drive individual- or facility-level practice, but they are being used more broadly, informing regulations or establishing standards of care. The chair of the IOM committee is exploring creating a guideline rating system, which will help users identify which guidelines are trustworthy and can be adopted broadly.

Challenges are associated with every set of guidelines. Methods are particularly challenging in infection control as more information becomes available from better-designed studies, and as more research is conducted. The absence of evidence can be challenging in creating considerations and guidance to help facilities make decisions. There are limitations to the ability to generate high-quality evidence, particularly in infection control in which many interventions are bundled together. Other challenges are associated with the inability to conduct certain studies for ethical or logistical issues. It is difficult to conduct appropriately-powered studies in rare diseases. The rapidly-evolving evidence base presents challenges to updating guidelines. Operational and resource challenges are considerable. As the audiences for the guidelines expand, it is challenging to suit the needs of each group. Some groups expect traditional, “textbook” guidance, while other groups have different expectations. It is important to balance the expectations and to refer to other tools, such as SHEA’s *Compendium of Strategies to Prevent HAIs in Acute Care Hospitals* that can help end users guide their practices. It is important to balance the need for a trustworthy, rigorous process and for creating actionable, practical guidance.

CDC and HICPAC have opportunities to work with partners to lead the field of infection control. Few tools and resources are available for the evolution of the guideline development process, and other groups and organizations share the struggle to find a meaningful, reproducible, transparent way to look at a wide range of evidence. It is a challenge to adapt the available tools to the field of infection control. It is important to harmonize methods so that different groups can share the burden of systematic reviews.

Some areas of methodological development include:

- Developing and refining existing study quality assessment tools which systematically and transparently appraise the literature to determine whether a study is valuable and can lead to recommendations.
- Exploring modifications to the classical evidence hierarchy. Options other than the current grading system may be more appropriate to embrace the kinds of studies that are conducted in infection control.
- Expanding guideline methods to more fully assess harms and benefits, looking not only at evidence quality, but also harm-benefit assessment.
- Guidelines should be usable for different audiences. Several groups are focusing on incorporating clinical practice guidelines into clinical decision support software, for instance. The recommendations should be expressed clearly, avoiding jargon.

Fifty-three commenters provided feedback during the SSI Draft Guideline public comment period. Many of the comments shaped HICPAC's agenda for this meeting. The comments are available online: <http://www.regulations.gov/#!docketDetail;D=CDC-2014-0003>. The public comment phase will close on May 8, 2014. Thirty days for public comment is a standard timeframe, but it can take longer to obtain input for these guidelines given the number of stakeholders and the size of many contributing organizations. Therefore, the public comment period for the SSI Draft Guideline was extended for 30 days beyond the initial period. Input from the HICPAC liaison members during the guideline development process would be helpful to ensure that for future guideline development, public comment periods are of sufficient length to ensure optimal input.

Draft SSI Guideline Public Comments Summary

Public Comments: Methods

- The SSI guidelines abbreviated the Methods section and provided links to references. Some elements need further clarification, such as the inclusion/exclusion criteria for the clinical practice guidelines in the SSI Guideline.
- The literature search stopped in 2011, and comments noted literature published after 2011.
- Questions were posed regarding the categorization of evidence and recommendations.
- Study types are limited to RCTs and systematic reviews as opposed to including other, non-randomized issues.

Public Comments: Content-Specific

Content-specific comments included clarifications of the intent of the recommendations, wording suggestions, categorizations, and submission of new articles for consideration. The content areas in the public comments included the following:

- Antimicrobial prophylaxis
- Antimicrobial coated sutures

- Antimicrobial dressings
- Antiseptic skin prep
- Antimicrobial sealant
- Antibiotic irrigation/ointment
- Glycemic control
- Intraoperative irrigation
- Normothermia
- Oxygenation
- Plastic adhesive drape
- Pre-operative bathing

Public Comments: Topics Not Included

Commenters felt that several topics that were not included in the Draft Guideline were important to address. Some of these topics were included in the 1999 Guidelines:

- *Staphylococcus aureus* (*S. aureus*) screening and decolonization
- Pre-operative shaving
- Surgical hand scrub
- AMP (colorectal and bowel prep), choice and dose, multidrug-resistant organisms (MDROs), other
- Patient risk factors: obesity, smoking, diabetes
- Pediatric-specific recommendations
- Pulse irrigation in laparotomy
- Surgical attire (in addition to orthopaedic space suit)
- SSI prevention bundle
- Wound edge protectors
- Antimicrobial impregnated cement and beads in arthroplasties

The Executive Summary of the Draft SSI Guideline specifies that the select areas of focus were informed by feedback from clinical experts and HICPAC. The Core section includes recommendations intended to be generalizable across surgical procedures, and the specific Prosthetic Joint Arthroplasty section focuses on this frequently-performed procedure with a high human and economic burden. The Executive Summary further specifies that the guidelines do not provide guidance on comprehensive infection control recommendations for prevention of SSIs. Certain recommendations in the 1999 Guidelines were not carried over to the new guidelines and/or did not require an update or re-review. The guidelines also do not address issues such as burns, trauma, and practices and procedures. Other guidance documents are available for issues not addressed in guidelines.

HICPAC Discussion

It is important to find ways to share resources and collaborate, especially given that the background work is labor-intensive. Guidelines should be developed with the end user in mind. One of the chief barriers that healthcare organizations experience is that guidelines use imprecise language, so they are not easily implementable. The idea that guidelines will be put into clinical decision support mechanisms is a good “lens” to use upfront in the development process. As additional guidelines are developed, HICPAC liaison organizations can develop and release tools and translational documents to help with the practical challenges of implementation.

Draft SSI Guideline: Options for Addressing “No Recommendations”

Mary Hayden, MD
HICPAC Member

The “No Recommendation” workgroup of HICPAC was formed in response to the large number of questions in the SSI Core and the Prosthetic Joint Infection Prevention Guidelines for which no recommendation could be made. The group was tasked with considering whether additional explanation or clarification is needed for the “no recommendations” conclusions. Some questions cannot be answered, but the group was tasked with suggesting modifications of the guideline development process that might minimize “no recommendation” or “insufficient evidence” conclusions. The workgroup reviewed the Draft SSI Guideline Update, which includes excellent summaries of the rationales for when the conclusion is a “no recommendation.” The information is heavily cited and included in the Evidence Review sections of the guidelines, but there is concern that readers either will not read the Evidence Review or might misinterpret the “no recommendation” category.

The workgroup suggested that the Executive Summary and Summary of Recommendations sections be modified to provide additional information to help readers understand and interpret the “no recommendation” category. They felt it was important not to add new interpretations or references, but rather to excerpt or paraphrase explanatory language from the Evidence Review sections. The workgroup discussed whether to cite other clinical practice guidelines that are already included in the SSI Guidelines. Some “no recommendation” conclusions are more controversial than others, but they all should be addressed in the same manner.

Modifying the Executive Summary & Summary of Recommendations:

Regarding the Executive Summary, the workgroup suggested highlighting key criteria for selection of studies for the evidence review. This information is included in the Methods section, but only RCTs and systematic reviews were included in the SSI Core Guidelines, while all study designs were included in the SSI Prosthetic Joint Prevention Guidelines.

The workgroup suggested adding an interpretation of the “no recommendation” category. The following language was proposed:

“The ‘no recommendation/unresolved issue’ category represents unresolved issues for which there was either (1) low to very-low quality evidence with uncertain tradeoffs between benefits and

harms or (2) no published evidence on an outcome deemed critical to weighing the risks and benefits of a given intervention.

“This categorization does not imply a recommendation against a particular intervention; instead, it indicates an opportunity to identify evidence gaps and future research opportunities. In the interim, healthcare personnel and facilities should continue to follow existing standards of care, if available. Other clinical practice guidelines are noted in this guideline.”

HICPAC Discussion

“No recommendation” is not useful to readers. When a recommendation cannot be made due to lack of evidence, that “no recommendation” may be interpreted as license for users to do as they please. If there is no recommendation and no supporting literature for a question, then an organization might consider the experiences of its team; however, they should avoid a scenario in which each locality operates slightly differently, according to their local experts. For instance, it would be a great service if people in the field knew that 90% of HICPAC administers weight-adjusted doses of antimicrobials.

There was discussion regarding when the guidelines should refer to other products such as SHEA’s *Compendium* and what the guidelines should indicate in terms of expert opinion. The goals of guidelines and of guidance documents such as the *Compendium* are complementary, but different. It is important to have rigorous, evidence-based guidelines and recommendations. At the same time, complementary guidance documents interpret the guideline recommendations and perhaps add expert consensus. Together, those resources provide front-line personnel with practical tools. The societies and groups working on the *Compendium* have latitude to offer recommendations that may not be based on the full strength of evidence required for CDC or HICPAC guidelines. Language should note that the referenced guidelines were created using different standards for the evidence and that HICPAC’s references to other guidelines do not constitute a formal endorsement of them.

CDC Guideline recommendations are often translated into regulations, which is problematic if there is insufficient evidence to support these recommendations. The narrative should be specific regarding what is meant by “low-quality,” “very low-quality,” and “no published evidence.” There may be no published RCTs or meta-analyses, but there could be observational studies. Some of the “no recommendation” questions may not meet the criteria for a Level I or Level II recommendation, but their evidence is better than some of the other “no recommendation” questions. The “no recommendation” classification on some of the core practices may imply that it is acceptable not to do them. Other practices, such as antimicrobial sutures, are classified as “not necessary.” It is important to frame the data for each recommendation. HICPAC agreed with the suggested changes to the Executive Summary, highlighting the key criteria for selection of studies in the evidence review, and adding a disclaimer pertaining to references to other guidelines and guidance documents.

Modifying Summary of Recommendations Sections

The workgroup suggested highlighting the rationale for each “no recommendation.” These generally fall into one of three categories: Lack of evidence, conflicting evidence, and concern for bias in the available studies. The group

also suggested adding explanatory text from the Evidence Review section to the Summary of Recommendation sections, including citations to other clinical practice guidelines that are already cited in the Evidence Review. An alternative approach would be to direct the reader to the Evidence Review section for a discussion of the decision-making process. Adding explanatory text would be advantageous because the information would be available to readers who are only reading the summary; however, the addition would lengthen the section and would be redundant. Further, if the text is only present for the “no recommendation” items, it may seem out-of-place if similar text is not provided for the conclusions for which the Guidelines have a recommendation. The question of whether including other guidelines implies endorsement of them pertains to this issue.

An example of the proposed change is as follows, with the proposed changes in italics:

“Q1A. What is the optimal timing of preoperative AMP?”

“Administer preoperative antimicrobial agent only when indicated, based on published clinical practice guidelines and timed such that a bactericidal concentration of the agent is established in the serum and tissues when the incision is made (Category IB)¹²

*No further refinement of timing can be made for preoperative antimicrobial agent based on clinical outcomes. **(No recommendation/unresolved issue)***

Rationale: *There are no randomized clinical trials or systematic reviews of antibiotic timing. Other clinical practice guidelines recommend administering by the intravenous route a single dose of prophylactic antimicrobial agent only when indicated. These guidelines also recommend administration should be within 60 minutes prior to incision (vancomycin and fluoroquinolones within 60-120 minutes prior to incision).^{12, 183, 228-232}”*

Another option is to create a new, freestanding “no recommendations” table to include the question, the list of “no recommendation” conclusions, a category of rationales, and additional information, such as citations of other available guidelines. This information would be excerpted from the evidence review.

Another option is not to add additional explanation, but highlight the rationale for “no recommendation” as follows, with changes in italics:

“Q1A. What is the optimal timing of preoperative AMP?”

“Administer preoperative antimicrobial agent only when indicated, based on published clinical practice guidelines and timed such that a bactericidal concentration of the agent is established in the serum and tissues when the incision is made (Category IB)¹²

*No further refinement of timing can be made for preoperative antimicrobial agent based on clinical outcomes because there are no randomized clinical trials of antibiotic timing. See Evidence Review: Core section, p. 28 for discussion and citations. **(No recommendation/unresolved issue)**”*

HICPAC Discussion

Tables are often the most useful parts of guidelines. In this case, a “living table” could be updated as additional research becomes available, as the “no recommendations” are based on literature that was available up to a certain time, and ongoing literature searches may yield information to modify the recommendations in the draft. It will be most useful to organize the table by process and then list the items within each area according to the strength of the recommendations. There was general agreement among HICPAC with this approach.

Creating a table only for “no recommendations” and not for other categories may place undue emphasis on the unresolved issues in the guidelines and will ignore the positive actions that should be taken to prevent SSIs. Equal weight should be given to the recommendations for which there is good evidence and rationale.

It is important to include information about how HICPAC decided which clinical practice guidelines were “worth citing.” Not all clinical practice guidelines are equal, and a rational and thoughtful method was applied to choosing the ones that were cited.

While HICPAC favored utilizing a table, they cautioned against over-emphasizing the questions for which the guidelines have no recommendation. Expanding the table to include all questions and organizing them by category would be useful for users. The Summary of Recommendations will remain in the document, organized by topic. It will include the rationale and reference to the evidence review.

Suggested Modifications of Guidance Development Process to Minimize “No Recommendation” Conclusions

The idea of a “living guideline” applies to this concept and to much of the guideline. It is important to pay continued careful attention to the scope, key questions, and outcomes of interest. The workgroup discussed instituting an early evaluation of evidence review, or “guideline timeout.” In this process, it could be determined whether there is sufficient quantity and quality of data available to answer the key question.

HICPAC Discussion

During the early evaluation of evidence, it might be possible to engage in alternate review. This process would acknowledge that although there is not sufficient high-quality randomized controlled trial (RCT) evidence to answer the questions, a body of literature of high-quality observational and before-and-after studies could be submitted to rigorous review and could support a recommendation. This approach might minimize the “no recommendation” conclusions.

Draft SSI Guideline: Reviewing the 1999 Recommendations

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One of the first steps in creating the updated guidelines was to review the 1999 Guidelines to assess areas that are sufficiently addressed as well as gaps. Additionally, CDC staff interacted with surgical specialty groups and asked for input from HICPAC. They received approximately 600 questions to address in the update. The criteria for selecting questions included focus on high-priority, pertinent clinical questions. By moving to a “living document” format, they will be able to generate recommendations in a timelier manner and at different intervals as new information is available or to address new issues. CDC staff considered recommendations in other guidelines that were vague or outdated and issues for which no recommendations were presented. They placed priority on questions that focused on prevention strategies and had policy implications.

The methods and categorization schemes in the 1999 Guidelines were different. Of the Category I recommendations in the 1999 Guidelines, 43 are not addressed in the updated guidelines, as they were areas that were settled, some through the Surgical Care Improvement Project (SCIP). These include 13 pre-operative, 22 intra-operative, 2 post-operative, and 6 surveillance recommendations.

HICPAC’s input is requested in several areas:

- Which strong recommendations from the 1999 Guidelines still apply and could be carried to the new guidelines as “accepted practice?” The CAUTI Guideline addressed those issues by incorporating them into the “Summary of Recommendations,” but 43 may be too many to treat in this manner.
- Are these recommendations now part of the Core Surgical Practices, or is there another format in which they could be highlighted?

Because these topic areas were strong recommendations in 1999, it is not likely that new research has been conducted pertaining to them since then. The recommendations fall into the following categories:

- Preparation of the patient
- Hand and forearm antisepsis for the surgical team
- Management of infected and colonized surgical personnel
- Antimicrobial prophylaxis
- Facility guideline construction and ventilation
- Cleaning and disinfection of environmental surfaces
- Microbiologic sampling
- Surgical attire and drapes
- Asepsis and surgical technique
- Post-operative incision care
- Surveillance

HICPAC Discussion

If the current methodology was applied to some of the 1999 recommendations, they would be classified as “no recommendation.” The dissonance and inconsistency is a struggle. Bringing forward the 1999 recommendations implies that no progress has been made in evaluating data since then and could erode the new guidelines’

credibility. All recommendations are included in the new guidelines should be vetted and analyzed. The majority of the 1999 guidelines are not supported by RCTs.

There are compelling reasons to exclude the 1999 recommendations so that the new guidelines only include recommendations with strong evidence to support them. The end users, however, look to the Guidelines to implement processes in their institutions. The 1999 recommendations that were not addressed in the new guidelines should be presented with a statement describing the process behind the decision not to include them. However, this approach may not meet the needs of the end users who want to know if HICPAC still thinks that the recommendations should be practiced.

There was discussion regarding grading the 1999 recommendations. HICPAC agreed that they should not be graded. If they were, then they should be subjected to the same methodology as the rest of the document. However, bringing the recommendations forward without rating them could be challenging.

There was discussion regarding whether the Core Practices Workgroup of HICPAC could recommend which of the 1999 recommendations should be included as core practices. That body can consult subject matter experts (SMEs) as needed. The Core Practice Workgroup's goal was to be less specific; however, those guidance statements should be available somewhere. A separate Workgroup could be formed to determine which of the 1999 recommendations are accepted practices and present their conclusions to HICPAC. The SSI Guidelines workgroup of HICPAC could be reconvened for this purpose. They would not be asked to review evidence, but to contribute their expertise to decide which of the 1999 recommendations should remain.

Hand and forearm antisepsis for the surgical team: Many of the recommendations for to hand and forearm antisepsis are addressed in the 2002 Hand Hygiene Guideline Recommendations. The SSI Guidelines could link to the Hand Hygiene Guidelines. Some of the recommendations pertaining to cleaning and disinfection of environmental surfaces are included in the 2003 Environmental Guideline and the 2009 Disinfection Guideline. A statement in the Executive Summary of the SSI Guidelines could point out the importance of surveillance and direct users to current, evolving surveillance methodology protocols.

Preparation of the patient and hand/forearm antisepsis for surgical team: The guidelines do not need to address every acceptable clinical practice, but they might consider issues that are still not routine practice. HICPAC must evaluate the basic elements of practice that should not be lost. Some recommendations for patient preparation should be reiterated at institutions. If the guidelines do not include a statement about removing hair, for instance, then users might assume that the recommendation does not exist anymore, and practice might move away from them. A table of the 1999 Guidelines that are still relevant could be created. It should be clear that these guidelines are from the 1999 document and have not been re-reviewed with the same methodology, but that they are considered to be standard core practices. The accompanying language could clearly indicate that "the following recommendations remain unchanged and were not re-reviewed for this Guideline."

Management of infected/colonized surgical personnel: Most of the topics will be included in the Health Care Personnel (HCP) guidance, which is unlikely to contradict the points from 1999.

Intraoperative (Ventilation): The American Institute of Architects is releasing their updated guideline in 2014.

Cleaning and Disinfection of Environmental Surfaces: These topics will be evaluated to determine whether new guidance has been released.

Asepsis and Surgical Technique: The recommendation about “[using] delayed primary skin closure or leav[ing] an incision open to heal by second intention if the surgeon considers the surgical site to be heavily contaminated” is still standard practice with a Class 3 and Class 4 recommendation.

Draft SSI Guideline: Antimicrobial Prophylaxis Public Comments & Proposed Next Steps

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Four important questions pertain to AMP, including appropriate timing of the dose before the incision; weight-based dosing; intraoperative redosing; and antimicrobial duration. The SSI Guideline does not address antibiotic selection, as this topic is addressed by the American Society of Health-System Pharmacists (ASHP) Multi-specialty Society Guidelines.

Pre-Incision dose timing

The draft recommendation is:

“Administer preoperative antimicrobial agent only when indicated, based on published clinical practice guidelines and timed such that a bactericidal concentration of the agent is established in the serum and tissues when the incision is made. (Category IB)”

“No further refinement of timing can be made for preoperative antimicrobial agent based on clinical outcomes. (No recommendation/unresolved issue)”

The latter point is an unresolved issue because no RCTs or systematic reviews evaluate different intervals of timing of the delivery of the antibiotics before the incision. In 1999, the guideline recommended that preoperative administration be timed such that a bactericidal concentration of the drug is established in the serum and tissues when the incision is made. Multiple other guidelines based on observational studies recommend starting antibiotics in the 60 minutes before incision, or 120 minutes before fluoroquinolones and vancomycin.

Numerous public comments were submitted on this point. Most of the comments noted that the recommendation is vague and requests were made for the recommendation to specify exact timing. One comment suggested adding the “theoretical best practice” and argued that timing 5 to 15 minutes before the incision was not ideal. Many comments suggested aligning this recommendation with the Multi-specialty Society Guidelines that were published in 2013. One comment suggested adding “the entire parenteral preoperative AMP dose must be administered prior to inflating the tourniquet.” RCTs have evaluated that question, but the trials

have not been subjected to the literature review, and they found no difference in infection rates based on AMR delivery and the timing of the tourniquet.

The SSI Guideline writing group recommends making no change to the recommendation, but listing the issue as a “no recommendation” in the decided-upon form. The group is conducting an updated literature review to address SSI rates and tourniquets. The quality of the data is not high because the operations have low infection rates, and the studies are not sufficiently powered.

HICPAC Discussion

Since systematic reviews are of RCTs, including “systematic reviews” is redundant.

Weight-Based Dosing

The draft recommendation reads:

“No recommendation can be made regarding the safety and effectiveness of weight-adjusted dosing of parenteral prophylactic antimicrobial agents for the prevention of surgical site infection. (No recommendation/unresolved issue) (Key Question 1C)”

No recommendation is offered on this point due to a lack of RCTs that have an impact on SSI. Other guidelines have provided specific weight-based dosing recommendations based on observational studies, but for a limited group of antibiotics: Cefazolin, Vancomycin, and Gentamicin.

