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 Summary Report
November 3-4, 2011
Washington, DC

TABLE OF CONTENTS

ATTACHMENT 1
Agenda
Healthcare Infection Control Practices Advisory Committee

Centers for Disease Control and Prevention
Embassy Suites Washington, DC Convention Center (Capital CD Room)
900 10th Street, NW
Washington, DC 20001

Thursday November 3, 2011

Time	Topic	Presider/Presenter
9:00	**Welcome and Introductions** Administrative issues: Meeting logistics Conflicts of interest declarations	Neil Fishman Jeff Hageman
9:30	Update on Healthcare Personnel Guidelines	David Kuhar
10:15	**Break**	
10:30	Draft Guideline for Prevention of Infections Among Patients in NICU	Alexis Elward
11:30	HAI Perspective from CDC Washington Office	Michael Craig
12:00	**Lunch**	
1:15	HAI Surveillance Working Group- NHSN definitions for CLABSI and SSIs	Scott Fridkin
2:30	Update on CDC's State HAI Prevention Activities	Arjun Srinivasan
3:30	Break	
3:45	Carbapenem-Resistant *Enterobacteriaceae* Infection Prevention and Control	Alex Kallen
4:30	Public Comment	
4:40	**Liaison/ Ex-officio Reports**	
5:00	**Adjourn**	

Friday November 4, 2011

Time	Topic	Presider/Presenter
9:00	CDC Guideline Development Plan	Jeff Hageman
10:00	Draft Guideline for the Prevention of Surgical Site Infections	Sandra Berrios-Torres
11:00	E-Surveillance and Impact on Infection Prevention	Michael Bell
11:40	Public Comment	
11:45	Summary and Wrap Up	
12:00	**Adjourn**	

ATTACHMENT 2

List of Participants

(*Note:* The Designated Federal Official opened the floor for introductions on November 3 and 4, 2011 and verified the presence of a quorum with voting members and *ex-officio* members for HICPAC to conduct its business on both days of the meeting.)

NOVEMBER 3, 2011

HICPAC Members

Dr. Neil Fishman, Chair
Ms. Judene Bartley
Dr. Dale Bratzler
Dr. Ruth Carrico
Dr. Daniel Diekema
Dr. Alexis Elward
Dr. Ralph Gonzales
Dr. Mary Hayden
Dr. Susan Huang
Dr. Tammy Lundstrom
Dr. Stephen Ostroff
Dr. William Schecter
Dr. Thomas Talbot

Designated Federal Official

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

***Ex-Officio* Members**

Dr. William Baine (Agency for Healthcare Research and Quality)
Dr. David Henderson (National Institutes of Health)
Dr. Daniel Mareck (Alternate, Health Resources and Services Administration)
Ms. Jeannie Miller (Centers for Medicare and Medicaid Services)
Dr. Sheila Murphey (Food and Drug Administration)
Dr. Gary Roselle (Department of Veterans Affairs)

Liaison Members

Ms. Joan Blanchard (Association of periOperative Registered Nurses)
Dr. William Brock (Society of Critical Care Medicine)
Ms. Barbara DeBaun (Association of Professionals of Infection Control and Epidemiology, Inc.)
Ms. Lisa Graybert (Alternate, (American Hospital Association)
Dr. Charles Huskins (Infectious Disease Society of America)
Dr. Marion Kainer (Council of State and Territorial Epidemiologists)
Ms. Lisa McGiffert (Consumers Union)
Ms. Shirley Paton (Public Health Agency of Canada)
Ms. Kelly Podgorny (Alternate, The Joint Commission)
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)
Ms. Rachel Stricof (Advisory Council for the Elimination of Tuberculosis)

CDC Representatives

Dr. Beth Bell, NCEZID Director
Dr. Denise Cardo, DHQP Director
Dr. Michael Bell, Deputy Director, DHQP
Sandra Berrios-Torres
Michael Craig (Washington, DC Office)
Scott Fridkin
Rita Helfand
Martha Iwamoto
Gail Janes
Alexander Kallen
David Kuhar

Clifford McDonald
Elizabeth Skillen
Arjun Srinivasan
J. Todd Weber
Heidi Williams

Guest Presenters and Members of the Public

Portia Ash (GOJO Industries, Inc.)
Steven Brash (Nemours Foundation/ Alfred I. duPont Hospital for Children)
Russ Castioni (3M Company)
Paul Etkind (National Association of County and City Health Officials)
Daniel Gallardo (Department of Health and Human Services)
Hudson Garrett, Jr. (Professional Disposables International, Inc.)
Joseph Gillis (3M Company)
Peter Gordon (Germguard Lighting)
Vikas Gupta (CareFusion)
Marilyn Hanchett (Association of Professionals of Infection Control and Epidemiology, Inc.)
Elizabeth Hechenbleikner (Johns Hopkins University)
Karen Hoffmann (Centers for Medicare and Medicaid Services)
Rani Jeeva (Department of Health and Human Services)
Jane Kirk (GOJO Industries, Inc.)
Jeffrey Kline (C.R. Bard)
Nancy Klinger (3M Company)
Clifford Ko (University of California, Los Angeles)
Ian Kramer
Brian Leas (University of Pennsylvania Health System Center for Evidence-Based Practice)
Aime Lenz (Professional Disposables International, Inc.)
Martin Makary (Johns Hopkins University)
William Martin (American Academy of Orthopaedic Surgeons)
Heather Misner (Association of State and Territorial Health Officials)
Erin O'Malley
Daniel Schwartz (Centers for Medicare and Medicaid Services)
Edward Septimus (Hospital Corporation of America)
Joseph Solomkin (University of Cincinnati)
Michelle Stevens (3M Company)
Amber Taylor (Department of Health and Human Services)
Lisa Tomlinson (Association of Professionals of Infection Control and Epidemiology, Inc.)
Thomas Weaver (Association of Professionals of Infection Control and Epidemiology, Inc.)
Craig Umscheid (University of Pennsylvania Health System Center for Evidence-Based Practice)
Cindy Winfrey (Professional Disposables International, Inc.)
Melanie Young (Society for Healthcare Epidemiology of America)

NOVEMBER 4, 2011

HICPAC Members

Dr. Neil Fishman, Chair
Ms. Judene Bartley
Dr. Dale Bratzler
Dr. Ruth Carrico
Dr. Daniel Diekema
Dr. Alexis Elward
Dr. Ralph Gonzales
Dr. Mary Hayden
Dr. Susan Huang
Dr. Tammy Lundstrom
Dr. William Schecter
Dr. Thomas Talbot

Designated Federal Official

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

***Ex-Officio* Members**

Dr. William Baine (Agency for Healthcare Research and Quality)
Dr. Daniel Mareck (Alternate, Health Resources and Services Administration)
Dr. Sheila Murphey (Food and Drug Administration)

Liaison Members

Ms. Joan Blanchard (Association of periOperative Registered Nurses)
Dr. William Brock

(Society of Critical Care Medicine)
Ms. Barbara DeBaun (Association of Professionals of Infection Control and Epidemiology, Inc.)
Ms. Lisa Graybert (Alternate, (American Hospital Association)
Dr. Charles Huskins (Infectious Disease Society of America)
Dr. Marion Kainer (Council of State and Territorial Epidemiologists)
Ms. Lisa McGiffert (Consumers Union)
Ms. Shirley Paton (Public Health Agency of Canada)
Ms. Kelly Podgorny (Alternate, The Joint Commission)
Dr. Mark Rupp (Society for Healthcare Epidemiology of America)
Dr. Mark Russi (American College of Occupational and Environmental Medicine)
Ms. Rachel Stricof (Advisory Council for the Elimination of Tuberculosis)

CDC Representatives

Dr. Denise Cardo, DHQP Director
Dr. Michael Bell, Deputy Director, DHQP
Sandra Berrios-Torres
Michael Craig (Washington, DC Office)
Scott Fridkin
Rita Helfand
Martha Iwamoto
Gail Janes
Clifford McDonald
Daniel Pollock
Elizabeth Skillen
J. Todd Weber
Heidi Williams

Guest Presenters and Members of the Public

Portia Ash (GOJO Industries, Inc.)
Steven Brash (Nemours Foundation/ Alfred I. duPont Hospital for Children)
Catherine Cairns (Association of State and Territorial Health Officials)
Russ Castioni (3M Company)
Paul Etkind (National Association of County and City Health Officials)
Daniel Gallardo (Department of Health and Human Services)
Hudson Garrett, Jr. (Professional Disposables International, Inc.)
Joseph Gillis (3M Company)
Peter Gordon (Germguard Lighting)
Vikas Gupta (CareFusion)
Mary Hayden
Elizabeth Hechenbleikner (Johns Hopkins University)
Karen Hoffmann (Centers for Medicare and Medicaid Services)
Rani Jeeva (Department of Health and Human Services)
Rachel Kelz (University of Pennsylvania Health System Center for Evidence-Based Practice)
Jane Kirk (GOJO Industries, Inc.)
Jeffrey Kline (C.R. Bard)
Nancy Klinger (3M Company)
Clifford Ko (University of California, Los Angeles)
Ian Kramer
Brian Leas (University of Pennsylvania Health System Center for Evidence-Based Practice)
Aime Lenz (Professional Disposables International, Inc.)
Martin Makary (Johns Hopkins University)
William Martin (American Academy of Orthopaedic Surgeons)
Heather Misner (Association of State and Territorial Health Officials)
Erin O'Malley
Daniel Schwartz (Centers for Medicare and Medicaid Services)
Edward Septimus (Hospital Corporation of America)
Joseph Solomkin (University of Cincinnati)
Michelle Stevens (3M Company)
Amber Taylor (Department of Health and Human Services)
Thomas Weaver (Association of Professionals of Infection Control and Epidemiology, Inc.)
Craig Umscheid (University of Pennsylvania Health System Center for

Evidence-Based Practice)
Elizabeth Wick (Johns Hopkins University)
Cindy Winfrey (Professional Disposables International, Inc.)
Melanie Young (Society for Healthcare Epidemiology of America)

ATTACHMENT 3

Glossary of Acronyms

AAMI	Association for the Advancement of Medical Instrumentation
AAP	American Academy of Pediatrics
ACET	Advisory Council for the Elimination of Tuberculosis
ACIP	Advisory Committee for Immunization Practices
ACOEM	American College of Occupational and Environmental Medicine
ADT	Admission/Discharge Transfer
AHA	American Hospital Association
AHRQ	Agency for Healthcare Research and Quality
AMP	Antimicrobial Prophylaxis
AORN	Association of periOperative Registered Nurses
APIC	Association for Professionals in Infection Control and Epidemiology, Inc.
ARRA	American Recovery and Reinvestment Act
ARV	Antiretroviral
AZT	Azidothymidine
BMT	Bone Marrow Transplant
C. difficile	*Clostridium difficile*
CAUTI	Catheter-Associated Urinary Tract Infection
CDA	Clinical Document Architecture
CDC	Centers for Disease Control and Prevention
CLABSI	Central Line-Associated Blood Stream Infection
CLSI	Clinical and Laboratory Standards Institute
CMS	Centers for Medicare and Medicaid Services
CRE	Carbapenem-Resistant Enterobacteriaceae
CSTE	Council of State and Territorial Epidemiologists
CVC	Central Venous Catheter
DHQP	Division of Healthcare Quality Promotion
E. coli	*Escherichia coli*
EHRs	Electronic Health Records
FDA	Food and Drug Administration
FTC	Emtricitibine
GAS	Group A Streptococcus
GI	Gastrointestinal
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
GVHD	Graft-Versus-Host Disease
HAI	Healthcare-Associated Infection
HBV	Hepatitis B Virus
HCP	Healthcare Personnel
HCV	Hepatitis C Virus
HHS	Department of Health and Human Services
HICPAC	Healthcare Infection Control Practices Advisory Committee
ICU	Intensive Care Unit
IDSA	Infectious Diseases Society of America
IPC	Infection Prevention and Control
IPs	Infection Preventionists

IV	Intravenous
LTACHs	Long-Term Acute Care Hospitals
LTCFs	Long-Term Care Facilities
MDRO	Multidrug-Resistant Organism
MeSH®	Medical Subject Headings
MRSA	Methicillin-Resistant *Staphylococcus aureus*
MSSA	Methicillin-Sensitive *Staphylococcus aureus*
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NHSN	National Healthcare Safety Network
NICU	Neonatal Intensive Care Unit
NQF	National Quality Forum
PCR	Polymerase Chain Reaction
PEP	Postexposure Prophylaxis
PHS	U.S. Public Health Service
RAL	Raltegravir
RCTs	Randomized Controlled Trials
RSV	Respiratory Syncytial Virus
RTV	Ritonavir
S. aureus	*Staphylococcus aureus*
SCCM	Society of Critical Care Medicine
SHEA	Society for Healthcare Epidemiology of America
SHM	Society of Hospital Medicine
SSI	Surgical Site Infection
TDF	Tenofovir
TPN	Total Parenteral Nutrition
UPHS-CEP	University of Pennsylvania Health System Center for Evidence-Based Practice
UTI	Urinary Tract Infection
VA	Department of Veterans Affairs
VAP	Ventilator-Associated Pneumonia
ZDV	Zidovudine

EXECUTIVE SUMMARY

The Division of Healthcare Quality Promotion (DHQP), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on November 3-4, 2011 in Washington, DC.

