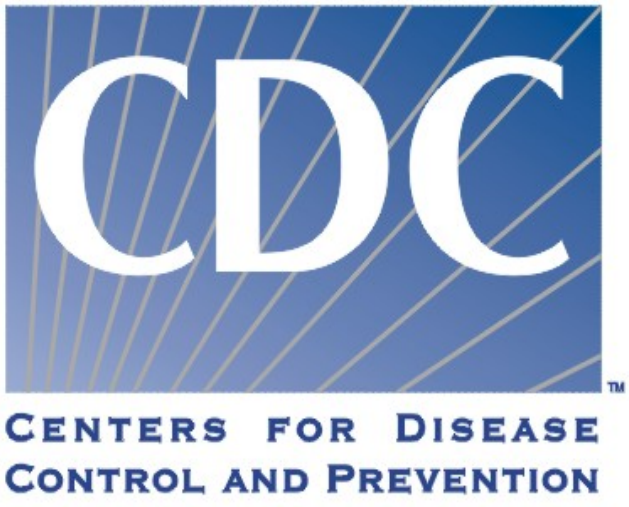
DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

National Center for Preparedness, Detection, and Control of Infectious Diseases

Division of Healthcare Quality Promotion



Healthcare Infection Control Practices Advisory Committee

November 13-14, 2008

Washington, DC

Record of the Proceedings

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List of Participants

HICPAC Members
Dr. Patrick Brennan, Chair
Ms. Lillian Burns
Dr. Alexis Elward
Dr. Jeffrey Engel
Dr. Tammy Lundstrom
Dr. Yvette McCarter
Ms. Denise Murphy [via conference call]
Mr. Russell Olmsted
Dr. David Pegues
Dr. Keith Ramsey
Dr. William Schecter
Ms. Barbara Soule
Dr. Kurt Stevenson

Designated Federal Official
Dr. Michael Bell, Associate Director for Infection Control, DHQP

***Ex-Officio* and Liaison Members**
Dr. William Baine (Agency for Healthcare Research and Quality)
Ms. Nancy Bjerke (Association of Professionals of Infection Control and Epidemiology, Inc.)
Ms. Joan Blanchard (Association of periOperative Registered Nurses)
Dr. David Henderson (National Institutes of Health)
Dr. Marion Kainer (Council of State and Territorial Epidemiologists)
Dr. Lisa Maragakis (Society for (Healthcare Epidemiology of America)
Ms. Lisa McGiffert (Consumer's Union)
Dr. Sheila Murphey (Food and Drug Administration)
Dr. Michael Ochs (Infectious Disease Society of America)
Dr. Gary Roselle (Department of Veterans Affairs)
Dr. Mark Russi (American College of Occupational and Environmental Medicine)
Ms. Roslyn Schulman (American Hospital Association)
Ms. Rachel Stricof (Advisory Council for the Elimination of Tuberculosis)
Ms. Katherine Tillman (Centers for Medicare and Medicaid Services)
Dr. Robert Wise (The Joint Commission)

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Michael Craig
Cecilia Curry
Karen Deasy
Carolyn Gould [via conference call]
Rita Helfand
Tara MacCannell
Jacqueline Watkins
Abbigail Tumpey
Wendy Vance

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Mayra Alvarez (Office of Senator Richard Durbin)
Kalah Auchincloss (Foley Hoag LLP)
Ronald Bracken (Bard Medical)
Jennifer Bright (Society for (Healthcare Epidemiology of America)
Saran Despres (Oversight and Government Reform Committee)
Daniel Griffin (SPI)
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Angela Jeansonne (American Osteopathic Association)
Jane Kirk (GOJO Industries)
Hollie Lewis (Cepheid)
Julie Moreno (Department of Health and Human Services)
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Kathy Warye (Association of Professionals of Infection Control and Epidemiology, Inc.)
Hui-Hsing Wong (Department of Health and Human Services)

EXECUTIVE SUMMARY

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on November 13-14, 2008 in Washington, DC. None of the HICPAC voting members declared any new conflicts of interest for the record that were pertinent to the published agenda.

The Deputy Assistant Secretary for Health (Science and Medicine) at the HHS Office of Public Health and Science provided a comprehensive update on HHS's two ongoing initiatives to reduce healthcare-associated infections (HAIs): (1) development of the *National Action Plan for Reducing Healthcare-Associated Infections* and (2) Department-wide activities to address the serious public health problem of low influenza vaccination rates among healthcare personnel.

The DHQP Director provided an extensive report on DHQP's key activities in FY'07-FY'08. The Director's Report covered DHQP's current organizational structure; outbreak investigations and laboratory support; funded extramural research projects and surveillance for the prevention of HAIs, particularly the rapid and tremendous growth of the National Healthcare Safety Network (NHSN); enhanced use of electronic data sources; investigations on blood, organ and other tissue safety; patient education activities and resources; and the Strategic Plan and budget.

HICPAC workgroup chairs and CDC presented status reports on four guidelines: *Guideline for Preventing Catheter-Associated Urinary Tract Infections* (CAUTI); *Sterilization and Disinfection in Healthcare Settings Guideline*; *Healthcare Worker Vaccination Guideline* (in partnership with the Advisory Committee on Immunization Practices); and *Guideline for the Prevention and Management of Norovirus Outbreaks in Healthcare Settings*.

HICPAC unanimously approved the CAUTI Guideline with the exception of unresolved issues that were noted in the record.