Most of the public comments received on this topic suggested deferral to already-published guidelines, particularly the 2013 Multi-specialty Society Guidelines. A comment also noted that “pharmacology studies show that obese patients may not achieve tissue levels of antimicrobials that exceed the minimum inhibitory concentration (MIC) of common SSI organisms.” Those studies focused on tissue levels of antibiotics, not at surgical infection rates, and were all observational. Another comment noted that there may never be an RCT on this topic, as it may not be ethical to conduct a study of different dosing regimens on patients of different weights. Other comments indicated that the language is vague and that the guidelines should be specific about dosing, particularly about Cefazolin. The Multi-specialty Society Guidelines state that all adults should receive at least two grams of Cefazolin, and adults above 120 kilograms should receive three grams. The HICPAC guideline does not look at specific recommendations; rather, its focus was on whether doses should be adjusted based on weight.

The writing group recommends including this issue as “No Recommendation.” The text will include the rationale that no RCTs are focused on SSIs as the outcome of interest and highlight that other guidelines have made this recommendation based on observational studies.

HICPAC Discussion

Many institutions have shifted toward weight-based dosing based on the Multi-specialty Society Guidelines. These institutions could see in the HICPAC Guidelines that CDC found no good evidence to support the practice and question why they are doing it. Small institutions that do not have strong infection control support might choose not to engage in a practice unless the CDC guidelines endorse it. There was discussion regarding whether SCIP might be modified in response to the Multi-specialty Society Guidelines. SCIP is not a guideline, but a set of performance metrics that are based on other published guidelines. At this point, there are no ongoing efforts to

include dosing or re-dosing in SCIP. Some who have seen the draft HICPAC recommendations are advocating for SCIP to align with HICPAC recommendations.

Intraoperative Re-Dosing

The draft recommendation reads as follows:

*“No recommendation can be made regarding the safety and effectiveness of intraoperative redosing of parenteral prophylactic antimicrobial agents for the prevention of surgical site infection. **(No recommendation/unresolved issue)**”*

The draft recommendation was made because no RCTs or systematic reviews were found that evaluated intraoperative AMP re-dosing and its impact on the risk of SSI. A number of published observational studies have assessed tissue levels of antimicrobials and SSI rates. These studies suggest that intraoperative redosing is appropriate. Based on these studies and on expert opinion, other clinical guidelines recommend prophylactic antimicrobial agent redosing whenever the duration of the procedure exceeds two times the half-life of the agent that was administered, or in patients with extensive blood loss or with extensive burns. No recommendations are provided for the optimal prophylactic antimicrobial agent dosing in obese and morbidly obese patients when redosing because no data are available on which to base a recommendation.

Many public comments on this issue referred to the Multi-specialty Society Guidelines and suggested aligning with them. Other public comments noted that “pharmacology studies show that if the procedure lasts longer than four hours, intraoperative re-dosing of the prophylactic antimicrobial is required to maintain bactericidal tissue levels of the agent.” Tissue levels do fall, particularly with short half-life antibiotics that are administered before incision. Observational studies suggest that the infection rate can be lowered by re-dosing. Additionally, an RCT may never be conducted on this topic, as it may not be ethical to withhold antimicrobials in a long case when a short half-life drug was utilized. There was concern that the statement could be interpreted that the CDC does not support re-dosing of prophylactic agents, and therefore institutions should not do so, but that was not the intent—not recommending does equate to not supporting.

The writing group suggested no changes in the recommendation and including it as a “no recommendation.”

HICPAC Discussion

The “no recommendation” conclusions for these four AMP questions are problematic. There are unintended consequences associated with “no recommendation” in AMP. Even with good intentions and explanations regarding the “no recommendation” category, they run the risk of the practices not being implemented. It is important to explain why there is no recommendation and to point clearly to other guidelines. Where there are no RCTs, there is often good guidance for clinicians to follow when treating patients.

It should be clear that “no recommendation” does not mean “not supported.” It means that no RCTs are available on the practice. All of these practices are explicitly addressed in the *Compendium*. The proposed table for “no recommendation” accomplishes that goal by explaining why no recommendation was included in the guidelines and then referring to information that is available to support the practice.

The Guidelines provide an evidence-based guide to practice; however, if they get so sophisticated with the research that they lose practice-based elements, then they might lose the completeness of the document. At the same time, the function of guideline development is to use a critical review of the evidence that is commercial-free, conflict-free, and transparent. The quality of the observational studies supporting some of the AMP practices varies.

Systematic reviews are evidence-driven, and practice guidelines are practice-driven. The “no recommendation” category is characteristic of a systematic review because it does not guide practice. A revision could state that *“intraoperative redosing may prevent SSI”* or *“may be safe and effective.”* This approach serves to guide practice while acknowledging that the issue is still unresolved due to a gap in the evidence.

The narrative could address the lack of RCTs. It might be possible to suggest that the science needs to be developed in an area, as opposed to areas in which there will never be RCTs, and therefore never any CDC recommendations about them. No good RCTs are available for hand hygiene, for example. The best approach is to consider the practices and determine which reflect the standard of care as practiced now and highlight them in a sensible way. The recommendation could be revisited if additional information becomes available.

There was discussion regarding whether HICPAC should endorse a specific practice. In their guidelines for venous thromboembolism (VTE), the American College of Chest Physicians (ACCP) published whether the recommendations were unanimous or whether there were dissenting opinions.

The “no recommendation” issues will be included with statements explaining why there was no recommendation. There will be links to other guidance. CDC can provide additional tools to help clarify and implement the guidelines.

Postoperative Duration

The draft recommendation reads:

“In clean and clean-contaminated procedures, do not administer additional prophylactic antimicrobial agent doses after the surgical incision is closed in the operating room, even in the presence of a drain. (Category IA)”

A number of RCTs are available on this topic. The Multi-specialty Society Guidelines indicate that all antimicrobials should be stopped within 24 hours of the end of surgery for all operations. The SCIP performance measures require stoppage within 24 hours or less of the end of surgery for most operations, for 48 hours or less for cardiac surgery. The American Academy of Orthopedic Surgeons (AAOS) guidelines indicate stoppage in 24 hours or less, and the Society of Thoracic Surgeons (STS) guidelines indicate stoppage in 48 hours or less. AAOS and STS both recommend ignoring the presence of drains when decisions are made regarding AMP.

Many public comments were received regarding this recommendation. Two urged that the guidelines align with the SCIP metrics, since hospitals are accountable for them. Many societies and surgeons are uncomfortable with stopping antibiotics. One comment pointed out that RCTs are not published for antibiotic duration for every type of operation. Another comment suggested amending the wording to read: *“in clean and clean-contaminated*

procedures as determined at the end of the case, do not administer additional prophylactic antimicrobial agent doses, etc.” Most comments supported the language pertaining to the presence of a drain.

The group is updating the literature review and is deferring the decision on changing this recommendation based on that review. Regarding aligning with SCIP, it was noted that some who have seen the draft HICPAC recommendations are advocating for SCIP to align with HICPAC recommendations. SCIP is not a guideline; the measures are based on other published guidelines.

Draft SSI Guideline: Other Content-Specific Public Comments and Proposed Next Steps

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Several public comments noted that the literature search is outdated. Approximately 148 new references were included in the public comments. Of those, approximately 44 were related to topics that were not included in the SSI Guidelines. Of the remaining references, 25 fit the inclusion criteria. Several of them were already included in the Guidelines. Ultimately, 13 new RCTs were cited in the public comments. Ten of them were in the area of antimicrobial-coated sutures. Additional references may surface from the updated literature search that will be conducted.

Four draft recommendations in Category IA received comments:

- 3A.1. Glycemic Control
- 4. Normothermia
- 6. Oxygenation
- 8b. Intraoperative Skin Preparation

The theme of the comments was that the evidence does not support a Category IA recommendation. There were questions regarding the application of the draft recommendations across surgical procedures. Comments also suggested aligning the draft recommendations with SCIP process measures, specifying target levels, and specifying timing. Some commenters felt that the draft recommendations needed clarification or were contradictory.

Category IA Draft Recommendations: Glycemic Control

“3A.1. Implement perioperative glycemic control and use blood glucose target levels <200mg/dL in diabetic and non-diabetic patients. (Category IA)^{80,81} (Key Question 3)

“3A.2. No recommendation can be made regarding the safety and effectiveness of lower (<200mg/dL) or narrower blood glucose target levels, nor the optimal timing, duration, or delivery

method of perioperative glycemic control for the prevention of surgical site infection. (No recommendation/unresolved issue) (Key Question 3)"

Public comment: This recommendation is not supported by evidence for Category IA. Questions were also raised regarding the application of this recommendation across surgical procedures, as most of the cited studies were conducted post-operatively in intensive care units (ICUs) or in specific patient populations and not general surgery patients.

Clarification: Moderate-quality evidence suggests no benefit of strict glucose target levels, defined as 80-100mg/dL⁸⁰ or 80-130mm/dL⁸¹, as compared to standard blood glucose target levels, defined as <200mg/dL⁸⁰ or 160-200mg/dL⁸¹, in diabetic and non-diabetic cardiac patients. The recommendation was based on no differences between the groups for a composite outcome variable and for an SSI in both studies. High-quality evidence suggests no increased risk of hypoglycemia with strict blood glucose target levels. The 1999 guidelines recommended implementing perioperative glycemic control in diabetic patients, but they did not specify a level. The level of <200mg/dL was derived from a quote within the text that referred to a study that used <200mg/dL.

Public comment: Blood glucose levels of <180mg/dL should be specified to be consistent with SCIP procedures. Further, there was question regarding whether the data are strong enough to support levels of <180mg/dL

Clarification: The draft recommendation aligns with SCIP INF-4. It also aligns with other recommendations. The literature search did not reveal the safety and effectiveness of lower (<200mg/dL) or narrower blood glucose target levels, nor the optimal timing, duration, or delivery method of perioperative glycemic control for the prevention of surgical site infection.

Public comment: Improvements in clarity are needed, as “diabetic and non-diabetic” patients could be “all patients.” There were also questions regarding pediatric patients.

Clarification: The recommendation applies to all adult patients, as the evidence review states that “Seventy to 80% of patients in both of these studies are non-diabetics, highlighting the importance of glycemic control in both diabetic and non-diabetic populations.” Because the new recommendation represents a broadening of the 1999 recommendation, which was for diabetic patients only, the content experts deemed it important to specify that the recommendation was for both “diabetic and non-diabetic” patients. The search did not identify RCTs or systematic reviews that evaluated perioperative glycemic control and its impact on SSI in the pediatric population.

Public comment: The level of <200mg/dL for non-diabetic patients will require additional monitoring without corresponding benefit to patient outcomes

Clarification: Both studies on which the recommendation was based were conducted in predominantly non-diabetic patients.

Proposed action:

- Discuss reevaluating the Category IA designation and the applicability across surgical procedures.
- The recommendation is in alignment with SCIP; HICPAC’s input is requested regarding whether the guideline should reference SCIP.
- Consider editing the recommendation to be more specific that it refers to the adult patient population.

HICPAC Discussion

The question of a recommendation's applicability to all surgical procedures will emerge for other issues. The 1999 recommendation does not specify cardiac patients only, but it does specify diabetic patients. The studies on which the recommendation was based were only conducted in cardiac patients. It is logical to broaden the recommendation, but if hospitals implement this practice for all surgical procedures, it will represent a significant logistical change. The Guidelines may need to provide additional detail to support why the recommendation was broadened. Based on observational studies, the *Compendium* recommends this practice across all operations. There is a great deal of observational data regarding glucose control in other operations, such as general and orthopedic surgery.

Category IA Draft Recommendations: Normothermia

"4. Maintain perioperative normothermia (Category IA)⁸²⁻⁸⁴ (Key Question 4)

"5. No recommendation can be made regarding the safety and effectiveness of strategies to achieve and maintain normothermia, the lower limit of normothermia, or the optimal timing and duration of normothermia for the prevention of surgical site infection. (No recommendation/unresolved issue) (Key Question 5)"

Public comment: There is a lack of data to support the benefits of this recommendation and to classify it as Category IA. There was also concern because the references are limited to specific patient populations, but the recommendation is not procedure-specific.

Clarification: High-quality evidence suggests a benefit of patient warming over no warming. This conclusion is based on a reduced risk of SSI in a meta-analysis (N=616) of two RCTs and reduced risk of ASEPSIS scores of <20 with warming and maintenance of normothermia using various warming techniques in patients undergoing elective hernia repair, varicose vein surgery, breast surgery, and elective colorectal surgery.^{82,83} Normothermia was also associated with lower mean units of blood transfused per patient, fewer patients transfused, and reduced hospital length of stay.⁸³ No difference in mortality was observed.⁸³

Public comment: Procedures with therapeutic cooling should be excluded.

Clarification: The evidence reviewed did not specifically address this issue. SCIP INF-10 excludes procedures with therapeutic cooling.

Public comment: Define "normothermia."

Clarification: The evidence review states that the lower limit of normothermia has been inconsistently defined and ranges from a core temperature of 35.5°C to 36°C. Recent efforts of the American Society of Anesthesiologists are focusing on establishing the definition at 35.5°C. The currently-available evidence was not sufficient for the SSI Guidelines to state that level.

Public comment: Normothermia recommendations 4 and 5 seem to contradict each other, as they make a strong recommendation to maintain normothermia but do not present guidance on how to achieve or maintain it.

Clarification: The section on “other guidelines” includes evidence-based clinical practice guidelines that have recommendations on perioperative management of normothermia. The document clearly indicates whether a guideline is evidence-based, or whether it is a clinical practice guideline based on the review of the literature and expert opinion. The normothermia recommendations are evidence-based, and the literature search did not identify RCTs or systematic reviews that evaluated the most effective strategies for achieving and maintaining normothermia and their impact on the risk of SSI.

Proposed action:

- Recommendation 4 should recommend maintaining perioperative normothermia.
- The recommendation’s classification as Category IA and its applicability across surgical procedures should be reviewed.
- HICPAC’s input is requested regarding the exclusion of therapeutic cooling procedures; the definition of normothermia; and how to address the request for a specific target level.

HICPAC Discussion

There was discussion regarding whether the guidelines should specify that there is no recommendation about one approach to normothermia over another. The public comment did not address comparative methods, and there is no evidence to indicate that one method is preferable to another. The recommendation should be carefully worded so as not to give the impression that an endorsement is being made of a commercial warming system. There are ways other than proprietary products to keep patients warm. HICPAC suggested adding rewording the recommendation to read, “no recommendation can be made regarding the relative safety and effectiveness of specific strategies to achieve and maintain normothermia.” HICPAC agreed to exclude cooling procedures. No comments were offered regarding defining the level of normothermia.

Category IA Draft Recommendations: Oxygenation

“6A. For patients with normal pulmonary function undergoing general anesthesia with endotracheal intubation, administer increased fraction of inspired oxygen (FiO₂) both intraoperatively and post-extubation in the immediate postoperative period. To optimize tissue oxygen delivery, maintain perioperative normothermia and adequate volume replacement. (Category IA)⁸⁵⁻⁹⁰ (Key Question 6)

“7. No recommendation can be made regarding the optimal target level, duration, and delivery method of the fraction of inspired oxygen (FiO₂) for the prevention of surgical site infection. (No recommendation/ unresolved issue) (Key Question 7)”

Public comment: Available evidence does not support classifying this recommendation as Category IA. The recommendation is not applicable across surgical procedures, as data are not available validating its use in non-abdominal procedures.

Clarification: Moderate-quality evidence suggests a benefit of supplemental 80% FiO₂ based on a 40% reduction in SSI reported in three studies at low risk of bias; no difference in one multicenter, mixed surgical population study at low risk of bias; and no significant difference in adverse events. The studies reporting SSI reduction all optimized perioperative oxygen delivery by maintaining normothermia and avoiding hypo- or hypovolemia. Other studies were problematic, so the workgroup focused on the fact that in the studies in which tissue delivery was optimized, reductions in SSI were achieved.

Public comment: A target level for FiO₂ should be included. A lower level should be declared if a target cannot be identified.

Clarification: A specific target level cannot be specified. Every study uses 80% FiO₂ as the target level, and no studies have been conducted to evaluate differences in optimal target levels. Other evidence-based guidelines from the National Institute for Health and Care Excellence (NICE) indicate that it is important to maintain patient homeostasis by optimizing the oxygenation during major surgery. The specific recommendation only refers to the recovery period, which is why they stipulate the level of 95% hemoglobin saturation.

Public comment: suggested re-wording the recommendation to read: “Although the precise clinical consequences of oxygen toxicity remain incompletely understood, the potential risks should be balanced against the benefits of an increase in arterial oxygen content. The FiO₂ and duration of oxygen exposure at which clinically significant oxygen toxicity occurs cannot be predicted with certainty in a given individual, but adherence to the general therapeutic principle of ‘less is better’ appears prudent.”

Proposed action:

- Re-evaluate the designation of Category IA for this recommendation and its applicability across surgical procedures
- Maintain Recommendation 7 as “no recommendation/unresolved issue.”
- Make no changes or additions regarding specifying a target level.

HICPAC Discussion

It is not appropriate to set a standard FiO₂ level, as patients have different sets of co-morbidities and other factors that will impact their appropriate highest level. The text could clarify that the goal is elevated FiO₂, not a specific set. The text could indicate that the studies were not evaluating differences in peripheral oxygen saturation; they evaluated differences in FiO₂. The text should include language pertaining to exclusion for patients who have been exposed to bleomycin or are in other situations in which this intervention could be life-threatening. The recommendation could address the need for a definition of “elevated FiO₂” by stating that all of the studies were with 80%. This point could be highlighted in the table. The updated literature search could yield new information to drive the recommendation in one direction or another. This question could be tabled until the review is complete.

Category IA Draft Recommendations: Intraoperative Skin Preparation

“8B. Perform intraoperative skin preparation with an alcohol-based antiseptic agent, unless contraindicated. (Category IA)¹⁰³⁻¹¹⁶ (Key Question 8B)”

Public comment: Evidence was not presented to warrant a Category IA recommendation for the use of alcohol-based antiseptic agents for several reasons. No study has shown chlorhexidine gluconate (CHG)-alcohol to be superior to aqueous CHG. Because of the lack of comparisons of CHG-alcohol versus aqueous CHG and the lack of benefit of iodophor-alcohol to aqueous iodophor, the recommendation should be clarified to reflect the evidence or changed to an “unresolved issue.” The recommendation for povidone-iodine (with alcohol) is not based on RCTs but on expert opinion. Some commenters felt that CHG-alcohol should be recommended for pre-operative skin preparation, as it is proven superior to aqueous povidone iodine. The guideline does not provide evidence that alcohol skin preps are superior.

Clarification: The evidence review noted no difference for the other comparators, but given that no RCTs compare CHG-alcohol versus aqueous CHG, it is not possible to discern whether the true effect in CHG-alcohol versus povidone iodine is due to the CHG or to the alcohol. Further, there was moderate risk of bias in several of the studies. Other clinical practice guidelines recommend skin preparation with an antiseptic agent, but they do not favor one agent over another. There may be contraindications to the use of specific antiseptic skin preparation agents. Of the three studies suggested in the public comments, two of the RCTs are already in the guidelines, and one systematic review from 2013 is a Cochrane review that does not include additional new studies.

Public comment: The CDC recommendation that alcohol hand agents are superior to handwashing may be incorrect. Consider the influence of conflict of interest in the deliberation of the “safe practices” committee at the National Quality Forum (NQF) and a CHG-alcohol manufacturer. Consider burn risk in the operating room (OR). Acknowledge the caveat concerning prepping different sites, such as flammability with the use of alcohol-based products in areas with hair and contact with mucous membranes.

Clarification: The evidence review was limited to evidence for intraoperative skin preparations, not hand hygiene. Any potential conflicts of interest have been reported in the studies, were included in the analyses, and were reported in the guideline. The caveat pertaining to prepping different sites cannot be made based on the reviewed evidence. The burn risk with the use of alcohol products and caveats around appropriate site-specific product application, including contact time and drying time, are all addressed in manufacturer product inserts.

Public comment: Clarification is needed regarding whether the recommendation implies the exclusion of aqueous iodophor preparation alone, which would represent a major change in practice. Another comment addressed whether there is a difference between alcohol-based versus aqueous- or iodine-based, versus CHG-based, or a combination?

Clarification: The recommendation does not exclude the use of aqueous iodophor alone as appropriate. The guidelines indicate the possibility of contraindications to the use of specific antiseptic skin preparation agents. Of the two systematic reviews cited in the public comments, one fits the inclusion criteria, but all if the studies in the

review are already included in the Guidelines. The other review addresses preoperative bathing, not intraoperative skin preparation, and does not fit this area.

Public comment: Many referenced studies in this section only examine decrease in bacterial flora.

Clarification: Although several studies' primary outcome of interest was skin contamination or bacterial flora, every study included in the review reported SSI as an outcome.