The Designated Federal Official (DFO) verified the presence of a quorum with voting members and *ex-officio* members for HICPAC to conduct its business on both days of the meeting. The HICPAC voting members declared their conflicts of interest for the record. The participants recognized an outgoing member, Dr. William Schecter, for his outstanding contributions to CDC, HICPAC and the broader healthcare infection control practices community.

Updates on three draft CDC guidelines were presented:

1. Healthcare Personnel (HCP) Infection Prevention and Control Guideline
2. Neonatal Intensive Care Unit (NICU) Infection Prevention Guideline
3. Prevention of Surgical Site Infection Guideline

HICPAC provided suggestions and input to assist the CDC writing groups in continuing their efforts to develop, revise and finalize these guidelines.

CDC's Washington Office presented an overview of current Congressional issues related to the prevention of healthcare-associated infections (HAIs). These topics included current and upcoming budget cuts at the federal level, the implications of these cuts on HAI prevention activities at the state level, the "Partnership for Patients: Better Care, Lower Costs" initiative, and value-based purchasing. HICPAC made several suggestions to ensure that investments in HAI prevention are maintained in light of CDC's upcoming budget cuts.

A comprehensive update was provided of ongoing efforts by the HAI Surveillance Workgroup to provide input into potential modifications in the National Healthcare Safety Network (NHSN) definitions for central line-associated bloodstream infection (CLABSI), surgical site infection (SSI) and ventilator-associated pneumonia (VAP). The workgroup presented HICPAC with pros and cons of potential changes which are intended to increase credibility of the definitions among the clinical community while maintaining reliability for public reporting purposes. HICPAC devoted a considerable portion of the meeting to providing CDC with input and suggestions to further modify the CLABSI, SSI and VAP definitions for NHSN.

CDC presented an update on its funded state HAI prevention activities in the areas of development and support of an HAI infrastructure, HAI monitoring, and HAI prevention. Process measures and other preliminary outcomes from CDC's evaluation of state HAI prevention activities to date were highlighted. Important characteristics for states to take leadership in HAI prevention were described. HICPAC commended CDC on providing states with tremendous support for HAI prevention. HICPAC proposed several suggestions to address current challenges and strengthen state HAI prevention efforts in the future.

CDC presented its proposal to expand the 2009 Guidance on the Control of Carbapenem-resistant Enterobacteriaceae (CRE) in healthcare settings. The objectives of the expanded CDC CRE guidance will be to update the 2009 recommendations, acknowledge substantial

knowledge gaps and controversies, and provide information for settings outside of acute care facilities. Key points in the Background, Definitions, Surveillance and Interventions Sections of the expanded CRE guidance were highlighted. HICPAC was pleased that CDC plans to apply the expanded CRE guidance to long-term care facilities. HICPAC proposed a number of suggestions for CDC to consider in updating the document.

The DFO provided an update on the HHS Action Plan to Prevent HAIs, including the current revision of the document and the HHS National Awards Program to recognize facilities and units that have achieved significant reductions in CLABSI and VAP.

The DFO presented an update on the CDC guideline development plan. HICPAC including liaison organizations were asked to consider and provide input on several questions in preparation of the next meeting.

1. What are the critical gaps, questions and issues that should be considered in developing guidelines?
2. What guidelines are your organizations currently developing or revising? Does your organization use GRADE or a comparable methodology to develop guidelines?
3. What should be the next topic areas after the NICU, HCP and SSI Guidelines are completed?
4. What should be the next specialty component after arthroplasties for the SSI Guideline?

HICPAC proposed several suggestions to start the process of creating a guideline development plan for the future.

CDC presented an overview of e-surveillance and its impact on infection prevention. HICPAC was asked to provide input on areas that will need to be addressed to make the shift to e-surveillance. HICPAC's potential role in this effort could be to draft an e-surveillance document for the infection prevention and control community (IPC) or make presentations during national events. HICPAC agreed that the IPC community should take steps at this time to shift to e-surveillance. HICPAC identified a number of challenges and proposed several suggestions that should be considered in this effort. The Chair raised the possibility of HICPAC developing e-surveillance standards.

HICPAC's liaison and e*x-officio* members submitted written reports and provided additional details during the meeting on recently completed, ongoing and upcoming activities of their organizations and agencies. The verbal and written reports highlighted organizational and agency position statements, new or pending legislation, campaigns and related activities, press activities, publications, and other items of note.

The Chair reviewed the presentations that were made over the course of the meeting and noted that none of these issues required a HICPAC vote or formal action. The Chair called for public comments at all times noted on the published agenda for the November 3-4, 2011 meeting.

MEETING SUMMARY

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). The proceedings were held on November 3-4, 2011 at the Embassy Suites Washington, DC Convention Center in Washington, DC.

Opening Session: November 3, 2011

Mr. Jeffrey Hageman, MHS
Deputy Chief, Prevention and Response Branch
and HICPAC DFO
DHQP, CDC

Mr. Hageman opened the floor for introductions to determine the HICPAC voting members, *ex-officio* members and liaison representatives who were in attendance. He asked the voting members to declare any conflicts of interest for the record.

- Alexis Elward, MD: Recipient of research funds from SAGE Products.
- Dale Bratzler, DO, MPH: Consultant for Janssen Pharmaceuticals, Inc. and Johnson & Johnson.
- Tammy Lundstrom, MD, JD: Recipient of travel reimbursement funds for an ACPE lecture.
- Daniel Diekema, MD: Recipient of grant funds from Innovative Biosensors.

Mr. Hageman verified that the voting members and *ex-officio* members in attendance constituted a quorum for HICPAC to conduct its business on November 3, 2011. He called the proceedings to order at 9:02 a.m. and welcomed the participants to the meeting. He asked the HICPAC members to be mindful of conflicts of interest and recuse themselves from participating in discussions or voting on issues in which they have a real or perceived conflict. The list of participants is appended to the minutes as Attachment 1.

Mr. Hageman introduced two guests in the audience. Dr. Craig Umscheid is the Director of the University of Pennsylvania Health System Center for Evidence-Based Practice (UPHS-CEP) and provides external expertise and oversight of the CDC guideline development process. Dr. William Martin III is the Chief Medical Officer of the American Academy of Orthopaedic Surgeons.

Mr. Hageman announced that Dr. William Schecter's term as a HICPAC member has expired. Since his appointment in August 2007, Dr. Schecter has played an integral role in developing the Surgical Site Infection Guideline; provided valuable insight and experience from a surgeon's perspective; and participated in other HICPAC activities. The participants joined Mr. Hageman

in applauding Dr. Schecter's outstanding contributions to CDC, HICPAC and the broader healthcare infection control practices community.

Dr. Schecter confirmed that he was honored to have an opportunity to represent the American College of Surgeons on HICPAC. He was impressed with the vast amount of knowledge and wisdom of his HICPAC colleagues in a variety of fields. He noted that the multidisciplinary expertise of the members is one of HICPAC's key strengths. Although his term had expired, Dr. Schecter confirmed his continued commitment to working with his colleagues toward the publication of the Surgical Site Infection Guideline.

Neil Fishman, MD
Associate Chief Medical Officer
University of Pennsylvania Health System
HICPAC Chair

Dr. Fishman joined Mr. Hageman in welcoming the participants to the HICPAC meeting. He reviewed the agenda items that would be presented over the course of the meeting. He asked HICPAC to consider whether a 1.5-day meeting is sufficient time due to the extensive amount of information that is presented during meetings. To address this issue, HICPAC meetings could begin earlier than 9:00 a.m. or end later than 12:00 p.m. on day 2. Dr. Fishman planned to discuss these two options with HICPAC in more detail on the following day.

Update on the Healthcare Personnel (HCP) Infection Prevention and Control Guidelines
David Kuhar, M.D.
Medical Officer, DHQP
Centers for Disease Control and Prevention

Dr. Kuhar presented an update on the *U.S. Public Health Service (PHS) Guideline for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis (PEP)*. In 1990, PHS issued its first statement on the management of occupational exposure to HIV. In 1996, PHS issued updated provisional recommendations for chemoprophylaxis following occupational exposure to HIV. In 1998, PHS issued guidelines for the management of HCP exposure to HIV and recommendations for PEP. In this guidance, HIV PEP regimens were expanded and an exposure risk assessment algorithm was introduced to determine the appropriateness of a 2- versus 3-drug regimen. In 2001, PHS issued updated guidelines for the management of occupational exposure to hepatitis B virus (HBV), hepatitis C virus (HCV) and HIV as well as recommendations for PEP. The guidelines and recommendations for these three diseases were consolidated into a single document. In this guidance, the need for expert consultation for the management of HBV, HCV and HIV was more strongly emphasized. Moreover, the list of HIV PEP regimens was expanded to account for new drugs that had been added to the armamentarium since the release of the 1998 PHS guidelines. In 2005, PHS issued updated guidelines for the management of occupational exposure to HIV only and recommendations for PEP. The guidelines also included an updated list of drug regimens.

Since the updated PHS recommendations were released in 2005, no new large randomized controlled trials (RCTs) have been conducted to guide the use of ARVs for occupational exposure to HIV and HIV PEP. Several new medications, including 2 new drug classes, have been developed and approved for the treatment of HIV-infected persons. Compared to the ARVs recommended in the 2005 PHS guidelines, some of the new medications are better tolerated, have less toxicity, and are considered to be "first-line" drugs in the treatment of HIV-infected persons.

In July 2011, DHQP convened a meeting with the PHS Workgroup and external experts to discuss challenges in following and updating the 2005 PHS guidelines. The key discussion topics during the meeting included new evidence to guide the use of HIV PEP, the role of newer medications in HIV PEP, the impact of pregnancy on newer medications, and a reevaluation of the 2005 guidelines and areas for improvement.

The experts noted several major challenges in the 2005 PHS guidelines. No new large RCTs have been conducted to guide the use of HIV PEP, including the role of newer medications. The recommended drugs (e.g., Azidothymidine (AZT), Lopinivir and Ritonavir (RTV)) have significant side effects and toxicities. A single recommended initial PEP regimen would be clearer and more desirable than a collection of drug combinations.

