

**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  
February 11-12, 2008  
Atlanta, Georgia**

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**Record of the Proceedings**

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## ATTACHMENT 1

### List of Participants

#### **HICPAC Members**

Dr. Patrick Brennan, Chair  
Ms. Lillian Burns  
Dr. Jeffrey Engel  
Dr. Steven Gordon  
Dr. Tammy Lundstrom  
Dr. Yvette McCarter  
Ms. Denise Murphy  
Mr. Russell Olmsted  
Dr. David Pegues  
Dr. Keith Ramsey  
Dr. Nalini Singh  
Ms. Barbara Soule  
Dr. Kurt Stevenson

#### **Designated Federal Official**

Dr. Michael Bell, Executive Secretary

#### **Ex-Officio and Liaison Members**

Ms. Nancy Bjerke (Association of Professionals of Infection Control and Epidemiology, Inc.)  
Dr. William Baine (Agency for Healthcare Research and Quality)  
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. Stephen Kralovic (Veterans Administration)  
Dr. Lisa Maragakis (Society for Healthcare Epidemiology of America)  
Ms. Lisa McGiffert (Consumer's Union)  
Dr. Sheila Murphey (Food and Drug Administration)

Dr. Mark Russi (American College of Occupational and Environmental Medicine)  
Ms. Roslyne Schulman (American Hospital Association)  
Ms. Rachel Stricof (Advisory Council for the Elimination of Tuberculosis)  
Dr. Robert Wise (Joint Commission)

#### **CDC Representatives**

Dr. Denise Cardo, DHQP Director  
Elizabeth Bolyad  
Robert Carey  
Carolyn Gould  
Jeff Hageman  
Rita Helfand  
Teresa Horan  
Preeti Kutty  
Tara MacCannell  
Melissa Morrison  
Daniel Pollock  
Gina Pugliese  
Chesley Richards  
Kristin Rainisch  
Lynne Schulster  
Jane Seward  
Arjun Srinivasan  
Wendy Vance  
Joni Young

#### **Guest Presenters and Members of the Public**

Denise Graham (Association of Professionals of Infection Control and Epidemiology, Inc.)  
Jaime Ritter (Bard Medical)  
Craig Umscheid (University of Pennsylvania Health System Center for Evidence-Based Practice) [via conference call]

## EXECUTIVE SUMMARY

During the opening session of the Healthcare Infection Control Practices Advisory Committee (HICPAC) meeting on February 11-12, 2008, no members declared any new conflicts of interest for the record. The opening session also included an introduction of HICPAC's new Committee Management Specialist and a presentation of a "conflict of interest" video.

The final draft of the "HICPAC/Association for Professionals in Infection Control and Epidemiology Surveillance Definitions for Home Health Care and Home Hospice Infections" was distributed to HICPAC with the revised bloodstream infection (BSI) and clinical sepsis sections. During the November 2007 meeting, HICPAC agreed to vote on the final iteration of the home health care definitions after the revised BSI and clinical sepsis sections were presented. None of the HICPAC members opposed the motion to adopt the final draft of the home healthcare definitions.

Two HICPAC workgroups provided progress reports on the norovirus and catheter-associated urinary tract infection (CA-UTI) guidelines. Both of the HICPAC workgroups are using the same process to conduct a literature search, formulate key questions, define exclusion criteria, assess the quality of the studies, and design quality scales to grade the strength of the evidence. Both workgroups also are using outside expertise from the University of Pennsylvania Health System Center for Evidence-Based Practice to develop the guidelines.

HICPAC commended both workgroups for their outstanding efforts to date in developing the norovirus and CA-UTI guidelines as well as the evidence tables. HICPAC made suggestions for the workgroups to consider in their ongoing efforts.

An update was provided on the healthcare worker (HCW) vaccination guideline that HICPAC is jointly revising with the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices. HICPAC extensively discussed the guideline and noted several important issues that should be considered in revising the document. HICPAC agreed to revisit the HCW vaccination guideline during the June 2008 meeting in an effort to resolve issues that were raised by the members.

CDC presented extensive data and answered a number of HICPAC's questions to support its request for HICPAC to approve the proposed change in the guidelines for mumps isolation and precautions from nine days to five days in healthcare settings. HICPAC **approved a motion by a majority vote** of 12 to 1 to adopt CDC's proposed change in the guidelines for five-day isolation of mumps.

HICPAC's policy workgroups provided updates in three areas. For issue 1, HICPAC decided against developing model legislation for public reporting due to its expertise and charter to provide advice and evidence-based recommendations to the Secretary of the Department of Health and Human Services (HHS) and the Director of CDC on infection

control practices in healthcare settings. HICPAC agreed to develop an overarching framework for model legislation as a test case.

For issue 2, HICPAC agreed to develop healthcare-associated infection (HAI) preventability guidance because the following phrase was inserted into the Deficit Reduction Act (DRA): “The Centers for Medicare and Medicaid Services (CMS) will not reimburse for infections that could reasonably have been prevented by applying existing guidelines.” A table was distributed to HICPAC as an example of the extent to which HAIs are reasonably preventable.

For issue 3, a HICPAC member agreed to chair an external peer review of the Division of Healthcare Quality Promotion’s (DHQP) surveillance activities that will be held in May 2008.

HICPAC’s liaison and *ex-officio* members reported on ongoing and future activities of their respective organizations and agencies.

An update was provided on HICPAC’s role in the Society for Healthcare Epidemiology of America (SHEA)/Infectious Disease Society of America (IDSA) guidelines on six HAIs. HICPAC convened a conference call in January 2008 to review the latest iteration of the guidelines and discuss its formal position on the documents. During the conference call, HICPAC reaffirmed its inability to formally endorse the guidelines due to (1) the lack of transparency in the process used to grade the recommendations; (2) strengths or weaknesses of the evidence resulting in recommendations with “high” grades; and (3) variances from the National Healthcare Safety Network (NHSN) definitions.

HICPAC approved the overall SHEA/IDSA guideline development process and agreed to produce an editorial to accompany the guidelines. HICPAC summarized key points from its editorial that is currently being drafted and will be published in *Infection Control and Hospital Epidemiology*. HICPAC **unanimously approved** a motion recommending that SHEA and IDSA change the title of the six HAI documents from “guidelines” to “implementation strategies.”

DHQP reported that its proportion of CDC’s outbreak investigations has dramatically increased from five in 2004 to 16 in 2007, representing 25% of all CDC responses being provided by DHQP, a small division with only ~100 employees. Surgical site infections (SSIs), methicillin-resistant *Staphylococcus aureus* and *Clostridium difficile* still serve as the major sources of DHQP’s outbreak investigations. However, changes over the past few years include an increase in the number of community-associated infections, gram-negative pathogens, outbreaks following ambulatory procedures, compounded medical products, organ- and tissue-related outbreaks, adverse drug reactions, and national product investigations.

DHQP’s outbreak investigations have characterized emerging pathogens, facilitated the development of policy and practice guidance, and enhanced collaborations with the Food and Drug Administration to an unprecedented level of cooperation. HICPAC agreed to draft a letter to the HHS Secretary and the CDC Director to emphasize the need for additional resources to DHQP due to the increasing demand for DHQP’s expertise in outbreak investigations.

DHQP presented an update on the DRA. The following conditions will have payment implications beginning on October 1, 2008: serious preventable events, CA-UTIs, pressure ulcers, vascular catheter-associated infections, SSIs, and falls and trauma. CMS is considering other conditions for Inpatient Prospective Payment System rulemaking in the future. CDC emphasized the critical need for HICPAC and other parts of the infectious disease community to provide feedback to CMS on the DRA.

DHQP presented an update on its continued involvement in public reporting legislation. The number of healthcare facilities participating in NHSN is projected to dramatically increase to >2,000 by November 2008. The increase in the use of NHSN to report HAIs has presented a number of challenges for DHQP, including training to hospitals and infection control practitioners, requests by states to change specific components of NHSN, resource limitations in shifting toward the use of electronic data sources, and efforts to avoid duplicate data collection in the CDC and CMS systems.

HICPAC agreed to draft a letter to the HHS Secretary and the CDC Director to emphasize the need for additional resources to DHQP due to the increase in the number of healthcare facilities that are scheduled to participate in NHSN by November 2008.

DHQP reported that the U.S. Government Accountability Office (GAO) completed its investigation in November 2007 regarding collaborative efforts among HHS agencies in improving the prevention of HAIs. A hearing will be convened in the spring of 2008. The draft GAO report contains the following recommendations to the HHS Secretary regarding HICPAC.

HICPAC's recommended practices should be prioritized. Strategies should be developed to promote implementation of HICPAC's guidance. A determination should be made on whether to incorporate a select number of HICPAC's recommended practices into CMS's conditions for participation of hospitals. HICPAC should more fully engage HHS agencies outside of CDC to identify additional approaches to prioritize existing recommendations and assure better implementation in the field. GAO concluded that the 1,200 recommendations in HICPAC's 13 guidelines were excessive. HICPAC agreed to convene a conference call to assist CDC in crafting talking points in preparation of the upcoming GAO hearing.

HICPAC reviewed its business items that were raised over the course of the meeting. The next HICPAC meeting is scheduled for June 12-13, 2008 in Atlanta, Georgia. However, efforts will be made to ensure that HICPAC maintains a quorum despite four of the 14 voting members being unable to attend the next meeting due to a scheduling conflict.

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**HEALTHCARE INFECTION CONTROL  
PRACTICES ADVISORY COMMITTEE  
February 11-12, 2008  
Atlanta, Georgia**

**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 February 11-12, 2008 at CDC's Global Communications Center, Building 19, Auditorium B3 in Atlanta, Georgia.

**Opening Session**

Dr. Patrick Brennan, Chair of HICPAC, called the meeting to order at 9:07 a.m. on February 11, 2008. He welcomed the attendees to the proceedings and opened the floor for introductions. No members declared any new conflicts of interest for the record. The list of participants is appended to the minutes as Attachment 1.

Dr. Michael Bell, Executive Secretary of HICPAC, was pleased to introduce Ms. Wendy Vance, the new Committee Management Specialist for HICPAC. The HICPAC members welcomed Ms. Vance in her new role.

Dr. Bell announced that the first portion of the morning session would be devoted to HICPAC viewing a "conflict of interest" video. He explained that all members of federal advisory committees chartered under the Federal Advisory Committee Act must adhere to conflict of interest policies and procedures while serving as Special Government Employees. None of the HICPAC members posed any questions to CDC after viewing the conflict of interest video.

## **Update on the Home Healthcare Definitions**

Ms. Nancy Bjerke, HICPAC's liaison to the Association for Professionals in Infection Control and Epidemiology (APIC), pointed out that the final draft of the "APIC-HICPAC Surveillance Definitions for Home Health Care and Home Hospice Infections" was distributed to HICPAC for review. She noted that in response to HICPAC's comments during the November 2007 meeting on the clinical sepsis and bloodstream infection (BSI) definitions, a conference call was held to further discuss and revise these sections of the document.