HICPAC workgroup chairs presented status reports on three draft documents: manuscript on *Estimating the Annual Number of Reasonably-Preventable HAIs and Associated Costs and Mortality*; guideline methods paper; and guidance document on model legislation for methicillin-resistant *Staphylococcus aureus*.

CDC presented draft recommendations and an algorithm that would be submitted to the *Morbidity and Mortality Weekly Report* (*MMWR*) in January 2009 for publication. The MMWR article would provide infection control, surveillance and laboratory guidance for *Klebsiella pneumoniae* carbapenemase (KPC)-producing organisms in acute care facilities.

HICPAC unanimously approved the draft infection control, surveillance and laboratory recommendations for KPC-producing organisms in acute care facilities with the revisions that were noted in the record.

CDC provided an overview of a meeting that was held in August 2008 with 23 national and international experts on *S. aureus* decolonization. The objective of the meeting was to discuss issues related to *S. aureus* decolonization in healthcare and community settings, including current evidence that supports or does not support decolonization and existing research gaps. CDC highlighted the key findings of the expert panel.

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 written reports highlighted organizational and agency position statements, legislation, campaigns and related activities, press activities, publications, and other items of note.

HICPAC engaged in an extensive discussion to update and improve its guideline development process. The key discussion topics included (1) HICPAC's decision on whether to develop a new ambulatory care guideline; (2) HICPAC's suggestions on completed guidelines that need to be updated at this time; (3) the integration of guidelines between HICPAC and professional societies; and (4) potential new elements to include in guidelines, such as process measures, prevention targets, prioritization of recommendations and risk assessments.

HICPAC's discussion on the guideline development process resulted in two key actions. DHQP would convene a meeting with HICPAC and professional societies to further discuss the guideline integration effort, including potential new elements to include. **HICPAC unanimously agreed by a vote** that its top two priorities at this time would be to develop the new ambulatory care guideline and update the 1999 surgical site infection guideline.

HICPAC presented its final recommendations from the DHQP Surveillance Branch External Peer Review Panel that was convened in May 2008. **HICPAC unanimously approved a motion** to reaffirm its previous endorsement of NHSN as the standard for HAI surveillance.

Future agenda items and other business items that were raised over the course of the meeting were reviewed, particularly scheduling of a conference call in mid-December 2008/early January 2009 for HICPAC to discuss and approve the CAUTI guideline in its entirety and the final draft of the *MMWR* KPC recommendations.

The next HICPAC meeting would be held on February 12-13, 2009 in Atlanta, Georgia at the CDC Global Communications Center.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Preparedness, Detection, and Control of Infectious Diseases
Division of Healthcare Quality Promotion

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE
November 13-14, 2008
Washington, DC

Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC). The proceedings were held on November 13-14, 2008 at the Washington Marriott Hotel in Washington, DC.

Opening Session

Dr. Patrick Brennan, Chair of HICPAC, called the proceedings to order at 9:05 a.m. on November 13, 2008. He welcomed the attendees to the meeting and opened the floor for introductions. No members declared any new conflicts of interest for the record that were pertinent to the November 13-14, 2008 HICPAC agenda. The list of participants is appended to the minutes as Attachment 1.

Update on HHS Efforts to Reduce Healthcare-Associated Infections (HAIs)

Dr. Anand Parekh is the Deputy Assistant Secretary for Health (Science and Medicine) in the HHS Office of Public Health and Science (OPHS). He provided a progress report on HHS's *National Action Plan for Reducing Healthcare-Associated Infections*. HHS undertook this effort because HAIs account for an estimated 1.7 million infections and 99,000 associated deaths annually. Moreover, HAIs affect 5%-10% of hospitalized patients each year and add nearly $20 billion to healthcare costs annually.

In March 2008, the Government Accountability Office (GAO) issued a report on HAIs with three specific recommendations to HHS. First, central coordination of HHS-supported HAI prevention and surveillance activities should be improved. Second, CDC's recommended clinical practices should be prioritized to promote implementation of high-priority practices and assure compliance in hospitals. The prioritized recommendations should be considered for inclusion in the Centers for Medicare and Medicaid Services (CMS) *Conditions for Participation*. Third, consistency,

compatibility and interoperability of data collected across HHS should be enhanced to increase the reliability and robustness of national estimates of HAIs.

In response to the GAO report, HHS established a Steering Committee on HAI Reduction to develop the consensus-based National Action Plan. The National Action Plan will establish national goals for reducing HAIs; include short- and long-term benchmarks; outline opportunities for collaboration with external stakeholders; and coordinate and leverage HHS resources to accelerate and maximize impact.

The Steering Committee prioritized six "Tier 1" HAIs for hospitals: CAUTI, CLABSI, SSI, VAP, methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* (*C. difficile*). Tier 2 priorities will be established in the future for additional HAIs and other types of healthcare facilities. HHS will include the National Action Plan in the package of transition documents for the new Administration to use as a blueprint to tackle this important public health issue.

After the HHS clearance process is completed, the National Action Plan will be published in the *Federal Register* for public comment and revised based on comments submitted. HHS intends to release the final National Action Plan in late January 2009.

Dr. Parekh informed HICPAC of HHS's initiative to address the serious public health problem of low influenza vaccination rates among healthcare personnel (HCP). Although HHS established a *Healthy People 2010* target of annual vaccination of 60% of all HHS HCP by 2010, only 45% of HCP in the United States were vaccinated in 2007.

HHS is implementing the initiative with both internal and external components. First, influenza vaccination coverage will be increased among HHS employees. HHS operating divisions with HCP include the Indian Health Service (IHS), Federal Occupational Health, U.S. Public Health Service Commissioned Corps, NIH Clinical Center and CDC. Second, influenza vaccination will be promoted to non-federal healthcare organizations and HCP.