Interpretation of the 2005 guidelines also has led to a number of challenges (e.g., definition of when an exposure has truly occurred and risk stratification of the exposure; initial management of HCP in settings of a source patient with an unknown HIV status; concerns of the accuracy of the rapid HIV test in making decisions regarding PEP; and the impact of a drug-resistant source HIV virus in the prompt provision of appropriate HIV PEP).

The PHS workgroup has started to draft the first section of the guideline. Draft of this guidance is planned to be completed in 2012.

HICPAC supported the PHS workgroup's approach to more strongly emphasize early initiation of PEP. HICPAC also was in favor of the new recommendation to manage all occupational exposures to HIV with a medication regimen of $\geq$3 ARVs.

Dr. Fishman closed the discussion by asking HICPAC to provide him or Mr. Hageman with any additional comments on the updated HCP guidelines in general and gaps in the proposed research questions in particular for distribution to the workgroup.

Update on the Neonatal Intensive Care Unit (NICU) Infection Prevention Guideline

Alexis Elward, MD, MPH
Assistant Professor, Pediatrics Infectious Diseases
Washington University School of Medicine
HICPAC Member

Dr. Elward covered the following topics in her update on CDC's NICU guideline. The writing group has completed several tasks since providing an update at the June 2011 HICPAC

meeting. Inclusion and exclusion criteria were refined for each topic. Full-text reviews by 2 reviewers were completed for all of the papers. A search was performed on the use of chlorhexidine in infants to determine its safety in this patient population.

The chlorhexidine text and abstracts were reviewed. Drafts were developed of the table master lists, evidence tables, GRADE tables, and a narrative summary for the *C. difficile* key question. The workgroup is currently focusing on the data extraction and synthesis phase of the NICU guideline development process to place data into evidence tables and draft narrative summaries.

The writing group engaged a broad range of stakeholders in developing the guideline, including infection preventionists (IPs), neonatologists, neonatal NICU nurses, pediatric infectious disease experts and hospital epidemiologists. These stakeholders represent the American Academy of Pediatrics (AAP), Society for Healthcare Epidemiology of America (SHEA), Association for Professionals in Infection Control and Epidemiology, Inc. (APIC), Vermont Oxford Network, and National Association of Neonatal Nurses. AAP is a co-sponsor of the NICU guideline along with HICPAC.

Of 2,980 abstracts that initially were reviewed, 1,738 full-text studies and ultimately selected 349 full-text studies for inclusion in the NICU guideline: 6 for varicella, 6 for *C. difficile*, 13 for pertussis, 55 for respiratory infections, 56 for MRSA, 86 for central line-associated bloodstream infections (CLABSI), and 127 for fungal disease.

The writing group agreed that studies with original data or systematic reviews with original data would be included in the NICU guideline. The top 3 exclusion criteria were studies with no primary research, studies with no relevance to the key research questions, and case reports only. Other criteria for studies to be excluded from the NICU guideline were abstracts only, no full text available, language other than English, no NICU patients or infants in the study, a mixed patient population without a NICU or infant subgroup analysis, methods on healthcare-associated infection (HAI) surveillance only, and non-U.S. descriptive epidemiology studies only. Only a small number of studies were excluded from the NICU guideline based on non-English language.

Dr. Elward summarized the workgroup's refinement of the inclusion and exclusion criteria for each of the 5 topics that will be included in the NICU guideline. Dr. Elward presented an example of an evidence table for key question 4b: What are the most effective strategies to prevent invasive infection with Candida and Malassezia? The sample table included the reference identification, author and year of the study, intervention strategy, study design, risk of bias, cohort size, infections in the treated and control groups, adverse events, and odds ratio with a 95% confidence interval.

Based on the strength of the design, each study will be given an initial grade of "high" (e.g., RCT), "low" (e.g., observational study) or "very low" (e.g., expert opinion or any other evidence). The initial grade will be decreased based on study quality limitations, inconsistency, indirectness, imprecision or publication bias. The initial grade will be increased based on strength of an association, dose-response, or confounding factors. Based on the criteria to

increase or decrease the initial grade, each study will be assigned an overall quality grade of "high," "moderate," "low" or "very low."

An overall quality grade of "high" will be defined as further research is very unlikely to change confidence in the estimate of effect. An overall quality grade of "moderate" will be defined as further research is likely to impact confidence in the estimate of effect and may change the estimate. An overall quality grade of "low" will be defined as further research is very unlikely to impact confidence in the estimate of effect and is likely to change the estimate. An overall quality grade of "very low" will be defined as any estimate of effect is very uncertain.

Dr. Elward summarized the decisions made in drafting the NICU guideline to date. For the GRADE tables, the norovirus model will be followed in which categories will be used for multimodal interventions. These categories will be applied to the sections on MRSA prevention strategies and respiratory pathogen outbreak containment. Points will be assigned for consistency if the intervention consistently is part of a successful outbreak control strategy. Points will be deducted for magnitude of effect if the study does not report a relative risk or odds ratio. The workgroup is aware that the reported outcome in many of the studies is the incidence of disease pre-/post-outbreak.

RCTs will be included in the GRADE tables if available, but the writing group needs guidance from HICPAC on whether to include observational studies if RCTs are available. The writing group proposes to review observational studies to identify data on adverse events for fungal interventions and include these studies if additional information is provided. The writing group agreed to identify *C. difficile* as a research gap because the amount of evidence on this topic is insufficient to make a recommendation on the key questions. However, Dr. Elward asked HICPAC for guidance whether the *C. difficile* recommendations should be presented in a GRADE table or addressed in a narrative summary only.

Dr. Elward concluded her update by highlighting the next steps to finalize the NICU guideline. The CLABSI summary tables will be completed and the GRADE tables will be revised. The expert panel will review the bibliography and begin drafting and reviewing the narrative summaries for each of the 5 topics.

Craig Umscheid, MD, MSCE
Director, University of Pennsylvania Health System Center for Evidence-Based Practice

Dr. Umscheid is an external expert supported by CDC to provide methodology expertise and guidance to CDC's guideline writing groups. He and Dr. Elward provided additional details on decisions in response to HICPAC's specific questions. The writing group agreed to grade quasi-experimental studies as observational studies with an initial low GRADE. The grading scheme is based on therapeutic interventions rather than all types of interventions.

Also discussed was the possibility of deducting 1 point for precision if the evidence was supported by only one study that addressed an outcome in a particular area. However, the

writing group plans to systematically reevaluate its inclusion and exclusion criteria if 1 or 2 RCTs addressed the key questions and a large, well-designed quasi-experimental study was identified.

In terms of observational studies, advantages and disadvantages of "poor data" versus "no data" were weighed The ability to extract data and convey clear, consistent and evidence-based messages is extremely difficult and time-consuming if observational study results are inconsistent with those of well-designed RCTs. To address these issues, considering the possibility of including observational studies in the NICU guidelines if no RCTs are available and if adverse events were reported.

HICPAC commended Dr. Elward and her colleagues on the tremendous amount of work that has been completed on the NICU guideline since the June 2011 meeting. The members made several comments and suggestions for the workgroup to consider in its ongoing efforts to finalize the NICU guideline.

- Some HICPAC members believed that the *C. difficile* recommendations should be presented in a GRADE table because this format would be much more helpful to end-users than text. Other HICPAC members believed that a table for the *C. difficile* recommendations should not be developed due to the poor quality of evidence. As a result, the NICU guideline should acknowledge the poor quality of evidence and emphasize the critical need for additional research on *C. difficile* in NICU patients.
- Large observational studies that disagree with RCTs or those with a high GRADE should be included in the NICU guideline. These data provide solid evidence on the strength and consistency of the recommendations and implementation of the interventions.
- Consideration should be given to whether the MRSA recommendations could be applied to MSSA prevention in the NICU patient population. The workgroup potentially could include this issue as a research gap in the NICU guideline.
- The scheme to grade quasi-experimental studies should be reconsidered. The workgroup's proposed approach might show a bias toward lower quality of evidence versus stronger infection prevention data that are actually published in the literature. For example, a quasi-experimental study using the Stepped Wedge design or concurrent controls is different than a case-control study.
- The NICU guideline should include a statement regarding the strong focus of the GRADE process on internal validity of the effect size rather than on generalizability. The statement also should emphasize the generalizability of the recommendations based on the study populations.
- Risk factor data should be reviewed to include the origin of the patient as a key research question in the NICU guideline. For example, NICU patients who were transferred between 2 hospitals were involved in a major MRSA outbreak in Chicago.

Dr. Michael Bell is the Deputy Director of DHQP. He agreed with HICPAC's comments that transparency and reproducibility are important factors in the guideline development process. However, he noted that HICPAC's ability to clearly explain the criteria to include or exclude studies in guidelines is in its infancy and would be refined and evolve over time. As a result, he

urged HICPAC to apply lessons learned, particularly those from the urinary tract infection and norovirus guidelines, and not allow the inclusion/exclusion criteria to delay progress in finalizing the NICU and future guidelines.

Overview of Current Congressional Issues and HAI Prevention
Michael Craig
Congressional Liaison, Office of the Associate Director for Policy
CDC, Washington Office

Mr. Craig presented an overview of Congressional issues that are related to HAI prevention. CDC and other federal agencies currently are operating under a continuing resolution until Congress reaches agreement on the FY2012 budget. CDC's FY2011 budget was 11% below the FY2010 budget (or a reduction of ~$750 million). This decrease was the largest budget cut in CDC's history. DHQP's base budget was 3%-5% below the FY2010 budget. Affordable Care Act dollars allowed CDC to continue supporting state health departments, but this support was at a level below that of the American Recovery and Reinvestment Act (ARRA).

The FY2012 House level for CDC is $863 million less than the FY2011 budget with no Prevention Fund dollars. The FY2012 Senate level is $174 million more than the FY2011 budget, including $848 million from the Prevention Fund. Neither the House nor Senate included the proposed increases for CDC's HAI prevention activities related to the National Healthcare Safety Network (NHSN).

The Super Committee is charged with finding additional savings of at least $1.2 trillion over 10 years. If this goal is not achieved, enforcement mechanisms (e.g., sequestration) will be triggered. Under the Deficit Reduction Agreement that established the Super Committee, 10-year caps now exist on aggregate discretionary spending. Budget cuts or sequesters will come from security accounts (50%) and non-security accounts (50%).

Based on a rough estimate, $500 billion would be cut from each account over 10 years. Medicare providers would receive a maximum payment cut of 2%. CDC's predicted cut would be ~8% below FY2012 levels. The Super Committee's authority to cap, cut or eliminate the Prevention Fund would impact funding that is allocated to states for HAI prevention. The President's FY2013 budget will be released in February 2012.

The specific aims of the "Partnership for Patients: Better Care, Lower Costs" initiative are two-fold. By the end of 2013, preventable HAIs would decrease by 40% compared to 2010. If goal 1 is achieved, patients would sustain ~1.8 million fewer injuries and >60,000 lives would be saved over the next three years. HHS is allocating ~$500 million to achieve the HAI prevention goal.

By the end of 2013, preventable complications during a care transition would be decreased to achieve a 20% reduction in hospital readmissions compared to 2010. If goal 2 is achieved, 1.6 million patients would recover from illness without suffering a preventable complication that would require re-hospitalization within 30 days of discharge. HHS is allocating ~$500 million to

achieve the hospital readmission goal. Achievement of the two goals potentially could result in cost-savings of >$35 billion across the healthcare system over the next three years, including up to $10 billion in Medicare savings.

Value-based purchasing is underway. Section 3001 of the Affordable Care Act describes HAIs as measured by the prevention metrics and targets outlined in the HHS Action Plan. Many other metrics also are included in Section 3001. CDC and the Centers for Medicare and Medicaid Services (CMS) formed a partnership to use current, revised and new NHSN measures for value-based purchasing requirements in acute care settings. The interagency partnership also will be used to develop NHSN measures for other settings (e.g., dialysis centers, long-term acute care hospitals (LTACHs), inpatient rehabilitation facilities, and ambulatory surgical care centers).