Proposed action:

- Consider re-evaluating this recommendation as Category IA.
- Review an updated literature search for new evidence.
- Consider changing the recommendation to read, based on the 1999 Guideline that is now standard practice (the 1999 Guidelines did not include a "no recommendation" in this area):

"8B.1. Perform intraoperative skin preparation with an appropriate antiseptic agent. (Category IB)¹⁰³⁻¹¹⁶ (Key Question 8B)

"8B.2. No recommendation can be made regarding the safety and effectiveness of specific intraoperative skin preparation antiseptic agent(s) for the prevention of surgical site infection. (No recommendation/unresolved issue).¹⁰³⁻¹¹⁶ (Key Question 8B)"

HICPAC Discussion

There was discussion regarding the proposed changes in wording for 8B.1 and 8B.2. As with AMP, it is important to avoid unintended consequences. Several members of HICPAC preferred the original wording to the proposed change. The wording of 8B.2 is not entirely accurate, as the evidence allows for some statements about specific agents. The *Compendium* makes specific recommendations about the use of an alcohol-based antiseptic. The evidence does not support recommending a specific agent; however, while no studies compare every possible combination, there is a body of literature comparing aqueous iodophor to CHG-alcohol, and the CHG-alcohol is better. It is not possible to say that CHG-alcohol is preferred, but the guidelines should not ignore the body of literature supporting CHG-alcohol by not making any recommendation at all. No studies have examined CHG-alcohol versus CHG. The evidence on iodophor versus iodophor with alcohol shows no difference. Therefore, it is not possible to assert that the iodophor with alcohol is superior to aqueous iodophor. Data are available on aqueous iodine with alcohol as opposed to povidone iodine, and they are equivalent. There is evidence that other preparations are better than povidone iodine alone. In some procedures, povidone iodine is the appropriate agent to use. There is concern that the recommendation could be interpreted as not supporting the use of aqueous iodophor when it is appropriate. In some procedures, only aqueous iodophor can be used. That concept is captured in the original wording, which states "unless contraindicated."

A comment could be added to refer to the relative effectiveness for the specific procedure being performed. Given the available products, there will be continued research in this area. It may be more helpful to include a more general statement about the relative safety, effectiveness, and appropriateness for specific surgical procedures.

HICPAC decided to recommend applying the verbiage from the June 2013 iteration of the SSI Guidelines, with a slight modification:

“Perform intraoperative skin preparation with an alcohol-based antiseptic agent. (Category IB)

“[Sub-bullet]: Use CHG-alcohol in preference of aqueous iodophor skin preparation, unless contraindicated. (Category IA)

“No recommendation can be made regarding the safety and effectiveness of CHG-alcohol as compared to iodophor alcohol or to aqueous CHG skin preparation. (No recommendation/unresolved issue)”

HICPAC stood in recess from 3:23 pm to 3:44 pm.

Category IB Draft Recommendation: Pre-operative Bathing and Showering

“8A. Advise patients to shower or bathe (full body) with either soap (antimicrobial or non-antimicrobial) or an antiseptic agent on at least the night before the operative day. (Category IB)⁹⁴⁻¹⁰² (Key Question 8A)

“8A.1. No recommendation can be made regarding the optimal timing of the preoperative shower or bath, the total number of soap or antiseptic agent applications, or the use of chlorhexidine gluconate washcloths for the prevention of surgical site infection. (No recommendation/ unresolved issue) (Key Question 8A)”

Public comment: A breadth of public comments was submitted on this topic. Some commenters stated that there is evidence for preoperative showering or bathing, others said there is not. Some commenters asserted that there is no evidence for soap, that there is evidence for CHG as an antiseptic agent, and that there is evidence for CHG clothes as an antiseptic agent. There was also a request to add a recommendation regarding implementation. Of the 40 references submitted as updated evidence in this area, only one RCT fit the inclusion criteria. Public comments suggested changing the recommendation in a number of ways, including the following:

- Keep 1999 Recommendation (Change back to “antiseptic agent”)
- Keep 1999 Recommendation and specify CHG antiseptic agent and timing and number of showers
- Keep 1999 Recommendation and specify CHG antiseptic agent and add CHG cloths
- Keep 1999 Recommendation and specify CHG cloths
- Specify CHG antiseptic agent and timing and contact time
- Specify CHG antiseptic agent after bland soap

Clarification: Regarding evidence for preoperative showering or bathing, high-quality evidence suggests no benefit of preoperative bathing or showering with 4% CHG solution versus placebo. No benefit of preoperative showering with CHG is noted as compared to no wash, but there was significant heterogeneity in the meta-analysis supporting this conclusion. Five RCTs were conducted prior to the 1999 recommendation to require

patients to shower or bathe with an antiseptic agent on at least the night before the operative day. A subsequent study in 2009 was not conducted in the US. Preoperative bathing and showering is understood to an accepted practice in the US. Questions regarding the optimal timing, agent, and application methods remain unanswered. Since the evidence does not show differences between agents, including non-antibacterial soap, the 1999 recommendation was expanded to include soap. It is unlikely that future studies will evaluate the safety and effectiveness of preoperative bathing or showering versus no preoperative bathing or showering in reducing the risk of SSI.

Regarding public comment to specify an antiseptic agent type; dose; timing and number of showers or baths or product applications; and contact time, the literature search did not identify RCTs or systematic reviews that evaluated any of these issues. In addition, none of the evidence evaluated differences in contact time and its impact on SSI.

Proposed action:

- Update the literature search to find references in addition to the 2011 RCT that was submitted.
- The following revisions to the recommendation are proposed:

“8A. Advise patients to shower or bathe with an antiseptic agent on at least the night before the operative day.⁹⁴⁻¹⁰² (Category IB)

“8A.1. No recommendation can be made regarding the optimal timing of the preoperative shower or bath, the total number of antiseptic agent applications, or the use of chlorhexidine gluconate washcloths for the prevention of surgical site infection. (No recommendation/ unresolved issue) (Key Question 8A)”

HICPAC Discussion

The literature for antiseptics is conflicting and does not indicate a clear benefit. The recommendation should be worded carefully, as a patient could purchase a product that may or may not reduce the risk of SSI. Confusion about this question stems from the issue of *S. aureus* colonization that was noted in public comment referring to the Bode 2010 study. It may be necessary for the guideline to specify that these recommendations do not apply to patients known to be *S. aureus* colonized. Further discussion on this topic was deferred pending the literature review.

Category II Draft Recommendations

The Category II recommendations that garnered public comment were as follows. All five topics were originally presented as “not recommended” in Category IA, based on the evidence, and they were revisited to revise the categorization.

Autologous Platelet Rich Plasma:

“2B.2. Application of autologous platelet rich plasma is not necessary for the prevention of surgical site infection. (Category II)⁷³⁻⁷⁵ (Key Question 2B)”

The comments indicated that the recommendation’s wording is vague and difficult to interpret.

Antimicrobial Coated Sutures:

“2C. Use of antimicrobial coated sutures is not necessary for the prevention of surgical site infection. (Category II)⁷⁶⁻⁷⁹ (Key Question 2C)”

Public comment indicated that the wording is vague and may be interpreted not to use the antimicrobial coated sutures. It was recommended that the wording be amended to read: *“Upon reviewing available data, recommendation that use of triclosan-coated antibacterial sutures prevent bacterial colonization, thus potentially reducing the incidence of SSI, is warranted.”* The comment further suggested that if CDC will not revisit its methodology, the guideline should indicate no recommendation.

Antimicrobial Sealant:

“8C. Application of an antimicrobial sealant immediately following intraoperative skin preparation is not necessary for the prevention of surgical site infection. (Category II)¹¹⁷⁻¹¹⁹ (Key Question 8C)”

Comments cited three references to support the recommendation and suggested a Category IA recommendation.

Plastic Adhesive Drapes:

“8D. Use of plastic adhesive drapes with or without antimicrobial properties is not necessary for the prevention of surgical site infection. (Category II)^{104,120-124} (Key Question 8D)”

A comment stated that the evidence supports “no recommendation/unresolved issue” on this point, as studies found that iodine-impregnated drapes decreased bacterial counts, but no correlation was established with SSI. More research should be conducted before recommendations are made. Another comment supported a recommendation against iodophor-impregnated plastic adhesive drapes, noting that other guidelines recommend that if a plastic adhesive drape is required, then an iodophor-impregnated one should be used. The HICPAC guideline should reiterate that evidence does not support this practice.

Intraoperative Antiseptic Irrigation:

“9A. Consider intraoperative irrigation of deep or subcutaneous tissues with aqueous iodophor solution for the prevention of surgical site infection. Intra-peritoneal lavage with aqueous iodophor solution in contaminated or dirty abdominal procedures is not necessary. (Category II)¹²⁵⁻¹³¹ (Key Question 9)”

Public feedback suggested clarifying “deep or subcutaneous tissue” and whether it refers to traumatic wounds or any wounds. Another comment suggested changing the recommendation wording to read: “Consider intraoperative irrigation of deep and subcutaneous tissues with US Food and Drug Administration (FDA)-approved surgical irrigation solutions containing antiseptics including chlorhexidine and povidone iodine,” and delete 2A.1 referring to AMP Irrigation as contradictory. No public comments were offered regarding the categorization of this recommendation as Category II, but its classification could be impacted by HICPAC’s discussions.

Clarification: Challenges associated with the Category II recommendations include situations in which moderate- to high-quality evidence indicates no benefit of a practice, or indicates no adverse events. Moderate-quality evidence for Topic 2B.2 indicates increased risk of delayed wound closure, but other moderate-quality evidence shows no benefit. Many of the studies are not necessarily looking for harms, which presents more challenges. When the recommendation states “it is not necessary,” that conclusion is based on finding no benefit. Recommendation 9A regarding intraoperative antiseptic irrigation is phrased using “consider” because moderate- and high-quality evidence shows a benefit. For both scenarios, the recommendation is weak, and the use or application is optional.

Proposed action:

- Review an updated literature search to ascertain whether new evidence is available to impact the categorization scheme. New RCTs were provided by public comment for antimicrobial coated sutures and for antimicrobial sealant.
- HICPAC’s input is requested regarding how to improve the Category II recommendation wording so that it better reflects the group’s conclusions, or whether to re-categorize these topics to “no recommendation/unresolved issues.”

HICPAC Discussion

The document is making weak recommendations in Category II on topics about which HICPAC feels less strongly than topics that are included in the “no recommendation/unresolved issue” category. Some of the Category II topics will be prioritized higher than some of the “no recommendation” topics which they know, from a practice perspective, are important. It may be preferable to classify the Category II topics as “no recommendation” so that they will be part of the table that describes the evidence that is available. Some HICPAC members felt that these topics should not be classified as “no recommendation” because there are studies available to inform them, although the studies showed neither benefit nor harm. The “no recommendation” topics either have no studies to support them, or the available studies have conflicting outcomes or are potentially biased.

There was discussion regarding why HICPAC would assign an intervention a Category II recommendation if there is moderate-quality evidence that it shows no benefit. This issue arises with adhesive drapes. Although the practice showed no benefit in reducing SSI, it did not show harm, and there could be other reasons why it would be useful in the intraoperative setting. The decision was made not to classify the topic as Category I and recommend against the practice, but rather to classify it as “not necessary.” In order to remain consistent with that decision and language, the other topics were deemed “not necessary.”

“Is not necessary” could be interpreted as “do not use,” or as “do use” if the practice is thought to be helpful. Data indicate that these practices are not helpful for SSI prevention, not that they should not be used for any purpose. “Do not use” means that if an intervention is used, it will cause harm. The designation is not used

because of a lack of evidence or because of low-quality evidence. In these cases, they do not know that a practice causes harm. However, if a practice does not provide benefit, then there is some harm associated with it from a cost perspective. The wording “is not recommended for the prevention of SSI” rather than “do not use” was suggested. An alternate approach would be to make no recommendation “with respect to the efficacy of these interventions to prevent SSIs.”

Re-evaluate Non-Parenteral AMP Meta-analyses: Antimicrobial Irrigation

“2A.1. No recommendation can be made regarding the safety and effectiveness of intraoperative antimicrobial irrigation (e.g., intra-abdominal, deep or subcutaneous tissues) for the prevention of surgical site infection. (No recommendation/unresolved issue) (Key Question 2A)”

Public comment: The wording is vague. Another comment stated that the draft guideline cites the 2008 NICE Clinical Guideline, but the evidence provided by NICE shows no benefit of antibiotic irrigation.

Clarification: The literature search did not identify RCTs or systematic reviews that evaluated the safety and effectiveness of antimicrobial irrigation or the soaking of surgical implants in antimicrobial solution prior to insertion and its impact on SSI. The 2008 NICE clinical practice guideline recommends against antimicrobial wound irrigation or intra-cavity lavage to reduce the risk of SSI.²³⁴

“2B.1. Do not apply antimicrobial agents (i.e., ointments, solutions, powders) to the surgical incision for the prevention of surgical site infection (Category IB)⁶⁶⁻⁷² (Key Question 2B)”

Public comment: The comments again suggested that the wording of the recommendation is vague and also asked for clarification on timing.

Clarification: This recommendation is based on a meta-analysis in one systematic review for ampicillin versus no topical antimicrobial prophylaxis that showed no benefit. There were two separate comparators: one with chloramphenicol versus no topical antimicrobial, and one with rifampin versus to topical antimicrobial. Based on these studies, there is no evidence of benefit. Another set of guidelines indicates potential harm with use of the ointment.

Proposed action:

- Review the 2008 NICE Guideline.
- Consider separating the Charalambous 2003 systematic review meta-analysis. The three “solution” RCTs use different volumes. They could qualify as irrigation solution and should be used as a separate meta-analysis to answer the antimicrobial irrigation question. Additionally, the powder RCT in that systematic review could be evaluated separately with the two ointment RCTs.
- Review the updated literature search.

Minor Edits to Recommendations

Antimicrobial Sealant:

“8C. Application of an antimicrobial sealant immediately following intraoperative skin preparation is not necessary for the prevention of surgical site infection. (Category II)¹¹⁷⁻¹¹⁹ (Key Question 8C)”

Public comment pointed out that “microbial sealant” more appropriately describes the function of the sealant. That term was used in the Lipp 2013 Cochrane Review. The proposed revision is:

“8C. Application of a microbial sealant immediately following intraoperative skin preparation is not necessary for the prevention of surgical site infection. . (Category II)¹¹⁷⁻¹¹⁹ (Key Question 8C)”

Plastic Adhesive Drapes:

“8D. Use of plastic adhesive drapes with or without antimicrobial properties, is not necessary for the prevention of surgical site infection. (Category II)^{104,120-124} (Key Question 8D)”

Public comments suggested amending the recommendation to “plastic adhesive incise drapes” to avoid confusion regarding any surgical drape made with adhesive materials, such as adhesive strips. With that in mind, the proposed new guideline reads:

“8D. Use of plastic adhesive incise drapes with or without antimicrobial properties, is not necessary for the prevention of surgical site infection. (Category II)^{104,120-124} (Key Question 8D)”

Antiseptic Irrigation:

“9A. Consider intraoperative irrigation of deep or subcutaneous tissues with aqueous iodophor solution for the prevention of surgical site infection. Intra-peritoneal lavage with aqueous iodophor solution in contaminated or dirty abdominal procedures is not necessary. (Category II)¹²⁵⁻¹³¹ (Key Question 9)”

Public comment suggested separating this recommendation into three points, as placing them together leads to questions in clarifying how the second sentence relates to the first. The suggested edited recommendation is:

“9A.1. Consider intraoperative irrigation of deep tissues with aqueous iodophor solution for the prevention of surgical site infection in clean procedures. **(Category II)**¹²⁵⁻¹²⁶ (Key Question 9)

“9A.2. Consider intraoperative irrigation of subcutaneous tissues with aqueous iodophor solution for the prevention of surgical site infection in clean-contaminated, contaminated and dirty procedures. **(Category II)**¹²⁷⁻¹²⁸ (Key Question 9)

“9A.3. Intra-peritoneal lavage with aqueous iodophor solution in contaminated or dirty abdominal procedures is not necessary. **(Category II)**¹²⁹⁻¹³¹ (Key Question 9)”

Biofilm: Cement modifications:

“20A. No recommendation can be made regarding the safety and effectiveness of cement modifications and the prevention of biofilm formation or surgical site infection in prosthetic joint arthroplasty. **(No recommendation/unresolved issue)**^{171,172} (Key Question 20A)”

In response to public comment requests for clarification regarding “cement modifications,” the suggested recommendation is:

“20A. No recommendation can be made regarding the safety and effectiveness of cement modifications such as antimicrobial and nanoparticle loading, and the prevention of biofilm formation or surgical site infection in prosthetic joint arthroplasty. **(No recommendation/unresolved issue)**^{171,172} (Key Question 20A)”

Biofilm: Prosthesis surface modifications:

“20B. No recommendation can be made regarding the safety and effectiveness of prosthesis modifications for the prevention of biofilm formation or surgical site infection in prosthetic joint arthroplasty. **(No recommendation/unresolved issue)** (Key Question 20B)”

No public comment was submitted on this point, but based on the clarification requested for 20A, the following modification is suggested:

“20B. No recommendation can be made regarding the safety and effectiveness of prosthesis surface modifications such as antimicrobial coating, galvanic couples, “printing” technologies, and nanotechnology for the prevention of biofilm formation or surgical site infection in prosthetic joint arthroplasty. **(No recommendation/unresolved issue)** (Key Question 20B)”

No changes are proposed to the following recommendations. Changes are not anticipated either because public comment was not received; public comment agreed with the recommendation; and/or because no other guidelines are available on the topics.

- 1B. Parenteral AMP Timing- Cesarean section
- 2A.2. Soaking Prosthetic Devices-AMP solution
- 3B. Hemoglobin A1C
- 6B. Oxygenation- General (no intubation) or Neuraxial Anesthesia
- 6C. Oxygenation- Facemask postoperative only
- 9B. Soaking Prosthetic Devices- Antiseptic solution
- 10. Repeat application of antiseptic agent to skin prior to surgical incision closure
- 11B. Blood Transfusion- Withholding
- 18. Orthopaedic Space Suits
- 20C. Biofilm - Vaccines
- 20D. Biofilm - Biofilm Control Agents

HICPAC Discussion

HICPAC indicated agreement with the proposed edits.

Update of the Draft CDC/HICPAC Guideline: Infection Prevention in Healthcare Personnel

David T. Kuhar, M.D.

Medical Epidemiologist

The 1998 guideline document is well-liked by the user community because it provides the needed information in a useful format. The update, therefore, will be similar to the original guideline. There is little evidence available to grade for much of the update, so the work will rely on expert opinion as well. This approach will be stated explicitly in the “Methods” section of the document.

The content of the guideline will focus on infection prevention topics for an occupational health service and not on other issues that occupational health services typically address, such as falls; back injuries; chemical exposures; and other non-infectious, disease-related issues. The update will not duplicate guidelines or work that has already been done. When possible, the document will refer to other relevant CDC guidelines.

The update will have three main sections:

- Section 1: A draft has been distributed to HICPAC. It is intended to be fairly general as it addresses the objectives of an occupational health service for infection prevention as well as necessary infrastructure and practices for provision of sufficient infection prevention services to personnel.

- Section 2: Provides information on the prevention of selected infections that may be transmitted among personnel and patients.
- Section 3: Addresses special populations who may require more individualized considerations for infection prevention.

Significant updates are anticipated for Section 2. The list of diseases included is slightly different from the list in the 1998 guidelines. The list was created based on previous input from HICPAC and from other experts. Some diseases will require extensive updating, while others may not require any updates. The scope of each individual disease section has previously provided information on the transmission and epidemiology of the disease; prevention of transmission; postexposure management; and work restrictions for exposed or ill personnel.

Section 3 will include considerations regarding the general health of the provider, such as being immunocompromised, as well as considerations for those who may be traveling or working in non-hospital based or non-traditional healthcare settings.

The current writing group members include CDC staff members from either DHQP or the National Institute for Occupational Safety and Health (NIOSH). Other members include representatives from HICPAC and professional societies. The writing group has not yet had an opportunity to provide full input into the draft.

The draft of Section 1 that HICPAC received is similar to the 1998 guideline. The major points are that the update will more directly address the needs for expanded healthcare settings, such as outpatient settings, long-term care settings, and others. In addition, the update will refer to updated practices and current guidelines and references for recommended screening, immunization, and postexposure management.

Questions for HICPAC's consideration include:

- Are there any major points relevant to expanded healthcare settings that are not addressed in this draft?
- Are all objectives and elements applicable to all settings?
- Should there be a specific section dedicated to non-hospital settings?
- Should the infection prevention objectives for an occupational health service be added or modified? The objectives in the draft are:
 - Educating personnel about the principles of infection prevention
 - Collaborating with the infection prevention department (and others) in monitoring and investigating relevant infectious exposures and outbreaks involving HCP
 - Providing care for work-related illnesses or exposures
 - Identifying work-related infection risks and instituting appropriate preventive measures
 - Containing costs by preventing infectious diseases that result in absenteeism and disability
- Should elements of an occupational health service for infection prevention be added or modified?
 - Coordinated Planning and Administration
 - Medical Evaluations
 - HCP Health and Safety Education Programs
 - Immunizations Programs

- Management of Potentially Infectious Illnesses and Exposures
 - Health Counseling Programs
 - Maintenance of Records, Data Management, and Confidentiality
- Any additional comments on topics within each element discussed that should either be added, expanded, or removed?

HICPAC Discussion

Section 1 is very general and sets the tone for the guideline. Readers who are trying to justify setting up an occupational health service or who are looking for structural guidance on a service will find the information helpful.

Healthcare is becoming decentralized and is increasingly delivered outside the currently-accredited environment. Often occupational health services are contracted, as smaller settings are not likely to establish their own, in-house occupational health service. This structure makes it all the more important for the clinics that offer occupational health services to understand the specific needs of the healthcare setting.

The text refers to “infection prevention departments.” This terminology may be problematic, as small facilities may have only one part-time person in that role. Infection prevention may be a function, not a person, in non-accredited facilities. Correctional facilities and outpatient behavioral health settings, such as group homes, have unique needs to address.