DHQP Director's Report

Dr. Cardo covered the following areas in her update. DHQP's organizational structure includes three branches that focus on the prevention of HAIs: the Clinical and Environmental Laboratory Branch, Prevention and Response Branch, and Surveillance Branch. The Office of Blood, Tissue and Organ Safety and the Office of Antimicrobial Resistance are two new offices that were added to DHQP over the past two years. The Immunization Safety Office was recently relocated to DHQP.

DHQP's current organizational structure has expanded its role in providing leadership for CDC's patient safety activities and assuring consistency with FDA's activities related to adverse drug events (ADEs) and blood, tissue and organ safety. DHQP is now responsible for ADEs, HAIs, transfusion and transplant safety, immunization safety, antimicrobial resistance and healthcare preparedness. DHQP performs its functions through outbreak investigations, implementation of

interventions, laboratory research, surveillance, prevention recommendations, and partnerships and collaborations. DHQP's draft strategic plan embraces the concept of HAI elimination and describes key approaches to achieve this goal: fully adhering to recommendations, collecting data and disseminating results to consumers, evaluating progress, recognizing excellence, identifying and responding to emerging threats, and improving science for prevention through research.

Update on the HICPAC Guidelines

Dr. David Pegues is a HICPAC member and chair of the workgroup that developed the *Guideline for Preventing Catheter-Associated Urinary Tract Infections*. He pointed out that the executive summary of the guideline was distributed to HICPAC for review and comment. The workgroup developed the guideline by focusing on three key questions: (1) Who should receive urinary catheters? (2) What are the best practices for persons who might require urinary catheters? (3) What are the best practices for preventing UTI associated with obstructed urinary catheters? The workgroup also addressed seven sub-questions under the three key questions.

The workgroup has completed several tasks since the June 2008 HICPAC meeting. Evidence summaries, tables for the "Grading of Recommendations, Assessment, Development and Evaluation" (GRADE) system, and recommendations for key questions 2C, 2D and 3 were developed. Multiple meta-analyses were performed for silver alloy catheters.

The executive summary, background, scope, purpose and methodology of the guideline were drafted and extensively revised. A summary of the recommendations was drafted and revised, including sections on implementation, audit and further research. The workgroup revised the guideline based on comments submitted by CDC editors and internal and external reviewers.

In addition to developing specific guidance for the six sections, the workgroup also highlighted other areas that are important for CAUTI. The guideline contains six priority recommendations for appropriate urinary catheter use, aseptic insertion of urinary catheters, and proper urinary catheter maintenance.

Recommendations on performance measures cover internal reporting of process and outcomes measures through compliance with educational programs, documentation of catheter insertion and removal dates, and documentation of indications for catheter placement as well as rates of symptomatic CAUTI and BSI secondary to CAUTI. Recommendations on external reporting cover data collection and reporting required by states, external quality initiatives for hospitals, and certification or accreditation processes.

Overall, the workgroup's in-depth guideline review describes the organization of appendices; outlines strategies for literature searches; summarizes the primary literature; provides links to the recommendations; and illustrates the evidence, GRADE and quality assessment tables.

Dr. Pegues concluded his update by thanking Drs. Carolyn Gould of DHQP and Craig Umscheid of the University of Pennsylvania Health System Center for Evidence-Based Practice for their outstanding efforts in drafting and extensively revising multiple versions of the CAUTI guideline.

Dr. Brennan summarized HICPAC's next steps on the CAUTI guideline. A vote would be called on the following day for HICPAC to formally approve the parts of the guideline that have no controversial issues or do not need to be changed. Following the resolution of these issues, the next iteration of the guideline would be circulated to HICPAC for review and a conference call would be held for HICPAC's final approval of the entire document. The guideline would then be submitted to the CDC clearance process.

Dr. Bell reported that the *Sterilization and Disinfection in Healthcare Settings Guideline* is now available on the CDC web site. DHQP will have a follow-up discussion with the authors over the next two weeks to decide whether to wait on CDC's lengthy clearance process associated with *Morbidity and Mortality Weekly Report* (*MMWR*) publications or proceed with disseminating the guideline in other venues.

Dr. Bell reported that the joint HICPAC/Advisory Committee on Immunization Practices (ACIP) *Healthcare Worker Vaccination Guideline* has not yet been completed. Issues related to the measles, mumps and rubella vaccine for HCP are still being addressed due to the measles outbreak over the past year. The authors plan to participate in a conference call with HICPAC in mid-December 2008/early January 2009 to further discuss the guideline, resolve any outstanding issues, and obtain HICPAC's formal approval of the document.

Dr. Kurt Stevenson is a HICPAC member and chair of the workgroup that developed the *Guideline for the Prevention and Management of Norovirus Outbreaks in Healthcare Settings*. He explained that the workgroup developed the guideline by drafting and then revising five key questions based on the literature review:

1. What patient, virus or institution characteristics increase or decrease the risk of norovirus infection in healthcare settings?
2. What interventions best prevent norovirus outbreaks in healthcare settings?
3. What are the best methods to identify a norovirus outbreak in a healthcare setting?
4. What patient management interventions best contain norovirus outbreaks in healthcare settings?
5. What environmental management interventions best contain norovirus outbreaks in healthcare settings?