Ms. Bjerke reviewed the changes to these two sections on pages 9-10 of the final draft of the document:

- "Primary BSI" includes laboratory-confirmed BSI and clinical sepsis. A positive blood culture alone may be used to define bacteremia.
- "Clinical sepsis" must have at least one of the following clinical signs with no other recognized cause: fever; hypotension (systolic pressure <90 mm Hg); oliguria (<20 mL/hr); hypothermia; apnea; bradycardia; AND blood culture is not done OR no organisms detected in blood; AND no apparent infection at another site; AND physician institutes treatment for sepsis; AND hospital admission for clinical sepsis and/or death due to clinical sepsis.

Dr. Brennan reminded HICPAC of two key outcomes during the November 2007 meeting regarding the home healthcare definitions. HICPAC unanimously approved adoption of the sections of the home healthcare definitions that did not require revision. HICPAC agreed to vote on the final iteration of the document after the BSI and clinical sepsis sections were revised.

Dr. Brennan also pointed out that issues requiring formal action by HICPAC would be called for a vote on the following day. In the interim, however, Ms. Burns moved for HICPAC to approve the final draft of the home healthcare definitions based on the changes Ms. Bjerke summarized for the BSI and clinical sepsis sections. None of the HICPAC members opposed adoption of the final draft of the home healthcare definitions.

## **Update on the Norovirus Guideline**

Dr. Kurt Stevenson, a HICPAC member, is leading the workgroup that was formed to develop HICPAC's "Guideline for the Prevention and Management of Norovirus in Healthcare Settings." He reported that the workgroup performed a guideline search in September 2007 as an initial effort in developing the norovirus guideline. In November 2007, the workgroup reviewed relevant guidelines and vetted the data with clinical experts to formulate five key questions to guide the development of the norovirus guideline:



1. What patient characteristics increase or decrease the risk of norovirus infection in healthcare settings?
2. What practices decrease the risk of a norovirus outbreak in healthcare settings?
3. What are the best methods to identify norovirus outbreaks in healthcare settings?
4. What patient management strategies decrease the spread of norovirus during outbreaks in healthcare settings?
5. What environmental management strategies decrease the spread of norovirus during outbreaks in healthcare settings?

The workgroup also created an analytic framework to answer the five research questions. The framework was designed to focus on patients at baseline, sporadic infection, outbreaks, and morbidity and mortality during the spread of a norovirus outbreak. The workgroup expects to complete its literature search in February 2008 by identifying databases, creating a search strategy, storing references and resolving duplicates.

The workgroup anticipates completing three additional activities by June 2008. First, the abstract and full-text screening process will be initiated to determine studies with relevance to one or more of the five key questions; categorize the data as “primary analytic research,” “systematic reviews” or “meta-analyses; and identify studies that are written in English.

Second, data will be extracted and synthesized into evidence tables in preparation of assessing the quality of the studies and performing meta-analyses. Third, preliminary recommendations will be formulated and experts will be identified to review the data. The guidance will be revised and finalized after the workgroup grades the strength of the evidence.

Dr. Stevenson presented a sample of the workgroup’s search strategy with the MEDLINE database. Based on a search of MEDLINE and five other databases as of February 7, 2008, the workgroup determined that 6,777 abstracts would need to be reviewed. However, the workgroup will exclude several studies based on the following criteria:

- The publication was not in English.
- The data contained a meeting abstract only with no publication of full text.
- The data could not be defined as “primary analytic research,” such as systematic reviews of analytic research; economic and meta-analyses; interventional studies; and prospective and retrospective observational studies, *i.e.*, cohort, case-control or analytic cross-sectional studies.

- The data were not relevant to one of the five key questions.
- The full text was published, but was not available for review.

Dr. Stevenson reviewed examples of quality scales that the workgroup identified to grade the strength of the evidence. For “randomized controlled trials,” studies would be described as randomized or double-blind. Randomization would be appropriately performed. Study participants, outcome assessors or investigators would be blinded. Attrition would be described, smaller than 10%-15% of assigned patients or appropriately analyzed, such as an intention-to-treat analysis for superiority studies.

For “cohort and case-control studies,” all study groups would be derived from similar sources and reference populations. Attrition would not be significantly different across all study groups. Measures of exposure and outcome would be valid. Investigators would be blinded to endpoint assessments. Potential confounders would be identified. Statistical adjustments for potential confounders would be performed.

HICPAC commended the workgroup for its outstanding efforts to date in developing the norovirus guideline. Dr. Stevenson confirmed that he would present another update on the workgroup’s progress during the June 2008 meeting. He recognized Dr. Rajender Agarwall, Ms. Gretchen Kuntz and Dr. Craig Umscheid, of the University of Pennsylvania Health System (UPHS) Center for Evidence-Based Practice, for their valuable contributions and tremendous efforts in supporting the development of the norovirus guideline. Dr. Stevenson emphasized that the UPHS team was primarily responsible for the workgroup achieving its goals to date.

### **Update on the Healthcare Worker (HCW) Vaccination Guideline**

Dr. Steven Gordon, a HICPAC member, serves as HICPAC’s liaison to CDC’s Advisory Committee on Immunization Practices (ACIP). He reported that HICPAC and ACIP are jointly modifying the healthcare worker (HCW) vaccination guideline. Although the guideline is not expected to undergo significant revisions, vaccination of HCWs will be recommended as one prevention strategy and the cost-benefit ratio of vaccination will be emphasized.

HICPAC extensively discussed the HCW vaccination guideline and noted several important issues that should be considered in revising the document, including:

- The tremendous impact and influence of the Occupational Safety and Health Administration (OSHA) on HCW vaccination.
- Issues and concerns related to HCW vaccination expressed by risk management and human resource departments in healthcare facilities.
- The disconnect between recommendations for HCW vaccination and actual implementation in hospitals.

- The critical need to offer vaccination to all HCWs.
- The significant benefits of adult vaccination.
- CDC's existing guidelines on HCW vaccination.
- Educational gaps in healthcare in general and the lack of education regarding vaccination among HCWs in particular.
- Uncertainties related to policy changes and economic analyses of HCW vaccination.
- The need for HICPAC and ACIP to issue strong recommendations in support of HCW vaccination.

Dr. Bell concluded the discussion by confirming that HICPAC would revisit the HCW vaccination guideline during the June 2008 meeting in an effort to resolve the issues raised by the members.

### **Update on the Catheter-Associated Urinary Tract Infection (CA-UTI) Guideline**

Dr. David Pegues, a HICPAC member, is leading the workgroup that was formed to update HICPAC's 1981 "Guideline to Prevent Catheter-Associated Urinary Tract Infections." He reported that after the June 2007 HICPAC meeting, the workgroup finalized three key study questions to guide the revision of the CA-UTI guideline:

1. Who should and should not receive urinary catheters?
2. For persons who might require urinary catheters, what practices decrease their risk of infection?
3. What are the best methods to manage urinary catheter-associated CA-UTI complications?

Dr. Pegues presented a sample of the workgroup's search strategy with the MEDLINE database. The number of CA-UTI references was 7,645 based on a search of the MEDLINE database. Based on the workgroup's exclusion criteria, however, the final number of references from the MEDLINE database was 5,332. The workgroup applied the same search strategy to other existing databases and determined that 8,065 abstracts would need to be reviewed after resolving duplicates.

Of 8,065 potentially relevant studies that were reviewed, 7,005 were immediately excluded based on title and abstract screening. Of the remaining 1,060 studies that were retrieved, reviewed and included for full text evaluation, 726 were further excluded based on the same criteria the Norovirus Workgroup used.

Dr. Pegues reported that the workgroup developed a working draft of the CA-UTI guideline. The current draft of ~134 pages includes 334 abstracts that are organized around specific themes and designed to answer the three key study questions. The 334 abstracts also will be used for data extraction or meta-analyses and abstraction into evidence tables. The workgroup is on target with its timeline to present draft recommendations on the CA-UTI guideline to HICPAC during the June 2008 meeting. The workgroup anticipates finalizing the recommendations and submitting the CA-UTI guideline for publication later in the summer of 2008.

Dr. Pegues asked for three to four HICPAC members who do not serve on the workgroup to independently review the evidence tables, summary of recommendations, grades assigned to the evidence, and the draft CA-UTI guideline. After the independent review by the HICPAC members, the workgroup will submit the CA-UTI guideline and evidence tables to three outside experts for an external review. Dr. Pegues concluded his update by acknowledging the outstanding efforts of the UPHS team in updating the CA-UTI guideline and producing the evidence tables.

Dr. Carolyn Gould, of DHQP, is a member of the CA-UTI Workgroup. She distributed and reviewed three sample evidence tables to provide HICPAC with representative data that the workgroup extracted and will use to grade the studies. For example, one evidence table was designed to determine whether one type of catheterization would be better than another and also to clearly distinguish between suprapubic and urethral catheterization. The two remaining sample evidence tables focused on meatal care and silver-coated catheters.

The workgroup created the evidence tables to obtain information in eight categories: (1) the author of the study and year of publication; (2) study design; (3) quality of the study using a number scale of 1-8 based on the study design; (4) objective of the study; (5) population and setting of the study; (6) number of trials included in the systematic review; (7) results and outcomes of the study; and (8) comments or points of interest by the workgroup that might impact the quality of the study.

Dr. Gould also reviewed examples of quality scales that the workgroup identified to grade the strength of the evidence for randomized controlled trials and cohort or case-control studies. The workgroup applied the same quality scales as those used by the Norovirus Workgroup.

Dr. Gould conveyed that the workgroup is proposing to use the "Grading of Recommendations, Assessment, Development and Evaluation" (GRADE) system to assign an overall grade to the full body of evidence for a given topic and also to evaluate the quality of individual studies.

The GRADE system is based on the study design and other factors that might increase or decrease the overall quality of the evidence base, such as the quality, consistency and

directness of the study. For example, a serious limitation in the quality of the evidence base might reduce the overall grade to “low” or “very low.” An observational study that is adjusted for all confounders might increase the overall quality of the evidence base from “low” to “high.”

The GRADE categories are defined as follows. A “high” grade indicates that further research is very unlikely to change the confidence in the estimate of effect. A “moderate” grade indicates that further research is likely to impact the confidence in the estimate of effect and also might change the estimate. A “low” grade indicates that further research is very likely to impact the confidence and estimate and also is likely to change the estimate. A “very low” grade indicates that any estimate of the effect is very uncertain.

Dr. Gould presented a table to illustrate the translation from HICPAC’s traditional ranking scheme to the GRADE system:

<u>HICPAC Ranking Scheme</u>		<u>GRADE System</u>
Category IA	=	“High” grade
Category IB	=	“Moderate” grade
Category IC	=	“High” to “very low” grade
Category II	=	“Low” to “very low” grade
No recommendation/unresolved issue	=	“Very low” grade

Dr. Umscheid joined the meeting by conference call to answer several methodological questions posed by HICPAC. The workgroup decided against including all of the primary studies due to the need to balance data from high-quality systematic reviews. Moreover, the workgroup determined that replicating >25 systematic reviews identified for the CA-UTI guideline would require several months.