Overall, the Congressional issues have important implications for HAI prevention. Spending ceilings for the next 10 years will be unprecedented. A flat budget or budget cuts coupled with increasing efforts related to CMS value-based reporting most likely will require CDC to pause, delay or discontinue some HAI prevention activities. HAI prevention successes by state health departments could be jeopardized if the Prevention Fund is cut or eliminated. The outcomes of Patients for Prevention and value-based purchasing could be very important to determine the Congressional view on prevention of HAIs and hospital-acquired conditions in future years.

HICPAC proposed several suggestions to ensure that investments in HAI prevention are maintained in light of CDC's upcoming budget cuts.

- Simpler, more reproducible and less time-intensive strategies should be explored to conduct surveillance of HAIs and validate data. These strategies should be designed to decrease the time required to capture data and allow more time to improve HAI prevention.
- CDC should consider alternative mechanisms to continue to fund NHSN. Because multiple federal agencies use NHSN data, the possibility of leveraging support from these sources should be explored.
- The professional societies should widely publicize NHSN success stories in their respective newsletters. NHSN's critical role in strengthening capacity to measure HAIs and decreasing the number of HAIs in individual hospitals, regions and states should be highlighted. Professional societies also should systematically educate and report the impact of NHSN to legislators.
- Federal agencies should enhance their current partnerships and form new collaborations to maximize resources and achieve patient safety goals across the continuum of care.

Dr. Denise Cardo is the Director of DHQP. She emphasized that both HHS and CDC would rely on HICPAC's expertise when decisions need to be made in the future to pause, delay or discontinue HAI prevention activities.

Update by the HAI Surveillance Workgroup: Session 1
Scott Fridkin, MD
Deputy Chief, Surveillance Branch, DHQP
CDC

Dr. Fridkin presented his update on activities by the HAI Surveillance Workgroup in two sessions. Session 1 would focus on the CLABSI definition and session 2 would focus on the surgical site infection (SSI) and ventilator-associated pneumonia (VAP) definitions.

Since the June 2011 HICPAC meeting, the workgroup has almost exclusively focused on its top priority issue. The CLABSI definition will be changed in NHSN in an effort to increase its credibility among the clinical community while maintaining reliability for public reporting purposes. The workgroup is charged with articulating the implications of these changes.

The workgroup developed a process with several strategies to evaluate the risks and benefits of potential changes. The published literature and meeting abstracts that highlight issues related to NHSN surveillance definitions and methodologies are peer reviewed. Examples of concerns expressed by NHSN users are illustrated and potential solutions to these problems are proposed. Outreach is targeted to experts on the workgroup and other partners with access to particular data sets or experience with large surveillance programs.

The workgroup includes representation by experts in the fields of infection prevention, surgery, neonatology, healthcare epidemiology, and hematology/oncology in both pediatric and adult populations. HICPAC, DHQP, several professional societies and healthcare institutions serve on the workgroup as either members or external experts who review and provide input on the modified CLABSI definition.

Dr. Fridkin summarized the workgroup's discussions on three key issues related to the modified CLABSI definition in NHSN, including the current problem and the pros and cons of the proposed solutions.

Issue 1 is the narrowness of the contaminant list that does not reflect the 2012 reality. The current CLABSI definition includes a single positive blood culture for "recognized pathogens" that are frequently considered to be contaminants. Enterococcus is identified in the literature as a primary concern for patients. Misclassification of contaminants as BSI inflates CLABSI rates and allows for reporting of CLABSI events that are not true infections. The workgroup's goal would be to identify changes to the CLABSI definition that would reduce reporting of contaminants as CLABSI.

Based on pros and cons of various strategies, the workgroup agreed that changes to the current CLABSI definition to address contamination potentially would jeopardize interpretability of the data and increase subjective and complexity. Improvement in blood culturing practices should be described as the primary method to prevent reporting of contaminants as CLABSI.

Issue 2 is the CLABSI definition in patient subpopulations. NHSN HAI definitions do not allow BSI in patients with mucositis, graft-versus-host disease (GVHD) or neutropenia to be classified

as secondary BSI. NHSN counts these infections as CLABSI by default. For oral and gastrointestinal (GI) organisms, the BSI source is considered to be translocation due to the invasion of indigenous intestinal bacteria through the gut mucosa into normal sterile tissues that cause disease. The clinical community believes that these CLABSIs are "not preventable."

The current CLABSI definition inflates rates due to reporting of CLABSIs that are not BSI-associated with the central line and the absence of an impact by CLABSI prevention measures. The current CLABSI definition also affects hematology/oncology and bone marrow transplant (BMT) locations in addition to those with "mixed" patient locations. The impact of risk adjustment is decreased due to the patient location.

Proposed Solution: A modified CLABSI definition should be developed. CLABSI surveillance should be limited to a specific set of organisms in defined patient subpopulations. The pros of solution 3 include increased clinical credibility of the CLABSI measure, continued ability to monitor BSI trends in hematology/oncology patients, and an existing precedent to use modified definitions in patient subpopulations. The cons of solution 3 include major changes to the NHSN application, the need to retrain NHSN users, increased complexity of the definition, and the need to clearly define subpopulations and candidate organisms.

The workgroup discussed several issues to modify the CLABSI definition. "Translocation" is liberally interpreted at this time and also is difficult to clearly diagnose or define. The strength or weakness of evidence to detect translocation varies across populations. The ability to establish the presence of relevant underlying conditions (e.g., GVHD and mucositis) related to translocation is difficult. Different grading scales are used based on clinical judgment. Documentation may be inconsistent and highly subjective.

The goal in developing a modified CLABSI surveillance definition would be to identify organisms and patient populations for which a laboratory-confirmed BSI most likely would be attributable to translocation. Two key objectives were discussed to achieve this goal. For objective 1, a list of organisms that are more likely due to translocation rather than central line would need to be identified and simply conveyed to IPs. In the modified CLABSI definition, 10 GI/oral commensals would be eligible: Streptococcus viridans, Enterobacteriaceae, Enterococcus, Bacteroides, Prevotella, Fusobacterium, Peptostreptococcus, Clostridium, Veillonella and Candida. The identified 10 eligible organisms were based on published studies, papers and the following issues. Capacity to maintain an up-to-date list at the organism level would be difficult due to frequent changes in identification, taxonomy and technology over time. Specific organisms should be excluded from the 10 eligible organisms (e.g., gram-negative bacteria and Candida parapsilosis that causes catheter-related BSI and translocation). The 10 eligible organisms would be simpler for NHSN users.

For objective 2, objective criteria that will be documented in medical records for IPs to use in identifying eligible patient populations at risk for BSI due to translocation would need to be identified. In the modified CLABSI definition, two patient populations would be eligible: BMT recipients with GVHD and patients with hematologic malignancy and neutropenia.

The two eligible patient populations were based on the following issues. Capacity to use objective criteria to identify eligible patients can be difficult. Mucositis was excluded due to multiple grading scales that have no consensus and inconsistent use across the wide spectrum of healthcare facilities. The inclusion of patients without hematologic malignancy may include solid organ transplant patients, liver transplant patients only, pediatric patients with short gut syndrome, and patients with neutropenia regardless of underlying illness.

Simplicity was favored in identifying eligible population criteria over accuracy and other issues. The evidence was less strong in solid organ transplant and neutropenia patients regardless of the cause of illness. The risk of allowing all preventable CLABSIs to be dismissed in these populations was higher and not fully justified by the gains achieved. Input by the neonatal experts diminished the importance of including special populations (e.g., neonates with short gut syndrome).

Eligibility criteria was refined for the two patient populations by discussing and testing these issues with experts in the field. For BMT recipients with GVHD, the patient must be a BMT recipient and have documentation of acute GVHD affecting the GI tract within 7 days of a positive blood culture or have documentation of chronic GVHD manifested by oral or GI symptoms during the 3 months prior to positive blood culture. For patients with hematologic malignancy and neutropenia, the patient must have documentation of hematologic malignancy and at least 1 value of an absolute neutrophil count $\leq$500 cells/mm^3 or a white blood cell count $\leq$500 cells/mm^3 documented within 7 days of a positive blood culture.

The modified CLABSI definition will be field tested with semantics and other refinements. Changes will be made to the NHSN protocol and software. Training will be offered to NHSN users. CDC estimates that January 2013 will be the earliest date to deploy the modified CLABSI definition. Discussions will be initiated with CMS and the National Quality Forum (NQF) regarding the modified definition.

Issue 3 is unreliable application of the CLABSI definition and NHSN criteria that has resulted in unfair inter-facility comparisons of CLABSI rates and poor inter-rater reliability. Users have improperly and inconsistently applied NHSN criteria and definitions due to lack of awareness of the criteria or the use of clinical opinion or definitions versus surveillance definitions. Subjective judgment is required for some NHSN criteria (e.g., present or incubating at admission versus healthcare facility onset of infection).

Potential solutions to address the issue of reliability in the application of the CLABSI definition include *Solutions 1-2:* To increase awareness, education and training should be provided to NHSN users through continued support and efforts by NHSN staff, and implementation of state-based NHSN data validation efforts. *Solutions 3-4:* To reduce subjectivity, more objective criteria for NHSN surveillance definitions and electronic algorithms for CLABSI detection and public reporting should be used.

CDC's next steps in further development of the modified CLABSI definition are to create an implementation timetable and develop a communications plan to inform and promote the changes to NHSN users and the clinical community.

HICPAC was pleased with the efforts to clarify and simplify the CLABSI definition to assist NHSN users and the clinical community in better addressing complex issues that impact surveillance. HICPAC particularly supported the approach to include more objective criteria for NHSN surveillance definitions and electronic algorithms for CLABSI detection and public reporting. HICPAC's position was that this strategy would reduce uncertainty and subjectivity among IPs and improve their performance in reducing HAI rates.

The HICPAC members made several comments and suggestions for the workgroup to consider in further modifying the CLABSI definition.

- For translocation, the definition should rely on the GVHD diagnosis in the admission record rather than documentation of acute GVHD affecting the GI tract within 7 days of a positive blood culture.
- The definition for patients to have documented neutropenia within 7 days of a positive blood culture might be too lengthy. A shorter time period should be considered for ease of documentation.
- The proposed shift from 3 to 2 calendar days for the NHSN criteria and definitions will be valuable to patients and consumers. This change also will result in a more accurate proxy measure that mimics the actual epidemiologic definition.
- Future discussion about the possibility of revising the MDRO definition to match the CLABSI definition.
- The definition for a device to be in place for >2 calendar days in order for the infection to be considered device-associated is questionable. Most notably, a patient will not present to a healthcare facility with a device and the device will not be present on admission.
- The modified CLABSI definition will have a profound effect on training NHSN users and implementing the recommendations in the field, particularly for GVHD and documentation in the medical record. As a result, some aspects of the modified CLABSI definition should be piloted in the field to obtain lessons learned and make course corrections prior to broad implementation of changing the NHSN format. This goal could be achieved by CDC soliciting volunteer facilities to use custom fields and inform the decision-making process.
- The modified CLABSI definition should be consistent with definitions in the NHSN LabID Event.
- An absolute neutrophil count or white blood cell count $\leq$500 cells/mm^3 should not be used to define patients with neutropenia. The value is too inclusive and should be lowered.
- The GVHD definition should be based on a "pathologic biopsy proven" diagnosis rather than a "clinical" diagnosis. A clinical diagnosis will result in tremendous subjectivity of the definition due to the number of self-reported GVHD cases.
- Small bowel transplant patients should be included as an additional special population due to the high risk of translocation in this group.
- Consideration should be given to modifying the denominator definition or risk adjusting for the number of CVCs catheters simultaneously in place in NICU patients. Scientific evidence increasingly has been collected to change this methodology.