The workgroup created an analytic framework to answer research questions for the norovirus guideline based on evaluating patients at baseline, identifying sporadic infections and outbreaks, preventing transmission of an outbreak, and focusing on environmental cleaning. From September 2007-June 2008, the workgroup reviewed existing guidelines, developed and revised the five key questions, conducted a literature search, and completed the abstract and full-text screening process.

The workgroup is currently extracting and synthesizing data, assessing the quality of studies, and developing GRADE and evidence tables. In February-June 2009, the workgroup will complete the data extraction and synthesis process, finalize the GRADE and evidence tables, summarize the evidence, and formulate draft recommendations.

Dr. Stevenson concluded his update by thanking Dr. Umscheid and his team for conducting most of the activities to develop the norovirus guideline.

Overview of the Carbapenem-Resistant *Klebsiella pneumoniae* (CRKp) Outbreak

Dr. Bell provided an overview of CDC's investigation of CRKp in Puerto Rico in 2008. Of 26 cases of hospital-acquired CRKp infection, 42% died during hospitalization. Of 13 community-onset cases identified based on positive culture ≤48 hours of admission, six were previously admitted to the same hospital. Wounds and patient transfers between wards were identified as significant risk factors in the cases. Successful control measures in the cases included cohorting of patients and staff, active surveillance, and enforced adherence to infection control practices.

NHSN data show that CRKp prevalence increased from <1% in 2000 to 8% in 2007. CRKp isolates are defined by resistance to all beta-lactams and many are resistant to quinolones and aminoglycosides. A New York study of CRKp showed ~30% aminoglycoside resistance, 100% quinolone resistance, and ~10% tigeclycline or colistin resistance. The same study reported attributable mortality from *K. pneumoniae* infections of 38% with CRKp and 12% with carbapenem susceptible *K. pneumoniae*.

CDC will summarize the Puerto Rico outbreak in an upcoming *MMWR* article and provide infection control, surveillance and laboratory recommendations for KPC-producing organisms in acute care facilities.

Dr. Brennan conveyed that a vote would be called on the following day for HICPAC to formally approve CDC's draft infection control, surveillance and laboratory recommendations for KPC-producing organisms in acute care facilities before publication in the *MMWR*.

Overview of the CDC Decolonization Meeting

Dr. Bell reported that DHQP held a decolonization meeting in August 2008 with 23 national and international experts on *S. aureus* decolonization. The objective of the meeting was to discuss issues related to *S. aureus* decolonization in healthcare and community settings, including current evidence that supports or does not support decolonization and existing research gaps.

The key findings of the expert panel are highlighted as follows. Current evidence is insufficient to recommend for or against decolonization in healthcare settings with endemic MRSA. For the prevention of SSI, evidence supports decolonization for cardiac surgery and potentially for other surgical procedures involving implantation of hardware. However, candidates should have confirmation of colonization.

For hemodialysis and peritoneal dialysis, evidence supports both nasal decolonization and use of antimicrobial or antiseptic agents at catheter sites. Current practice favors the latter. Evidence is lacking regarding the incremental benefit of decolonization, its use in patients without catheters, and optimal agents or regimens to use. Screening and decolonization, including HCP with an epidemiological link to an outbreak, are reasonable during an outbreak that has not responded to other interventions.

The expert panel further concluded that understanding of the biology and epidemiology of *S. aureus* colonization as well as the impact of new MRSA strains in community settings is limited. For patients with recurrent *S. aureus* infections, decolonization should be considered after active infection resolves if hygiene and correct wound care alone do not prevent recurrence of culture-confirmed *S. aureus*.

Dr. Cardo asked HICPAC to review the MDRO guideline and determine whether the 2002 recommendations on the care of vascular catheters and guidance need to be updated at this time. She pointed out that the proceedings from the expert meeting on decolonization would be published and available to HICPAC for review.

Dr. Brennan agreed that HICPAC should develop a process to incorporate new data into its completed guidelines. He planned to further discuss this issue with Drs. Bell and Cardo.

HICPAC Workgroup Reports

HAI Preventability Workgroup. Dr. Brennan reported that the "Mortality from Reasonably Preventable HAIs" report was distributed during a Congressional committee hearing in April 2008. SHEA and Dr. Umscheid's team at the Center for Evidence-Based Practice developed the report in response to a Congressional inquiry about the extent to which deaths from HAIs in the United States are preventable. The report contained a range of estimates on preventability of both deaths and infections from HAIs.

Dr. Umscheid reported that the draft manuscript on *Estimating the Annual Number of Reasonably-Preventable HAIs and Associated Costs and Mortality* was presented at the June 2008 HICPAC meeting. HICPAC raised concerns about the workgroup's focus on estimates of

preventable mortality because these projections had the most assumptions. HICPAC advised the workgroup to place more emphasis on estimates that were the basis of projections of preventable mortality, such as estimates of preventable infections. Based on HICPAC's input, the workgroup revised and expanded the draft manuscript to include avoidable costs.

Dr. Bell viewed the draft manuscript on HAI preventability as a solid synthesis of available data, and he raised the possibility of the manuscript serving as the basis of a set of concrete recommendations from HICPAC. For example, HICPAC could advise CDC to encourage AHRQ to fund studies to fill existing knowledge and research gaps related to HAI preventability.

Dr. Brennan confirmed that the next iteration of the draft manuscript would be circulated to HICPAC via e-mail or during the next meeting. HICPAC would make a decision at that time on next steps with the document.

Guideline Methods Workgroup. Dr. Umscheid reported that the workgroup is continuing to draft the methods paper to describe the need to update HICPAC's guideline development process. The CAUTI guideline will be featured in the methods paper as a model to illustrate the updated guideline process. The methods paper will be disseminated with the CAUTI guideline as a companion document.