The workgroup also agreed not to create a combined score for the studies because experts can passionately disagree on weighting grades for each criterion. Instead, the workgroup supported the current trend of describing specific factors that were used to judge criteria and clearly outlining the process in which each study included in the review met the criteria. The workgroup considered a number of factors in addition to the quality of individual studies, such as the capacity to generalize the evidence base for a particular question and the consistency of results across the evidence base.

Dr. Umscheid proposed a strategy in which HICPAC’s IC category could be reserved for strong recommendations that are mandated, but the quality of evidence for this guidance would be “low” to “very low.” HICPAC’s IA and IB categories could be used for recommendations that are mandated, but the quality of evidence for this guidance would be “high” or “moderate.” Alternatively, strong recommendations could be ranked as category I alone. “A” or “B” then could be added in parentheses after category I to clearly explain the quality of the evidence. Overall, Dr. Umscheid emphasized the need for HICPAC’s ranking scheme to be transparent to users.

HICPAC commended the workgroup for its outstanding efforts to date in developing the CA-UTI guideline and evidence tables. Several members made suggestions for the workgroup to consider in its ongoing efforts.

- The evidence tables should be released as both an appendix to the CA-UTI guideline and an electronic document that is posted on the HICPAC web site.
- Mandatory recommendations should be given a special rating and the name of the federal or state regulatory agency should be identified.
- The workgroup should revise its timeline for the two reviews by HICPAC members and outside experts to occur simultaneously.
- Strong recommendations and the quality of the evidence should be separated in HICPAC's ranking scheme for consistency with the GRADE system.

Dr. Denise Cardo, Director of DHQP, asked the HICPAC liaison and *ex-officio* members to assist in the review process by identifying potential problems with actual implementation of the evidence tables in the field. She noted that this proactive step could ease the official clearance process.

Dr. Brennan concluded the discussion by summarizing two key outcomes. First, a number of HICPAC members expressed an interest in serving as independent reviewers of the evidence tables and CA-UTI guideline. Dr. Brennan would engage in offline discussions with these members to confirm their participation and forward these names to Dr. Pegues. Second, HICPAC did not reach consensus on the modified GRADE system for the CA-UTI guideline that the workgroup proposed. Dr. Brennan confirmed that HICPAC would revisit this issue at a later time.

### Update on Mumps Isolation Precautions

**Dr. Jane Seward**, of the CDC Division of Viral Disease (DVD), explained that mumps are transmitted by respiratory droplets and saliva and are considerably less infectious than measles, varicella and pertussis. A study conducted in the United Kingdom in 1952 showed that household secondary attack rates for mumps among susceptible children <15 years of age were 31% compared to 61% for varicella and 72% for measles. The maximal infectious period for mumps is 2-3 days before to 2-3 days after onset of symptoms. However, virus has been isolated in saliva from seven days before to eight days after onset of illness in parotitis cases.

In the pre-vaccine era, mumps were an acute and self-limited illness that lasted ~4 days with an incubation period of 16-18 days, ranging from 12-25 days. Mumps were asymptomatic in 20%-30% of cases, but were more common in children than in adults. The clinical presentation of mumps includes parotitis in 60%-70% of cases or other salivary

gland swelling; orchitis or aseptic meningitis without parotitis; or non-specific or respiratory symptoms.

Morbidity from mumps in the pre-vaccine era included deafness, aseptic meningitis, orchitis and mastitis. Hospitalization was uncommon due to the short duration of the disease. Mortality was extremely rare except for the most serious complication of encephalitis. Overall, treatment for mumps is supportive.

In the current vaccine era, an effective live attenuated mumps virus vaccine is used for mumps prevention and control. The original mumps vaccination policy was one dose to children 1-4 years of age and low-risk adults. However, the policy was changed in 2006 in which two doses of mumps vaccine would be administered to children  $\geq 4$ -6 years of age, older persons and the following high-risk adults: HCWs, international travelers, and students in post-high school educational facilities.

From 1968-2007, implementation of the mumps vaccine program in the United States has resulted in >90% coverage among preschool students with one dose of the measles, mumps and rubella (MMR) vaccine and high coverage among adolescents with two MMR doses. The high coverage rates have resulted in an extremely low incidence of disease despite two resurgences of mumps in the 1980s and 2006. The mumps resurgence in 2006 resulted in 6,584 cases with the highest incidence of cases reported among persons 18-24 years of age.

Based on existing guidance, Iowa and other states used five days rather than nine days during the 2006 multi-state outbreak for isolation of mumps cases in community settings. Although some cases were reported among HCWs during the 2006 outbreak, no serious problems in healthcare settings were identified. CDC received numerous queries regarding isolation, precautions, exclusion and vaccination of mumps. Vaccine coverage of HCWs with one MMR dose was found to be sub-optimal.

Dr. Seward summarized changes in the previous and current guidelines for isolation and precautions for mumps. The previous guidance of nine days for case isolation in healthcare settings, exclusion of HCWs in patient care, and droplet precautions was not changed in the current guidance. The previous guidance of nine days for case isolation or exclusion in the community and exclusion of HCWs in ambulatory care settings was changed in the current guidance to five days. CDC has communicated these changes to immunization grantees and will soon release a "notice to readers" publication.

**Dr. Preeta Kutty**, of DVD, explained that mumps in healthcare settings have not been described as a problem with respect to healthcare infections. Even in the past when vaccine coverage in HCWs was low, transmission of mumps in HCWs was rarely described. In patients, mumps have not been described as a more severe disease in immunocompromised populations, including children with acute lymphoblastic leukemia. The published literature does not contain reports of mumps in healthcare settings, including



intensive care units (ICUs), pediatric ICUs, high-risk nurseries, transplant centers, burn units, long-term care facilities (LTCFs) or ambulatory care facilities.

The published literature describes a hospital survey that was conducted in 1986-1987 during a community-wide mumps outbreak in Tennessee. The survey was administered to infection control practitioners (ICPs) in 154 hospitals throughout the state of Tennessee. Of 146 responding hospitals, 7.5% reported that susceptible employees were not immunized with mumps vaccine.

In the 11 affected hospitals, 15 HCWs developed mumps without a known hospital exposure. The majority of the HCW cases were from household contacts with no transmission in the hospital setting. In three different hospitals, six HCWs developed mumps following exposure to patients. In two LTCFs, nine adolescent patients who contracted mumps while hospitalized had substantial contact with the community.

Limited data have been collected on transmission of mumps, but evidence suggests that transmission may occur from asymptomatic infections during the prodromal phase of illness or sub-clinical infections. The mumps virus in saliva or respiratory secretions is relevant to transmission. Viral isolation and viral load are considered to correlate with the risk of transmission. Of eight studies that were conducted from 1934-2008 on the isolation of mumps virus from saliva specimens with the number of participants ranging from 1-60, only four detected mumps virus within five days.

A study that was published in 2005 on the viral load of mumps used a rapid diagnostic method for detection of mumps virus. The study showed that the viral load dramatically decreased over the first four days of natural infection and was extremely low thereafter. Four key strategies are typically implemented for the prevention of mumps transmission in healthcare settings.

Cases are isolated or excluded by isolating patients and restricting work responsibilities of HCWs. HCWs are excluded from work following exposure. Isolation precautions are applied, including standard precautions for all patients in all healthcare settings for the duration of the hospital stay; respiratory hygiene and cough etiquette; and droplet precautions for transmission-based mumps. Vaccination is administered prior to exposure to ensure that HCWs have evidence of immunity to care for a case.

The 2006 mumps outbreak presented a number of challenges in implementing isolation precautions in the community. A study that is currently in press showed that of 183 students at a Kansas university with suspected mumps, 132 requested to stay isolated. The multivariable analysis was significant and demonstrated that students who were isolated for 1-4 days were three times more compliant than those who were isolated for 5-9 days.



Of 48 students who were advised to remain isolated for nine days, 65% fully complied for nine days and 98% fully complied for at least four days. Outcomes at the Kansas university and other affected academic institutions throughout the country played a significant role in changing the guidance from nine to five days for isolation or exclusion of mumps cases in the community and exclusion of HCWs in ambulatory care settings.

The effectiveness of patient isolation in healthcare settings in the prevention of mumps transmission has been well documented. A study that was published in 1968 showed that mumps was contagious before onset of parotid swelling among 15 exposed children. All of the children were infected despite the isolation of all cases. A study that was published in 1996 demonstrated that the isolation of patients was not an extremely effective measure to prevent subsequent cases. The study showed that secondary cases became infected before a diagnosis of the index case due to asymptomatic patients. The study concluded that adequate vaccination of HCWs was the best preventive strategy.

Dr. Kutty summarized the current guidelines for the prevention of mumps transmission in healthcare settings. HCWs with mumps should be excluded from duty for nine days after onset of parotitis. HCWs exposed to a mumps case should be excluded from duty for 12-26 days following exposure. Three precautions should be taken for HCWs who care for a mumps case: (1) standard precautions of respiratory hygiene and cough etiquette for the duration of the hospital stay; (2) droplet precautions for nine days; and (3) no care given by HCWs without evidence of immunity if immune caregivers are available.

Pre-exposure vaccination is the optimal method for prevention of exposure to and transmission of mumps virus. In 2006, ACIP revised the mumps vaccine policy for HCWs from one to two doses of MMR vaccine. Five important factors have been identified to support the proposed change in isolation and precaution guidelines for mumps.

Even in immunocompromised patients, mumps is not a particularly severe disease. Contagiousness is low with maximum viral shedding before the onset of symptoms. Mumps has not been described as a nosocomial disease problem. Isolation has not been an effective tool for preventing transmission in hospital settings. The low risk of transmission after five days questions the need to maintain droplet precautions for nine days. For example, isolation and precautions for five days in the United Kingdom have not resulted in documented problems with healthcare-associated mumps infections.

Based on these factors, CDC is proposing to change the guidelines for mumps isolation and precautions from nine days to five days in healthcare settings. CDC's rationale to support this change is based on three key factors. Difficulties are anticipated in releasing different isolation guidelines for community settings and inpatient/outpatient healthcare settings. State epidemiologists and health departments have expressed concerns regarding different guidelines for community and healthcare settings. A common isolation guideline would be preferable and less confusing to implement in the field.

Drs. Kutty and Seward answered a number of questions posed by the HICPAC members regarding the proposed change in the guidelines for mumps isolation and precautions from nine days to five days in healthcare settings. Questions by the HICPAC members focused on the following issues:

- the availability of data on the dynamics between persons who receive one versus two doses of the mumps vaccine;
- the specific length of time that HCWs who are exposed to a mumps case would be excluded from patient care in the revised guidelines;
- the strength of the evidence to support the new recommendation for mumps isolation and precautions for five days, particularly since ~20% of individuals shed the virus on days 6-7;
- actions that would need to be taken to administer a second MMR dose to HCWs; and
- the need to hold HCWs who work in inpatient settings to a higher standard.