The area of injection safety merits emphasis. Reusable injections and bottles and multiuse vials are common practice in various settings. Diabetic testing equipment is another concern, as is equipment in the home care setting. Other pertinent settings include alternative medicine clinics, daycare centers, and more.

Section 3 may address the needs of traveling healthcare settings, such as hospital-in-home, home-based primary care, home nursing agencies, and other structures. International travel of HCP will also be addressed in this section.

There was discussion regarding the need to understand the reasons that employees are not at work. It may be important to know what employees’ illnesses are, especially if they are transmissible to patients. Union contractual issues in many settings may prevent ascertaining why workers call in sick. A section on the Health Insurance Portability and Accountability Act (HIPAA) could be included to review those restrictions and could also expand to encompass other issues, including union-based restrictions.

Public Comment

Dr. Jeffrey Hammond, Group Medical Director for Ethicon, addressed HICPAC. He appreciated the vigorous discussion regarding the “not necessary” language. In dealing with customers in the field, he has observed that “not necessary” is often equated with “not recommended.” He stated that the updated literature review for antimicrobial sutures will yield a significant amount of qualifying literature that has been published since mid-

2011. It is possible that the recommendation will be rewritten based on the new literature. He asked whether another round of public comment would be opened in the case of a significant revision.

Mr. Hageman responded that consideration can be given to another public comment period, depending on timing. An additional comment period has not been made available in the past, so consideration will have to be given to how best this could be accomplished. The recommendations will not be finalized without acquiring a range of input.

Liaison Reports

The full written reports submitted by HICPAC liaisons are included in this document as Attachment #2.

National Institutes of Health (**NIH**): The Influenza Immunization Program at the Clinical Center is a voluntary program that has 96% compliance in vaccinating healthcare workers who have face-to-face contact with patients. They hoped for the tissue culture vaccine, but they could not get any doses. The report describes efforts to adjust to the increasing prevalence of CREs in the community.

Centers for Medicare and Medicaid Services (**CMS**): Nothing to report.

United States Department of Veterans Affairs (**VA**): Nothing to report.

Association of Professionals of Infection Control and Epidemiology (**APIC**): APIC has been working on multiple revisions to their Implementation Guidelines for CAUTI, Central Line-Associated Bloodstream Infection (CLABSI), and Ventilator-Associated Events (VAE). Implementation guidelines for hand hygiene and for preventing infections in long-term care facilities are forthcoming. The fourth edition of the APIC text will be available prior to the annual conference on June 7-9, 2014 in Anaheim, California.

Association of State and Territorial Health Officials (**ASTHO**): Two capacity-building projects are ongoing. One includes grants to four states to assemble teams to assess policy barriers for implementing state HAI prevention programs. One focus area is access to electronic health record (EHR) data by health departments; the other is evidence-based policies for implementing antimicrobial stewardship programs. ASTHO has ongoing evaluation projects. An evaluation project with CDC and other partners involves examining implementation of laws or the absence of an HAI law and identifying facilitators and barriers for successful state HAI programs. The other evaluation project is being conducted with CDC and other technical experts to look at state-led prevention collaboratives, using surveys and informants to understand how they work and to assess their impact. ASTHO will convene two round-table sessions at the Council of State and Territorial Epidemiologists (CSTE) annual conference in June 2014: one on innovating healthcare response to HAI outbreaks, considering barriers and benefits to EHR access; one on combating AMR policies to promote antimicrobial stewardship programs.

SHEA: The annual spring SHEA meeting was successful. They are updating their online fellows course. SHEA is working with the Cystic Fibrosis Foundation to update that guideline. SHEA released its first Expert Guidance Paper on HCP attire. Several other guidance papers are being developed, with topics including animals in healthcare facilities and isolation precautions for visitors. The Compendium is in progress and will address many issues about

important topics for which sufficient data are not available to offer specific guidance. SHEA has been active in influencing policy decisions and produced a White Paper on a “road map for research.” The SHEA Research Network is involved in a number of initiatives. Their International Ambassador program is progressing well, and they have been pleased with its success and the support they have received from industry.

American College of Occupational and Environmental Medicine (**ACOEM**): Nothing to add to written comments.

Public Health Agency of Canada: Two initiatives are ongoing: an antibiotic awareness campaign for the public; and development of a federal framework for tuberculosis (TB) prevention and control. The agency was successful in having cross-representation on their infection control expert committee. Dr. Bell attended their February 2014 meeting. This work is an example of engaging with other governments in the development of guidelines and other tools.

AHRQ: CUSP has registered over 1400 hospital units in 41 states, the District of Columbia, and Puerto Rico. Data from the first six cohorts show a 16.1% relative reduction in CAUTI. Combating Antibiotic-Resistant Bacteria (CARB) is a new national AMR program. AHRQ has also conducted a study in workarounds for Electronic Medical Records (EMRs).

Society of Hospital Medicine (**SHM**): SHM its annual meeting in Las Vegas, Nevada, in March 2014. Hospitalists are very involved in QI activities, both locally and nationally, and they hope to become more involved in infection prevention implementation activities. SHM is a key partner, with SHEA, APIC, CDC, and others, in the CUSP. There is a 26% reduction in CAUTI on the floor, and only about a 4% reduction in ICUs. They are looking for guidance to reduce CAUTI further. SHM is working with AHRQ, CDC, APIC, and others to look at a broad definition of stewardship to prevent CAUTI in the long-term care arena. This work includes stewardship over the catheter, urine culture, and antibiotics.

Surgical Infection Society (**SIS**): The annual SIS meeting will take place in Baltimore, Maryland, in May 2014. The meeting is multidisciplinary, with approximately 45% attendees from basic science, and 55% from clinical science. SIS has published several opinion pieces and guidelines on a diverse set of topics, from biofilms to procalcitonin. SIS is making inroads in the education arena. Many different societies come to SIS for infection training. The fellowship training in acute care surgery, which is a burgeoning field, drew its core curriculum for surgical infections from SIS.

Consumers Union: Consumers Union submitted comments on the HHS Action Plan on the Elimination of HAIs. Their comments called for the addition of targets for antibiotic use and antibiotic stewardship, as well as CRE- and pneumonia-related measures. Consumers Union is still concerned that the plan does not consider individual hospital-level progress, only at aggregate progress. There should be a means for assessing how many hospitals are and are not achieving their targets and identify them regionally. Consumers Union has been working on infection legislation in several states. One bill in Missouri will expand hospital infection reporting to include antibiotic stewardship programs using the NHSN module. Regulations in Kentucky are related to hospital infection reporting. In Maryland, legislation was introduced that was turned into a study that examined exempting oncology clinics from the compounding laws. Consumers Union and other advocates were concerned about this exemption, as there are examples of patients becoming infected with, and some dying from, Hepatitis C from an oncology clinic. The study will determine appropriate standards of sterilization. Consumer Reports issued another health rating score. This safety score was an aggregate composite score. Out of a possible 100 points, the highest score was 78. The lowest was 11, so there is more work to be done. The Safe Patient Project is still working on a campaign for warranties for hip and knee implants.

DNV Healthcare Accreditation: DNV Healthcare is launching the Managing Infection Risk designation and certification for healthcare facilities. This designation is an opportunity to join a Center of Excellence. This published standard reflects 18 elements. Hospitals that conform to those elements can achieve this level of designation. A workshop will be held at their national headquarters in Houston, Texas, on May 19-20, 2014. The workshop will assist healthcare facilities and make them aware of the certification designation and their ability to enroll. A number of hospitals have already enrolled.

National Association of County and City Health Officials (NACCHO): NACCHO continues to work on an HAI prevention demonstration project with local health departments. Year Two of the project is complete. An infection prevention symposium on antimicrobial stewardship and CRE was held in Philadelphia, Pennsylvania. Several counties that were involved in the project attended the CDC HAI grantees meeting. All four health departments from the previous years are participating in Year Three. NACCHO continues to attend meetings to obtain updates on infection safety, HAIs, AMR, and infection control. NACCHO has initiated planning with DHQP to host an HAI outbreak tabletop exercise during a pre-conference workshop at the July 2014 NACCHO conference. NACCHO is developing the HAI prevention demonstration project summary, which will correspond with state health departments' and DHQP's efforts in an HAI guidance document that will be released to the public. NACCHO is updating its policy statement on local health department access to HAI data from NHSN.

America's Essential Hospitals: This year is the second in which America's Essential Hospitals is undergoing a hand hygiene compliance and improvement initiative with the Center for Transforming Healthcare at the Joint Commission. America's Essential Hospitals is participating with CMS as one of the 26 national hospital enrichment networks.

Society of Critical Care Medicine (SCCM): In the intensive care units, SCCM contributes substantially to HAIs. SCCM is collaborating with SHM to address early identification and treatment of sepsis. Four statewide joint efforts are ongoing. SCCM is also collaborating with the European Society of Intensive Care Medicine on a revision of the standard sepsis guidelines used for trials. A task force has been created, and publication of new consensus definitions regarding sepsis is expected in 2015. SCCM released five elements that physicians and patients should question regarding the "Choosing Wisely" campaign. Two of those elements are associated with HAIs: deep sedation and early inappropriate use of parenteral nutrition. SCCM has invested in support material for a website called ICU Liberation (www.iculiberation.org), which focuses on managing getting patients off of ventilators quickly to prevent VAEs. SCCM has released several publications recently pertaining to antimicrobial stewardship and HAI definitions in the intensive care population.

Association of periOperative Registered Nurses (AORN): The AORN annual conference in April 2014 in Chicago, Illinois convened 4900 perioperative nurses and 4900 exhibitors. The conference was a success, and the AORN Congress approved four position statements that will be released. Currently, AORN's "recommended practices for preoperative patient skin anasepsis" is available for public comment. They are awaiting feedback from the National Guideline Clearinghouse to ensure that the document will meet the new criteria. Before the next HICPAC meeting, AORN's Surgical Attire Recommended Practice document, which is evidence-rated, will be available for public comment. It will complement the recent SHEA document.

Joint Commission: Five projects are ongoing, and interim data analysis is underway.

The meeting stood adjourned at 5:10 pm.

Friday, April 11, 2014

The second day of the meeting of HICPAC was called to order at 9:09am on Friday, April 11, 2014. A roll call was conducted to establish quorum, and HICPAC members declared conflicts of interest.

Planned Enhancements to NHSN for Releases in July 2014 and January 2015

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The Change Control Board plans for two releases per year, one late in July and the other before the end of January. The January release includes items that will change definitions, criteria, protocols, and other items that will affect data and its comparison and standardization. Data are analyzed on the calendar year, so this approach assures consistency. The July release focuses on added components, modules, reporting, or small, optional “tweaks” that will not affect the overall collection and analysis of the data. Changes and fixes to improve ease for users and additional reports or outputs may also be released in July. The items listed as planned for a release are subject to change right up until the time of release. The release planned for July 26, 2014 includes the following:

- New Dialysis Component: inclusive of all reporting related to Outpatient Dialysis Facilities (AMB-HEMO)
- New AMR Option of the Antimicrobial Use and Resistance (AUR) Module
- Add HCP Vaccination reporting capability for Inpatient Rehabilitation Facilities (IRFs)
- Add alerts for unusual antibiotic susceptibility profiles in Patient Safety Component reporting
- Removal of Patient Influenza Vaccination reporting from Patient Safety Component
- Revisions to multiple Output Options reports and datasets

A new dialysis component will be created when dialysis event reporting is pulled out of the patient safety component. Users will only notice the change because it will “clean up” their reporting view. Users will follow the same forms and satisfy the same fields, but the new component will help NHSN. Outpatient dialysis facilities are different from inpatient facilities, but they use the same module for event reporting. Separating the event reporting will make it easier to change without affecting the whole, interconnected system. Separating the event reporting also reporting more straightforward. Users only see the forms they need to use to report.

The addition of the AMR option to the AUR Module is exciting. The AMR option is similar to the Laboratory-Identified (LabID) Event. Nineteen organisms are on the required list in the module. A number of antimicrobials are reported with each of those organisms when they are identified. The report looks for isolates from blood, cerebrospinal fluid (CSF), urine, and lower respiratory only. A one-per-month rule applies to urine and lower-respiratory, and a 14-day rule applies to blood or CSF for that patient and that organism in that facility. Under this

option, susceptibility is not just reported at the interpretation level of a susceptible intermediate resistant, but the MIC value, E-test value, or zone diameter is also being collected. The cut points are then available to understand detected changes. The protocol is posted online, and the implementation guide is available for vendors.

New CMS rules added new facility types that will be added this fall for influenza season for HCP vaccination reporting. NHSN needed tweaks to include ambulatory surgery centers and Inpatient Rehabilitation Facilities (IRFs) to begin that reporting. This work is challenging because a number of IRFs are units within acute care facilities.

Another important addition is adding alerts for unusual antibiotic susceptibility profiles. When HAIs are reported, users will be alerted at data entry to certain antimicrobial profiles with specific organisms. The system will immediately notify the user that “this is a pattern in your facility” and ask for confirmation that the entry is accurate. This addition will address potential data entry errors and will increase communication within the facilities to ensure that all personnel are aware of the important elements that should be tracked and reacted to in a facility. The alert message also informs the user that the state or local health department might want to know about an isolate. When the entry is confirmed, NHSN will create reports so that groups or users can determine patterns and other relevant knowledge for facilities.

Patient Influenza Vaccination reporting will be removed from the Patient Safety Component. This element has been available in the system for years, but very few facilities use it. CMS has collected this information for a long time, and many facilities have their own system to track this information within their EMRs. Because the system is so complicated, one of their goals as they add new elements is to “clean up” the system and remove elements that are not used in order to make better use of the space.

The January 2015 release is planned for January 24, 2015 and will include:

- Additions for Procedures/SSIs: Present at Time of Surgery (PATOS) variable; Infection at index joint for Hip Prosthesis (HPRO) and Knee Prosthesis (KPRO); ICD-10 – Clinical Modification/ Procedure Coding System (CM/PCS) and Current Procedural Terminology (CPT) codes – delayed
- Potential implementation of 14-day rule for HAI reporting and possible change to assignment of Date of Event
- Simplified central line and catheter days denominator reporting
- Addition of VAE denominator – Episodes of Mechanical Ventilation
- Update to CAUTI definition and CLIP definition
- Update to LabID Event protocol and addition of CRE-Enterobacter
- Revisions to “non-Big 5” HAI definitions – Chapter 17 HAIs
- Revisions to Clinical Document Architecture (CDA) Implementation Guides and Output Options reports and datasets

Adding the PATOS variable will enable the system to identify an infection that is present at the time of surgery and will allow for separate analyses on those procedures and infections. The system will also collect information about infection at the index joint for hip and knee replacements. NHSN was preparing for the shift to ICD-10-CM/PCS and CPT codes, but that shift is delayed due to the delay in ICD-10. CDC staff will continue to work to ensure that

they are prepared well in advance of ICD-10, providing crosswalks to users so that they will know which ICD-10 codes map to the NHSN procedures that are collected.

The January 2015 release may implement a 14-day rule between HAIs. This change will eliminate subjectivity. The system currently indicates reporting when an infection has resolved and signs and symptoms have resolved. If new symptoms are observed, then a new HAI is reported. This process is rather subjective and leads to a number of technical support questions. The Date of Event element was moved from the first piece of criteria to the last piece of criteria. The ideal definition of Date of Event will help identify whether an infection was present on admission or is a true HAI. NHSN should be simple and standardized, avoiding instituting multiple rules that switch among HAIs or different parts of reporting.

Central line and catheter day denominator reporting will be simplified and conducted on one or two specific days per week. This approach will accurately represent an everyday count of central lines. The calculation will then be built into the system and ensure that it is standardized. One VAE denominator will be added to capture episodes of mechanical ventilation. Research indicates that this count is important in addition to, or possibly instead of, Ventilator Patient Days. The denominator is not yet fully defined. It will be added as an optional field to begin collecting the data.

A large group of internal and external experts has been working toward refining the CAUTI definition. It is being finalized now, and the forms are being created for electronic reporting and implementation. Some variables were added to the form. For now, information on yeast will continue to be collected, and the new form will allow those data to be studied separately. A small change is planned for the Central Line Insertion Practices (CLIP) definition. This change will indicate when there is a contraindication for the sensitivity for use of chlorhexadine in babies less than 60 days old. This definition is mandated in California and New Hampshire, and it is important to ensure that the reporting does not appear to be an unsuccessful following of the bundle.

Some changes are planned for LabID Event. CRE is important for tracking, and there is a great deal of discussion regarding the best definition of CRE and how to go about collecting information from states and facilities. CDC is working with internal and external partners, including CSTE, on this point. LabID Event is a step toward the AUR Module, which will be all-electronically-captured and will yield more specific data. There is a great deal of uptake of LabID Event, so CRE-*Enterobacter* will be added to CRE-*E.coli* and CRE-*Klebsiella*, which are already collected. All three will be reported together.

NHSN works closely with the Emerging Infections Program (EIP). They evaluate gaps and changes in surveillance between the two. In response to this work, LabID Event will collect where patients came from before they enter a facility. A great deal of MRSA and *C. difficile* infections come from nursing homes, and this approach will close that knowledge gap regarding community-onset into acute care facilities. Additionally, LabID has a stringent definition regarding collecting the specimen on the same day of admission. The protocol will be updated so that reports will be made from the emergency department and the observation units. Users at facilities have expressed interest in making this change, as the current structure does not illustrate true community-onset versus hospital-onset infections, or where the infections begin.

The NHSN release will include revisions to the “non-Big-5” HAI definitions. Chapter 17 includes approximately 40 definitions beyond SSIs, CLABSI, CAUTI, VAE, and pediatric Ventilator-Associated Pneumonia (VAP). Most facilities use these definitions for secondary bloodstream infection (BSI) reporting. If a BSI is identified with a positive blood culture, then it can be attributed as secondary BSI, not primary BSI or CLABSI. The definitions are used

regularly and need to be updated and “cleaned up,” especially for consistency in the wording. This work affects states such as Pennsylvania, which have a mandate for all HAI reporting.

Every time changes are made to the NHSN manual, application, and protocol, new variable additions and changes are made through a ballot cycle for the CDA Implementation Guide to ensure vendors can incorporate the changes electronically. Revisions are also made to Output Options, reports, and datasets. NHSN also creates separate reports for facilities to use for CMS reporting.

A number of changes are planned for 2015 due to ongoing discussion and feedback because of a high level of uptake. After 2015, fewer changes will be instituted. The 2015 data will be used as a re-baseline. Current CLABSI and SSI baseline data are from 2006-2008, CAUTI baseline is from 2009, and LabID Event data are from 2010-2011. At that time, only five states had mandated LabID. Bringing all HAIs to the same baseline will allow for a full view of the entire nation, as more data is available now as state mandates and CMS reporting have increased. NHSN is working with states and CMS to ensure that all parties are prepared for how the changes may affect data.

HICPAC Discussion

PATOS SSIs will be excluded from SIR. The plans are not “solid,” but it is recognized that those data are important and will be available in 2015 so that a clear determination can be made. Mucosal Barrier Injury (MBI) has been reported as part of CLABSI. In the revision, it will be required reporting now that the Implementation Guide and electronic reporting capture it. When data are re-analyzed for re-baselining, those data will be pulled out. No final decisions have been made regarding the pediatric VAE definition. The process is currently on hold.

Even though feedback is being gathered from a range of perspectives, the CAUTI definition should not be finalized without presentation to HICPAC. There was concern about the possibility of “locking in” definitions that may lead to detrimental practices or may lead to tracking elements that are not infections. CDC is assessing potential unintended consequences associated with what is included in the definition and the potential impact of the changes on facilities, now and in the future. Data from a pilot project will have an impact on the definition. If variables are added, even if they are not used, then that information is important for vendors. The HICPAC meeting in July 2014 will include an update on these points.

Collecting information regarding the facilities that patients with resistant organisms have come from, particularly nursing homes and other non-acute care centers, is important; however, it is possible that previous exposures of those patients are not captured. Some facilities are part of a network and have information about a patient’s movements through the continuum of care, while others are disconnected and will not have that information. There is concern about the burden associated with tracking facilities. A first step toward collecting this data is including it on the LabID form.

There was discussion regarding unrealistic expected events of MRSA at some facilities. The expected number of events are drawn from baseline data from 2010-2011 and from the incidence rates from those years when the risk adjustments for the SIR were created. When they re-baseline, the data will feed into a new SIR, and there may be changes because more representative data will be available.

2015 data will become the new SIR baseline that will be compared to 2016 data and every subsequent year. The changes cannot be instituted until 2015. Facilities report both electronically and manually, and they must remain on the same path and use the same timeline. The 2015 data will include the new variables and fields. The 2014 data release will compare to prior levels, and the five-year projects set to end in 2013 will be extended to six years

so that there will not be a gap in data or a lapse in reporting SIRs. The proposals for new levels to meet are created based on estimates of the 2015 baseline.

Input into the NHSN revisions comes from state health departments that have engaged in data collection or validation. Users, including large healthcare systems and collaboratives, provide feedback routinely. CDC formed a CAUTI Workgroup to provide continuous input. When the Chapter 17 definitions were revised, SMEs were asked to contribute in certain areas, such as burns. They have ongoing relationships with CTSE and CMS as well. It is important to engage with the front-line end users and stakeholders who are held accountable for the data collection when working on definitions.

Core Practices for Infection Prevention and Control: Minimum Expectations for Safe Care Across Healthcare Settings

Gina Pugliese, RN, MS
HICPAC Member

The goals of the Core Practices are to:

- Describe a core set of infection prevention elements and practices that are applicable across all settings and for all patients and levels of care. Many of these practices are not supported by RCTs, but they are applicable in every setting.
- Limit redundancy in listing core practices in numerous CDC/HICPAC guidelines by including them in a single, readily-available document that shares language across guidelines; and
- Maintain an online document that can be updated to reflect new evidence-based core practices and that can link to other guidelines.