- "Translocation" should not be used in the modified CLABSI definition because the word refers to a mechanism rather than a risk group. Moreover, "translocation" has no meaning in patients with hematologic malignancy and neutropenia.
- Blood culture contamination should be used as a quality improvement metric for aseptic technique in infection prevention related to vascular catheters.
- CDC should distribute a statement to experts in the infectious disease community, medical directors and hospital administrators to address adjudication and interpretation of granular clinical data. Various interpretations decrease the reliability of clinical data.

Update on CDC's State HAI Prevention Activities
CAPT Arjun Srinivasan, MD
Associate Director for HAI Prevention Programs
DHQP, CDC

Dr. Srinivasan covered the following topics in his update on CDC's state HAI prevention activities. In the past, infection prevention interventions almost were exclusively conducted at individual hospitals. Innovations were slow to be adopted by other facilities. Only IPs and healthcare epidemiologists really focused on HAI data and prevention. HAIs were viewed as an unavoidable consequence of providing care.

CDC promulgated HAI prevention guidelines and monitored infection rates, but no mechanisms were developed to promote adoption of the guidelines or to take action in this area. State health department activities on HAIs were limited to outbreak investigations in almost all states. Public reporting through state HAI legislation has dramatically changed from 2004 to 2009. Disclosure of HAI rates is now required in >50% of states.

States have provided leadership in HAI reporting. In 2009, a Congressional mandate was implemented for all U.S. states to develop a formal HAI prevention plan based on the National HAI Action Plan. Each state plan was required to describe the federal targets that would be achieved and outline specific strategies to meet these targets. CDC provided states with a template to develop their HAI prevention plans and gave feedback.

Congress allocated $40 million in ARRA dollars for CDC to fund state HAI prevention activities in three key areas: development and support of an HAI infrastructure (Part A), HAI monitoring (Part B) or HAI prevention (Part C). Because states requested more than $60 million, CDC implemented a competitive process to distribute the ARRA funds.

The Part A grantees included 49 states, the District of Columbia and Puerto Rico. The states used these funds to hire an HAI coordinator to coordinate HAI prevention activities and support activities of the state HAI Advisory Group. These multidisciplinary groups of stakeholders (e.g., payers, consumers, HCP and healthcare facilities) were charged with identifying HAI prevention priorities for their respective states and determining strategies to meet the priorities.

The Part B grantees included 30 states. The states used these funds to train HCP to monitor HAIs through NHSN and validate data submitted to NHSN. The Part C grantees included 27

states. The states used these funds to conduct multi-facility prevention collaborative projects focusing on a variety of HAIs.

Based on preliminary evaluation data of the ARRA funds, states are incorporating HAI prevention activities into their core public health roles. States with existing HAI activities are improving and expanding these initiatives, while states with no HAI prevention portfolio in the past have initiated activities in this area. Local expertise on HAI prevention has increased and visibility of HAI prevention among state public health officials has expanded.

All states have established a multidisciplinary HAI Advisory Group to convene all stakeholders with an interest in HAI prevention. These groups have improved coordination, collaboration and awareness of HAI activities across states. Numerous front-line HCP across the country have received infection control training. New HAI Prevention Collaboratives have been formed. HAIs are being prevented.

Dr. Srinivasan highlighted process measures and other preliminary outcomes from the ARRA evaluation to date. Overall, the preliminary evaluation demonstrated that all states have made some improvement in HAI prevention efforts, but early success has been variable. The variability is explained by baseline capacity to some extent, but not fully. Funding can help to both initiate and accelerate progress in HAI prevention.

Dr. Srinivasan informed HICPAC that participants at CDC's recent meeting with HAI prevention grantees described important characteristics for state HAI leadership. The ability to serve as a "neutral" convener of a myriad of diverse partners in HAI prevention is critical. Each group has an important constituency and perspective. All stakeholders in HAI prevention must be heard and respected. Efforts must be made to ensure that HAI prevention efforts are collaborative and not duplicative. Capacity to work in all healthcare settings must be demonstrated (e.g., acute care hospitals, LTCFs, LTACHs and nursing homes).

Capacity must be available to access HAI data in order to take action. State health departments have produced excellent models to use HAI data to identify problems and drive improvement. State HAI leadership must be transparent and publicly accountable. Consumers and payers are increasingly demanding more transparency and accountability of HAIs. To entice and enforce compliance, leadership must be able to add value to HAI activities and access regulatory and oversight mechanism. A facility's refusal to take action on HAIs is no longer acceptable.

Leadership must be able to evaluate the impact and cost-effectiveness of HAI prevention efforts at the state level. Because HAI prevention efforts perfectly fit within the broader context of public health, stakeholders have reached broad agreement that state health departments are uniquely suited to fill the role as the leader of state HAI prevention efforts. However, several challenges exist to achieving this goal.

Most states were not given increased funding to implement HAI prevention mandates. Some states that received support had their HAI prevention funds diminish or disappear over time. Most states were not given increased support to act on public reporting data that were being collected. Most states were not given support to promote and ensure data quality. This

challenge is a significant threat to the fundamental merits of public reporting of HAI data. State health departments have a need and desire to increase their expertise in HAI prevention, but diminishing resources limit the ability to expand knowledge in this area.

Federal funding has been a tremendous resource in both initiating and expanding state-based HAI prevention activities, but states are challenged by planning and hiring efforts due to the limited time of these funds. The field of HAI prevention at the state level is becoming crowded and may result in overlapping activities (e.g., State Hospital Associations, Quality Improvement Organizations, and Partnership for Patients). Capacity to coordinate state-based HAI prevention efforts has never been more important or difficult.

State health departments must play a central in HAI prevention efforts due to their existing capacity, characteristics and responsibility to the public. However, the fiscal challenges and realities for states to serve as the leader of HAI prevention efforts are significant. To overcome these challenges, state health departments are exploring strategies to sustain HAI prevention activities through new funding opportunities, new mechanisms to leverage partnerships, and new partners to engage support.

Federal partners also are exploring strategies to improve collaboration and coordination with state health departments through Quality Improvement Organizations and Partnership for Patients. CDC is continuing to provide technical support and subject-matter expertise to state health departments in the areas of data analysis and training on HAI prevention. CDC also is continuing its ongoing efforts and exploring new strategies to support state health department HAI prevention efforts through improved access to data and assistance with validation activities.

In addition to support at state and federal levels, states still need assistance from other partners in HAI prevention efforts. Clinicians, policymakers and the public should understand the role of state health departments in HAI prevention. Communities, providers, professional organizations and other stakeholders should be engaged in HAI Advisory Groups to ensure that gaps and needs in HAI prevention are being identified and addressed. State health departments should be kept informed of other HAI prevention initiatives to promote collaboration and prevention duplication.

Overall, state health departments have, will and must play a key role in HAI prevention. However, strategies must be determined to help state health departments in these efforts. States that are currently making progress need assistance to accelerate these activities. States that have recently initiated their HAI prevention portfolios need assistance to sustain and grow these efforts.

HICPAC commended CDC on providing states with tremendous support for HAI prevention. The members proposed several suggestions to address current challenges and strengthen state HAI prevention efforts in the future.

- CDC should take caution in publicizing “success” in enrolling hospitals in NHSN. The tremendous increase in public reporting most likely was due to the mandate for hospitals with ICU beds to report CLABSI rates.

- More emphasis should be targeted to coordinating multiple overlapping HAI prevention efforts at the state level. Most notably, state health departments that will be awarded hospital engagement contracts, group purchasing organizations, and other large groups all have a stake in encouraging providers to become involved with their individual HAI prevention activities and priorities. These groups have contractual obligations to expend their funds and should be extensively involved in state-based coordination activities. CDC and its partners should ensure that the contracting process is consolidated and sufficiently flexible at the federal level in order for funded HAI prevention contractors to coordinate scopes of work and collaborate on activities at the state level.
- The primary focus on HAI prevention should shift from hospitals to include other settings across the entire healthcare system (e.g., hemodialysis centers). Other opportunities for prevention exist outside of device-associated infections and SSI.
- CDC should explore the possibility of allocating adequate HAI prevention funds to a smaller number of states to have a more significant impact. The level of ARRA dollars given to some states is extremely insufficient to achieve any meaningful impact.
- The fragmented nature of the Prevention Collaboratives should be streamlined for a unified and coordinated approach for hospital IPs.
- CDC should collect and widely distribute data to publicize the significant cost-savings states, hospitals and other healthcare facilities will generate in reducing HAIs. Facilities should be reminded of their fundamental responsibility to be a part of Prevention Collaboratives and invest in HAI prevention at the state level to ensure patients are not infected during their hospital stays. Hospital epidemiologists, IPs and states could use CDC's data to clearly demonstrate the return on investing in HAI prevention to hospital administrators, state policymakers and state Medicare agencies.
- The cost-savings and value of HAI prevention should be considered from the patient's perspective in addition to those of the hospital. Harm to patients from HAIs or medication errors has a broader impact at the societal level, including longer hospital stays, decreased productivity and lost wages. CDC's cost-savings data also should account for societal costs.
- CDC should develop and disseminate a compendium of best practices and effective strategies states have utilized to decrease HAI rates. HAI prevention models by New York and Tennessee should be reviewed in this effort.
- Stronger efforts should be made to harmonize measures to standardize data reporting and reduce the data burden on front-line HCP. More emphasis also should be targeted to bridging the gap between accurate bedside data that are clinically vetted and administrative data.

Overview of CDC's Expanded CRE Guidance in Healthcare Settings

Alexander Kallen, MD, MPH
Medical Epidemiologist\
DHQP, CDC

Dr. Kallen presented an overview of CDC's plan to expand the 2009 Carbapenem-resistant Enterobacteriaceae (CRE) guidance for healthcare settings. The 2009 CRE recommendations were based on the 2006 MDRO guidance in healthcare settings, the 2009 Clinical and

Laboratory Standards Institute (CLSI) guidelines, and experience from CDC-led outbreaks. The 2009 guidance was structured with an algorithmic approach to CRE and emphasized "incidence at a facility" as the starting point for evaluation.

The 2009 recommendations provided guidance on CRE to acute care facilities in the areas of infection prevention and control, laboratory standards and surveillance. CDC has encountered several issues since the 2009 CRE guidance was published. The number of questions and requests for assistance has increased. New information and more solid expertise emphasize the need for clearer "CRE" definitions and more useful interventions. The 2009 guidance was intended for acute care facilities only and resulted in confusion on strategies to proceed if the facility did not start with a laboratory look-back. The recommendations were limited to facilities where CRE was more common.

The objectives of CDC's expanded CRE guidance will be to update the 2009 recommendations, acknowledge substantial knowledge gaps and controversies, and provide information for settings outside of acute care facilities. The first part of the CRE guidance will be targeted to healthcare settings, while the second part will be targeted to state and local health departments.

Dr. Kallen highlighted key points of the expanded CRE guidance. Dr. Kallen concluded his overview by asking HICPAC to provide input on CDC's plans to expand the 2009 CRE guidance, particularly tools to accompany the document that would be helpful to IPs and hospital epidemiologists.

HICPAC was pleased that CDC plans to apply the expanded CRE guidance to LTCFs. The members proposed a number of suggestions in response to Dr. Kallen's request for input on the proposed CRE guidance.