Several HICPAC members supported the proposed change in the guidelines for mumps isolation and precautions from nine days to five days in healthcare settings. In terms of patient management, the HICPAC members noted that rarely would mumps patients in the pediatric population and other age groups remain in the hospital for nine days.

The HICPAC members also pointed out that the mumps virus does not appear to cause more severe disease in immunosuppressed patients. The HICPAC members generally agreed that the proposed change in the guidelines most likely would not result in extra risk of mumps transmission in healthcare facilities. Overall, a number of HICPAC members found the current nine-day period to isolate HCWs with mumps to be excessive.

The HICPAC members made two key suggestions for CDC to consider in revising the current mumps guidelines. First, patient care and ambulatory care should not be separated in the revised guidelines. Second, a thorough evaluation should be conducted after the revised guidelines are implemented in the field to determine if compliance is solid at four days.

Dr. Brennan informed Drs. Kutty and Seward that HICPAC meetings are organized for the members to listen to presentations and updates on day 1 and vote on issues on day 2. He confirmed that on the following day, HICPAC would revisit the issue of whether to approve the proposed change in the guidelines for mumps isolation and precautions from nine days to five days in healthcare settings.

## Update by the HICPAC Policy Workgroups

Dr. Brennan announced that following the November 2007 meeting, HICPAC formed workgroups to focus on three policy issues: (1) the Deficit Reduction Act (DRA) to decrease payments for reasonably preventable conditions occurring in hospitals; (2) model legislation at federal and state levels related to healthcare-associated infections (HAIs); and (3) surveillance peer review.

**Model Legislation Workgroup.** Dr. Bell reported that a number of HICPAC members expressed concerns during the November 2007 meeting about replicating ongoing activities related to the development of model legislation for public reporting. However, a need exists for HICPAC to create examples of model legislation to specifically address methicillin-resistant *Staphylococcus aureus* (MRSA).

CDC is aware that an increasing number of areas are attempting to pass legislation for public reporting of MRSA. HICPAC's role in this effort could be to provide its expertise in infection control and healthcare epidemiology. The overarching goal of HICPAC's involvement would be to create a model to guide legislators in considering useful outcomes that would be beneficial to the prevention of both MRSA and other HAIs.

Dr. Tammy Lundstrom is representing HICPAC on the Model Legislation Workgroup. During offline discussions with Dr. Bell, the possibility was raised of expanding model legislation for MRSA to broadly include multidrug-resistant organisms (MDROs). Dr. Lundstrom mentioned that the focus should not be placed on MRSA or any other specific organism because hospitals are reporting problems with other gram negative-resistant organisms and the science is rapidly changing.

Dr. Lundstrom reported that she and Dr. Bell also discussed the need to review the APIC/Society for Healthcare Epidemiology of America (SHEA) model legislation to determine whether this document could be modified for HICPAC's purposes.

Dr. Cardo made a number of clarifying remarks to guide the discussion. HICPAC's efforts in developing model legislation for public reporting must be coordinated with the Council of State and Territorial Epidemiologists (CSTE) and the Association of State and Territorial Health Officials (ASTHO) because states have asked these two groups to provide guidance in this area. Moreover, HICPAC's engagement of CSTE and ASTHO would ensure that a unified voice would be presented and inconsistencies in guidance would be minimized.

Dr. Cardo explained that HICPAC's role in this activity would be to develop "ideal" model legislation for states based on guiding principles from the public reporting document. However, the model legislation would not serve as an evidence-based HICPAC guideline to advise states and organizations on appropriate actions to take in public reporting of HAIs.

Instead, HICPAC's model legislation would serve as CDC's response to requests for guidance by CSTE, ASTHO, states and other organizations.

Dr. Cardo proposed another option for HICPAC to consider. Instead of developing model legislation for public reporting, HICPAC could provide states with a list of guiding principles that should be considered while creating legislation. The "guiding principles" document could be designed as a simpler version of the public reporting document. For example, expanding the guiding principles document to include MDROs would complicate the overall process and would not provide clear guidance to states and professional associations that are requesting advice from CDC at this time.

Dr. Cardo cited an example of HICPAC's previous impact on legislation to further emphasize the need for its involvement in this effort. The majority of public reporting bills that were passed did not contain language on the need to include ICPs, healthcare epidemiologists and other relevant experts. However, 90% of the bills were revised to include this language after HICPAC's public reporting document was released.

Ms. Denise Graham, of APIC, conveyed that similar to other organizations, APIC also would solicit HICPAC's expertise and guidance on MRSA laws and pending public reporting legislation. She noted that seven states are intending to make MRSA reportable and another eight states are reviewing legislation to possibly make *Clostridium difficile* and vancomycin-resistant *Enterococcus* reportable. Ms. Graham pointed out that HICPAC could assist APIC and other professional associations in guiding collaborative efforts between ICPs and legislators.

Several members commented on the possibility of HICPAC developing and distributing model legislation or guiding principles for public reporting of HAIs.

- HICPAC should consider the significant unintended consequences of public health authority over healthcare facilities. For example, MRSA as a reportable disease would be disastrous in some states due to the absence of resources to handle the myriad of laboratory reports and the lack of capacity to react to these reports with control measures that are known to be effective.
- HICPAC should develop and disseminate guiding principles or specific language that should and should not be included in model legislation. HICPAC's guidance would be extremely helpful because legislators are asking some states to provide a strategy to measure HAI rates. HICPAC's guiding principles also could be used to present more information to legislators and other policymakers to assist in the decision-making process of public reporting of HAIs at the state level.
- HICPAC and CDC should publish an article on public reporting of HAIs in a peer-reviewed journal because this approach would have a much greater impact than proposing model legislation.

- HICPAC should determine whether evidence exists to support the effectiveness of mandatory reporting or active surveillance culture in protecting patients and improving health in the community. Based on these findings, HICPAC should compile current evidence and knowledge to develop and disseminate models of successful interventions rather than model legislation. Model legislation might eliminate flexibility within individual healthcare facilities that do not have problems with MRSA or other specific pathogens at this time.
- HICPAC should reconsider its involvement in developing model legislation due to its charter to advise the HHS Secretary and CDC Director. A more effective approach might be for public policy committees of APIC, SHEA, CSTE and other professional associations to aggressively assist state legislators in understanding problems with public reporting of HAIs.

On the one hand, Dr. Bell appreciated and understood the concerns that some HICPAC members raised regarding the development of model legislation. He was aware of the discomfort of several members in venturing outside of HICPAC's expertise of providing advice and evidence-based recommendations to the HHS Secretary and CDC Director on infection control practices in healthcare settings. He also recognized that a number of members noted HICPAC's lack of experience in developing model legislation.

On the other hand, Dr. Bell emphasized that a number of groups and individuals are developing public reporting legislation without the benefit of HICPAC's expertise and experience in this area. He reiterated that HICPAC's guidance would be extremely beneficial to states and professional associations. To resolve this dilemma, he proposed that HICPAC develop an overarching framework for model legislation as a test case, such as "HICPAC's five major points to consider in the development of public reporting legislation."

Dr. Brennan concluded the discussion by outlining HICPAC's next steps in developing a framework for model legislation. HICPAC would engage CSTE, ASTHO, the lead authors on the SHEA/APIC model legislation, and CDC's policy and legal experts in developing a framework for model legislation of public reporting. Dr. Lundstrom would continue to represent HICPAC in this effort. The workgroup would present a progress report during the June 2008 meeting.

**HAI Preventability Workgroup.** Dr. Bell reported that HICPAC's role in this effort would be to take a prospective approach in developing HAI preventability guidance as a result of the following phrase being inserted into the DRA: "The Centers for Medicare and Medicaid Services (CMS) will not reimburse for infections that could reasonably have been prevented by applying existing guidelines."

Dr. Bell outlined two key parameters for HICPAC's HAI preventability guidance. The guidance would be designed to ensure that hospital epidemiology, infection control,

laboratory sciences, and existing publications and other data are taken into account during the decision-making process by CMS of decreasing payments for reasonably preventable conditions occurring in hospitals. The guidance would be designed to provide a percentage or range of preventable HAIs that would be transparent to users based on existing data, but specific recommendations would not be given.

Dr. Brennan is representing HICPAC on the HAI Preventability Workgroup with outside assistance from UPHS. Dr. Umscheid, of UPHS, rejoined the meeting by conference call and noted that a table was distributed to HICPAC as an example of the extent to which HAIs are reasonably preventable. For purposes of the table, CA-UTIs were selected as the HAI and data were extracted from the SHEA/Infectious Disease Society of America (IDSA) guideline. The table was designed to illustrate the best-case and worst-case scenarios for the incidence of CA-UTIs in hospital populations.

The intervention arm of randomized controlled trials showed the lowest incidence of CA-UTIs or the best-case scenario. The control population in randomized controlled trials showed a median of CA-UTIs. Results from retrospective cohort studies or data registries served as the worst-case scenarios because the incidence of CA-UTIs was only counted in particular hospital populations. The table also demonstrated that the incidence of CA-UTIs would be higher when infection outcomes were measured as surrogates, such as bacteriuria or symptomatic UTIs.

Dr. Cardo emphasized the need to bundle several strategies instead of assessing a specific intervention because the impact would not be as high, particularly for BSIs. In addition to traditional infections, such as BSIs and ventilator-assisted pneumonia (VAP), she encouraged the workgroup to also focus on events that should never occur, such as the reuse of needles and inappropriate application of basic infection control practices.

Dr. Brennan's position was that HICPAC should take advantage of existing opportunities to rapidly inform the CMS process by identifying the best performance under the best outcomes, including both bundled and specific interventions. He was in favor of HICPAC using these findings to develop and release a short report on HAI preventability over the next few months.

Dr. Chesley Richards, Deputy Director of DHQP, further clarified that HICPAC's role in developing HAI preventability guidance would be to provide a realistic view to CMS of reasonably preventable HAIs from either a patient or facility perspective.

Several members commented on the possibility of HICPAC developing and distributing HAI preventability guidance.

- The workgroup should review other recent studies that have focused on the preventable proportion of HAIs, such as the 2003 published paper in the *Journal of Hospital Infection*.



- The workgroup should expand its focus from HAI preventability to include guidance that would assist institutions in conducting a statistically significant risk assessment or hazard analysis to prevent HAIs.
- The workgroup should take a proactive approach by reviewing CMS's list of reasonably preventable HAIs that are being proposed for inclusion in the next cycle.

Dr. Brennan concluded the discussion by confirming that HICPAC would revisit its involvement in the development of HAI preventability guidance on the following day after Dr. Richards' presentation.

**Surveillance Peer Review Workgroup.** Dr. Bell reported that Dr. Russell Olmsted is representing HICPAC on the Surveillance Peer Review Workgroup. HICPAC's role in this effort will be to assist CDC in responding to a requirement to conduct peer reviews of its programs on a regular basis. Surveillance activities will be the first program that will be peer reviewed in DHQP.