Model Legislation Workgroup. Dr. Tammy Lundstrom reported that the workgroup created an outline of the draft guidance document for jurisdictions considering MRSA legislation. The document will be no longer than five pages to ensure its usefulness to the target audience. The document will cover HAI and the impetus for legislation; the background and intent of legislation; the potential for unintended consequences; language and elements to avoid and include in legislation; and a short list of source articles.

To assure alignment with previous recommendations, the workgroup's data sources will include the CDC/Fridkin paper on measurements, the NHSN MDRO module, the HICPAC guidance document on public reporting, the APIC/SHEA document on "Legislating Active Surveillance Cultures," and the public reporting toolkit.

The workgroup also developed a table describing the attributes of current MRSA legislation in 11 states. The workgroup will not encourage specific prevention activities in the document due to ongoing changes in science. The workgroup plans to present the draft guidance document on model legislation during the February 2009 meeting for HICPAC's review, discussion and formal vote.

A number of HICPAC members reiterated their previous concerns about limiting the model legislation guidance document to MRSA. The members noted that many jurisdictions have no issues with MRSA, but other HAIs are problematic at the local level. The members also pointed out that another organism most likely would replace MRSA as a priority issue in the near future.

Liaison and *Ex-Officio* Reports

Dr. Brennan reminded HICPAC that a new process was introduced during the June 2008 meeting to streamline the liaison and *ex-officio* reports. Since that time, CDC developed a standardized template for the liaison and *ex-officio* members to submit written reports into the official HICPAC record. The template allows the liaison and *ex-officio* members to describe activities of their organizations and agencies in the following areas: position statements, legislation, campaigns and related activities, press activities, publications, and other items of note.

The following liaison and *ex-officio* members submitted written reports into the official HICPAC record for the November 13-14, 2008 meeting:

- Rachel Stricof, MPH, CIC (Advisory Council for the Elimination of Tuberculosis) (ACET)
- William Baine, MD (Agency for Healthcare Research and Quality)
- Mark Russi, MD, MPH (American College of Occupational and Environmental Medicine)
- Roslyne Schulman, MHA, MBA (American Hospital Association) (AHA)
- Joan Blanchard, RN, BSN, MSS, CNOR, CIC (Association of periOperative Registered Nurses) (AORN)
- Nancy Bjerke, BSN, RN, MPH, CIC (Association of Professionals of Infection Control and Epidemiology, Inc.)
- Marion Kainer, MD, MPH (Council of State and Territorial Epidemiologists)
- Sheila Murphey, MD (Food and Drug Administration) (FDA)
- Robert A. Wise, MD (The Joint Commission)
- David Henderson, MD (National Institutes of Health)
- Lisa Maragakis, MD, MPH (Society for Healthcare Epidemiology of America)

Several liaison and *ex-officio* members supplemented the written reports with additional details on recent activities of their organizations and agencies.

- Dr. Jeffrey Engel reported that the CDC Public Health Law Program is conducting a number of TB legal preparedness activities, including the development of model legislation on state TB control. CDC is undertaking this effort in consultation with ACET.

- Ms. Blanchard reported that AORN analyzed the cost of instruments for ophthalmology surgeons to avoid flash sterilization. The direct cost with eight new instruments would be <$12/smear for each cataract case, but the addition of indirect costs would increase this total. However, the cost of instruments would decrease over time. AORN is concerned about the ~1.5 hours that are required to process each smear with cleaning, decontamination, cooling, inspection and other infection control practices. A document on flash sterilization practices was submitted with the AORN report.

- Ms. Lisa McGiffert reported that the Consumers Union disseminated a press release and briefing document on *C. difficile*. She would provide these materials to HICPAC.

- Dr. Sheila Murphey reported that the heparin contamination problem has not yet been resolved. FDA recently seized a large shipment of heparin from a central laboratory prior to distribution to users. FDA has warned device manufacturers to thoroughly check and ensure that no materials were used from implicated lots. FDA will maintain its surveillance because heparin-contaminated materials are still in commercial circulation. FDA posted a heparin warning on its web site. A manufacturer sent warning letters to its customers about problems with residual fluid that might remain in endoscopes and cause damage to mucosa.

- Dr. Gary Roselle reported that the VA launched a large initiative in an effort to eliminate healthcare-associated Legionella. The VA is partnering with CDC to conduct a follow-up survey to determine findings, actions and results based on the initial survey.

With no further discussion or business brought before HICPAC, Dr. Brennan recessed the meeting at 5:30 p.m. on November 13, 2008.

Update on the HICPAC Guideline Development Process

Dr. Brennan reconvened the HICPAC meeting at 9:05 a.m. on November 14, 2008 and explained that this agenda item would include an extensive discussion on three key topics. First, HICPAC would provide input to advance the revised guideline development process to ensure that its future guidelines inform healthcare in general and ICPs in particular. The discussion would cover two subtopics: (1A) HICPAC's decision on whether to develop a new ambulatory care guideline and (1B) HICPAC's suggestions on completed guidelines that need to be updated at this time.

Second, HICPAC would discuss the integration of guidelines based on the release of the SHEA/ IDSA *Compendium of Practical Implementation Strategies for the Prevention and Monitoring of Healthcare-Associated Infections in Acute Care Hospitals*. Harmonization of guidelines by various groups will be critical to reduce inconsistencies and provide the most helpful information to the field. Third, HICPAC would explore new elements to include in guidelines, such as process measures, prevention targets, prioritization of recommendations and risk assessments.