Core Practices is intended for front-line healthcare workers who provide direct or indirect care, not for infection prevention programs at hospitals. Elements that are expected parts of an infection control program are not included.

The process of creating the Core Practices was to:

- Identify an initial list of core practices
- Review current CDC and HICPAC guidelines to identify core practices and to compare the language and grading of the recommendations
- Review current US infection prevention and control guidance, as well as Canadian and World Health Organization (WHO) Core Practices, as well as CDC's Outpatient Oncology and Ambulatory Settings guidance document
- Create a draft summary table with the key domains, core practices, rationale, source documents, and key references
- Review and refine the core practices: workgroup led by HICPAC members

The workgroup found different language and explanations of the different core practices across the guidelines, as well as a variety of grading. Not all core practices are included, or are necessarily appropriate for inclusion, in all of the guidelines. Some core practices are no longer included in current guideline revisions. Some activities that the workgroup felt to be “core” are not included the guidelines. The group also discovered variability in the specificity of how the different guidelines defined a “core practice.”

The final list of core practices is as follows, with the italicized practices representing additions to the initial list.

- Leadership support
- Education and training of HCP on infection prevention
- Patient family and caregiver education
- Performance Monitoring
- Standard precautions
- Hand hygiene
- Personnel protective equipment
- Respiratory hygiene and cough etiquette
- Transmission-based precautions
- Aseptic technique
- Injection and medication safety
- Environmental hygiene
- Invasive medical devices
- Occupational health

The workgroup observed inconsistencies across many of the guidelines they reviewed. An example of these inconsistencies is in the area of education and training of HCP. The Infection Control in Healthcare Personnel Guideline refers to providing education annually and when the need arises via in-service training and to providing education on infection control that is appropriate and specific for their work assignments so that personnel can maintain accurate and up-to date knowledge about the essential elements of infection control. That guideline was rated IB/IC. The Isolation Guideline is more general and was rated II. The Multidrug-Resistant Organism (MDRO) Guideline rates the guideline at IB and is more specific about providing and intensifying education. The Norovirus Guideline rated the guideline at II, and the CRE Guidance does not refer to education and training for HCP.

The HICPAC Core Practices Workgroup includes members of HICPAC, HICPAC liaisons, and others who provided input into the final draft. The core practices will provide some references to other CDC and HICPAC guidelines, but they will not be highly detailed references.

1. Leadership Support

- Executive leadership is accountable for the development and support of the infection prevention and control program that address the risks for the patients and services provided in the specific setting
- Align infection prevention and control activities with the strategic goals of the organization

- Allocate appropriate resources, both human and material, to infection prevention and control activities to enable consistent, agile, and immediate response to infection risks
- Empower and support positional authority to those responsible for the infection prevention and control activities to enable consistent, agile, and immediate response to infection risks

Rationale: To be successful, infection prevention and control activities require visible and tangible support from all levels of the healthcare facility's leadership. This should include executive-level involvement.

HICPAC Discussion

The language should include "governing body" and "executive leadership" as well as "leadership support." The governing body and executive leadership are accountable. "Governing body" is an appropriate term for CMS, Joint Commission, and other accrediting organizations.

The presence of a comprehensive system for infection control throughout a facility is a concrete measure of leadership support, but this guideline is intended for front-line workers and leadership that is needed to ensure compliance with the broad infection control program, not the infection prevention program. The workgroup tried to be inclusive of a range of activities that need to be in place in an environment. It should be evident that the infection control program crosses the entire organization at every function.

2. Education and Training of Healthcare Personnel on Infection Prevention and Control

- Ensure that those providing education are competent to provide the content
- Ensure that all HCP are competent to perform the care that is required for their roles and job responsibilities
- Include training specific to infection prevention and control as appropriate to job responsibilities
- Provide training and education that is specific for the setting and work assignments
- Enhance education and training by using reading level, language, and culturally appropriate material for the target audience
- Ensure access to materials such as tools, resources, and policies that support the training and education needs of the target audience
- Provide education and training for all HCP prior to providing patient care and/or performing duties and update periodically. (e.g., annually)
- Promptly provide education and training for HCP; when evidence demonstrates adverse outcomes including outbreaks, lapses in practice, and increased infection rates; target and intensify education and training to those HCP for which it is most relevant

Rationale: Measures that ensure the workforce is competent to perform job responsibilities are critical elements of an infection prevention and control process. HCP must be educated regarding best practices and have training designed to allow application of knowledge and practice. Training should, therefore, be adapted to reflect the growing diversity of the workforce and should take into consideration age, language, and cultural differences. In addition, training should be directed towards the many disciplines involved in care delivery and include an emphasis on teams and interprofessional practice.

HICPAC Discussion

There was discussion regarding how to strengthen basic training in academic programs. The workgroup discussed the "next step" of implementing the core practices. Suggestions included incorporating the core practices into

training through the Clinical Learning Environment Review (CLER) program. Physicians should be educated and trained in infection control practices as early as medical school. The American Association of Medical Colleges (AAMC) could provide helpful input and buy-in, as well as equivalent organizations for other medical trainees. Various practice groups will apply the core practices to specific implementation guides for each of their settings. One of the sections of the document could be developed into a sample implementation guide that could be used as a template.

The core practices are similar to some of the Joint Commission standards and some of the Conditions of Participation or Conditions of Coverage under CMS. CMS has these conditions for approximately 13 different provider/supplier types. The infection control language is not consistent across all of those providers and suppliers. The interpretive guidelines address educational expectations. They are not regulatory, but they express what CMS thinks facilities should do in order to be in compliance.

3. Patient, Family and Caregiver Education

- Provide infection prevention education to patients, family members, and those included in the caregiving network, as appropriate
- Include specific information regarding mechanisms for pathogen transmission and prevention
- Ensure that those providing education are competent in the patient care aspects as well as methods of instruction for patients, family members and others
- Apply principles of adult learning that incorporate reading level, language appropriate materials, and cultural competence
- Focus education on enabling and empowering the patient, family, and caregivers to perform infection prevention activities
- Provide supportive resources such as instruction sheets, pictorial guides, and frequently asked questions specific to the activity or condition for which education is provided

Rationale: In order to facilitate understanding of disease processes and infection prevention strategies, provide education to the patient and his or her entire caregiver network. This may include visitors as well as those who may be involved in care either at home or in another healthcare setting. Instructional materials, design and techniques should address varied levels of education, reading and language comprehensive and cultural diversity. Using a variety of instructional materials helps to ensure understanding, application, and ongoing use of infection prevention activities in all care settings.

HICPAC Discussion

The document could be streamlined by combining concepts. The order in which the items within each topic area are presented is important, as is the order of the topic areas themselves. The guideline has the potential to become regulatory, so they should consider how it could be used in that context, as well as how a surveyor will determine how each element is being performed.

The list of practices should be culled to a core of concrete components that absolutely must be done. These elements will not be reiterated in future guidelines. A rationale section can include considerations for implementation or additional beneficial factors. Some information in the elements is related to implementation. The information is important, but implementation is a next step after the core practices document. When materials are developed, all of the rationale should be taken into consideration. Checklists can incorporate peripheral language, header paragraphs, footnotes, or any tools that will make a surveyor's job easier.

An additional column for “additional considerations” was suggested between the “core practice elements” and “rationale.”

4. Performance Monitoring

- All HCP should be held accountable for performing their duties in a safe and effective manner
- Monitor performance to enhance adherence to best practices
- Develop and implement performance monitoring elements based upon the patient population cared for and services provided in the facility
- Develop and use standardized monitoring tools and definitions that enable widespread use and reliable analysis
- Train staff to monitor performance and document results with targeted data collection tools
- Periodically assess the adequacy of performance monitoring processes
- Provide regular feedback of outcomes to staff performing the processes being monitored and to facility leadership
- Intensify the frequency of performance monitoring of HCP when evidence demonstrates adverse outcomes including outbreaks, lapses in practice, and/or increased infection rates; target performance monitoring to those HCP for which it is most relevant

Rationale: Performance monitoring should include process and outcomes measures. Staff involved in performance monitoring should be trained in the aspects of monitoring as well as the processes or outcomes under review.

HICPAC Discussion

This domain could be titled “performance monitoring and feedback” to emphasize the importance of feedback to performance monitoring. A response to an outbreak should not just be to intensify monitoring. The response should include other approaches.

5. Standard Precautions

- Standard precautions should be utilized in the care of all patients in all settings

Rationale: Standard Precautions are the minimum infection prevention practices that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting where healthcare is delivered. These practices are designed to both protect HCP and prevent HCP from spreading infections among patients and include: 1) hand hygiene, 2) use of personal protective equipment (e.g., gloves, gowns, face masks) depending on the anticipated exposure, 3) respiratory hygiene/cough etiquette, 4) safe injection practices, and 5) safe handling of potentially contaminated equipment or surfaces in the patient environment. Each of these elements of Standard Precautions is described in the sections that follow. Education and training on the principles and rationale for recommended practices are critical elements of Standard Precautions because they facilitate appropriate decision-making and promote adherence. Further, in each facility/patient care setting, an understanding of the specific procedures performed and typical patient interactions will assure that necessary equipment is available.

5a. Standard Precautions: Hand Hygiene

- Ensure that sinks and/or hand hygiene products are readily accessible in all areas where patient care is being delivered

- Ensure that HCP perform appropriate hand hygiene in accordance with CDC and WHO recommendations
- Use an alcohol-based hand rub or, alternatively, an antimicrobial or non-antimicrobial soap, for the following indications:
 - Before touching a patient
 - After touching a patient or the patient's immediate environment
 - After contact with blood, body fluids or excretions, or wound dressings
 - Before performing an aseptic task (e.g., placing an indwelling device, preparing an injection) or handling invasive medical devices
 - Before moving from a contaminated body site to a clean body site on the same patient
 - After glove removal
 - Ensure that HCP perform hand hygiene with soap and water (an antimicrobial or non-antimicrobial soap) for the following indications:
 - When hands are visibly soiled
 - After using the bathroom
 - After eating
 - Use a multi-modal strategy to improve hand hygiene adherence that includes education of HCP and availability of appropriate products

Rationale: Appropriate hand hygiene is critical to reducing the risk of spreading infections in all patient care settings. An alcohol-based hand rub is recommended by the CDC and WHO because of its activity against a broad spectrum of epidemiologically important pathogens and because compared with soap and water, use of alcohol-based hand rubs in healthcare settings can increase compliance with recommended hand hygiene practices by requiring less time, irritating hands less, and making it easier to perform hand hygiene at the patient bedside. For these reasons, using an alcohol-based hand rub is the preferred method for hand hygiene except when hands are visibly soiled (e.g., dirt, blood, body fluids). Refer to "CDC Guideline for Hand Hygiene in Health-Care Settings" for details.

HICPAC Discussion

HICPAC commented that only CDC guidelines should be referenced.

It was suggested that the document emphasize hand hygiene, but refer to the Hand Hygiene Guidelines without providing explicit detail. The workgroup felt that if this document will be used by a broad range of HCPs, then it will be useful to have some detail in some of the elements. Not all users will refer to other guidelines, and it is important not to lose the salient points that every healthcare practitioner is expected to implement. Hand hygiene is a particular area in which a level of detail regarding expectations for every front-line worker is helpful.

5b. Standard Precautions: Personal Protective Equipment (PPE)

- Ensure that sufficient and appropriate PPE is available and readily accessible to HCP
- Educate all HCP on proper selection and use of PPE
- Remove and discard PPE before leaving the patient's room or area
- Wear gloves for potential contact with blood, body fluids, mucous membranes, non-intact skin or contaminated equipment

- Do not use the same pair of gloves for care of more than one patient. Do not wash gloves for the purpose of reuse
- Wear a gown to protect skin and clothing during procedures or activities where contact with blood or body fluids is anticipated
- Wear mouth, nose and eye protection during procedures that are likely to generate splashes or sprays of blood, respiratory secretions, or other body fluids

Rationale: PPE refers to specialized clothing or wearable equipment that is intended to protect HCP from exposure to or contact with infectious agents and materials. Examples of PPE include gloves, gowns, face masks, respirators, goggles and face shields. The selection of PPE is based on the nature of the patient interaction and potential for exposure to blood, body fluids or infectious agents. Refer to “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, 2007,” as well as Occupational Safety and Health Administration (OSHA) requirements for details.

5c. Standard Precautions: Respiratory Hygiene and Cough Etiquette

- Educate HCP about the importance of infection prevention measures to prevent the spread of respiratory pathogens when examining and caring for patients with signs and symptoms of a respiratory infection
- Discourage visitors with symptoms of respiratory infection (e.g., cough, runny nose, fever) from entering the facility
- Ensure that patients and essential visitors with symptoms of respiratory infection contain their respiratory secretions by, for example, providing tissues or surgical masks and instructional signage or handouts at points of entry and throughout the facility
- Separate patients with respiratory symptoms from other patients (e.g., place them into a separate examination room or as far from other patients as possible in the waiting room) as soon as possible after entry into the healthcare facility

Rationale: Use respiratory hygiene and cough etiquette to prevent the transmission of respiratory infections in the facility to and from HCP, patients, accompanying family members, caregivers, and visitors. “Respiratory hygiene/cough etiquette” is an element of Standard Precautions that highlights the need for prompt implementation of infection prevention measures for all persons with signs and symptoms of respiratory illness, including cough, congestion, rhinorrhea, or increased production of respiratory secretions at the first point of entry or encounter with the facility or care settings (e.g., reception, triage areas, patient care areas) and continues throughout the duration of the visit. Refer to “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, 2007” for details.

6. Transmission-Based Precautions

- Implement additional precautions (i.e., Contact, Droplet, and/or Airborne Precautions) in situations where contact with the patient, their body fluids, or their environment presents a substantial transmission risk despite adherence to standard precautions
- Ensure rapid notification of laboratory results back to healthcare providers as a means of enabling them to quickly implement appropriate precautions
- Ensure that HCP have immediate access to and are able to select, put on, remove, and dispose of PPE in a manner that protects themselves, the patient, and others

Rationale: The risk of infection transmission and the ability to implement all the elements of Transmission-Based Precautions will differ depending on the patient care settings (e.g., inpatient, outpatient, long-term care) and facility design characteristics. As such, specific strategies for Transmission-Based Precautions need to be developed to control the spread of transmissible diseases pertinent to their setting. This includes developing and implementing systems for early detection and management of potentially infectious patients at initial points of entry to the facility or care setting and each transition of care. Specific syndromes involving diagnostic uncertainty (e.g., diarrhea, respiratory illness involving fever, illnesses involving rash and fever) deserve specific triage. To the extent possible, this includes prompt placement of such patients into a single-patient room while awaiting clinical assessment, and a systematic approach to transfer or admission when appropriate. If arranging for patient transfer, the transporting agency and accepting facility should be informed of the suspected infection type. Refer to “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, 2007” for details.

HICPAC Discussion

Healthcare workers may become confused in this area, because PPEs are not just personal protective equipment, they are personal and patient protective equipment. The section could have a different title and describe specifics regarding the type and purpose of protective attire in the rationale. A statement about including OSHA could also be included. If this document is a summary of guidelines, then it should not develop a new reference language. Future documents may address these questions, but this document should not use language that is not commonly used and understood.

Education about respiratory etiquette and discouraging visitors could be included. These ideas apply to HCP as well as to patients. These ideas are mentioned in the occupational health section but merit reiterating. The elements of “6. Transmission-Based Precautions,” seem like program operationalization, but in order to work, they should be implementable by any healthcare worker. The concepts are important for Intensive Care Unit (ICU)-based providers and appropriate for front-line providers. Fast laboratory results are important, but the rationale emphasizes that the application of transmission-based precautions should be syndrome-based. That detail might not need to be included in the core practices, as institutions have wide variability in their access to diagnostics.

The Joint Commission has conducted a number of evaluation programs and focus groups to determine why people do not wash their hands. The studies found that even if sinks are located conveniently, if there is not a place for people to put their things down during hand-washing, then they are less likely to wash. This point is a management or implementation approach, but an important aspect that needs to be shared.

7. Aseptic Technique

- Use appropriate precautions to prevent contamination and transmission of microorganisms from one person, body site, or contaminated object or surface to another
- Clearly separate clean from soiled equipment in patient care areas and during patient care activities
- Do not share patient care items between patients unless the items have been cleaned and disinfected between use and are labeled as appropriate for multiple patient use
- Store patient care supplies and equipment in clean storage spaces that minimize opportunities for contamination
- Do not reuse or share between patients any items packaged or labeled as single patient use unless reprocessing of the item is FDA-approved

- Ensure that when multiple items are packaged together (e.g., gloves in a glove box) that the items are maintained in a manner that minimizes contamination opportunities
- Store patient care items in areas that are free from conditions that may compromise the item (e.g., contact with water)

Rationale: Aseptic technique does not imply sterility, but it does imply preventing transfer of microorganisms from one person, body site or contaminated object to another. Aseptic technique relies on proper handling of equipment, supplies, and adherence to other core practices such as hand hygiene, injection and medication safety, standard precautions, and use of PPE.

HICPAC Discussion

Some of these points are addressed in Injection and Medication Safety. Aseptic technique includes issues such as the disruption of sterile fields during a bedside procedure, contaminating the wrong part of a pair of sterile gloves, or errors in the transfer of injectable medications. Those items are not in this section; rather, this section considers environmental materials and hygiene. Contamination during a procedure should be added back to the elements. Basic microbiology is a diminishing factor in education across healthcare. People need to be reminded that they cannot see microbes. The rationale could include a checklist or flowchart diagram to serve as basic re-education.

In the available guidelines, asepsis is only addressed as a patient issue as part of a discussion of hand hygiene. A definition for asepsis was not readily available, even though it is frequently mentioned. The workgroup tried to combine the different definitions of asepsis into one. The term refers to all practices for clean and dirty procedures, including sterile and not sterile. If the Core Practices are reorganized, then one domain might address “precautions” and include standard, transmission-based asepsis. Some groups are moving away from the language of “aseptic” toward “sterile technique” when referring to a sterile field. Aseptic technique is not necessarily sterile because of the larger scale of clean, dirty, and sterile.

8. Injection and Medication Safety

- Use aseptic technique when preparing and administering medications
- Clean the access diaphragms of medication vials before inserting a device into the vial
- Never administer medications from the same syringe to multiple patients, even if the needle is changed or the injection is administered through an intervening length of intravenous tubing
- Do not reuse a syringe to enter a medication vial or solution
- Do not administer medications in single-dose or single-use vials, ampules, or bags or bottles of intravenous solution to more than one patient
- Do not use fluid infusion or administration sets (e.g., intravenous tubing) for more than one patient
- Dedicate multidose vials to a single patient whenever possible; if multidose vials are used for more than one patient, restrict the medication vials to a centralized medication area and do not bring them into patient treatment areas (e.g., operating room, patient room/cubicle)
- Dispose of used syringes and needles at the point of use in a sharps container that is closable, puncture-resistant, and leak-proof
- Adhere to federal and state requirements for protection of HCP from exposure to bloodborne pathogens

Rationale: Unsafe injection practices put patients and HCP at risk of infectious and non-infectious adverse events. Safe injection practices are part of Standard Precautions and are aimed at maintaining basic levels of patient safety and provider protections. As defined by the WHO, a safe injection does not harm the recipient, does not expose the provider to any avoidable risks, and does not result in waste that is dangerous for the community.

HICPAC Discussion

Injection safety is part of the standard precautions, so it could be included as a subgroup of that domain. However, because there have been recurrent problems with basic injection safety issues, specific practices might be reiterated. The document can also point to injection safety materials that have been produced, highlighting the elements that constitute major mistakes such as cross-contaminating a multi-dose vial and using a saline bag as a flush reservoir. There may be added value in explaining that a centralized medication area needs to be clean and in providing guidance indicating that medications should not be prepared near sinks. This area has been identified as problematic in some of the injection case studies and outbreaks. The CDC Oncology Guide includes a section with core practices and best practices for injection safety.

9. Environmental Hygiene

- Select US Environmental Protection Agency (EPA)-registered disinfectants or detergents/disinfectants with label claims for use in healthcare
- Use an EPA-registered disinfectant with appropriate germicidal claim for the infective agent of concern (may vary depending on situation)
- Assign responsibility for routine cleaning and disinfection to appropriately trained HCP
- Follow manufacturer's recommendations for use of cleaners and EPA-registered disinfectants (e.g., amount, dilution, contact time, safe use, and disposal)
- Prioritize adequate cleaning and/or disinfection of environmental surfaces that are most likely to become contaminated (e.g. frequently touched or in close proximity or direct contact with the patient), that are visibly soiled or where there is a question of cleanliness, and following spills of blood or other potentially infectious materials
- Follow the equipment manufacturer's instructions to ensure that reusable medical equipment (e.g., blood glucose meters and other point-of-care devices, surgical instruments, endoscopes) is cleaned and appropriately reprocessed prior to use on another patient

Rationale: Routine cleaning and disinfecting of non-critical environmental surfaces in the healthcare setting is essential to reduce the risk of transmission of infectious agents between and among HCP, patients, and visitors. Refer to "CDC Guidelines for Environmental Infection Control in Health-Care Facilities" and "CDC Guideline for Disinfection and Sterilization in Healthcare Facilities" for details.