Dr. Daniel Pollock, Branch Chief of DHQP's Surveillance Program, presented background information on this initiative. DHQP will convene an external peer review of its surveillance activities on May 13-14, 2008. In addition to Dr. Olmsted's leadership in chairing the peer review panel, DHQP also will invite 6-9 other peer reviewers with expertise in infection control, hospital epidemiology, patient safety measurement and monitoring, state and federal public health, and informatics/information technology (IT).

The peer review panel will be charged with evaluating the following areas:

- DHQP's surveillance activities in the context of public reporting.
- The rapid surge in the use of the National Healthcare Safety Network (NHSN) by >1,100 hospitals in 40 states.
- The patient safety component of NHSN.
- NHSN's adequate or inadequate coverage of HAIs.
- The potential need for NHSN to cover additional events due to possible gaps.
- DHQP's capacity to meet expectations by using NHSN as a tool to enable public reporting.
- DHQP's working relationships with federal and state agencies.
- DHQP's use of IT in surveillance activities.
- DHQP's migration path to greater use of electronic data.

Dr. Pollock outlined the steps and timeline of the external peer review process. DHQP will provide the peer review panel with background information in advance of the site visit. DHQP will make presentations and answer questions posed by the peer review panel during the site visit. The peer review panel will engage in closed deliberations in the absence of DHQP staff to begin developing conclusions and recommendations with assistance from a technical writer.

The peer review panel will reach consensus on the final draft report and submit the document to DHQP in June 2008. Dr. Olmsted will update HICPAC on the report of the peer review panel during the June 2008 meeting. DHQP will use the recommendations and findings of the peer review panel to inform its surveillance activities, strategic planning and other programmatic efforts in the future.

### Liaison and *Ex-Officio* Reports

**Ms. Rachel Stricof** reported on key topics that were discussed during the meeting of the Advisory Council for the Elimination of Tuberculosis (ACET) in November 2007. ACET noted that extensively drug-resistant TB (XDR-TB) demonstrated the lack of a clear and consistent legal framework to address potential public health threats. As a result, ACET advised CDC to evaluate a sample of key statutory, regulatory and subsequent case laws at state and local levels to determine best practices and develop model legislation.

ACET advised CDC to conduct a more thorough review of the recent literature to develop a BCG statement or guidance for international travelers. CDC recommended using the "AZT" model in which AZT post-exposure prophylaxis was considered for HCWs with occupational exposure.

ACET emphasized that drug susceptibility testing for second-line anti-TB drugs is an imperative at both national and global levels. CDC presented data to illustrate the small number of laboratories in the United States that perform testing on second-line drugs. These findings emphasized the need to (1) ensure access to rapid and comprehensive second-line drug testing; (2) review quality standards and proficiency testing programs; and (3) improve current practices, methods and algorithms to rapidly detect drug resistance.

**Dr. William Baine** reported that the Agency for Healthcare Research and Quality (AHRQ) will soon publish a notice of proposed rulemaking in the *Federal Register* for public comment on the Patient Safety and Quality Improvement Act of 2005. The proposed rulemaking will include language on HAIs in the context of patient safety.

The Senate Appropriations Committee earmarked one-year funding of \$5 million in FY'08 for AHRQ to use in reducing MRSA and related infections. AHRQ issued a task order to six hospitals to focus on data entry and other strategies to improve data reporting capacity in radically reducing MRSA.

**Ms. Roslyn Schulman** reported that the American Hospital Association (AHA) will continue to convene its successful series of hospital conference calls with CDC experts in 2008 to improve hospital infection control activities.



AHA is supporting the reporting of Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measures on patients' experiences with care as a part of updating the public/private Hospital Compare web site. AHA's position is that hospitals can use HCAHPS measures to support quality of care improvements. AHA will provide technical assistance to help hospitals in improving HCAHPS scores.

AHA sent a letter to the HHS Secretary regarding the decision by the HHS Office for Human Research Protections (OHRP) to halt data collection for the Michigan Health and Hospital Association's Keystone Project until all participating hospitals obtained Institutional Review Board (IRB) approval.

AHA asked the HHS Secretary to retract any of OHRP's statements that implied quality improvement efforts should undergo IRB review and consent should be obtained from all patients before changes could be incorporated. AHA's letter also pointed out the need for collaborative efforts to assure the protection of patient privacy and ensure that the welfare of patients remains the central concern.

**Dr. Mark Russi** reported that the American College of Occupational and Environmental Medicine (ACOEM) will publish its revised Practice Guidelines in the spring of 2008 on medical treatment and rehabilitation of common workplace injuries. ACOEM's revised guidelines will serve as the standard of care in a number of states.

ACOEM will hold its annual spring meeting in New York City on April 11-16, 2008. Key topics that will be covered during the meeting include emerging infection issues in medical centers and laboratories, toxicology, occupational lung diseases, pandemic influenza, XDR-TB, and medical center occupational health and safety.

ACOEM recently endorsed the National Foundation for Infectious Diseases "Call to Action" regarding administration of influenza vaccine to HCWs. ACOEM is continuing its strong support of robust, multifaceted and voluntary programs that address the range of barriers known to affect compliance with influenza immunization. ACOEM is aware that these types of initiatives have yielded vaccination rates in excess of 75%. However, ACOEM does not support mandatory vaccination of HCWs and remains unconvinced of the utility of declination statements.

**Ms. Joan Blanchard** reported that the Association of periOperative Registered Nurses (AORN), APIC and SHEA convened the "12<sup>th</sup> Conference on Infectious Disease" in December 2007. Key topics that were covered during the conference included worldwide health and infectious diseases, "HAI myths," MDROs, use of allograft tissues, pandemic influenza, infection control and prevention success stories, bundling for prevention of BSIs, urology practices, probiotic use, the impact of new technologies and practices on patient safety, and the growing use of rapid diagnostics in infection control.

The “2008 AORN Standard, Recommended Practices and Guidelines” book was released with updates on recommended practice in a number of areas, including environment of care, skin preparation, electrosurgery, sterilization, prevention of hypothermia, positioning, moderate sedation, and environmental care and cleaning of instruments and powered equipment. AORN plans to release updates on other recommended practice in 2008, such as fluid management, hand scrubs, transfer of care, endoscope cleaning and processing, disinfection, laser safety, and anesthesia equipment cleaning and processing.

AORN will hold its 55<sup>th</sup> Congress in Anaheim, California in March 2008. AHRQ, CDC and other groups will make a number of infection prevention and control presentations during the conference. AORN is currently developing a perioperative electronic health record and expects to complete this activity over the next two years for implementation in the field.

**Ms. Nancy Bjerke** reported that APIC launched its “Targeting Zero” initiative in January 2008 as part of the emerging culture of zero tolerance for non-compliance with the prevention of HAIs. A series of educational innovations aimed at eliminating HAIs will be targeted to APIC’s membership and healthcare institutions. APIC programs will provide ICPs with a comprehensive package of education, research and guidance.

APIC added two new links to its web site: (1) [www.skinisthesource.org](http://www.skinisthesource.org) provides tips to avoid or reduce the risk of acquiring infection and (2) [www.strikeoutinfection.org](http://www.strikeoutinfection.org) provides the public with an empowerment resource on additional infection prevention. APIC held its Annual Leadership Orientation and Board Meeting the week of January 2008.

APIC recently convened a conference call with several of its partners to discuss the consolidation of the former “Hospitals for a Healthy Environment.” This initiative was launched to advance voluntary and non-profit efforts in greening healthcare facilities. The project resulted in the development of a document that addresses green operations within healthcare institutions.

APIC plans to inform Practice Greenhouse about its concerns with the document because some of the recommendations are inconsistent with existing federal guidance on reducing the risk of infection transmission in healthcare settings. For example, the document opposes the use of disinfectants, alcohol rubs for hand washing, antiseptics and other products in healthcare settings that are not environmentally friendly or do not support global greening efforts. The Practice Greenhouse Workgroup did not engage healthcare clinicians or other subject matter experts in developing the green guidance.

Dr. Brennan confirmed that on the following day, HICPAC would revisit the issue of whether to formally provide scientific and expert guidance on greening healthcare facilities before the Practice Greenhouse document is publicly released.

**Dr. Nalini Singh** reported that the Coordinating Center for Infectious Diseases Board of Scientific Counselors (BSC) has not held a meeting since its October 2007 meeting.

However, the BSC convened a conference call earlier in the day to discuss CDC's FY'08 budget of \$6.4 billion, representing \$125 million over the FY'07 budget.

Of CDC's total appropriation, \$1.86 billion will be allocated to various infectious disease programs, including global health, terrorism, pandemic influenza, TB, and zoonotic, food-borne and vector-borne diseases. Of the \$1.86 billion appropriation for infectious disease programs, \$2.3 million in level funding will be allocated to NCPDCID, but this amount actually represents a decrease.

Other topics the BSC discussed on the conference call included a strategic planning proposal to address CDC's health protection goals. The BSC will hold a follow-up conference call on February 12, 2008 for CDC to discuss its involvement in various outbreaks and other topics. A number of NCPDCID centers and divisions are expected to present short-term priorities during the BSC's next meeting in May 2008.

The conference call also provided CDC with an opportunity to inform the BSC about its ongoing activities in several areas: (1) collaborative efforts with ten external partners; (2) appointments of key senior positions at the national center level; (3) enhancement of core laboratory capacity in Asia; (4) CDC's development of algorithms to respond to outbreaks with unknown etiology; and (5) a visit to Thailand by CDC leadership, including Dr. Julie Gerberding, Director of CDC, to discuss administration of the influenza vaccine to high-risk individuals.

**Ms. Lisa McGiffert** reported that Consumer's Union (CU) is continuing to respond to the growing public interest in MRSA and other HAIs. CU will monitor Congressional activity regarding HAIs and medical device-related infections during the spring of 2008. CU is aware that HAIs are becoming the focus of many state-based patient safety committees.

CU filed a petition with the Food and Drug Administration (FDA) in response to direct-to-consumer advertisements regarding implantable devices. CU's petition asked the FDA to require the inclusion of information on the risk of infection and the life span of the devices in direct-to-consumer advertisements.

**Dr. Marion Kainer** reported that CSTE is continuing to provide advice to states on federal legislation of HAIs. CSTE has emphasized the need to review the MDRO measurement guideline in terms of potentially using the document to inform reporting of MRSA.

CSTE will convene its annual conference on June 9-12, 2008 in Denver, Colorado. Sessions on MRSA and mandatory public reporting of HAIs will be offered during the conference. CSTE has been engaging in discussions with a number of partners regarding concerns about OHRP's policy on public health surveillance.

**Dr. Sheila Murphey** reported that FDA published a public health notification on October 31, 2007 entitled, "Avoiding Hazards with Using Cleaners and Disinfectants on Electronic

Medical Equipment.” The notification was a joint communication among FDA, CDC, OSHA and the U.S. Environmental Protection Agency. The notification also will be published as a note in the *Morbidity and Mortality Weekly Report* on February 15, 2008.