TOPIC 1A: Dr. Bell reminded HICPAC that he presented the concept for a new *Ambulatory Care Guideline for Infection Prevention* during the June 2008 meeting. On the one hand, the evidence base for ambulatory care infection control is extremely limited and presents a challenge in developing the new guideline. The guideline primarily would be supported with Category II recommendations. On the other hand, HICPAC could offer valuable guidance to the field by highlighting recommendations from acute care settings and providing a consistent "ambulatory care framework." HICPAC could develop and disseminate an ambulatory care "white paper" rather than a formal evidence-based guideline.

On a broader level, Dr. Bell's position was that HICPAC's new guideline development process should include various types of documents, such as formal evidence-based guidelines; brief

notices to the field with recommendations on priority or emerging issues; and less formal or restrictive "guidance" white papers with limited evidence. HICPAC documents also should address the importance of basic infection control practices to modify behaviors over time beyond the ICP community.

The HICPAC members made several comments and suggestions on the ambulatory care guideline.

- The ambulatory care guideline should address transmission of blood-borne pathogens in outpatient settings by multiple routes rather than transmission by direct contact alone.
- The ambulatory care guideline should not reflect an entirely new data collection effort because solid guidance that has been developed for hospitals can be applied to outpatient clinics. Infection control standards and principles should be consistent between hospital-based and outpatient-based clinical care. Organizations that survey ambulatory care clinics should be extensively engaged in this effort to increase adherence to the recommendations.
- Emphasis should be placed on education to ambulatory care clinics to minimize the challenges associated with the lack of oversight.
- The ambulatory care guideline should be written for and targeted to specific personnel who will actually be responsible for infection control practices in these settings.
- The ambulatory care guideline should include information from FDA's reprocessing guideline because these recommendations can be applied to outpatient settings.
- HICPAC should engage organizations that are currently educating medical school students on patient safety in developing the ambulatory care guideline. Ms. McGiffert would provide contact information for these groups.

HICPAC agreed to develop the ambulatory care guideline due to the critical need to provide infection prevention and control guidance to these settings.

HICPAC reiterated that the guideline should be broad, reflect a compilation of information from existing documents, and target recommendations to personnel who will actually be responsible for infection control practices in ambulatory care settings. Dr. Brennan asked HICPAC members with an interest on serving on the new "Ambulatory Care Workgroup" to notify him or Dr. Bell via e-mail.

TOPIC 1B: Dr. Brennan noted that ACIP established a process to review its existing guidelines every five years and make decisions on whether to minimally update, extensively revise or completely retire documents. He emphasized the need for HICPAC to develop a similar process. For example, HICPAC could review its oldest guidelines first and determine if these documents need to be updated or retired.

To facilitate the discussion on potential HICPAC guidelines to update, a table was distributed with numerous infection control and prevention guidelines that were developed over the past few years by HICPAC, SHEA, IDSA and APIC. Suggestions by the HICPAC members on the next guidelines to review and update are outlined below:

- Prevention of healthcare-associated pneumonia (2003)
- Prevention of intravascular device-related infections (2002)
- Prevention of SSI (1999)
- Prevention of TB transmission in healthcare facilities
- Infection control in HCP (1998)
- Use of vaccines and immune globulin in persons with altered immunocompetence (1993) (Joint HICPAC/ACIP guideline)
- Infection prevention and control definitions for LTCFs

HICPAC unanimously agreed by a vote that its top two priorities at this time would be to develop the new ambulatory care guideline and update the 1999 SSI guideline.

TOPIC 2: Dr. Brennan acknowledged the challenges in integrating guidelines developed by HICPAC and professional societies. As a federal advisory committee that is chartered to provide advice and recommendations to the CDC Director and HHS Secretary, HICPAC's ability to formally endorse or support guidelines developed by external groups is restricted.

Dr. Brennan was aware of the need to overcome these barriers due to delays in distributing important guidance to the field. For example, vetting of the SHEA/IDSA compendium was expected to be completed in one year, but this process required nearly two years. Although HICPAC's role is not to define implementation or other practices of an organization, HICPAC must comply with its federal charter. Dr. Brennan requested input on HICPAC's potential role in integrating guidelines.

Ms. Kathy Warye is the Executive Director of APIC. She explained that APIC's role in the guideline process is to translate scientific recommendations into actual practice for the field. For example, SHEA or IDSA would advise hospitals to conduct a risk assessment, while APIC would describe the actual steps involved in implementing the risk assessment.

Ms. Warye conveyed that unlike SHEA and IDSA, only 5% of APIC's 12,000 members have MDs or PhDs. APIC's membership represents the broader ICP community from novice hospital staff with a recent introduction to infection control and prevention to more seasoned hospital epidemiologists. APIC welcomes the opportunity to enhance its relationships with HICPAC, SHEA and IDSA to reach the specialized component of the ICP community through educational activities and dissemination of materials.

Ms. Jennifer Bright is the Executive Director of SHEA. She explained that SHEA is partnering with IDSA to bring more discipline to the guideline process. For example, SHEA's Guidelines Committee evaluates existing documents and identifies partner organizations that can assist in this effort.

Ms. Bright emphasized the need for HICPAC, SHEA, IDSA, APIC and other professional societies to develop and maintain strong partnerships; communicate and coordinate ongoing activities; and identify other key stakeholders with a role in developing and disseminating guidelines. HICPAC's role as a federal advisory committee restricts its "advocacy voice," but

professional societies can develop commentaries or identify research needs based on HICPAC guidelines.