HICPAC Discussion

There was discussion regarding the importance of stating that everything should be identified and cleaned at some point. The element could address prioritizing the frequency of cleaning and specify surfaces and equipment that come into contact with patients or HCP. All surfaces do not need to be approached the same way. The workgroup will need to compare the core practice elements to the original source material to maintain fidelity. However, some language from the original guidelines was omitted in order to make the elements more broadly applicable.

10. Invasive Medical Devices

- Ensure that all invasive medical devices have been appropriately cleaned, disinfected and/or sterilized and properly stored prior to use on a patient
- Cleaning must always precede disinfection or sterilization because residual debris reduces the effectiveness of the disinfection and sterilization processes
- During each healthcare encounter, assess the medical necessity of any invasive medical device (e.g., vascular catheter, indwelling urinary catheter) in order to identify the earliest opportunity for safe removal
- Ensure that HCP adhere to recommended insertion and maintenance practices

Rationale: Invasive medical devices (e.g., vascular catheters, indwelling urinary catheters) can be critically important in caring for patients. However, invasive medical devices can lead to patient complications, including device-associated infections. Early and prompt removal of invasive devices should be part of the plan of care and included in regular assessment. HCP should be knowledgeable regarding risks of the device, infection prevention interventions associated with the individual device, and advocate for the patient by working toward removal of the device as soon as possible. Refer to “CDC Guidelines for Environmental Infection Control in Health-Care Facilities” and “CDC Guideline for Disinfection and Sterilization in Healthcare Facilities” for details.

HIPCAC Discussion

The third bullet is the most important and should be listed first. The second bullet about disinfection or sterilization may not fit in this domain, but its concepts could be combined with the fourth bullet, as cleaning practices are part of recommended insertion and maintenance practices. The fourth bullet could specify “in all settings” or “throughout the healthcare facility.” The perception is that the OR is sterile, but many device insertions in the OR do not follow sterile technique. There will likely be more focus on device utilization ratios in the future.

11. Occupational Health

- Ensure that all HCP receive immunizations or have documented immunity against vaccine-preventable diseases as recommended by the CDC’s Advisory Committee on Immunization Practices (ACIP) and required by OSHA
- Ensure that HCP refrain from reporting to work when they develop signs or symptoms of acute illness (e.g. fever with or without rash, cough or runny nose; diarrhea or vomiting) to prevent transmission of their infections to patients and other HCP
- Ensure that HCP report signs, symptoms, and diagnosed illnesses that may represent a risk to their patients, coworkers, and their communities to their supervisor or healthcare facility staff who are responsible for occupational health

Rationale: It is the professional responsibility of all HCP to ensure that their practices support patient safety. This includes adherence to US Public Health Service recommendations as well as OSHA and public health department (state, local or territorial) regulations concerning immunization; work practices that support healthcare worker absence from work when ill; timely reporting of illness to employers when that illness may represent a risk to patients, HCP and others in that facility; and communication with public health authorities when the illness has public health implications.

HICPAC Discussion

Occupational health is important in every setting. Basic employee health practices such as immunizations and awareness of illness among employees are important. The immunization requirement for every HCP that provides care to patients should be stated. The Occupational Health Guidelines will be their own entity, but this section is still important to include. Some users will use this document without thinking that they need the Occupational Health Guidelines, so this document will set core practices and minimum standards. There was discussion regarding the possibility of legal and HIPAA concerns pertaining to ensuring reporting. The element may need to refer to developing a mechanism for safe reporting of illnesses to minimize risk of transmission to patients.

It was suggested that the second bullet include “infectious,” as allergies can have symptoms of acute illness. It is challenging to determine who should interpret whether symptoms are due to an infectious illness or an allergy, but without that clarification, the element could be interpreted as a directive for employees with a “runny nose” not to report to work, which is difficult to operationalize.

Because local health departments tend to find poor influenza immunization rates when they investigate influenza outbreaks in nursing homes, the first bullet could be broadened to add “promotion of vaccines” such as influenza where there are not current requirements at all facilities for healthcare workers to have that vaccine.

Next Steps

The Core Practices document will be finalized based on HICPAC’s feedback. Given the number of comments received, HICPAC will review a revised version before voting to approve it. The core points will be pared down to key elements in order to focus the primary message. The tone of the document will be re-examined so that it will be user-friendly and targeted to the audience of HCPs. Additional feedback mechanisms will be important to ensure that the document has impact. HICPAC liaisons can share draft documents with their user bases. This document is powerful not only for individual users, but also for infection control programs and for individuals to take to their facility leadership to get resources. The column with additional considerations will be helpful and add to the impact and uses of the document.

Public Comment

No public comment was offered.

Summary and Wrap Up

Neil Fishman, MD
HICPAC Chair

Dr. Fishman summarized the meeting, noting that in terms of NHSN, HICPAC looks forward to hearing details on definition changes at the next meeting, particularly with respect to the CAUTI and CLABSI definitions. HICPAC anticipates more work on several sections of the SSI Guideline, particularly pertaining to how to address some of

the elements included in the 1999 Guideline that were not carried forward in the update. Clarification is needed regarding AMP, and some HICPAC members are not comfortable with “no recommendation” in this area. New recommendations will be brought to HICPAC. Clarification is also needed regarding skin asepsis and skin preparation. Additional literature reviews are being conducted and should be completed by the July HICPAC meeting so that their results can be incorporated into the recommendations. This work highlights the challenges that they face when there are “shades of grey” in their evidence base. It is important to acknowledge the level of available data and decide how to incorporate it into the recommendations. Some HICPAC members advocated for writing about the challenges to producing evidence-based guidelines.

No additional comments were offered from HICPAC or HICPAC liaison representatives. Dr. Fishman thanked HICPAC for attending and the new members for their contributions.

With that, the meeting adjourned at 11:34 am.

Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the April 10-11, 2014, meeting of the Healthcare Infection Control Practices Advisory Committee, CDC are accurate and complete.

Date

Neil Fishman, MD
Chair, Healthcare Infection Control Practices
Advisory Committee, CDC

Attachment 1: Acronyms Used in this Document

Acronym	Expansion
AAMC	American Association of Medical Colleges
AAOS	American Academy of Orthopedic Surgeons
ACCP	American College of Chest Physicians
ACIP	Advisory Committee on Immunization Practices
ACOEM	American College of Occupational and Environmental Medicine
AHRQ	Agency for Healthcare Research and Quality
AMP	Antimicrobial Prophylaxis
AORN	Association of periOperative Registered Nurses
APIC	Association of Professionals of Infection Control and Epidemiology
AR	Antibiotic Resistance
ASEPSIS	Additional treatment, the presence of Serous discharge, Erythema, Purulent exudate, and Separation of the deep tissues, the Isolation of bacteria, and the duration of inpatient Stay
ASHP	American Society of Health-System Pharmacists
ASTHO	Association of State and Territorial Health Officials
AUR	Antimicrobial Use and Resistance
BSI	Bloodstream Infection
C. difficile	Clostridium difficile
CARB	Combating Antibiotic-Resistant Bacteria
CAUTI	Catheter-Associated Urinary Tract Infection
CDA	Clinical Document Architecture
CDC	Centers for Disease Control and Prevention
CHG	chlorhexidine gluconate
CLABSI	Central Line-Associated Bloodstream Infection
CLER	Clinical Learning Environment Review
CLIP	Central Line Insertion Practices
CM/PCS	Clinical Modification/Procedure Coding System
CMS	Centers for Medicare and Medicaid Services
CPT	Current Procedural Terminology
CRE	Carbapenem-Resistant Enterobacteriaceae
CSF	Cerebrospinal Fluid
CSTE	Council of State and Territorial Epidemiologists
CUSP	Comprehensive Unit-based Safety Program
DFO	Designated Federal Official
DHQP	Division of Healthcare Quality Promotion
EHR	Electronic Health Record
EIP	Emerging Infections Program
ESBL	Extended-Spectrum Beta-Lactamase
FDA	(United States) Food and Drug Administration
FY	fiscal year
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HAI	Healthcare-Associated Infection
HCP	Health Care Personnel
HHS	(United States Department of) Health and Human Services
HICPAC	Healthcare Infection Control Practices Advisory Committee
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus

Meeting Summary Report

April 10-11, 2014

Acronym	Expansion
HPRO	Hip Prosthesis
ICD	International Classification of Diseases
ICHE	Infection Control and Hospital Epidemiology
ICU	Intensive Care Unit
IOM	Institute of Medicine
IRF	Inpatient Rehabilitation Survey
JAMA	Journal of the American Medical Association
KPRO	Knee Prosthesis
LabID	Laboratory Identified
MBI	Mucosal Barrier Injury
MDR	Multidrug-Resistant
MDRO	Multidrug-Resistant Organism
MIC	Minimum Inhibitory Concentration
MRSA	Methicillin-resistant <i>Staphylococcus aureus</i>
N. gonorrhoeae	Neisseria gonorrhoeae
NACCHO	National Association of County and City Health Officials
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NHSN	National Healthcare Safety Network
NICE	National Institute for Health and Care Excellence
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NQF	National Quality Forum
OR	Operating Room
OSHA	Occupational Safety and Health Administration
PATOS	Present at Time of Surgery
PPE	Personal Protective Equipment
QI	Quality Improvement
RCT	Randomized Controlled Trial
S. aureus	Staphylococcus aureus
SCCM	Society of Critical Care Medicine
SCIP	Surgical Care Improvement Project
SHEA	Society for Healthcare Epidemiology of America
SHM	Society of Hospital Medicine
SIR	Standardized Infection Ratio
SIS	Surgical Infection Society
SSI	Surgical Site Infection
STS	Society of Thoracic Surgeons
TAP	Targeted Assessment for Prevention
TB	Tuberculosis
VA	(United States Department of) Veterans Affairs
VAE	Ventilator-Associated Event
VAP	Ventilator-Associated Pneumonia
VTE	Venous Thromboembolism
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: April 10-11, 2014

Meeting Location: Atlanta, GA

Liaison name: Mark Russi, MD, MPH

Organization represented: American College of Occupational and Environmental Medicine

Interim activities and updates

Position statements:

ACOEM recently released two position statements, the first an update addressing pertussis vaccination of healthcare workers, the second addressing biometric health screening for employers. Other recently released guidance documents include those addressing (1) the confidentiality of medical information in the workplace, (2) principles of safe management of pain medication prescriptions, and (3) protection of healthcare workers from tuberculosis (update).

Legislation:

Public comments include a statement issued January 20, 2014, supporting the NIOSH ICD-10 proposal; a statement issued January 28, 2014, supporting the proposed OSHA silica rule; comments issued February 14, 2014, addressing the NIOSH Carcinogen Classification Document; a statement issued March 4, 2014, supporting the Better Care, Lower Cost Act; and comments issued on March 11, 2014, on the proposed rule to improve tracking of workplace illnesses and injuries.

Campaigns and related activities:

n/a

Press activities:

Major Occupational Health Groups to Study Impact of Increased Use of Marijuana and Other Drugs on Workplace Health and Safety 3/10/2014

Small Effects of Social or Physical Changes to Work Environment 3/10/2014 ACOEM Releases Recommendations as Part of Choosing Wisely® Campaign 2/24/2014

Shiftworkers Have More “Pro-Inflammatory” Diets 2/7/2014

ACOEM Congressional Briefing Connects Workplace Health and Long-term Impacts on Medicare Costs 1/31/2014

Company Policy May Contribute to Health Impact on the Bottom Line 1/10/2014

UI Research Report Highlights Multiple Dimensions of ‘Total Worker Health’ 1/2/2014

“Zero-Cost” Workers' Comp Claims Aren't Really Zero Cost, Study Finds 12/10/2013

Job Strain Helps Explain Adverse Effects of Workaholism 11/11/2013 –

Publications:

See above.

Other items of note:

ACOEM will hold its national meeting in San Antonio, TX, April 26- April 30, 2014.

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)

Centers for Disease Control and Prevention

Meeting Date: April 10-11, 2014

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

Liaison name: Dr. Silvia Munoz-Price

Organization represented: America's Essential Hospitals (formerly known as National Association of Public Hospitals and Health Systems (NAPH))

Interim activities and updates:

There are two major activities at America's Essential Hospitals working on issues of Infection Control and Disease Prevention. The first activity is a partnership with The Center for Transforming Healthcare at the Joint Commission, currently in its second year. This year's series of webinars to improve hand hygiene compliance (six events) build on last year's series. A total of seven organizations are participating in this work with us from across the country – four carrying over from our initial year and three new additions. Two of the original cohort dropped out due to other pressing priorities. Our second activity is we are engaged with CMS as one of the 26 national Hospital Engagement Networks. Twenty-two of our members are participating in this program and reducing hospital acquired infections is a part of the targeted improvement. We are entering the third year of that contract and have seen reductions in rates of CAUTI, CLASBI and SSI.

Guidelines and Guidance:

Not at this time

Position statements:

Not at this time

Legislation:

Not related to issues of infection

Campaigns and related activities:

Not related to issues of infection

Press activities:

Not related to issues of infection

Publications:

We publish stories on website focusing on America's Essential Hospitals member successes in addressing and reducing hospitals acquired infections. These stories and examples can be accessed on our website:

HAI

<http://essentialhospitals.org/tag/hospital-acquired-infections-HAI/>

Studies Review Infection Prevention, Hand Hygiene Compliance

Report: MD Dress Code Can Help Curb Infection Spread

MetroHealth Cuts Harm with 'Wash-In, Wash-Out'

CLABSI

<http://essentialhospitals.org/tag/CLABSI/>

Process Redesign Leads to Lower CLABSI Incidence

NICU Culture Change Lowers Infection Rates

From CEO to Nurse, Teamwork Helps Santa Clara Cut CLABSIs

Blogs: Equity in Care Applies to Patient Safety

<http://essentialhospitals.org/equity-care-applies-patient-safety/>

Other items of note:

Not at this time



Agency for Healthcare Research and Quality
Ex officio Report
Healthcare Infection Control Practices Advisory Committee
Centers for Disease Control and Prevention
Atlanta
April 10-11, 2014

Progress for Priority Goal

Analysis of large-scale quality-improvement infection-control and prevention programs shows that the incidence of CAUTIs can be significantly decreased in hospitals throughout the United States by applying current approaches to intervention and measurement.

AHRQ's four-year nationwide project to promote the use of the Comprehensive Unit-based Safety Program (CUSP) to reduce CAUTIs has thus far registered over 1,400 hospital units in 41 states, the District of Columbia, and Puerto Rico.

Interim AHRQ data from the first six cohorts in CUSP for CAUTI show a 16.1% relative reduction in CAUTIs 14 months after the baseline.

Combatting Antibiotic-resistant Bacteria (CARB)

The National Security Staff (NSS) for Preparedness Policy and the Office of Science and Technology Policy hosted a restricted interagency policy committee (IPC) meeting on December 19 to launch the CARB policy development process.

Principals were also requested to nominate experts from their departments or agencies to support the President's Committee of Advisors on Science and Technology (PCAST).

On January 10, the CARB Sub-IPC held its inaugural meeting to discuss the charge from the President through the IPC to develop recommendations to prevent and mitigate the impact of antibiotic-resistant bacteria. Working Groups based on the CARB Action Areas were formed to provide recommendations and options for actions that Executive Branch departments or agencies could take: policy, regulatory, legislative/authority, budgetary/programmatic aspects in categories of short-, mid-, and long-term recommendations. Although CARB will focus domestically, representatives of departments and agencies engaged in international collaborations will be a part of all relevant working groups to facilitate ongoing and further efforts.

AHRQ will participate in Working Group 1: Human Healthcare and Antibiotic Stewardship and is already funding stewardship research. Other CARB workgroups include 2. Domestic Antibiotic Resistance Surveillance - Human, 3. International Antibiotic Resistance Surveillance and Collaboration, 4. Basic and Applied Research and Development, and 5. Agriculture Drivers, Use and Stewardship of Antibiotics and Integrated Surveillance.

Workarounds to Procedures Embedded in Electronic Health Records are Common, Even among Early Adopters

Using observation techniques initially developed in cultural anthropology, researchers found that staff in primary care outpatient clinics (PCOCs) find it helpful to develop paper or computer workarounds to electronic health record (EHR) processes. Paper and computer workarounds to improve efficiency, memory, and awareness were found at all three health care institutions involved in the study, which were all leaders in the development and application of EHRs. Workarounds involving knowledge/skill/ease of use, task complexity, trust, and no correct path were each found at two of the institutions. Four more workaround categories were each observed within a single institution.

The researchers noted that the workaround category "no correct path," previously unidentified in workaround research, described tactics developed at two of the institutions when a desired option did not exist in the computer workflow. Examples included lack of an option to show that the physician ordered a patient to take half a blood pressure pill twice daily, or when an EHR brings up a colonoscopy reminder even when the patient is already scheduled for a colonoscopy appointment.

Overall, the researchers observed 120 clinic staff and providers and 118 patients at 11 PCOCs affiliated with the three benchmark institutions. The study was funded in part by AHRQ (Contract No. 290-06-00013).

Flanagan ME, Saleem JJ, Millitello LG, et al. Paper- and computer-based workarounds to electronic health records used at three benchmark institutions," *Journal of the American Medical Informatics Association* 2013;20:e59-e66.

Liaison Report

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

Meeting Date: April 10-11, 2014

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

Liaison name: Amber Wood

Organization represented: AORN

Interim activities and updates:

AORN Prep Course for the CNS-CP Exam, January 17-18, Denver, CO

AORN Surgical Conference and Expo 2014, March 28- April 2, Chicago, IL

OR Executive Summit, March 30-April 1, Chicago, IL

Guidelines and Guidance:

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

The 2014 Perioperative Standards and Recommended Practices include 4 new evidence rated guidelines: Pneumatic Tourniquet, Environmental Cleaning, Sharps Safety, & Selection and Use of Packaging Systems for Sterilization. Ambulatory supplements provided in this edition. These guidelines are available in print and through electronic access. Information on how to obtain can be found at www.aorn.org.

Recommended Practices (RPs) that will soon be electronically released are Environment of Care, part 2 (formerly Traffic Patterns) and Specimen Management.

RPs that will be up for public comment soon include Preoperative Patient Skin Antisepsis, Surgical Attire, & Care and Cleaning of Surgical Instruments and Powered Equipment. 2015 RPs in development are Surgical Tissue Management, Thermoregulation (formerly unplanned hypothermia), Local Anesthesia and Moderate Sedation, & Radiation Safety.

Position statements:

Revised position statements- Noise in the Perioperative Practice Setting, Environmental Responsibility, The Role of the Health Care Industry Representative in the Perioperative Invasive Procedure Setting, and Advanced Practice Registered Nurses in the Perioperative Environment.

Legislation:

The AORN legislative priorities for 2014 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:

AORN continues its Sharps Safety Campaign.

Press activities:

AORN Ambulatory Administrator Boot Camp, June 18-20, Denver, CO

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

Publications:

2014 Perioperative Standards and Recommended Practices

AORN Journal

Perioperative Job Descriptions and Competency Evaluation

Perioperative Policies and Procedures

Other items of note:

Other events related to perioperative nursing can be found at www.aorn.org

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)

Centers for Disease Control and Prevention

Meeting Date: April 10-11, 2014

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

Liaison name: Michael Anne Preas, RN, BSN, CIC

Organization represented: Association for Professionals in Infection Control and Epidemiology (APIC)

Interim activities and updates:

Update of APIC Text progressing on-schedule for a June release of the 4th edition

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.

Revisions

- Implementation Guide for the Prevention of Catheter-Related Urinary Tract Infections Implementation Guide for the Prevention of Catheter-Related Bloodstream Infections
- Implementation Guide for the Prevention of Ventilator Associated Events

New

- Implementation Guide for Hand Hygiene
- Manual for the Prevention of Infections in Long Term Care Facilities

Position statements:

n/a

Legislative and Regulatory Activities:

- Submitted comments on draft HICPAC surgical site infections guideline
- Submitted comments to FDA on the Veterinary Feed Directive
- Preparing comments to FDA on the proposed rule on antimicrobial consumer hand soaps
- Preparing comments to HHS on the draft 2020 targets and metrics for the HAI Action Plan
- Preparing comments to FDA on the updated investigational new drug requirements for fecal microbiota for transplantation.
- Joined IDSA, and 29 other organizations in supporting the Antibiotic Development to Advance Patient Treatment (ADAPT) Act
- Joined other public health organizations in support of an increase to the 302(b) allocation to the Labor, HHS, Education and Related Agencies Appropriations Subcommittee, which would be distributed to agencies and programs under the Subcommittee's purview

Campaigns and related activities:

- Planning underway for International Infection Prevention Week, October 19-25.
- Discussions taking place on broadening reach of “Infection Prevention and You” campaign through partnerships with consumer organizations.

Press activities:

- Issued press releases on key articles in APIC’s scientific journal *AJIC*. Topics included:
 - December: Eradication of carbapenem-resistant Enterobacteriaceae gastrointestinal colonization with non-absorbable oral antibiotic treatment: a prospective controlled trial
 - January: Nationwide Reduction of Healthcare-Associated Methicillin-Resistant *Staphylococcus aureus* Infections in Veterans Affairs Long-Term Care Facilities
 - February: State of Infection Prevention in US Hospitals Enrolled in NHSN
 - March: Status of the implementation of the World Health Organization multimodal hand hygiene strategy in United States of America healthcare facilities
 - April: Are Community Environmental Surfaces Near Hospitals Reservoirs for Gram-negative Nosocomial Pathogens?
- Invited Washington DC APIC chapter president to participate in media interview with local CBS television station on germs in cars and infection prevention tips.
- Planning in progress for press activity in connection with APIC 2014 Annual Conference in Anaheim, CA.