- The guidance should advise facilities to perform screening at multiple times to identify patients who have lost carriage and can be taken off contact precautions. Data show that many MDROs are only intermittently detected by current methods.
- CDC should develop a strong and clearly defined implementation plan for the expanded CRE guidance in the field because many LTCFs are not well staffed with IPs.
- The guidance should include language about the importance of communicating information regarding the identification of CRE organisms to ensure that prevention efforts advance across the continuum of care for patients. For example, the guidance could advise facilities that the presence of CRE alone should serve as a reason not to accept a transferred patient.
- The guidance should advise laboratories to conduct molecular subtyping of CRE strains to determine the prevalence of these organisms at the local level.
- Consideration should be given to analyzing the role of the environment as a possible reservoir of CRE. This approach will be critical because the environment will impact the effectiveness of interventions to control outbreaks. However, conflicts in the existing data on this issue have been observed.
- The expanded CRE guidance should be consistent with the CLSI guidelines. For example, bullet points should be included to provide IPs with a clear definition of "CRE" and solid directions on the complexities of CRE testing.

- CDC should consider developing a consolidated or "bundled" resource for hospital IPs to easily and simply refer to general issues related to resistance, prevention and interventions of HAIs. This tool could "alert" IPs to specific issues or nuances for certain organisms (e.g., the role of the environment in CRE). Organism-specific guidelines (e.g., MRSA, *C. difficile* and CRE) will be extremely confusing to hospitals, most likely will not be harmonized, and will require a separate infrastructure based on the hospital perspective.
- Laboratory issues in the expanded CRE guidance will continue to be extremely problematic. Most notably, the ability of laboratories to appropriately alert IPs about HAIs is difficult, particularly for infections other than *Klebsiella* and *E. coli*. CDC should take a leadership role in harmonizing laboratory breakpoints between CLSI and FDA.

Liaison and *Ex-Officio* Reports

Dr. Fishman opened the floor for the HICPAC liaison and *ex-officio* members to provide updates of recently completed, ongoing or future activities of their organizations and agencies (e.g., position statements, new or pending legislation, campaigns and related activities, press activities, publications, and other items of note).

- William Baine, MD (Agency for Healthcare Research and Quality) (AHRQ). Dr. Baine had no additional details to add to the AHRQ written report.

- Jeannie Miller, RN, MPH (Centers for Medicare and Medicaid Services) (CMS). Ms. Miller announced that she would no longer serve as the *ex-officio* member for CMS after the current meeting. She and CMS leadership would identify her replacement. Ms. Miller was grateful for the opportunity to serve in this capacity and learn from her HICPAC colleagues. Dr. Daniel Schwartz, Chief Medical Officer for the CMS Survey and Certification Group, provided the CMS report. In August 2011, CDC and CMS completed the development of a new hospital infection control survey tool under the Partnership for Patients initiative. The goals of the tool are three-fold: (1) improve oversight and consistency of the survey process for the Medicare Condition of Participation for Infection Control; (2) shift the focus of the survey to patients and procedures to prevent transmission of infectious disease; and (3) provide hospitals with a self-assessment tool to evaluate their individual infection control programs. Webinar training was provided on the tool. The tool currently is being beta tested in 10 states, the District of Columbia and Puerto Rico in order for CDC/CMS to obtain input and make improvements as necessary. A new version of the tool will be drafted in January 2012 to develop a training program that will be launched in March 2012 in all 50 states. Each state will be asked to use the draft tool at least once in order for CDC/CMS to obtain additional feedback. CDC and CMS expect to incorporate the final tool into the CMS survey process in October 2012. CDC and CMS welcome input on the tool from HICPAC, The Joint Commission and professional societies.

- Sheila Murphey, MD (Food and Drug Administration) (FDA). Dr. Murphey reported that FDA and the Association for the Advancement of Medical Instrumentation (AAMI) led a summit in October 2011 with representation by several federal agencies, professional societies, industry and healthcare professionals. Key outcomes from the summit were

presented during the AAMI Sterilization Standards Committee and Workgroup meetings in November 2011. A commitment was made during the meetings for workgroups to develop technical information reports. Reprocessing of flexible and semi-flexible endoscopes, instructions for use of medical devices, loaner instrumentation and human factors will be addressed in the reports.

- Gary Roselle, MD (Department of Veterans Affairs) (VA). Dr. Roselle reported that the VA has formed a workgroup to address antimicrobial stewardship. The VA has shifted the focus of its MRSA Program to MDRO. The VA pilot sites have completed their HAI prevention projects on *C. difficile*. These projects will be rolled out nationwide in the near future. The VA is continuing its CLABSI, VAP and CAUTI projects as well as its focus on special populations. An analysis has shown that the prevalence of MRSA is high in spinal cord units. The VA is continuing its longitudinal study on MRSA and other HAIs in LTCFs. The VA currently is preparing for its fourth point prevalence survey.

- Daniel Mareck, MD (Alternate, Health Resources and Services Administration) (HRSA). Dr. Merrick reported that HRSA is continuing its involvement with the HHS HAI Action Plan by serving on the Phase III Long-Term Care Workgroup. Recommendations from the workgroup will be relevant to critical access hospitals and small rural hospitals. HRSA is participating in the development of an HAI curriculum for critical access hospitals in Regions VII and VIII. Dr. Paul Moore, HICPAC's *ex-officio* member for HRSA, is responsible for HRSA grantees and constituents under the Partnership for Patients initiative.

- Rachel Stricof, MPH (Advisory Council for the Elimination of Tuberculosis) (ACET). Ms. Stricof reported that ACET has not held a meeting since the June 2011 HICPAC meeting. The "Prevention Measures for Reduction of Multidrug Resistant and Extensively Drug Resistant TB Risk in U.S. Healthcare Workers and Volunteers Serving in High Risk International Settings" Guideline is still being revised for the CDC clearance process.

- William Brock, MD, FCCM, FCCP, FACP (Society of Critical Care Medicine) (SCCM). Dr. Brock reported that SCCM will publish its revised sepsis guidelines in the first quarter of 2012. The document will reflect significant changes in the sepsis bundle and include a stronger focus on the resuscitation bundle.

- Lisa McGiffert (Consumers Union). Ms. McGiffert reported that Consumers Union sent a letter to several senators seeking assistance with legislation to make Medicare accreditation surveys available to the public to increase transparency of this process. The letter was signed by 75 consumers, consumer organizations and business/employer groups. Consumers Union sent a letter to The Joint Commission with a request to improve its response process to patients who file complaints. The letter was signed by 21 consumer organizations.

- Shirley Paton, RN, MN (Public Health Agency of Canada): Ms. Paton reported that the World Health Organization launched a Global Infection Prevention and Control Network

in June 2011 to improve infection prevention and control (IPC), particularly in mid- and low-income countries. The network will launch four workgroups to develop a generic IPC curriculum that can be applied in diverse countries; conduct an inventory of existing IPC guidelines globally; create IPC implementation tools at national and local levels; and develop key indicators or evaluation tools at national and local levels.

- Mark Russi, MD, MPH (American College of Occupational and Environmental Medicine) (ACOEM). Dr. Russi reported that ACOEM has issued several position statements and offered commentary on legislation and guidance. ACOEM is represented on the expert advisory group that is revising the post-exposure guideline for HIV. ACOEM serves on the National Vaccine Advisory Committee to provide expertise on influenza vaccination of HCP. ACOEM submitted comments to the CDC Division of Viral Hepatitis on the draft guideline addressing HCP infected with HBV.

- Sanjay Saint, MD, MPH (Society of Hospital Medicine) (SHM): Dr. Saint reported that the number of hospitalists in the United States has increased from 500 in 1996 to ~35,000 in 2011. Hospital medicine programs are housed in 70% of U.S. hospitals. SHM is collaborating with several professional societies on a Comprehensive Unit-based Safety Program (CUSP) CAUTI initiative with a focus on ward patients to eliminate catheters.

- Marion Kainer, MD, MPH (Council of State and Territorial Epidemiologists) (CSTE). Dr. Kainer reported that CSTE issued two position statements on the prioritization of electronic reporting of HAI data for electronic health record vendors and creation of an HAI Standards Committee. The full position statements are attached to the CSTE written report.

- Joan Blanchard, RN, BSN, MSS, CNOR, CIC (Association of periOperative Registered Nurses) (AORN). Ms. Blanchard reported that AORN issued new position statements in 2011: (1) "Preventing Wrong-Patient, Wrong-Site, Wrong-Procedure Events;" (2) "The Role of the Healthcare Industry Representative in the Perioperative/Invasive Procedure Setting;" and (3) "Creating a Practice Environment of Safety." AORN released a new webinar in October 2011 on a multidisciplinary approach to sharps safety. AORN will distribute a sharps safety toolkit with several resources at no charge in the near future. AORN is continuing to implement its SYNTEGRITY® Standardized Perioperative Framework to facilitate the perioperative nursing plan, nursing documentation and compliance tracking. AORN is represented on the HICPAC NHSN Surveillance Workgroup.

- Charles Huskins, MD, MSc (Infectious Diseases Society of America) (IDSA). Dr. Huskins had no additional details to add to the IDSA written report.

- Lisa Graybert (Alternate, American Hospital Association) (AHA): Ms. Graybert reported that the AHA Health Research and Educational Trust recently was awarded the CUSP-CAUTI contract by AHRQ. AHA currently is in the final rounds of negotiation with CMS on a hospital engagement contract.

- Barbara DeBaun, MSN, RN, CIC (Association of Professionals of Infection Control and Epidemiology, Inc.) (APIC). Ms. DeBaun reported that fogging is emphasized as a "never-event" in HICPAC's 2003 Environmental Guideline and 2008 Sterilization Guideline. This language poses a practical challenge to many practitioners. APIC is interested in HICPAC clarifying the statement in the guidelines for fogging to never be performed based on new literature that addresses hydrogen peroxide vapor and mist.

- Mark Rupp, MD (Society of Healthcare Epidemiology of America) (SHEA). Dr. Rupp reported that SHEA is collaborating with partners to create an IPC guideline for Ronald McDonald Houses and revise the Compendium with updates on hand hygiene. SHEA formed a 501(c)(3) foundation for research and education. SHEA will hold its annual training meeting in April 2012 that will include an advanced epidemiologic methods course and a focused session on antimicrobial stewardship.

- Kelly Podgorny (Alternate, The Joint Commission): Ms. Podgorny reported that The Joint Commission revised its influenza vaccination standard for staffed and licensed independent practitioners to be stronger and more aligned with the Tier 2 Action Plan. The standard will become effective on July 1, 2012 and will be targeted to critical access hospitals and hospitals in long-term care. The Joint Commission will apply the revised standard to several of its other accreditation programs, including ambulatory care, behavioral health care, home care, laboratory and office-based surgery. The standard will be implemented in a phased approach in these settings from July 1, 2012-July 1, 2013. The Joint Commission will provide education on the standard to these various settings during the entire month of November 2011.

- Alexis Elward, MD (Advisory Committee for Immunization Practices) (ACIP): Dr. Elward reported that during its October 2011 meeting, ACIP approved universal human papillomavirus vaccination of boys 11-12 years of age with a permissive recommendation for males 13-26 years of age. ACIP approved HBV vaccination for all persons with diabetes through 60 years of age. Other presentations during the ACIP meeting included the measles outbreak in Quebec and national coverage of influenza vaccination among HCP (e.g., 53%-62%). The ACIP Hepatitis Workgroup is reviewing the need for revaccination with HBV vaccine for persons who were vaccinated early in life.

Public Comment Session

Dr. Fishman opened for the floor for public comments; no participants responded.

With no further discussion or business brought before HICPAC, Dr. Fishman recessed the meeting at 5:12 p.m. on November 3, 2011.

Opening Session: November 4, 2011

Mr. Jeffrey Hageman, MHS
Deputy Chief, Prevention and Response Branch
HICPAC Designated Federal Official
DHQP, CDC

Mr. Hageman opened the floor for introductions to determine the HICPAC voting members, *ex-officio* members and liaison representatives who were in attendance. He asked the voting members to declare any conflicts of interest for the record.

- Daniel Diekema, MD: Recipient of grant funds from Innovative Biosensors.