In December 2007, CDC notified FDA about its investigation of reports of two clusters of *Serratia* BSIs in Illinois and Texas. FDA posted a recall notice on its web site for pre-filled heparin lock flush syringes and normal saline IV flush syringes. FDA is continuing its extensive investigation of allergic reactions to heparin.

On January 11, 2008, FDA published a *Federal Register* notice announcing its intent to extend the public comment period on the Proposed Rule to establish regulations for blood and blood components until August 4, 2008. FDA’s Vaccines and Related Biological Products Advisory Committee will hold a public meeting on February 20-21, 2008 to discuss the rotavirus and influenza vaccines.

**Dr. Robert Wise** reported that the Joint Commission’s new president named infection control as one of his top two priorities for 2008-2009. The Joint Commission is continuing its participation on the HAI-Allied Task Force with IDSA, SHEA, APIC and AHA to compile existing evidence for guidelines on six BSIs. In April and May 2008, the guidelines will be publicly released through a news conference, posted on the SHEA web site, and published in *Infection Control and Hospital Epidemiology (ICHE)*.

Based on activities by the HAI-Allied Task Force, the Joint Commission is proposing three new HAIs related to National Patient Safety Goals (NPSGs): (1) epidemiologically important organisms, including MRSA and *Clostridium difficile*-associated disease (CDAD), (2) CA-BSIs, and (3) surgical site infections (SSIs). The proposed NPSGs were forwarded to the field for review and will be in effect on January 1, 2009 for hospitals and other applicable programs if approved. Joint Commission Resources published three infection-related books over the past year.

In response to HICPAC’s concerns regarding the proposed NPSGs for MRSA and CDAD, Dr. Brennan confirmed that he and Dr. Bell would coordinate a response to the Joint Commission.

**Dr. David Henderson** reported that the National Institutes of Health (NIH) is continuing its activities with two partners on the Bethesda Hospitals’ Emergency Preparedness Partnership (BHEPP). To date, BHEPP has completed three major collaborative drills and received a second infusion of funds from Congress for the FY’08 budget. BHEPP will use this funding for two major activities: (1) procure equipment and supplies to respond to emergent situations and (2) conduct a transportation feasibility study to determine options for assuring open transportation routes among the three partners.

NIH experienced a substantial case-cluster of multi-drug-resistant *Acinetobacter baumannii* infections beginning in May 2007. NIH simultaneously implemented several interventions to

resolve the outbreak, but the presence of an isolation monitor was found to be associated with the decline in cases. NIH has not identified any new isolates since December 4, 2007. NIH awarded a contract to a vendor following an open competitive process to develop an IT system to support hospital epidemiology and patient safety. NIH hopes to have the new IT system functioning by the summer of 2008.

**Dr. Lisa Maragakis** reported that SHEA offered scientific expertise to proposed revisions on the Institute for Healthcare Improvement's guidelines and patient materials addressing MRSA and central line and ventilator bundles. SHEA is continuing to collaborate with IDSA on making final revisions on guidelines for six HAIs. The executive summary, guideline and CDC's accompanying MDRO paper will be published as a supplement to *ICHE* in May or June 2008. SHEA is developing materials for patients and families related to the guidelines.

SHEA and APIC are continuing to partner on the "Building Healthcare Capacity Communications Network." This initiative was designed for SHEA and APIC members to provide a network for the distribution and collection of routine and emergency information. SHEA offered extensive comments to Congressional staff on evolving legislative proposals related to HAIs.

SHEA is continuing to participate in bimonthly conference calls with APIC, CSTE and IDSA to develop joint policy statements and coordinate efforts to influence the outcome of public policy issues regarding infection control in healthcare settings. SHEA and several of its partners participated in a meeting of the HAI Coordinating Council in November 2007 to jointly consider common positions on policy and research issues, identify research priorities, and determine potential areas for joint policy communication.

SHEA will convene its 18<sup>th</sup> Annual Scientific Meeting on April 5-8, 2008 in Orlando, Florida. SHEA will sponsor an epidemiology training course on April 25-29, 2008 in Arlington, Virginia. SHEA and two of its partners are finalizing an agreement to convene the 2010 Decennial in Atlanta, Georgia.

**Dr. Stephen Kralovic** reported that the Veterans Administration (VA) is a nationally distributed healthcare system with >150 medical centers, >120 nursing homes, a resident transition program, and an active home-based primary care program. In 2007, VA served >6 million persons in the system with its workforce of >220,000 employees.

VA recently relocated sterile processing activities to its Infectious Disease Program Office. VA began year 2 of its MRSA Prevention Initiative in January 2008. All of VA's acute care facilities and acute care units are operating the MRSA program. VA is taking initial steps to develop a standardized protocol for all VA facilities to create and report HAIs with electronic health records. VA is continuing its activities to improve infection control in LTCFs, such as taking inventories nationwide at nursing home facilities and administering two National Point Prevalence Surveys.

With no further discussion or business brought before HICPAC, Dr. Brennan recessed the meeting at 5:25 p.m. on February 11, 2008.

### Update on the SHEA/IDSA Guidelines

Dr. Brennan reconvened the HICPAC meeting at 9:15 a.m. on February 12, 2008 and reported that SHEA and IDSA are jointly developing guidelines on six HAIs: CA-UTI, MRSA, SSIs, VAP, *C. difficile* and central line-associated BSI (CLABSI). At this point, the guidelines have been extensively reviewed by the authors, SHEA and HICPAC and also have undergone a comprehensive vetting process.

Dr. Brennan reminded the members that HICPAC convened a conference call in January 2008 to review the latest iteration of the SHEA/IDSA guidelines and discuss its formal position on the documents. He reviewed the key outcomes of the conference call. HICPAC reaffirmed its inability to formally endorse the guidelines, but approved the overall guideline development process. HICPAC recommended changes to the content of the guidelines. HICPAC agreed to produce an editorial to accompany the guidelines.

Dr. Brennan summarized key points from HICPAC's editorial that is currently being drafted and will be published in *ICHE*.

- The editorial provides background information.
  - Changes in hospital settings have been dramatic over time in terms of patient populations, new technologies and other areas.
  - Comparisons of outcomes and risks in hospital settings between previous and current eras are faulty.
  - Infection risk or best practices to prevent infections are not fully known at this time, but problems are more prevalent in the implementation of guidance and sustainability of achievements in practice rather than the strength of the evidence.
- The editorial describes HICPAC's lengthy process to produce and release HHS/CDC guidelines.
  - For each guideline, HICPAC must research the literature, develop an initial draft, review numerous iterations, solicit public comment and publish the document.
  - Each HICPAC guideline must undergo this arduous process to ensure that the recommendations are evidence-based, consistently evaluated and weighted.
- The editorial contains laudatory remarks for the SHEA/IDSA guideline development process.



- The SHEA/IDSA recommendations are a remarkable collection of highly relevant guidelines that are compiled in a concise and easily applied format.
  - The timing of the SHEA/IDSA recommendations and the collection of data from respected sources are to be commended.
  - SHEA and IDSA have developed concise, succinct and much needed recommendations in a timely fashion.
- The editorial contains cautionary language.
    - Efforts to gather solid evidence on HAIs are difficult because data in this field are typically collected through multiple interventions rather than randomized controlled trials.
    - The SHEA/IDSA recommendations will be released at a time of ongoing or upcoming updates and reviews, particularly HICPAC's CA-UTI guideline.
    - Multiple guidelines should be accounted for in future updates of guidance documents.

Dr. Brennan concluded his summary by confirming that the final draft of the editorial would be distributed to HICPAC for review and comment before publication in *ICHE*.

Dr. Pegues is representing HICPAC on the task force to develop the SHEA/IDSA guidelines. He noted that HICPAC's major criticisms of the guidelines were (1) the lack of transparency in the process used to grade the recommendations; (2) strengths or weaknesses of the evidence resulting in recommendations with "high" grades; and (3) inaccuracies in the NHSN definitions.

Dr. Pegues pointed out that HICPAC agreed not to formally endorse the guidelines based on its reservations of these important issues. Although HICPAC expressed numerous concerns about the SHEA/IDSA guidelines, Dr. Pegues conveyed that the members believed the documents would still be tremendously useful to ICPs.

Dr. Cardo confirmed that she would contact CMS to clarify implementation of the SHEA/IDSA guidelines as HHS policy. The purpose of her discussion with CMS would be to avoid confusion resulting from various groups producing guidance documents. Because HICPAC advises both the CDC Director and HHS Secretary, she explained that HICPAC guidelines serve as official CDC and HHS guidance on infection control practices in healthcare settings.

As an example of the potential for confusion, Dr. Cardo pointed out that actual NHSN definitions are included in the SHEA/IDSA guidelines. However, a link should be provided to CDC due to the evolving nature of NHSN definitions. Dr. Cardo planned to reiterate CDC's support of the SHEA/IDSA guideline development process, but she also would emphasize to CMS that the SHEA/IDSA guidelines should not be viewed as a replacement

for HICPAC guidelines. She added that confusion with guidelines in the past was used as an excuse for non-compliance with or complete disregard of recommendations.

Dr. Bell agreed with Dr. Pegues that the SHEA/IDSA guidelines are extremely useful products. Recent publications were included and the guidance is targeted to clinicians who will apply the recommendations at the bedside. The SHEA/IDSA and HICPAC guideline development processes are somewhat complimentary. Moreover, the SHEA/IDSA guideline process reinforces the deliberate public evaluation of the strength of the evidence that is undertaken by HICPAC and other federal advisory committees. Relevant data were compiled and will be rapidly disseminated for actual implementation in the field.

Dr. Bell also agreed with Dr. Cardo about the potential for confusion with the SHEA/IDSA guidelines at the HHS level. Moreover, he was aware of HICPAC's concerns related to possible confusion in the field because both the SHEA/IDSA and HICPAC documents are labeled as "guidelines." In an effort to resolve this dilemma, Dr. Bell announced that he and the other authors of HICPAC's editorial are referring to the SHEA/IDSA guidelines as a "compendium of recommendations." However, he asked for HICPAC's input on the use of this term.

Dr. Wise clarified that the Joint Commission is interested in receiving a clear statement from HICPAC on situations where the SHEA/IDSA guidelines should and should not be used. For example, HICPAC could support the SHEA/IDSA guidelines, but also could emphasize the need to engage experts in the field to provide advice on actual implementation.

Several members commented on HICPAC's role in the SHEA/IDSA guidelines.