Publications:

- Consumer e-bulletins focused on:
 - January: How to be a good visitor for LTC
 - February: What is an HAI?
 - March: CDC *Vital Signs* report on antibiotic use in hospitals & *C. diff*
 - April: How to read health websites for critical information
- Members of APIC’s Communications Committee create and disseminate *AJIC* article reviews for membership on a monthly basis.
- Spring issue of *Prevention Strategist* featured articles on top 10 operating room infection prevention questions and answers, APIC 2014 Annual Conference keynote preview, Group A Strep, emergency preparedness at home, global hand hygiene, environmental cleaning toolkit success story, Capitol Comments, CIC profile, column from CBIC president, APIC president, and APIC CEO, and assorted news briefs.
- Special supplement created in collaboration with HRET focused on the *On the CUSP: Stop CAUTI project*. Articles: success stories from participating facilities, history of CUSP, Q&A with national faculty, etc. Mailed with spring issue of *Prevention Strategist*.
- Summer issue of *Prevention Strategist* will feature articles on the WV water crisis and infection prevention implications, new methodology of the CDC’s updated SSI guideline, Lyme disease, VAP reduction, Capitol Comments, CIC profile, column from CBIC president, APIC president, and APIC CEO, and assorted news briefs.
- Created a special online newsletter to promote APIC’s 2014 Annual Conference, highlighting keynote sessions and other educational offerings. Sent out on March 14.
- Consumer e-bulletins focused on:
 - January: How to be a good visitor for LTC
 - February: What is an HAI?
 - March: CDC *Vital Signs* report on antibiotic use in hospitals & *C. diff*
 - April: How to read health websites for critical information

Other items of note:

- Education, activity since November 2013

- EPI 101, EPI 201, ASC courses offered in Baltimore, March 7-11, 2014
- Delivered the following Webinars:
 - From Tragedy to Triumph to Trepidation: Antibiotics at Age 70
 - A New Role for Infection Preventionist - Corporate Wide IP Consultants and Directors for Multi-Hospital Systems
 - 10 Most Common Mistakes IP Make with Data - and How to Avoid Them
 - Steps to Reducing Infection Risk: A Multi-Hospital System Approach to HAI Reduction
- In-process APIC Education work
- Revision of APIC online classes:
 - Continuing the Care: Infection Prevention in the Long Term Care Setting
 - Disinfection and Sterilization
 - Infection Prevention Certification Review
 - Microbiology 101
 - Essentials of Infection Prevention
 - EPI Primer
 - Infection Prevention in Hemodialysis Settings
- Annual Conference 2014, Anaheim, CA, June 7-9, 2014
 - Nearly 100 educational sessions
 - Two pre-conference workshops for the more advanced practitioner
 - 13 NHSN-related sessions provided by CDC representatives
- Monthly Webinars on subjects provided by members (free for members)
- Creation of “Infection Prevention Training in the Long Term Care Setting” Certificate series
- Development/delivery of “virtual conference” on data standardization

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)

Centers for Disease Control and Prevention

Meeting Date: April 10-11, 2014

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:

Capacity Building Projects:

ASTHO awarded capacity building grants to four states (GA, IL, VA, and VT). The states assembled teams to assess policy barriers in implementing state HAI prevention programs and developed action steps to address these barriers. Participating states selected one of two focus areas: 1) timely health department access to EHR data; and 2) evidence-based polices for implementing state antimicrobial stewardship programs.

State team members have presented at the CDC HAI Grantees meeting and state partners (HAI coordinators) call. State teams will continue to disseminate project results. ASTHO is preparing a report on the stewardship projects to be released in mid-2014. The findings from the EHR project will feed into a broader CDC/ASTHO project evaluating options that would facilitate efficient state health agency access to EHR data states.

Evaluation Projects:

ASTHO is conducting two evaluation projects which will identify promising practices in HAI prevention. Results will be disseminated in the coming months.

1. ASTHO, CDC, and partners (Public Health Law Research, Columbia University, and The Keystone Center) are examining the implementation of laws, or the absence of an HAI law, to identify facilitators/barriers for successful state HAI programs.
2. ASTHO, CDC, and technical experts (NORC at the University of Chicago and the John H. Stroger, Jr. Hospital of Cook County) are closely examining several state-led prevention collaboratives through surveys and key informant interviews to better understand how they work, and eventually their impact.

Trainings and Presentations:

- ASTHO and the Virginia Department of Health will convene a roundtable session at the CSTE Annual Conference in June: *Innovating Public Health Response to Healthcare-Associated Infection Outbreaks by Understanding Barriers and Benefits to Electronic Health Record Access.*
- ASTHO and CDC will convene a roundtable session at the CSTE Annual Conference in June: *Combating Antibiotic Resistance: Policies to Promote Antimicrobial Stewardship Programs.*

Ongoing:

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

Guidelines and Guidance:

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

n/a

Position statements:

n/a

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/

New publications:

- State Strategies to Address Antimicrobial Resistance – Survey Results. This issue brief reports results from a 2013 survey of HAI coordinators, describing state health department activities in the areas of antimicrobial resistance, antimicrobial stewardship, and policy.

- Outbreak Investigation and Response. This ASTHO FY15 advocacy paper includes information on HAIs, the role of NHSN, and the profound impact state health agencies can have in addressing reductions in infection rates. The paper was distributed as part of ASTHO's Hill Day Congressional meetings March 6.

Other items of note:

n/a

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)

Centers for Disease Control and Prevention

Meeting Date: April 10-11, 2014

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

Liaison name: Janet Nau Franck Global Director, Managing Infection Risk (MIR)

Organization represented: DNV Healthcare Accreditation

Interim activities and updates:

DNV Healthcare Inc. is a provider of hospital accreditation, infection risk management and other select standards. The company was approved in 2008 by the US Centers for Medicare and Medicaid Services (CMS) to accredit acute care hospitals in the United States and since then has also been granted CMS deeming authority for critical access hospitals. DNV Healthcare has also developed quality-based certifications for specialty areas including Comprehensive and Primary Stroke Centers.

DNV Healthcare is part of the DNV GL Group which is a leading provider of classification, certification, verification and training services. With origins stretching back to 1864 and operations in more than 100 countries, our 16,000 professionals dedicated to helping our customers make the world safer, smarter and greener.

DNV has launched a new survey designation that enables hospitals to reduce their risk of infection through an innovative assessment of infection risk. It is called **Managing Infection Risk (MIR)** [<http://dnvglhealthcare.com/certifications/managing-infection-risk>]. Upon completion, the facility will become a DNV Center of Excellence to reflect the achievement.

The Managing Infection Risk (MIR) Standard provides a framework that healthcare organizations can use to build successful systems for risk reducing outcomes. This would include the identification, intervention, and evaluation of trends over time. It is a risk-based, management systems approach, designed to minimize HAIs and associated costs.

Guidelines and Guidance:

The Managing Infection Risk (MIR) Accreditation standard can be downloaded at no cost at www.dnv.com. Training courses and workshops are also listed and are continually updated.

Position statements:

DNV has developed the Managing Infection Risk standard along with the survey designation which results in certification designation as a Center of Excellence.

Legislation:

n/a

Campaigns and related activities:

Recent MIR initiatives have included launching initiatives in: US, Singapore, England, Spain, China, Poland, Brazil, Netherlands, Slovenia and Scotland (ISQUA) in 2013-14.

Press activities:

Article published in October, 2013 APIC's *Prevention Strategist* regarding the launching, program description, and benefit of MIR Certification and joining the Center of Excellence. It also describes the integral role of proactive risk assessment in mitigating risk and reducing the potential of HAIs.

Publications:

DNV Standard - DNV-DS-HC101- Standard for Managing Infection Risks (Apr 2012, Rev 1)

Other items of note:

Over 200 hundred hospitals have attended educational sessions and have expressed interest in pursuing this achievement for their facility. An International Learning Exchange will be formed for hospitals having enrolled in this status to idea share and network internationally. A Users Group for Infection Preventionists in all DNV hospitals is being created to form a clinical forum to discuss HICPAC Guidelines and evidenced based practices.

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)

Centers for Disease Control and Prevention

Meeting Date: April 10-11, 2014

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

Liaison name: Jennifer Sears, Philadelphia Department of Public Health (on behalf of Diana Gaviria)

Organization represented: National Association of County and City Health Officials (NACCHO)

Interim activities and updates:

- (Oct-Nov) Completed year two of NACCHO's local health department healthcare-associated infection (HAI) prevention demonstration project. Local health department activities (since the Nov 2013 liaison report) included:
 - Hosting an infection prevention symposium on antimicrobial stewardship and carbapenem-resistant Enterobacteriaceae (Philadelphia Department of Public Health; Oct)
 - Attending the CDC HAI grantees meeting to obtain updates on national and state HAI prevention activities and strengthen relationships with partners; (DuPage County and City of Milwaukee health departments; Nov)
 - (Jan-Apr) Initiated year three of NACCHO's local health department HAI prevention demonstration project and continued supporting the following local health departments in working with state health departments on HAI prevention efforts:
 - City of Milwaukee Health Department
 - DuPage County (IL) Health Department
 - Livingston County (MI) Department of Public Health
 - Philadelphia Department of Public Health
- Local health department activities included:

- Convening weekly by phone to (1) present year one and year two project activities and accomplishments; and (2) inform the development of an HAI guidance document for local health departments to engage in HAI prevention activities (Jan and early Feb)
- Initiating year three activities, including sustaining and expanding partnership with local healthcare stakeholders, continuing to assess HAI prevention needs within the community, and promoting HAI prevention and control messages
- Convening for additional monthly calls to discuss year three project activities (Jan-Apr)
- (Ongoing unless otherwise noted) 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 call (Jan)
 - Association of State and Territorial Health Officials (ASTHO) interview with the Indiana State Department of Health to learn about efforts to address antimicrobial resistance and related successes, challenges, and needs (Jan)
- Second discussion with Division of Healthcare Quality Promotion (DHQP) regarding opportunities and challenges with facilitating local health department access to HAI data from the National Healthcare Safety Network (NHSN) (Feb)
- (Feb) Continued working with ASTHO, Association of Public Health Laboratories, CSTE, Infectious Diseases Society of America, and the Public Health Foundation to update state antimicrobial resistance fact sheets
- (Mar) Initiated planning with DHQP colleagues to host an HAI outbreak tabletop exercise during a pre-conference workshop at the July 2014 NACCHO Annual conference
- (Ongoing) Shared HAI prevention and infection control news and resources (e.g. Get Smart about Antibiotics Week; CDC Vital Signs report on antibiotic prescription in hospitals) via NACCHO's regular communication channels

Guidelines and Guidance:

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

- (Ongoing) Developing (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) an HAI guidance document development for local health departments to engage in HAI prevention activities

Position statements:

- (Ongoing) Updating NACCHO's policy statement on local health department access to HAI data from the NHSN (current version available here: <http://naccho.org/advocacy/positions/upload/10-03-NHSN.pdf>)

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: April 10-11

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

Ex-officio name: David K. Henderson, M.D.

Organization represented: National Institutes of Health

Interim Activities and updates:

1. Influenza Immunization Program – the NIH Clinical Center completed its 2013-2014 influenza immunization program.
 - We vaccinated 96.5% of our 3428 staff members who have direct patient contact, with 100% of staff adhering to the policy. Implementing stricter rules for vaccine declination has helped us with consistency regarding provider immunization rates without jeopardizing employment or having to impose disciplinary penalties. Whereas we had hope that the availability of tissue culture-based vaccine would further reduce the number of declinations (making the vaccine available to staff who have egg allergies), we were unable to procure any doses of the tissue-culture vaccine this year.
 - NIH continues to study: the biology, pathogenicity, virulence factors, virology and epidemiology of influenza as well as the development of new interventions (e.g., novel approaches to the development of vaccines directed at conserved epitopes as well as the development of novel vaccines directed against potential new pandemic strains).
2. Management of Healthcare-Associated Transmission of Multiply Resistant Gram-Negative Bacilli in the Clinical Center.
 - The CC Hospital Epidemiology Program continues to maintain vigilance about the potential for transmission of highly resistant Gram-negative bacilli. We have continued monthly whole-house (except for behavioral health) surveillance, as well as twice weekly surveillance in the ICU and other high-risk units. We also now routinely culture every patient on admission, and routinely place patients who are transferred from other institutions on contact isolation. Through ongoing surveillance, we have detected twelve additional patients colonized with unrelated CRE isolates that are genetically distinct from the cluster strain. We have also initiated screening for metallo-beta-lactamase-producing organisms.

Position statements:

Dr. Palmore participated in the crafting of the SHEA guidance on healthcare personnel attire in non-operating-room settings.

Dr. Henderson participated in the CDC deliberations concerning the creation of new national approach to surveillance for ventilator-associated events.

Legislation:

None

Campaigns and related activities:

None

Press activities:

None

Publications:

1. Snitkin ES, Zelazny AM, Gupta J; NISC Comparative Sequencing Program, Palmore TN, Murray PR, Segre JA. Genomic insights into the fate of colistin resistance and *Acinetobacter baumannii* during patient treatment. *Genome Res.* 2013; 23(7): 1155-62.
2. Decker BK and Palmore TN. The role of water in healthcare-associated infections. *Curr Opin Infect Dis.* 2013; 26(4): 345-51.
3. Palmore TN, Henderson DK. Managing transmission of carbapenem-resistant *Enterobacteriaceae* in healthcare settings: a view from the trenches. *Clin Infect Dis* 2013; 57(11): 1593-9.
4. Zonios D, Yamazaki H, Murayama N, Natarajan V, Palmore T, Childs R, Skinner J, Bennett J. Voriconazole Metabolism, Toxicity and the Effect of Cytochrome P450 2C19 genotype. *J Infect Dis.* 2014 Jan 7. [Epub ahead of print]
5. Bearman G, Bryant K, Leekha S, Mayer J, Munoz-Price LS, Murthy R, Palmore T, Rupp ME, White J. Healthcare personnel attire in non-operating-room settings. *Infect Control Hosp Epidemiol.* 2014;35(2):107-21.
6. Decker BK, Palmore TN. Waterborne pathogen detection: more than just "location, location, location..." *Infect Control Hosp Epidemiol.* 2014;35(2):130-1.
7. Sharp D, Palmore T, Grady C. The ethics of empowerment patients as partners in healthcare-associated infection prevention. *Infect Control Hosp Epidemiol* 2014 Mar; 35(3):307-9.
8. Palmore TN, Henderson DK. Carbapenem-resistant *Enterobacteriaceae*: a call for cultural change. *Ann Intern Med.* 2014; *in press.*
9. Kost RG, Lee L, Yessis J, Henderson DK, Wesley R, Collier BS. Assessing participant-centered outcomes to improve clinical research. *N Engl J Med.* 2013; 369(23): 2179-81.
10. Magill SS, Klompas M, Balk R, MD, Burns SM, Deutschman CS, Diekema D, Fridkin S, Greene L, Guh A, Gutterman D, Hammer B, Henderson DK, Hess D, Hill NS, Horan T, Kollef M, Levy M, Septimus E, VanAntwerpen C, Wright D, Lipsett P. Developing a new, national approach to surveillance for ventilator-associated events: executive summary. *Infect Control Hosp Epidemiol* 2013; 34(12): 1239-43.
11. Ramsburg AM, Henderson DK. Managing HIV infection in the health care workplace: 30 years later. *Fed Practitioner* 2014; *in press.*

Other items of note:

n/a

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)

Centers for Disease Control and Prevention

Meeting Date: April 10-11, 2014

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

Liaison name: Kathleen Dunn

Organization represented: Public Health Agency of Canada

Interim activities and updates:

n/a

Guidelines and Guidance:

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

n/a

Position statements:

n/a

Legislation:

n/a

Campaigns and related activities:

- Antibiotic Awareness Campaign (pilot) targeting Canadian families, prescribing healthcare professionals, pharmacists and the media. Anticipated date of launch will be November 2014 including various educational, communications and social marketing activities.
- The primary objective of the pilot is to improve the general public's interactions with healthcare providers by improving knowledge and awareness of responsible antibiotic use among Canadian families and providing tools to healthcare professionals to support these conversations.
- If interested in learning more about the pilot awareness campaign or opportunities for cross-promotion (PHAC-CDC), please contact Dr. Howard Njoo, Director General, Centre for Communicable Diseases and Infection Control, Public Health Agency of Canada (howard.njoo@phac-aspc.gc.ca).

Press activities:

n/a

Publications:

Tuberculosis Prevention and Control in Canada: A Federal Framework for Action http://www.phac-aspc.gc.ca/media/nr-rp/2014/2014_0323-eng.php http://www.phac-aspc.gc.ca/media/nr-rp/2014/2014_0323-fra.php

Canadian Tuberculosis Standards, 7th Edition 2013

Joint project produced by the Canadian Thoracic Society (CTS) of the Canadian Lung Association (CLA) and the Public Health Agency of Canada (PHAC) <http://www.respiratoryguidelines.ca/tb-standards-2013>

Other items of note:

CDC attendance at Agency Infection Control Expert Working Group in February 2014.

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)

Centers for Disease Control and Prevention

Meeting Date: April 10-11, 2014

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:

1. SCCM is holding a Research Summit at the Emory Convention Center on 4/10/14 – 4/11/14. The title of the summit is, *Toward Better Critical Care: From Data to Information to Decision to Action*. Research scientists from healthcare and non-health industries will share perspectives on interoperability as it relates to information flow and decision making in a complex healthcare delivery environment. In 2016 and 2017 two additional summits will be held. All are funded by SCCM.
2. SCCM is working on early detection and intervention of sepsis on medical/surgical/telemetry wards of hospitals. Funding by the Gordon and Betty Moore Foundation, the Society is holding a series of three collaboratives in Illinois, New Jersey and California. A second grant was received for 10 additional hospitals in Florida bringing the total work to 63 hospitals. Learnings from the collaboratives will be published and materials shared at <http://www.survivingsepsis.org>.

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. The SCCM and the European Society of Intensive Care Medicine has convened a panel of experts from around the globe to publish a consensus statement as an update to the 2001 sepsis definitions paper. Publication is anticipated in 2015.
2. As part of the Choosing Wisely Campaign, The Critical Care Societies Collaborative released a list of 5 things physicians and patients should question.
 - Don't order diagnostic tests at regular intervals (such as every day), but rather in response to specific clinical questions.
 - Don't transfuse red blood cells in hemodynamically stable, non-bleeding ICU patients with a hemoglobin concentration greater than 7 mg/dL.
 - Don't use parenteral nutrition in adequately nourished critically ill patients within the first seven days of an ICU stay.
 - Don't deeply sedate mechanically ventilated patients without a specific indication and without daily attempts to lighten sedation.
 - Don't continue life support for patients at high risk for death or severely impaired functional recovery without offering patients and their families the alternative of care focused entirely on comfort.

Position statements:

ATS/AACN/ACCP/ESICM and SCCM are working on a policy statement: Responding to Requests for Futile and Potentially Inappropriate Treatments in Intensive Care Units. The document is currently in the comment period.

Legislation:

SCCM does not have a legislative function.

Campaigns and related activities:

1. SCCM recently launched a microsite related to its newest quality improvement initiative targeted to encourage ICU clinicians to screen for pain, agitation and delirium and also encouraging where appropriate to increase mobility for ICU patients. ICU Liberation offers tools including instructional videos, survivor stories and will soon have a social networking site for clinicians to share information, tips and to meet others working in this space.
2. SCCM continues work on Project Dispatch, an AHRQ grant with an aim of disseminating patient centered outcomes research to healthcare professionals. There are several podcast and webcast resources available on the SCCM website. Sites with stories to share are encourage to submit them to the Project Dispatch investigators for inclusion. An introductory You Tube video is available.

Press activities:

n/a

Publications:

SCCM's *Critical Care Medicine* has published the following recent articles which may be of particular interest to HICPAC:

1. Palomar M et al. Impact of a national multimodal intervention to prevent catheter-related bloodstream infection in the ICU: the Spanish experience. *Crit Care Med* 2013; 41: 2364-2372.
2. Klein Klouwenberg PM et al. Interobserver agreement of Centers for Disease Control and Prevention criteria for classifying infections in critically ill patients. *Crit Care Med* 2013; 41: 2373-2378.
3. Weiss CH et al. A clinical trial comparing physician prompting with an unprompted automated electronic checklist to reduce empirical antibiotic utilization. *Crit Care Med* 2013; 41: 2563-2569.
4. Magill SS et al. Developing a new, national approach to surveillance for ventilator-associated events*. *Crit Care Med* 2013; 41: 2467-2475.
5. Munoz-Price LS et al. Eighteen years of experience with *Acinetobacter baumannii* in a tertiary care hospital. *Crit Care Med* 2013; 41: 2733-2742.
6. Geurts M et al. Therapeutic hypothermia and the risk of infection: a systematic review and meta-analysis. *Crit Care Med* 2014; 42: 231-242.
7. Stevens JP et al. When policy gets it right: variability in u.s. Hospitals' diagnosis of ventilator-associated pneumonia*. *Crit Care Med* 2014; 42: 497-503.
8. Blot S et al. E-VS. Prevalence, risk factors, and mortality for ventilator-associated pneumonia in middle-aged, old, and very old critically ill patients*. *Crit Care Med* 2014; 42: 601-609.
9. Seguin P et al. Effect of oropharyngeal povidone-iodine preventive oral care on ventilator-associated pneumonia in severely brain-injured or cerebral hemorrhage patients: a multicenter, randomized controlled trial. *Crit Care Med* 2014; 42: 1-8.