This type of collaboration would allow HICPAC to apply its expertise and federal resources in gathering solid data to support evidence-based research. Professional societies could then support HICPAC's guidelines by developing white papers or other materials on data gaps, the lack of oversight and other problems in the IPC community.

The HICPAC members made three key suggestions to advance the integration of guidelines between HICPAC and professional societies.

- Efforts should be made to coordinate the release of documents developed by HICPAC and professional societies. For example, liaisons could be notified of expected dates for a HICPAC guideline to be formally approved and cleared. The liaisons could then notify their organizations to develop and distribute complimentary implementation tools or other resources at the same time as the release of the HICPAC guideline.
- HICPAC should replicate the APIC model in its guidelines by describing the step-by-step process of conducting an infection control risk assessment.
- HICPAC should engage the American Osteopathic Association (AOA) as another key partner in its efforts to integrate guidelines.

Dr. Brennan proposed the following process to advance the integration of guidelines between HICPAC and professional societies. DHQP would convene a meeting with a subset of HICPAC members and guideline authors from AHA, APIC, the Joint Commission, IDSA and SHEA. The purpose of the meeting would be to further discuss integration issues, including various roles and responsibilities, interaction among groups, and potential strategies to overcome barriers to integrating documents.

TOPIC 3: Dr. Bell conveyed that no action would need to be taken at this time on potential new elements to include in HICPAC guidelines. He confirmed that this issue would be addressed during the upcoming meeting with DHQP, HICPAC and the professional societies as part of the effort to integrate guidelines.

Update on the DHQP Surveillance Branch External Peer Review

Mr. Russell Olmsted is a HICPAC member and chair of the DHQP Surveillance Branch External Peer Review Panel that was convened in May 2008. The Panel was charged with evaluating the NHSN Patient Safety Component in the context of other NHSN capabilities and initiatives. The Panel was also asked to assess DHQP's other surveillance activities, including electronic HAI and ADE surveillance; population-based surveillance of MRSA and *C. difficile*-associated disease (CDAD); and use of the National Hospital Discharge Survey or National Inpatient Sample to estimate the public health burden of HAIs.

The Panel formulated its recommendations in response to three key questions posed by DHQP: (1) Did the Surveillance Branch's presentations omit important scientific, technical or policy features of the current landscape of HAI surveillance in the United States, including antimicrobial resistance and adherence to prevention guidelines? (2) Are the Surveillance Branch's current capacity, priorities and plans for NHSN adequate with respect to the current landscape of HAI surveillance? (3) What directions, strategies and steps are most important for the Surveillance Branch to meet new opportunities and challenges in HAI surveillance?

The Panel's final recommendations are outlined as follows. NHSN should broaden its focus beyond acute care hospitals to more accurately reflect the direction of care delivery outside of this traditional setting. HICPAC and DHQP, in collaboration with AOA, APIC, SHEA, the Joint Commission and other liaisons, should jointly develop a risk assessment template for facility- or setting-based application.

DHQP should prioritize the development of training, education and ongoing certification of current and new NHSN users to assure high-level performance of the system. DHQP should explore innovative strategies to achieve this goal, including partnerships with outside entities or organizations.

CDC should engage professional societies that represent ICPs, state hospital associations and other appropriate organizations to assist with training. CDC should expand the NHSN train-the-trainer model implemented in successful state-based initiatives in New York and South Carolina to other large groups that might simultaneously enroll in NHSN due to public reporting mandates.

CDC should encourage and promote the use of NHSN data by outside researchers. HICPAC should explicitly endorse NHSN as the standard for HAI surveillance and reinforce this endorsement in relevant guidelines and its other communications. HICPAC should assist DHQP and the HHS Secretary by playing a proactive role in determining appropriate actions that should be taken when existing surveillance data are inconsistent or conflicting. For example, HICPAC should establish a position on the value and efficacy of interventions related to HAIs, such as active surveillance detection for the presence of MDROs.

HICPAC, in collaboration with DHQP and others, should develop and publish an *HAI Surveillance Guide* that includes an overview of application of risk assessment methodology and uses HAI data upon which a facility can plan interventions to prevent HAIs. HICPAC and DHQP should consider extension of the risk assessment to site-specific application, e.g., related to SSI.

HICPAC, in collaboration with DHQP, should establish linkages between NHSN and evidence-based guidelines, new contributions to the literature, and information generated by other CDC divisions and HHS agencies to create a fully functional knowledge network. Technology-based media, such as blogs or an "e-network," might be considered as a platform for facilitating access to resources, such as the Health Alert Network or Epi-X.

CDC should take a multifaceted approach to improve the communication and timely output of NHSN data while increasing the visibility of NHSN analytic products. CDC should use innovative communication mechanisms to disseminate data to the public, such as developing and releasing a consumer version of NHSN and posting user-friendly information on web sites.

In addition to HICPAC's formal approval of the final recommendations, Mr. Olmsted also asked for volunteers to serve on a new workgroup to develop the *HAI Surveillance Guide*. He noted that this activity could be completed in a relatively short period of time because APIC and the Joint Commission have created similar materials.

Dr. Cardo confirmed that DHQP has started to use the Panel's recommendations to establish priorities, change certain practices, and leverage resources to meet the demands of NHSN's rapid growth. Efforts are underway to form a new steering committee to address NHSN issues on an ongoing basis. For example, the steering committee would be charged with exploring strategies to share NHSN data with outside researchers without violating data quality or jeopardizing the confidentiality of patients, hospitals or states. The membership of the steering committee will include HICPAC, states, NHSN facilities, professional organizations and CDC divisions.