- Efforts should be made to make a clearer distinction between the SHEA/IDSA and HICPAC guidelines to ensure clarity and avoid inaccuracies. Even if the SHEA/IDSA documents are not labeled as "guidelines," HICPAC's traditional grade categories of IA, IB, IC or II would still be applied and would be misinterpreted as an official HICPAC guideline. The SHEA/IDSA guidance was ranked without HICPAC's clearly defined search strategy or evidence-based review process. HICPAC should advise SHEA and IDSA to remove the "traditional HICPAC grading system" from the recommendations.
- HICPAC should make a strong recommendation to SHEA and IDSA to change the title of the documents from "guidelines" to a "toolkit of strategies" or "implementation strategies." This approach is extremely important because a strong possibility exists for the Joint Commission to adopt the SHEA/IDSA guidance into NPSGs as accreditation standards.
- HICPAC should revise its draft editorial to include language from a precautionary commentary that was published in the *Journal of the American Medical Association* in December 2007. The article discussed concerns about moving consensus guidelines or recommendations into the regulatory arena or accreditation standards.



- HICPAC should develop its guidelines to be more readable for ICPs in the field who will actually implement the recommendations. HICPAC guidelines also should be translated from technical documents to more user-friendly materials for the lay public. These strategies might decrease efforts by other groups in the future to produce infection control guidance without HICPAC's expertise or formal endorsement.
- HICPAC should incorporate a formal mechanism in its updated guideline development process to engage and productively collaborate with professional societies. A plan with clearly defined roles and responsibilities of all partners would help to ensure that recommendations produced by other groups in the future do not conflict with HICPAC guidelines or cause confusion in the field.
- HICPAC should revise the draft editorial to encourage institutions to use innovative and new infection control strategies to assist in generating the next body of evidence.

In response to HICPAC's suggestion to advise SHEA and IDSA to remove the "traditional HICPAC grading system" from the recommendations, Dr. Pegues clarified that the ranking scheme is consistent with existing IDSA guidelines. Although HICPAC is not in a position to change IDSA's ranking scheme, he raised the possibility of HICPAC requesting more transparency. HICPAC could provide SHEA and IDSA with its updated grading system as an example to support its request.

A motion was properly placed on the floor and seconded by Dr. Singh and Ms. Murphy, respectively, for HICPAC to recommend that SHEA and IDSA change the title of "guidelines" to "implementation strategies." HICPAC **unanimously approved** the motion with no further discussion.

Dr. Brennan outlined HICPAC's next steps on the SHEA/IDSA implementation strategies. HICPAC would establish a small workgroup to provide a formal response to the Joint Commission's field review of the NPSGs. Dr. Lundstrom agreed to lead this activity with support by Ms. Burns, Ms. Murphy, Dr. Olmsted and Ms. Soule. HICPAC would engage APIC, IDSA and SHEA in efforts to adopt a uniform grading system for future recommendations.

### Update on DHQP Outbreak Investigations

Dr. Arjun Srinivasan, Team Leader of the DHQP Response Team, explained that DHQP uses three methods to conduct outbreak investigations. Guidance is provided in response to one-time telephone calls or e-mail messages. Ongoing assistance is provided from CDC headquarters in Atlanta. Teams are deployed to the field to provide formal "Epi-Aids" at the invitation of state health departments. DHQP's involvement in CDC's Epi-Aids dramatically

increased from five in 2004 to 16 in 2007, representing 25% of all CDC outbreak responses being performed by DHQP, a small division with only ~100 employees.

The dramatic increase in DHQP's involvement in outbreak investigations could be attributed to better surveillance throughout healthcare, more awareness of DHQP's expertise, or the emerging climate of transparency and zero tolerance of healthcare infections that are prompting more calls to public health agencies. Although DHQP's outbreak investigations of SSIs, MRSA and *C. difficile* have not changed over the past few years, community-associated MRSA outbreaks have exceeded healthcare-associated MRSA and community-associated *C. difficile* is on the rise.

Other changes in DHQP's outbreak investigations include an increasing number of outbreaks caused by gram-negative pathogens, particularly multi-drug-resistant pathogens and *Acinetobacter*. Over the past three years, DHQP has provided 1-2 Epi-Aids for *Acinetobacter* each year compared to 0 Epi-Aids for this pathogen prior to this time.

Outbreaks following ambulatory procedures also are important and ongoing issues for DHQP, such as nationwide outbreaks of toxic anterior segment syndrome in ophthalmology clinics and infections after prostate biopsy and cystoscopy in urology clinics. Over the past few years, DHQP has been responding to 1-2 outbreaks per year related to compounded medical products.

Organ transplant issues have recently been reported in the media, but tissue-related outbreaks have occurred nearly every year. DHQP is increasing its involvement in responding to adverse drug reactions, such as the infectious investigation of BSIs among pulmonary hypertension patients receiving IV prostanoids and the non-infectious investigation of deaths among infants related to cough and cold medications.

National product investigations are another area of growth for DHQP because these situations appear to be more frequent now than in the past. On average, 1-2 of DHQP's investigations each year have resulted in a national recall of a medical product or device, including pre-filled heparin and saline syringes contaminated with *Serratia* and heparin-associated anaphylactic reactions.

The rise in national product outbreaks could be attributed to enhanced capacity by communication networks to link cases in different areas to common products and the increasing complexity of product manufacturing and distribution. For example, the current trend is for one or more companies to manufacture, assemble and distribute different components of the same medical product or drug. This practice has increased opportunities for problems.

Despite these issues, DHQP has achieved success in its outbreak investigations in three major areas. First, DHQP's outbreak investigations have helped to characterize emerging pathogens, such as the initial recognition and characterization of the BI/NAP1 epidemic

strain of *C. difficile* in the United States and the USA-300 strain of MRSA as a major cause of community skin and soft tissue infections. DHQP's overarching goal is to identify specific factors in each outbreak to prevent similar events from occurring in the future. This approach has led to the development of several policy and practice recommendations over the past few years.

Second, DHQP's outbreak investigations have facilitated the development of policy and practice guidance, including (1) guidelines for the use of human tissues contaminated with certain pathogens; (2) HICPAC's 2004 recommendation on the use of face masks for myelograms; (3) guidelines for the use of gadolinium in dialysis patients; (4) guidelines for reprocessing of cataract surgical equipment in collaboration with the American Society of Cataract and Refractive Surgery; and (5) recommendations against the use of cough and cold medications in children <2 years of age.

Third, DHQP's outbreak investigations have enhanced collaborations with FDA to an unprecedented level of cooperation. FDA is increasingly recognizing DHQP as a source of help in product investigations due to its epidemiologic and microbiologic expertise. DHQP and FDA are collaborating on a major patient safety initiative at this time.

Dr. Srinivasan described DHQP's future efforts to improve its outbreak investigations. New issues will be better characterized through collaborations with the CDC environmental microbiology laboratory. Studies will be designed and conducted to improve assessments of the transmission dynamics of healthcare pathogens.

DHQP will enhance its knowledge of the emerging issue of *Klebsiella pneumoniae* carbapenemase-producing (KPC) organisms. A stronger focus will be placed on this issue because sentinel surveillance data collected by the CDC antimicrobial susceptibility testing laboratory show that requests to characterize and confirm KPC isolates are increasing. KPC organisms have been recovered from various geographical areas throughout the United States, but the potential exists for global transmission due to matching strains of KPC organisms between patients in the United States and Israel.

DHQP will continue to conduct activities to advance policy and practice recommendations. Guidelines for infection control of pulmonary hypertension patients will be developed in collaboration with the Pulmonary Hypertension Association. Guidelines for reprocessing of urologic equipment will be developed in collaboration with the American Urological Association. Recommendations will be developed for evaluation and follow-up of breaches in instrument reprocessing. DHQP and FDA will explore opportunities for additional interagency partnerships. DHQP will continue to seek opportunities to partner with various professional societies and state and local health departments to enhance educational efforts.

Dr. Srinivasan concluded his update by describing HICPAC's potential role in improving DHQP's outbreak investigations in two areas. HICPAC could guide DHQP toward emerging

issues in infection control where investigations might yield early answers to problems that can be prevented. HICPAC could use its status and influence to better utilize outbreaks to educate individuals about infection control.

HICPAC commended DHQP on its accomplishments to date in conducting outbreak investigations. Several members made suggestions for DHQP to consider in its future activities.

- DHQP should make better use of bar coding, radio frequency identification and other point-of-use technologies to improve tracking and monitoring of events at the bedside, particularly infections related to defective medical devices and drugs. These innovations would help to advance outbreak investigations in the 21<sup>st</sup> century and more rapidly identify persons at risk.
- DHQP should make stronger efforts beyond publications in peer-reviewed journals and collaborations with professional societies to widely publicize outbreak investigations and better educate practitioners. Collaborations with specialty practices and medical school and nursing school curricula should be used to provide education because practitioners who need information on outbreaks are not necessarily members of a professional association.
- DHQP should thoroughly review and submit comments on FDA's sterilization guidance for 510(k) products. The draft document is undergoing a major revision at this time and will be released for comment in the *Federal Register* in the near future. DHQP should particularly provide advice to FDA on actions manufacturers should take to improve the labeling of devices that can be reprocessed in hospitals.

### Update on the DRA

Dr. Richards explained that CMS developed five key strategies to guide its quality improvement roadmap. Activities will be conducted through partnerships. Quality will be measured and comparative results will be reported. The quality of value-based purchasing (VBP) will be improved to avoid unnecessary costs. Adoption of effective health information technology will be encouraged. Innovation and the evidence base for effective use of technology will be promoted.

CMS established several goals for its VBP Program. Clinical quality and patient safety will be improved by reducing adverse events. More patient-centered care will be encouraged. Unnecessary costs will be avoided in the delivery of care. Investments in effective structural components or systems will be stimulated. Performance results will be made transparent and comprehensible to empower consumers to make value-based decisions about their health care and also to encourage hospitals and clinicians to improve quality of care.

Quality improvement and the need to avoid unnecessary costs were the two key factors that triggered the development of the CMS VBP Program. Medicare's various fee-for-service fee schedules and prospective payment systems are based on resource consumption and quantity of care rather than quality or the need to avoid unnecessary costs. Moreover, insolvency of the Medicare Trust Fund is looming.

CMS has received extensive support for the VBP Program through the President's budget and Congressional interest in pay-for-performance and other VBP tools. The VBP Program includes a number of initiatives, such as a physician voluntary reporting program, physician resource use, pay-for-reporting by home healthcare and ambulatory surgical centers, a physician quality reporting initiative, an inpatient and outpatient hospital quality initiative, a hospital VBP plan and report to Congress, and Medicaid state partnerships.

The hospital-acquired condition (HAC) provision under the VBP Program is a step toward implementation of Medicare VBP for hospitals. The provision has strong public support for CMS to pay less for conditions that are acquired during a hospital stay. Considerable national press coverage of HACs has promoted dialogue of potential strategies to further eliminate HAIs and conditions.

The DRA provides statutory authority for the HAC provision and required CMS to select at least two conditions by October 2007 that are (1) high-cost, high-volume or both; (2) assigned to a higher paying diagnosis-related group (DRG) when present as a secondary diagnosis; and (3) reasonably prevented through the application of evidence-based guidelines. Clear and unique ICD-9 codes are needed to implement the HAC provision. The code must be a major complication or comorbidity or a complication or comorbidity (CC).