Other items of note:

SCCM and ESICM have convened an investigatory panel to submit recommendations to the societies on how to provide guidance to resource limited nations on early sepsis detection and treatment. The first research has been submitted and the project is now in stage two.

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)

Centers for Disease Control and Prevention

Meeting Date: April 10-11, 2014

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

Liaison name:

Organization represented: Society for Healthcare Epidemiology of America

Interim activities and updates:

SHEA Spring 2014 Conference: Advancing Healthcare Epidemiology: Crisis & Controversies

(April 3-6, 2014 – Denver, CO)

As in prior years, the SHEA Spring 2014 Conference offers three tracks depending on an attendee's interest and training needs. For those who are new to the field or those who desire a

refresher, we offer the SHEA/CDC Basic Training Course in Healthcare Epidemiology. For the more experienced epidemiologists and infection preventionists, we offer two advanced tracks. The 'Responding to Crisis' track delves deeply into the difficult issues we face in hospital epidemiology including management of outbreaks and large scale exposures within the hospital, dealing with failures of sterilization, diversions, and environmental breaches. The second advanced track 'From MRSA to CRE: Controversies in MDRO's' explores the many facets of how we detect and manage some of our most difficult foes. In this track we will explore controversial issues such as whether regional management of CRE is our best defense, whether it is really necessary to isolate patients with MRSA, whether we should be banning white coats and going bare below the elbows in addition to infection control issues in emerging therapies such as fecal transplant for C.difficile patients. Exciting changes this year include the addition of scientific abstracts from fellows and infection preventionists on the topics of CRE and other MDRO's, as well as built-in networking time and ice breakers to encourage mentoring and professional connections. This conference is Chaired by: Dr. Sarah Haessler and track chairs; Drs. Arjun Srinivasan, Alex Kallen and Michael Edmond. Current registration is at 345 and we anticipate reaching our goal of 500 by the meeting date.

IDWeek 2014

As in 2013, SHEA is pleased to be joining IDSA, PIDS and HIVMA in IDWeek 2014 with Drs. Mary Hayden and Charles Huskins serving as SHEA's Chair and Co-Chair, respectively.

Online ID Fellows Course

SHEA has also presented a proposal to the Board on a possible Online ID Fellows Curricula on Healthcare Epidemiology and Infection Prevention. The goal is to develop a visually appealing, scenario-based learning and modern- online course (similar to the SHEA Fundamentals course) but also adding elements of the JHU Fellows Course and knowledge gained from the ID Fellowship Director Focus Groups. . This course will be housed on the SHEA website and will be featuring 7 modules targeting various core knowledge areas. The process will be structured similar to authoring a chapter. The steering committee will act as the Editors of the module. The "authors" of each module (could be comprised of a senior and junior faculty member) will develop case based slides based on the curriculum assigned.

Each module will have post-test questions and a certificate of completion. Feedback from the

task force and surveyed Fellowship directors emphasized the benefit for Directors to be able to use this as a measurement tool for their fellows. The committee was given an aggressive timeline from the Board. The goal is to present the final product to the ID Fellowship directors at IDWeek 2014 and launch shortly after.

ACCME

SHEA is in the middle of its reaccreditation cycle. The Self Study was submitted in July and SHEA will be notified of ACCME's decision in March 2014.

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.

SHEA Guidelines Committee, led by Chair Dr. Gonzalo Bearman and Past Chair Dr. Kristina Bryant

Guidelines:

The Cystic Fibrosis Foundation, with representation from SHEA, has finalized and submitted for publication in ICHE its update to the 2003 infection prevention guideline. The guideline will be published as a supplement in the June or July issues of the journal. SHEA continues to participate in guideline development with IDSA and others, covering topics including *C. difficile*, antimicrobial stewardship, infectious diarrhea, HAP/VAP, and nosocomial meningitis.

Expert Guidance Papers:

As a result of discussions between the Guidelines Committee, Research Committee, and Board of Trustees, the Guidelines Committee has embarked on several "expert guidance" statements designed to provide ungraded recommendations for practice questions that would otherwise go unaddressed for topics that lack the evidence to meet the GRADE system. These guidance statements are based on literature review, surveys, review of policies, and expert consensus. The first, *Healthcare Personnel Attire in Non-Operating Room Settings*, was published in February in ICHE. A multidisciplinary writing group is in the process of writing a guidance on the presence of animals in healthcare facilities. The committee is in the preliminary stages of researching two additional topics: isolation precautions for visitors, and discontinuation of contact precautions for endemic MRSA and VRE.

Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care

Hospitals

SHEA and IDSA, with AHA, The Joint Commission, and APIC, and with representation from additional professional societies are in the final stages of updating the Compendium sections: VAP, CAUTI, CLABSI, CDI, MRSA, and SSI, with a new section on Hand Hygiene. The public comment period for each section is complete, and remaining stages of review, including CDC clearance, are underway. The writing panels have given greater focus to implementation in each of the topic areas. Publication is scheduled beginning in the late spring in ICHE, and will occur through the summer. The sections will be bound with the Executive Summary as a supplement in ICHE in the fall.

SHEA is leading the writing process for a companion implementation document to HICPAC's "Guideline for Prevention of Infections among Patients in NICU." The writing group includes representatives from IDSA, PIDS, NANN, AAP, and Vermont Oxford, and is headed up by Kris Bryant (SHEA Guidelines Committee Past Chair) and Alexis Elward (HICPAC NICU Guidelines lead). The document will address the areas of *C. difficile*, CAUTI, MRSA, and respiratory infection prevention.

The update of the Compendium will include edits to the patient guides based on the chapters, and the Compendium Partners are working with the CDC Foundation to develop materials and facilitate dissemination of the guides.

Position statements:

Mandatory Immunization of HCP

SHEA, IDSA and PIDS issued a joint policy on Mandatory Immunization of Health Care Personnel according to the ACIP-Recommended Vaccine Schedule in December 2013.

Policy:

Antimicrobial Stewardship as a CoP

SHEA and IDSA submitted a joint letter to CMS in March 2014 offering the justification and supportive evidence to demonstrate how adopting antimicrobial stewardship as a Condition of Participation (CoP) would better patient care, improve outcomes, and lower the healthcare costs associated with antibiotic overuse (i.e. expenditures on antibiotics) as well as costs associated with infections and antimicrobial resistance.

HHS HAI Action Plan 2020 Targets

SHEA's Public Policy and Government Affairs Committee (PPGA) has reviewed and developed formal SHEA comments in response to HHS' release of a new set of proposed five-year measurable HAI targets for acute care hospitals with a 2015 baseline and 2020 target.

Joint SHEA/APIC testimony to House Appropriations on HHS FY 2015 Funding

SHEA and APIC submitted joint testimony to the House Appropriations Subcommittee on Health detailing our HAI prevention/research and antimicrobial resistance funding priorities in

the FY 2015 HHS budget.

SHEA Supportive of LPAD Initiative and ADAPT Act

SHEA has expressed its support of two IDSA initiatives including: 1) the 'Support Limited Population Antibacterial Drug (LPAD)' initiative – to create a new regulatory pathway for antibiotics (similar to that available for Orphan Drugs) that target special or limited patient populations and 2) the “Antibiotic Development to Advance Patient Treatment (ADAPT) Act” to establish the LPAD pathway and provide safeguards to guide the drugs’ appropriate use. SHEA recently joined IDSA and many other supporters in a letter to the bill sponsors in the U.S. House.

Alliance on Aging Research Events

Preeti Malani, MD, MSJ, represented SHEA during two events late last year sponsored by the Alliance on Aging Research. The Alliance held both a call-in and Capitol Hill briefing to highlight the release of its Silver Book publication on the value of vaccination in reducing infectious disease in older Americans. Dr. Malani was joined by Dr. Jeff Duchin, who participated on behalf of IDSA and Dr. Kiepp Talbot who spoke on behalf of NFID.

Campaigns and related activities:

SHEA Research Network (SRN) and Research Committee

The Research Committee, under the leadership of Chair Nasia Safdar, MD and Past Chair Ebbing Lautenbach, MD, MPH, MS, recently submitted to ICHE for publication this spring, “The Evolving Landscape of Healthcare-Associated Infections, Recent Advances in Prevention and a Roadmap for Research.” This white paper addresses changes and advances in healthcare epidemiology research since the original paper was published in 2010 in ICHE, and also provides an overview of priority research topics for the future.

The SHEA Research Network has several open projects, with one scheduled for launch in March:

- 2013 Epi Project (PI: Clare Rock), which seeks to develop a more accurate marker of overall hospital quality that can be objectively applied and compared across hospitals.
- 2013 end of year survey regarding members’ experiences belonging to the SRN, and several practice questions that the SRN will track year-to-year
- Electronic data to improve risk adjustment rates (PI: Anthony Harris)
- The role of the patient safety climate in CAUTI prevention (PI: Daniel Livorsi)

Press activities:

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/she/public/she

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.sheaonline.org/JournalNews/PressRoom/PressReleaseArchives.aspx.

- 03/05/14 - Inappropriate Antibiotic Use in Hospitals Putting Patients At Risk (CDC Vital Signs Statement)
- 02/26/14 - International Infection Experts Come to US for Training
- 02/12/14 - Well-Child Visits Linked to More Than 700,000 Subsequent Flu-like Illnesses
- 02/12/14 - Outbreak of Rare Bacteria in Outpatient Cancer Clinic Tied to Lapse in Infection Control Procedure
- 01/20/14 - Hospital Water Taps Contaminated with Bacteria
- 01/20/14 - Infectious Diseases Experts Issue Guidance on Healthcare Personnel Attire
- 12/23/13 - Infectious Diarrhea Germs Stick to Healthcare Worker Hands
- 12/23/13 - Antibiotics before Heart Surgery Protect Against Infection
- 12/12/13 - Infectious Diseases Experts Call for Mandatory Immunization of Health Care Personnel
- 11/20/13 - New Research Gives Clues of Antibiotic Use and Resistance in U.S.Children's Hospitals
- 10/16/13 - Use of Antibiotics to Treat Catheter-Associated Bacteriuria Futile in Efforts to Decrease Risk of Mortality

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:

SHEA Spotlight

SHEA launched a weekly electronic only newsletter with an outside vendor to summarize major stories for the specialty. The newsletter is available to members and non-members free of charge. A sample past issue can be found at: <http://multibriefs.com/briefs/SHEA/SHEA021314.php>. To subscribe: <http://multibriefs.com/optin.php?shea>.

Dedicated Issue of *Infection Control and Hospital Epidemiology* (ICHE) – Spring 2014

ICHE will have a special issue on multidrug-resistant organisms (MDROs) and carbapenem-resistant Enterobacteriaceae (CRE) coming out in April 2014 in time for the SHEA Spring 2014 conference.

Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care

Hospitals – 2014 Update

The updated Compendium will be released in a series of issues of ICHE over the spring and summer of 2014. SHEA will be publicizing these as part of ICHE and a dedicated supplement

with all the Compendium sections will be printed in time for distribution at IDWeek 2014.

Other items of note:

HHS/APIC/SHEA Partnership in Prevention Award

Our jointly sponsored HHS/APIC/SHEA Partnership in Prevention Award was presented to the University of Wisconsin Hospital and Clinics (UWHC) in November 2013 at HHS headquarters for achieving sustainable improvements toward eliminating HAIs.

SHEA IDWeek Awards

We are currently accepting applications for all the SHEA awards presented during IDWeek.

More information available here: <http://www.shea-online.org/About/SHEAAwards.aspx>.

2014 SHEA International Ambassadors

SHEA has selected the following group to serve as the 2014 SHEA International Ambassador delegation. The Ambassadors will be attending both SHEA Spring 2014 and IDWeek 2014 as part of a generous grant from 3M.

- Debora Silva De Mello, MSN, RN, Coordenação de Vigilância em Saúde (São Paulo, Brazil)
- Workeabeba Abebe Taye, MD, MPH, School of Medicine, Addis Ababa University (Addis Ababa, Ethiopia)
- Carmen Soria Segarra, MD, Hospital Luis Vernaza (Guayaquil, Ecuador)
- Nadeem Masih, RN, Shaukat Khanum Memorial Cancer Hospital Research Centre (Lahore, Pakistan)
- Wateba Ihou Majesté, MD, University of Lomé (Lomé, Togo)
- Nagwa Mustafa El Amin, MD, PhD, Soba University Hospital (Al Khartūm, Sudan)
- Savitha Nagaraj, MBBS, MD, DNB, St. Johns Medical College and Hospital (Bangalore, India)
- Fredrick Wambu, RN, Nairobi Hospital (Nairobi, Kenya)
- Indumathi Venkatachalam, MPH, MBBS, National University Health System, Singapore (Singapore)
- Diana Vilar MD, MSc, Instituto Nacional de Cancerología (Mexico City, Mexico)

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)

Centers for Disease Control and Prevention

Meeting Date: April 10-11, 2014

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

Liaison name: Dr. Sanjay Saint

Organization represented: Society of Hospital Medicine

Interim activities and updates:

- SHM is partnering with HRET on an 18 month CAUTI prevention initiative in nationally to educate hospital teams regarding best practices utilizing the Comprehensive Unit-based Safety Program (CUSP) model and catheterout.org toolkit
 - Facilitated multiple coaching calls with state hospital associations on CAUTI
 - Attended in-person learning sessions at state hospital associations providing hospital teams with strategies for reducing CAUTI and sustaining improvements

- SHM is supporting a CAUTI fellowship (Project Protect: Infection Prevention Fellowship) which provides enriched training, leadership development and expert mentorship to foster the growth of dedicated leaders and infection prevention champions committed to improving safety and reducing CAUTIs
- Currently planning the second Interdisciplinary Academy for Coaching and Teamwork (I-ACT) workshop
- The training is an advanced level course with a focus upon three main components: complex clinical CAUTI challenges, socio-adaptive issues among a multidisciplinary team and effective coaching
- Attendees will include Project Protect fellows, faculty experts and state leads
- Received notification of award for additional subcontract to work in partnership with HRET to reduce CAUTI in the long term care setting
 - Presently serving on Content Development and Recruitment Subcommittees
 - Identifying faculty experts who will provide coaching support for physicians and staff and long term care facilities

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 endorsed the update to the 2008 Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals as per the invitation provided from the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA), in partnership with the American Hospital Association (AHA), the Association for Professionals in Infection Control and Epidemiology (APIC), and the Joint Commission

Position statements:

- Signed letter supporting restoring the 302(b) funding allocation to the Labor, HHS, Education and Related Agencies to the FY2010 levels
- Provided feedback on the 2014 IPPS and PFS rules on measures in quality reporting and pay-for-performance programs
- Submitted comments to CMS on the Measures Under Consideration December 2013
- Signed letter supporting NQF and quality measure development as part of SGR reform efforts
- Signed on to letter supporting funding of AHRQ, CDC and other organizations that could be detrimentally impacted by budget sequestration

Legislation:

- Continue to monitor, comment upon or provide endorsement for a variety of rules related to Affordable Care Act
- Supported legislation addressing the antibiotics production pipeline

Campaigns and related activities:

- Participating in ABIM Foundation's Choosing Wisely campaign and submitted list of 5 over utilized or unnecessary tests or treatments in early September 2012 (both adult and pediatric lists)
 - One recommendation related to reducing utilization of urinary catheters
 - Managing grant to disseminate recommendations more broadly. Through the grant we will launch a case study competition in June 2014 to solicit submissions of innovative projects developed based upon the Choosing Wisely campaign.
- Funding for AHRQ (a legislative ask) during membership-wide Hill Day at HM13

Press activities:

n/a

Publications:

- Fewer Catheter-Related Complications with Central Access in ICU Patients
- Predictors of Clostridium difficile infections in hospitalized children
- No Benefits to Therapeutic Hypothermia for Severe Bacterial Meningitis

Other items of note:

- Some of the planned presentations at SHM's Annual Meeting (March 24-27, 2014) include:
 - Pneumonia State-of-the-Art Practice That Improves Outcomes
 - When Cellulitis Isn't: Identifying Cellulitis Mimics
 - Making Sense of Alphabet Soup: Practical Strategies Against KPC, ESBL, MRSA
 - CLABSI, CAUTI, and Clostridium: Strategies for Preventing Iatrogenic Infections

Liaison Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)

Centers for Disease Control and Prevention

Meeting Date: April 10-11, 2014

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 winter has been spent planning the annual meeting scheduled for May 1-3 at the Four Seasons Hotel in Baltimore. Presentations will include a half-day Surgical Infections course, 46 oral papers, 53 posters, and three update symposia related to the catastrophic abdomen, gender differences in sepsis, and the ability to achieve zero HAIs (I have taken the Con side). The program can be found at the SIS website (www.sisna.org). A strategic planning committee is completing work, focused mainly on how we can continue to partner with the diverse professional organizations that have interests in surgical and healthcare-acquired infections.

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 review:

Project: To summarize the level of evidence and determine grades of recommendations for the prophylaxis and treatment of infections in the context of traumatic injury.

A recent conference call yielded consensus that the following sub-projects will be pursued:

1. Sub-project 1: Facial trauma
 - a. 31 December 2013: completion of literature review
 - b. 31 January 2014: completion of analysis
 - c. 31 March 2014: manuscript submission to *Surgical Infections*
2. Sub-project 2: Orthopaedic trauma

- a. Pending sub-project 1
- 3. Project 3: TBD
 - a. Pending sub-project 2

Position statements:

Glycemic Control and Prevention of Surgical Site Infection full access
Lillian S. Kao, Uma R. Phatak
Surgical Infections. October 2013, 14(5): 437-444.

Legislation:

n/a

Campaigns and related activities:

n/a

Press activities:

n/a

Recent Publications:

Biofilm: Basic Principles, Pathophysiology, and Implications for Clinicians
Michael R. Hall, Edward McGillicuddy, Lewis J. Kaplan
Surgical Infections. February 2014, 15(1): 1-7.

The Efficacy of Procalcitonin as a Biomarker in the Management of Sepsis: Slaying Dragons or Tilting at Windmills? full access
Prasanna Sridharan, Ronald S. Chamberlain
Surgical Infections. December 2013, 14(6): 489-511.

Determining a Core Curriculum in Surgical Infections for Fellowship Training in Acute Care Surgery Using the Delphi Technique full access
Addison K. May, Joseph Cuschieri, Jeffrey L. Johnson, Therese M. Duane, Jill R. Cherry-Bukowiec, Matthew R. Rosengart
Surgical Infections. December 2013, 14(6): 547-553.

Procalcitonin as an Early Diagnostic Marker for Ventriculoperitoneal Shunt Infections full access
Ryosuke Tomio, Takenori Akiyama, Shunsuke Shibao, Kazunari Yoshida
Surgical Infections. October 2013, 14(5): 433-436.

Other items of note:

This is the body of the abstract of an SIS-managed, 521 patient randomized, controlled trial of the duration of antimicrobial therapy after the treatment of intra-abdominal infection. Presentation of the results will occur at the Annual SIS meeting in Baltimore 5-1-14. All are invited

The SIS Study To Optimize Peritoneal Infection Therapy (STOP-IT) Trial: Four Days of Antibiotics Result in Similar Outcomes Compared to Duration Based on Resolution of Physiological Response

Background: After source control, antibiotics are required to clear pathogens from the peritoneum. The most effective duration of antimicrobial therapy in this setting remains unclear.

Hypothesis: The administration of four days of antibiotics after source control leads to outcomes equivalent to a strategy where antibiotics are administered for two days beyond resolution of physiologic abnormalities.

Methods: The trial was a 23-center, randomized, controlled study of four full days of antibiotics after source control procedure (4 day) versus antibiotics given for two days beyond resolution of fever ($T \geq 38$), leukocytosis ($WBC \geq 11$), and ileus, with a maximum of 10 days ("clinical response" - CR). Antibiotic regimens adhered to SIS guidelines. The primary outcome was the composite of surgical site infection, recurrent intraabdominal infection, and death within 30 days of source control based on group allocation (intent-to-treat). Secondary outcomes included rates of extra-abdominal infection and subsequent infections with resistant pathogens, including *C. difficile*.

Results: 521 patients were enrolled: 263 in the CR group and 258 in the 4 day group. Colon/rectum was the most common source (159), followed by appendix (70), small bowel (69), and biliary tree (52). APACHE II was similar between groups: CR= 9.8 ± 0.4 (SEM), 4 day= 10.1 ± 0.4 . Median duration of antibiotics with interquartile range (IQR) was 8 (5-10) days in the CR group and 4 (4-5) days in the 4 day group ($p < 0.01$ by Mann-Whitney U test). There was no difference in the composite or component endpoints. No difference was found in rates of subsequent infection with resistant pathogens or *C. difficile*. There were fewer patients with extra-abdominal infections (principally urinary tract infections) in the CR day group than the 4 day group ($17/263=6.5\%$ versus $31/258=12\%$, $p=0.028$ by Pearson χ^2 test).

Discussion: In this multicenter, randomized, controlled trial, a fixed duration of four days of antibiotics to treat intraabdominal infections after a source control procedure yielded outcomes similar to a longer course based on resolution of physiologic abnormalities and was associated with significantly fewer days of antibiotic exposure. We recommend this approach as standard of care.

Outcome	CR (n = 263)	4 day (n = 258)	p
Surgical site infection	22 (8.4%)	16 (6.2%)	0.40
Recurrent intraabdominal infection	33 (12.5%)	39 (15.1%)	0.45
Death	2 (0.8%)	3 (1.2%)	0.68
Composite of above outcomes	57 (21.7%)	58 (22.5%)	0.83