Mr. Hageman verified that the voting members and *ex-officio* members in attendance constituted a quorum for HICPAC to conduct its business on November 4, 2011. He reconvened the meeting at 9:05 a.m. and recognized several guests in the audience who serve on either the HAI Surveillance Workgroup or CDC SSI guideline writing group: Dr. Clifford Ko, Dr. Joseph Solomkin, Dr. Rachel Kelz and Mr. Brian Leas.

Mr. Hageman announced that HHS representatives were unable to attend the meeting to provide an update on the HHS Action Plan to Prevent HAIs. However, he summarized the information HHS provided to CDC. The Action Plan currently is being revised to update the text on HAIs in acute care hospitals; describe advances in the last two years; and include new sections on increased influenza vaccination of HCP and the reduction of HAIs in ambulatory surgical centers and end-stage renal disease facilities.

HHS will release the updated Action Plan for public comment in December 2011 or January 2012. HHS welcomes public comment from all organizations and individuals, particularly on the new proposed measures, measurement systems and five-year reduction targets. In partnership with the Critical Care Societies Collaborative, HHS launched the second year of the National Awards Program to recognize facilities and units that have achieved significant reductions in CLABSI and VAP. The call for nominations was announced with a deadline of December 19, 2011. Additional information can be obtained from the HHS website.

Update on the CDC Guideline Development Plan
Mr. Jeffrey Hageman, MHS
Deputy Chief, Prevention and Response Branch
HICPAC Designated Federal Official
DHQP, CDC

Mr. Hageman announced that this topic periodically would be placed on HICPAC agendas and discussed during teleconferences to determine the future direction of developing guidelines. Advice from HICPAC on areas to focus and ordering of priority areas will help CDC plan moving forward and when considering staffing and resources. The CDC guidelines that currently are being developed are the NICU, HCP and SSI Guidelines. Recently completed guidelines

include the Norovirus and BSI Guidelines were released in 2011. The GRADE methodology was first applied to the CAUTI Guideline that was released in 2009. The BSI, Disinfection and Sterilization, Isolation Precautions, MDRO, Pneumonia, Environmental Infection Control and Hand Hygiene Guidelines were not developed with the GRADE methodology.

CDC views 18 to 24 months as the ideal timeline to develop guidelines, but this timeline could be shorter or longer depending on the scope of the guideline (e.g., number of key questions to address). CDC also is interested in reviewing each guideline every 3 to 5 years for updates. Many of the older guidelines are now due for a revision or update. All guidelines will be updated current approaches (e.g., application of the GRADE method, extensive involvement of all stakeholders at the outset, and efforts to avoid duplication or inconsistency with IPC guidelines that are developed by other groups).

Another key issue to consider in the development or revision of guidelines is the expanded audience. IPs and hospital epidemiologists previously were the primary users of guidelines, but health departments and facility surveyors now have a need for this information. Moreover, recommendations in the guidelines should be able to be implemented in a variety of settings across the spectrum of health care.

In preparation of the next meeting, Mr. Hageman asked HICPAC to consider and provide input on several questions related to the guideline development plan.

1. What are the critical gaps, questions and issues that should be considered in developing guidelines?
2. [HICPAC liaisons]: What guidelines are your organizations currently developing or revising? Does your organization use GRADE or a comparable methodology to develop guidelines?
3. What should be the next focus areas after the NICU, HCP and SSI Guidelines are completed? These options include revising an entire guideline, updating a specific section of an existing guideline, developing a guideline on an entirely new topic, issue or setting, focusing on pathogen-specific or syndrome-based guidelines, and making decisions on outdated guidelines that no longer are relevant to the field.
4. What, if any, should be the next specialty component after arthroplasties for the SSI Guideline?
5. Should infection control guidelines that were not developed with input from HICPAC be updated with HICPAC input? For example, CDC's recommendations on preventing transmission of infections among chronic hemodialysis patients were developed in 2001 by an outside expert panel. This guideline focused on hepatitis and viral issues rather than infection-related issues (e.g., BSI and MDRO in dialysis).
6. In what order should the next set of guidelines be updated?

HICPAC proposed several suggestions to start the process of creating a guideline development plan for the future.

- Non-licensed ambulatory care facilities should be an additional setting for the guidelines.

- Approaches should be explored to ensure that guidelines are not automatically outdated due to the lengthy gap in time between completion of the final draft and completion of the CDC clearance and approval process. After a guideline has been cleared for publication, for example, the authors could incorporate comments in the narrative regarding evidence that has been generated since the guideline was initially developed. Alternatively, the systematic review process could occur toward the end of the CDC clearance process.
- Consideration should be given to consolidating some guidelines due to the time and funds that are needed to develop a single guideline. For example, the Hand Hygiene, MDRO and Isolation Guidelines have substantial overlap. Alternatively, a process should be developed to systematically update recommendations that are applicable to various guidelines.
- "Minimum standards" for recommendations in the guidelines should be determined for ambulatory care and other settings.
- The guidelines should address unintended consequences of the recommendations in both the regulatory and reimbursement environments (e.g., patient flow and quality care).

Dr. Cardo noted that professional societies could play a leadership role in developing some guidelines. In these cases, HICPAC would provide external expertise. For example, SHEA is currently updating the Compendium and could address implementation issues in the Hand Hygiene Guideline.

Dr. Bell thanked HICPAC for providing extremely helpful input on the guideline development plan. He noted that many of the suggestions were very practical and could be easily included in the current process. He hoped HICPAC would increase its role in producing non-guideline statements for the field, particularly issues that need additional research and investment.

Update by the HAI Surveillance Workgroup: Session 2

Scott Fridkin, MD
Deputy Chief, Surveillance Branch, DHQP
Centers for Disease Control and Prevention

Dr. Fridkin continued his update on activities by the HAI Surveillance Workgroup by summarizing changes to the SSI and VAP NHSN definitions. The workgroup expanded its membership to include expertise in surgical practice and SSI surveillance. The new members represent the American College of Surgeons, AORN, and Emory University Department of Surgery. Other members are engaged as needed to address pediatric and adult subspecialty surgical issues.

The proposed surveillance operational and definitional improvements to the SSI definition in three categories based on feedback from facilities and NHSN users, expert opinion and CDC's discussions with the American College of Surgeons.

Category 1: Restrictive inclusion criteria for procedures to report are not reflective of current practices. All procedures are not limited to operating rooms, while many surgical incisions are

not closed during operations. The current NHSN requirement of only including primary closure before leaving the operating rooms might be too restrictive. The surgical and nursing communities have the perception of increasing use of non-traditional closure techniques, but minimal data support this perception. Due to suspicions regarding increased risk for infection, this practice currently is not reported to NHSN. CDC will make assessments to identify potential consequences of this change. AORN will administer a survey to evaluate the frequency of new wound closure techniques. The risks of requiring additional reporting will be more fully outlined. These risks include inaccuracy with documentation due to manual aggregation and an increased number of procedures for facilities to report. The benefits of requiring additional reporting will be more fully outlined as well (e.g., more accuracy of an SSI measure and prevention of gaming of the system).

A procedure must occur in an operating room be included as a surgical procedure in NHSN. However, the trend is shifting toward increasing use of non-traditional operative settings (e.g., minor procedure rooms, clinic settings and NICUs). The proposal is to continue to require performance in operating rooms. The issue of non-traditional settings is less relevant for high-priority procedures. The risk for infection would be high and the ability to capture procedures would be challenging in non-traditional settings.

Category 2: SSI criteria for procedures with infection have subjectivity that leads to variability between institutions. The ability to attribute SSI to a primary versus secondary incision site is difficult with multiple incision sites for one procedure (e.g., coronary artery bypass grafting with both chest and donor site incisions

Criteria to make an SSI diagnosis are subjective (e.g., purulent drainage). Physicians who can diagnose SSI are not clearly defined (e.g., an attending physician, resident physician, or any surgeon or consultant). Evidence of infection at the time of surgery lacks face validity of eligibility for SSI.

Variability in case finding and reporting is a major operational challenge. A non-standardized procedure has not been developed for facilities to utilize for case ascertainment. Moreover, variability exists in reliance on microbiology and administrative data to enhance case finding, networking between facilities, and classification of implants and follow-up time. Multiple procedures through the same incision are eligible for only a single SSI and may result in low rates for low-risk procedures, particularly when these types of procedures are required for reporting.

Category 3: Risk adjustment is sub-optimal for many procedures for the performance measurement paradigm. Clarification is needed on when a procedure is endoscopic versus open. The short-term goals for revising the SSI definition are to propose and vet changes for additional risk adjustment, maintain the timeline for implementation of the changes in 2013, conclude the assessment of refinements to operative procedures, and identify additional criteria to evaluate approaches to simplify the definition. The long-term goal is to propose standardized case finding for a subset of high-priority procedures that would be required for NHSN data reporters to utilize.

In terms of the modified VAP definition in NHSN, a separate process is underway. CDC is obtaining expert input from the Critical Care Societies Collaborative and several professional societies (e.g., SHEA, IDSA, CSTE and APIC). An evaluation will be conducted of the relationship between a streamlined VAP definition and a coordinated VAP prevention bundle that is implemented by CDC-funded Prevention Epicenters.

HICPAC made two key suggestions to consider in further modifying the SSI definition for NHSN.

- Facilities should not be allowed to define an "operating room." Based on lessons learned with previous national performance measures, the definition of an "ICU" greatly varied among facilities. An operation should be defined based on the procedure code rather than the setting.
- Facilities should not be required to distinguish between primary and non-primary closure. The need for facilities to identify patients with and without primary closure will require a review of operation notes of each procedure. This process is extremely labor-intensive due to the inability to obtain electronic information.

Update on the Prevention of Surgical Site Infection Guideline
Sandra Berríos-Torres, MD
Medical Officer, DHQP
Centers for Disease Control and Prevention

Dr. Berríos-Torres covered the following topics in her update on the SSI prevention guideline. The 2008 Anderson, *et al.* study reported that the current U.S. burden of ~300,000 SSIs per year accounts for 17% of all HAIs. SSI is the second most common HAI and occurs in 2%-5% of patients undergoing inpatient surgery. The overall SSI mortality rate is only 3%, but SSI is directly attributable to 75% of deaths among SSI patients.

In terms of morbidity, SSI accounts for long-term disabilities and additional postoperative hospital days of ~7-10 days. Depending on the procedure and pathogen, the estimated cost of SSI can range from $3,000-$29,000 for a total of up to $10 billion annually for treatment. The 2011 Umscheid study reported that 55% of SSIs may be preventable.

CDC proposed a new approach to update the 1999 SSI guideline to increase its impact. The "cross-specialty" core section will include recommendations that might be applicable across multiple surgical fields. The "procedure-specific component" section will focus on high-volume and high-burden procedures with a targeted and effective strategy to meet CDC's needs (e.g., rapid guideline development, timely updates, rapid response to emerging needs, and evidence to address key clinical questions). The surgical community will be engaged in a multidisciplinary approach. A foundation will be established to develop an evidence-based research agenda to guide future studies on SSI prevention.

Arthroplasties will be first specialty component of the SSI guideline. The 2007-2009 Kurtz, *et al.* studies reported that 1.2 million arthroplasties are performed in the United States each year with hips and knees accounting for 96% of these procedures. Arthroplasties are the highest volume procedure and the third highest number of SSIs reported to NHSN. SSIs in primary arthroplasties have a high treatment burden and account for an even higher burden in revision arthroplasties. Significant increases in both the number of procedures and SSIs are projected.

Dr. Berrios-Torres highlighted the writing group's accomplishments from June 2010-June 2011. The proposal to update the SSI guideline was presented to HICPAC. Content experts were convened from multiple surgical and nursing professional societies, infectious disease organizations, academic institutions, HICPAC and CDC. The core writing group was formed with representation by HICPAC, CDC and UPHS-CEP.