A motion was properly placed on the floor and seconded by Drs. Ramsey and Lundstrom, respectively, for HICPAC to reaffirm its previous endorsement of NHSN as the standard for HAI surveillance. **HICPAC unanimously approved the motion.**

HICPAC Votes

Dr. Brennan announced that two issues would require a formal vote. *ISSUE 1* was HICPAC's preliminary approval of the CAUTI guideline. A conference call would be held over the next few weeks for HICPAC's final approval of the entire document. The guideline would be submitted to the CDC clearance process in early January 2009.

Dr. Bell led HICPAC in a review of the unresolved issues for the CAUTI guideline that would be discussed on the upcoming conference call.

- "Silver alloy-coated catheters." Softer and more permissive language is needed. The Category II recommendation contains a number of disclaimers.
- Spatial separation of catheterized patients: "To minimize the changes of cross-infection, avoid placing infected and uninfected patients with indwelling catheters in the same room or adjacent beds." This recommendation was in older guidelines and should be updated to be more meaningful to current healthcare settings.
- "Properly clean and store reusable intermittent catheters according to the manufacturer's instructions." This recommendation is inconsistent with FDA language and needs to be revised.
- Revised wording for the catheter utilization ratio; instead of "catheter-days," use "patient-days" or "catheter-days that meet criteria for use in patients."

- "Properly secure indwelling catheters after insertion to prevent movement and urethral traction." Clear guidance is needed on the definition of "properly secure."
- "Sterile technique for intermittent catheterization in acute care settings." The workgroup needs to review this language.
- CMS requirements for "nurse-directed removal of unnecessary urinary catheters." The workgroup needs to discuss this language with CDC.

A motion was properly placed on the floor and seconded by Drs. Schecter and Stevenson, respectively, for HICPAC to approve the *Guideline for Preventing Catheter-Associated Urinary Tract Infections* with the exception of the unresolved issues noted in the record. **HICPAC unanimously approved the motion.**

ISSUE 2 was HICPAC's approval of CDC's draft infection control, surveillance and laboratory recommendations for KPC-producing organisms in acute care facilities that would be published in the *MMWR*.

The HICPAC members made several comments and suggestions for CDC to consider in revising the draft KPC recommendations.

- Reformat the laboratory recommendations. "Clinical microbiology laboratories should: [list the two recommendations]."
- Change recommendation B.1.b: "The facility should continue to periodically perform active surveillance until no new cases are identified if surveillance testing identified other cases."
- The recommendations will require institutions with routine hospital admissions for KPC-producing organisms to create an ongoing and active surveillance program for gram-negative bacteria. However, data are limited on body sites to culture and populations to target for this type of surveillance. CDC should collect data to support specific guidance on body site culturing. The revised surveillance recommendation should advise facilities in areas with regional or local incidence of KPC to target high-risk/subpopulations.

A motion was properly placed on the floor and seconded by Dr. Schecter and Mr. Olmsted, respectively, for HICPAC to approve the draft infection control, surveillance and laboratory recommendations for KPC-producing organisms in acute care facilities with the revisions noted in the record. **HICPAC unanimously approved the motion.**

HICPAC would convene a conference call in mid-December 2008/early January 2009 to discuss and approve the final draft of the KPC recommendations before CDC submitted the document to the *MMWR* in January 2009.

HICPAC Business Session

Dr. Brennan led HICPAC in a review of the business items that were raised over the course of the meeting.

- Dr. Bell/DHQP staff will organize a meeting with HICPAC and professional societies to further discuss issues related to integration of guidelines.
- Dr. Bell/DHQP staff will schedule a conference call in mid-December 2008/early January 2009 for HICPAC to discuss and approve the CAUTI guideline in its entirety and the final draft of the *MMWR* KPC recommendations.
- Dr. Brennan will follow-up with Dr. Umscheid on the draft HAI preventability manuscript and guideline methods paper.
- Dr. Brennan will solicit volunteers to develop the new ambulatory care guideline.
- Drs. Brennan and Bell will place the following items on the February 2009 agenda or future agendas:
  - Intravascular guideline by Dr. Naomi O'Grady.
  - Presentation by Dr. William Schecter on the role of infection control practices in perioperative care.
  - Presentation by Dr. Alexis Elward on HICPAC's role in pediatric infection control practices.
  - Presentation by the ACS National Surgical Quality Improvement Program (NSQIP).
  - HICPAC discussion on the possibility of APIC and SHEA jointly developing a course on infection control practices in outpatient settings that would be modeled on the Advanced Cardiac Life Support course.

- The HICPAC members will participate in the following ongoing or new activities:
  - Further revisions on the model legislation guidance document and the CAUTI and norovirus guidelines.
  - Participation on a new workgroup to develop the ambulatory care guideline.
  - Participation on a new workgroup to develop the HAI surveillance guide.
  - Assistance to CDC on securing representatives from ACS/NSQIP and the Surgical Infection Society to participate in the guideline integration effort.
  - Development of a new pediatric section for the HAI preventability manuscript.

Closing Session

The next HICPAC meeting would be held on February 12-13, 2009 in Atlanta, Georgia at the CDC Global Communications Center.

With no further discussion or business brought before HICPAC, Dr. Brennan adjourned the meeting at 12:00 p.m. on November 14, 2008.

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

Date

Patrick J. Brennan, M.D.
Chair, Healthcare Infection Control
Practices Advisory Committee