A preliminary review was conducted to identify existing guidelines and meta-analyses on SSI prevention. A preliminary list of 29 topics and 600 key research questions was developed. The broad list of key topics and questions was finalized. The core section of the SSI guideline will address 16 key questions and 37 related sub-questions covering 8 topics: glycemic control, tissue oxygenation, antimicrobial prophylaxis (AMP), normothermia, skin preparation, *S. aureus* colonization, surgical checklists and bundles.

The arthroplasty section of the SSI guideline will address 22 key questions and 38 related sub-questions covering 8 topics: transfusion, immunosuppressive therapy, anticoagulation, surgical attire, anesthesia, surgical techniques, environmental issues and biofilms.

The writing group is using several databases for the literature search: Ovid-MEDLINE®, Ovid-MEDLINE® In-Process and Other Non-Indexed Citations, Embase®, and the Cochrane Database of Systematic Reviews®. The broad SSI literature search of the Ovid-MEDLINE database from 1948 to the present resulted in 25,457 articles for the core section. After applying exclusion criteria, the literature search yielded 1,755 RCTs and 2,225 reviews and guidelines. "Surgical wound infection" was used as the MeSH® term and "SSI" was used as the keyword in the broad literature search.

After narrowing the broad literature search to 1998 to the present and applying exclusion criteria, 715 RCTs and 459 reviews and guidelines were identified for the core section. For the 10% random sample for the core section, 3 workgroup members reviewed 200 titles and abstracts from 1998 to the present across the four databases. Inclusion criteria were English language, a study design of a meta-analysis, systematic review or RCT, relevance to any core question, and animal studies. No relevance to a core question was the most common reason for excluding a title or abstract.

The writing group established specific criteria to resolve inter-reviewer discrepancies in the 10% random sample for the core section. Only direct regimen comparisons were included for AMP. AMP versus non-AMP studies and studies that compared different drug regimens were excluded. The exception to these criteria is studies that examine the most effective strategies for intravenous AMP for prevention of *S. aureus* SSI.

The writing group defined "guideline" as a document published by an organized body (e.g., hospital, committee, national or international body, or professional organization) that includes recommendations. Guidelines that were based on and included a systematic review were included in the 10% random sample. Guidelines that were not based on a systematic review were excluded from the 10% random sample. Pediatric studies and studies that answered arthroplasty questions were included in the 10% random sample.

A literature search was conducted and a 10% random sample was reviewed for the arthroplasty section. In the arthroplasty literature search, terms related to arthroplasty, orthopedic or joint procedures yielded ~1.1 million titles or abstracts. Terms related to infections yielded 158,415 titles or abstracts. Terms related to surgical procedures yielded ~3.5 million titles or abstracts. Terms related to joint or orthopedic procedures yielded 316,829 titles or abstracts.

The search yielded 26,888 titles or abstracts when the categories of terms were combined with "or"/"and." After applying exclusion criteria of 1998 to the present and English language studies, the search yielded 294 RCTs and 301 reviews and guidelines for the arthroplasty section. For the 10% random sample, 3 workgroup members reviewed 70 titles and abstracts from 1998 to the present in the Ovid-MEDLINE® database. Inclusion criteria were English language, a study design of a meta-analysis, systematic review or RCT, relevance to any arthroplasty or core question, a "guideline" as defined by the workgroup, animal studies, and pediatric studies. No relevance to the arthroplasty section was the most common reason for excluding a title or abstract.

The workgroup established specific criteria to resolve inter-reviewer discrepancies in the 10% random sample for the arthroplasty section. Studies that answered questions in the core section were included. Studies on oral or dental implants were excluded. After applying exclusion criteria, removing duplicate titles or abstracts, and eliminating the 10% random sample studies, the final literature search resulted in 2,674 titles and abstracts for both the core and arthroplasty sections that are left to be reviewed. This figure also includes references in the 1999 SSI guideline that might be relevant for review in the updated guideline.

The writing group's other accomplishments include face to face meetings with 21 of 29 core writing group members, content experts and external subject-matter experts. Plans for the SSI guideline were discussed or formally presented at six national meetings in 2011, including HICPAC. The SSI guideline also will be presented at four national meetings in 2012.

The next steps will be to complete the full title and abstract screen, develop a preliminary bibliography to identify gaps in the broad literature searches, conduct a full-text review, perform a targeted literature search to identify quasi-experimental or observational studies when RCTs or systematic reviews were not found, finalize the data extraction process, initiate the GRADE process, and create narrative summaries.

HICPAC applauded Dr. Berrios-Torres on her outstanding leadership in organizing the process to update the SSI guideline including involving all of the professional surgical societies in the actual development of the document. The multidisciplinary approach would increase acceptance and implementation of the SSI guideline in the field.

In general, HICPAC supported the approach to perform a targeted literature search to identify quasi-experimental or observational studies only when RCTs or systematic reviews were not found. However, some members were concerned with this approach because the defined patient population of RCTs might limit generalizability.

Overview of E-Surveillance and Its Impact on Infection Prevention
Michael Bell, MD
DHQP Deputy Director
Centers for Disease Control and Prevention

Dr. Bell presented an overview of e-surveillance and its impact on infection prevention. In the past, surveillance was a time-intensive paper-based process. However, the readiness of the infection prevention community to shift to e-surveillance at this time is uncertain due to certain requirements: electronic data sources, algorithms for detection, capacity to capture denominator data, and a process to securely transmit data.

Electronic health records (EHRs), pharmacy data, clinical laboratory information systems, admission/discharge/transfer (ADT) systems, and health information exchanges are sources of electronic data. ADT and clinical laboratory information systems are commonly used in acute care settings at this time, but standardization of these systems varies. Electronic medication administration records for pharmacies are increasingly becoming available in acute care hospitals, but these systems do not have a prominent role outside of these settings.

EHRs were used in ~12% of hospitals as of 2009, but ~80% of hospitals plan to use EHRs as a part of Meaningful Use for financial reimbursement. A number of vendors and pharmacy systems are willing to incorporate features into their products to extract and process data for e-surveillance.

For detection algorithms, CDC is collaborating with NQF to transform measures to eMeasures to flag outcomes. At this time, eMeasures have been developed for CLABSI and CAUTI. The CDC-funded Prevention Epicenters published detection algorithms to detect "probabilistic" CLABSI. This tool can be used to count infections or trigger a confirmation process. HAI detection algorithms increasingly are being embedded in vendor systems. To capture denominator data, vendor- and home-grown systems are being developed for generating device- or patient-days from electronic data systems. However, this process has not been standardized and gaps in transparency have not been addressed to date.

A clinical document architecture (CDA) and other standardized formats have been developed. NHSN currently accepts CDA files for CLABSI, CAUTI, SSI, MDRO and *C. difficile* through LabID events, central line insertion practices, and antimicrobial use. NHSN will be capable of accepting CDA files for dialysis events and antimicrobial resistance beginning in October 2012. To date, CDC has received >160,000 CDA records. At this time, 466 hospitals report to NHSN via CDA.

Many components of e-surveillance have been developed, but need to be strengthened, widely disseminated and broadly adopted. CDC projects that over the next 5-10 years, the bulk of surveillance data will be electronically transmitted. The benefits of e-surveillance for IPC activities include increased efficiency, more consistency, and additional opportunities to implement practices to improve care due to less emphasis on data collection. The implications of e-surveillance on IPC activities include a greater distance from source data and the need for ongoing validation and sources of new expertise.

Dr. Bell asked HICPAC to consider and provide input on areas that will need to be addressed to shift to e-surveillance. HICPAC's potential role in this effort could be to draft an e-surveillance document for the IPC community or make presentations during Infectious Disease Week in 2012 or other national events.

Dr. Cardo emphasized the importance of clearly defining "e-surveillance" and identifying a process to more broadly implement e-surveillance in the field. Most notably, electronic transmission of data is much easier than electronic capturing of data. This challenge has limited progress in shifting toward e-surveillance. Dr. Cardo raised the possibility of implementing surveillance in a parallel process with traditional methods and e-surveillance.

HICPAC agreed that the IPC community should take steps at this time to shift to e-surveillance. The members identified a number of challenges and proposed several suggestions that should be considered in this effort.

- A clear distinction should be made between surveillance and clinical definitions of an "infection." Payment models and systems should be sufficiently flexible to acknowledge that surveillance is imperfect. For example, different e-surveillance systems in a single hospital system can produce conflicting information (e.g., attribution of infection to a specific unit or ventilator settings).
- HICPAC should collaborate with APIC and SHEA to explore strategies to influence hospital administrators to allow vendors to perform e-surveillance. This approach would decrease the data collection burden on the IP workforce and increase the quality of care given to patients.
- HICPAC should issue a statement to the HHS Secretary to emphasize the critical need for CMS to take a different approach in selecting NHSN data for payment and validation purposes.
- Electronic surveillance systems should be designed to collect data on the actual "impact" of infections and risk stratification of infections in specific populations.
- CDC must resolve issues with the NHSN definitions before any actions can be taken to shift to e-surveillance.
- Electronic data sources should be used as tools to identify risk factors, determine the effectiveness of prevention strategies, and mine data for other important purposes. For example, e-surveillance data should be made available to third-party researchers and users.
- HHS should provide guidance to vendors to address the lack of transparency in e-surveillance and make efforts toward developing uniform and standardized systems for data collection.

- Creative strategies should be explored for front-line IPs and clinicians to accept and act on e-surveillance data. Potential options for implementation in the field include parallel testing of traditional methods and e-surveillance or identification of potential infections for IPs to report through e-surveillance as an interim measure.

Dr. Fishman closed the discussion by confirming that HICPAC would revisit e-surveillance during future meetings and provide more concrete input on its role in this effort. In preparation for the follow-up discussions, he raised the possibility of HICPAC developing e-surveillance standards.

Public Comment Session

Steven Brash
Nemours Foundation/Alfred I. duPont Hospital for Children
Mr. Brash informed HICPAC that his daily duties as an IP include collecting, consolidating and analyzing data, educating staff, developing policies, and solving problems throughout the hospital. He also is required to accurately report surveillance definitions to NHSN because CMS payment relies on accurate reporting. In the past, he has been asked to teach physicians on utilizing surveillance definitions to properly diagnose HAIs and accurately record these infections in the patient's chart.
Mr. Brash urged CDC to develop easy-to-use and credible NHSN definitions. Many hospital administrators are unwilling to make investments in IPC or an e-surveillance system. He hoped CDC and CMS would create a standardized e-surveillance system with uniform definitions that facilities would be required to utilize. This approach would allow Mr. Brash and other IPs to focus more on adhering to CDC guidelines to prevent infections throughout the hospital.

Peter Gordon
Germguard Lighting

Mr. Gordon announced that he attended the Innovation Day CDC hosted for vendors in October 2011. The key discussion topics in his breakout group included challenges in disseminating information, facilitating wider deployment of the use of ultraviolet lighting as a germicidal agent, and implementing solutions to infections and better interventions.

The participants agreed that problems exist in the basic science, systems engineering, validation of techniques and products, delivery mechanisms for novel approaches to inactivate germs and prevent infections, and implementation of the workflow. These problems require attention and innovation at this time.

Mr. Gordon discussed with CDC the possibility of establishing a workgroup with industry experts, inventors, innovators and designers to disseminate information on properly using systems to lower infection rates. He submitted written public comments for CDC to consider.

Closing Session

Dr. Fishman reviewed the presentations that were made over the course of the meeting. He noted that none of these presentations required a HICPAC vote or formal action. With no further discussion or business brought before HICPAC, Dr. Fishman adjourned the meeting at 11:43 a.m. on November 4, 2011.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

_____
Date

_____
Neil O. Fishman, M.D.
Chair, HICPAC