Hospitals are paid through several mechanisms in the Inpatient Prospective Payment System (IPPS). An established payment is made to hospitals for a given diagnosis or procedure. However, infections or other complications acquired in the hospital can trigger higher payments through outlier payments or CC-DRG payments. Based on the presence or absence of a CC, 121 sets of DRGs can be split. The CC-DRG in each pair would generate a higher Medicare payment. At this point, ~3,000 ICD-9 diagnoses qualify as CCs.

Congress instructed CMS to remove at least two HAIs or HACs from the CC list. The financial impact of the current structure of the HAC provision is projected to be ~\$20 million and would not affect the vast majority of hospitals. On October 1, 2007, hospitals began submitting data on claims for payment and indicating whether diagnoses were present on admission (POA). As of October 1, 2008, CMS will no longer be able to assign a case to a higher DRG based on the occurrence of one of the selected condition if that condition was acquired during the hospital stay. This provision does not apply to critical access,

rehabilitation and psychiatric hospitals or any other facility not paid under the Medicare Hospital IPPS.

The following conditions will have payment implications beginning on October 1, 2008: (1) serious preventable events defined as objects left in during surgery, air embolism and blood incompatibility; (2) CA-UTIs; (3) pressure ulcers; (4) vascular catheter-associated infections; (5) SSIs defined as mediastinitis after coronary artery bypass graft; and (6) falls and trauma defined as fractures, dislocations, intracranial injuries, crushing injuries and burns.

Three conditions are being considered for IPPS rulemaking in FY'09: VAP, *Staphylococcus aureus* septicemia, and deep vein thrombosis/pulmonary embolism. One or more policy or implementation issues must be resolved before these conditions can be selected. After exhaustive consideration, CMS determined that further analysis is required before the following three conditions can be considered: MRSA, CDAD and wrong surgery.

CMS has provided a number of formal and informal opportunities for public involvement. The public can give verbal statements and submit written comments during CMS's listening sessions. A proposed rule on IPPS rulemaking and instructions to submit comments are released in April of every calendar year. A final rule on IPPS rulemaking is released in August of every calendar year. CMS's other mechanisms to engage the public include listserv messages, regular updates on the [www.cms.hhs.gov/HospitalAcqCond](http://www.cms.hhs.gov/HospitalAcqCond) web site, open door forums, and an e-mail address at [hacpoa@cms.hhs.gov](mailto:hacpoa@cms.hhs.gov). Despite this outreach, CMS has received limited input from the infectious disease community.

Dr. Richards concluded his update by citing two examples that support the critical need for HICPAC, healthcare epidemiologists, ICPs, infectious disease specialists and professional societies to provide feedback to CMS on the DRA. First, Congress required CMS to remove at least two conditions from the CC list, but CMS selected eight and has initiated a process to choose even more conditions.

Second, CDC and other groups have provided CMS with a strong argument to show that VAP is an inappropriate condition from a preventability perspective. However, external organizations have advised CMS to select VAP in FY'09. Dr. Richards emphasized that the payment policy under the DRA is a dynamic and ongoing process and will continue to change over time.

The HICPAC members made three key suggestions for CDC to convey to CMS during the ongoing decision-making process of the DRA.

- CMS should conduct pilot projects in selected healthcare facilities to determine outcomes from a prevention perspective and identify resources that were diverted to the DRA.
- CMS should consider readmission as an indicator in the DRA because 17% of Medicare beneficiaries are readmitted to the hospital within 30 days.



However, Medicare is the only payer at this time that does not reimburse hospitals for readmissions within 30 days.

- CMS should allow time that will be needed for APIC, SHEA, front-line providers and other professional societies to use existing communication vehicles to craft accurate and appropriate messages about each one of the selected conditions. This time also would allow professional societies to clearly define caveats about preventability. This approach might initiate a groundswell of input to CMS from the broader infectious disease community.

## Update on Public Reporting

Dr. Cardo presented a map to illustrate the number of states that have passed public reporting legislation or have pending legislation at this time. The map also showed the number of states that are using NHSN to report HAIs. An increasing number of states are considering using NHSN as a tool for hospitals to collect data on HAIs and make this information available to the public.

The number of healthcare facilities participating in NHSN has dramatically increased to >1,000 since February 2007. This figure is projected to further increase to >2,000 healthcare facilities by November 2008. In January-July 2007, New York, Vermont and South Carolina required mandatory reporting of HAIs through NHSN. In January-July 2008, 11 additional states will adopt the same requirement. Arkansas is scheduled to require mandatory reporting of HAIs through NHSN in 2009. The 14 states that currently use NHSN are reporting the following HAIs: SSIs, VAP, process measures, dialysis events and CLABSI.

The increase in the use of NHSN to report HAIs has presented both tremendous opportunities and challenges for DHQP. Hospitals and ICPs must be trained in using NHSN, conducting surveillance and implementing effective infection prevention strategies. However, DHQP has achieved success in this area by engaging 100% of hospitals in New York State to participate in NHSN. Public reporting legislation has required small hospitals to collect data on several infections.

Many states have asked DHQP to change specific components of NHSN, such as including special numbers to identify patients. DHQP has had to extensively consider each request because modifications to NHSN require a significant burden of work. As a result, DHQP is making strong efforts to develop a process to respond to needs that are most important in preventing infections.

Resource limitations have hampered DHQP's progress in shifting toward the use of electronic data sources and obtaining electronic data sources from laboratories to enhance the MDRO module, particularly for MRSA, *C. difficile* and gram-negative organisms.

However, DHQP hopes to pilot NHSN with electronic data sources in the summer of 2008. CDC and CMS are collaborating to avoid the need for duplicate data collection in two different systems. Efforts are underway for healthcare facilities that collect process measures for CMS to transfer the same information to NHSN and make the data available to the public.

Dr. Cardo concluded her update by confirming that DHQP is continuing its efforts to use NHSN to respond to public reporting legislation. DHQP is convening conference calls with states and other NHSN users on a regular basis. Moreover, the May 2008 external peer review of DHQP's surveillance activities is expected to assist with providing solutions to requests that users have made to change NHSN.

### **Update on U.S. Government Accountability Office (GAO) Activities**

Dr. Cardo reported that GAO conducted an investigation of collaborative efforts among HHS agencies in improving the prevention of HAIs. GAO performed the investigation for nearly one year and completed this activity in November 2007. GAO distributed a draft report of its findings to the HHS agencies and plans to publish the final document in the spring of 2008. A hearing will be convened shortly thereafter.

During the investigation, GAO extensively reviewed the involvement of other HHS agencies in the development of HICPAC guidelines. The draft GAO report contains two major recommendations to the HHS Secretary. First, HICPAC's recommended practices should be prioritized. Strategies should be developed to promote implementation of HICPAC's guidance. A determination should be made on whether to incorporate a select number of HICPAC's recommended practices into CMS's conditions for participation of hospitals. CDC should more fully engage AHRQ and other HHS agencies to identify additional approaches to prioritize existing recommendations and assure better implementation in the field.

Second, a process should be developed to collect more consistent and compatible data on HAIs across HHS. Existing data systems in AHRQ, CDC and CMS should be aligned and leveraged to support this effort. However, GAO did not target this recommendation to HICPAC.

Dr. Cardo emphasized the need for HICPAC and CDC to convene a conference call in preparation of the upcoming GAO hearing. For example, GAO concluded that the 1,200 recommendations in HICPAC's 13 guidelines were excessive. The conference call should be used as an opportunity for HICPAC to provide CDC with specific talking points for the GAO hearing to clarify that the 1,200 recommendations should not be viewed as separate or independent. Instead, HICPAC's recommendations are bundled to provide guidance throughout the entire continuum of care.



Dr. Cardo announced that GAO initiated a new investigation to determine the number of HAIs attributable to new or reused medical devices and identify the causes of these infections. CDC will participate on the first conference call for the new GAO investigation the week of February 18, 2008.

Dr. Bell agreed with Dr. Cardo's suggestion for HICPAC and CDC to hold a conference call in preparation of the upcoming GAO hearing. In addition to the "excessiveness" of HICPAC's 1,200 recommendations, he pointed out that HICPAC's talking points also should respond to the GAO finding for HICPAC to prioritize its recommended practices.

Dr. Bell emphasized the need for CDC to take a firm position during the GAO hearing to defend the necessity of each of HICPAC's recommendations based on detailed steps in developing, revising and publishing evidence-based guidelines.

HICPAC commended DHQP on providing states with outstanding technical assistance and other support to report HAIs through NHSN. Several members made suggestions in response to both of Dr. Cardo's updates on public reporting and the GAO investigation.

- HICPAC should send a letter to the HHS Secretary and CDC Director to explain that despite level or decreased funding in the FY'08 budget, the demand for DHQP's expertise has and will continue to increase in the near future. HICPAC's letter should emphasize the urgent need for additional resources to maintain and enhance DHQP's infrastructure to accommodate the increased demand. HICPAC should cite two examples in particular to support its request: (1) the dramatic rise in the number of healthcare facilities that are scheduled to participate in NHSN by November 2008 and (2) DHQP's increasing involvement in CDC's outbreak investigations.
- CDC should provide a clear statement during the upcoming GAO hearing that *ex-officios* who represent federal agencies on HICPAC are non-voting members. CDC also should specify that non-federal experts in the field are responsible for developing and formally approving HICPAC guidelines. This explanation would help to clarify to GAO that CDC is not using HICPAC as a mechanism to require healthcare facilities to adhere to recommendations.
- HICPAC should engage engineers who can assist in simplifying complexities related to patient care processes. This approach would help to make HICPAC's guideline development process more transparent to federal agencies, front-line HCWs, industry partners, device manufacturers and the public.

## HICPAC Votes

Issue 1. Dr. Brennan reminded the members that on the previous day, CDC asked HICPAC to approve the proposed change in the guidelines for mumps isolation and precautions from nine days to five days in healthcare settings.

A motion was properly placed on the floor and seconded by Drs. Engel and Olmsted, respectively, for HICPAC to adopt CDC's proposed change in the guidelines for five-day isolation of mumps. HICPAC **approved the motion by a majority vote** of 12 to 1 with one member opposed.

Issue 2. HICPAC did not revisit the issue of whether to formally provide scientific and expert guidance on greening healthcare facilities.

## HICPAC Business Session

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

- Dr. Brennan will collaborate with his staff at UPHS to develop the methods document for HICPAC's revised grading system.
- Dr. Brennan will continue to lead the HAI Preventability Workgroup to make further progress on the development of this document. Background materials will be circulated to the entire HICPAC membership to support the review of this effort.
- Dr. Brennan will participate in a conference call with the SHEA/IDSA authors to discuss changing the name of the six HAI documents from "guidelines" to "implementation strategies."
- Dr. Brennan will draft a letter to the HHS Secretary and the CDC Director on the need for additional resources to DHQP due to the increasing demand for DHQP's expertise in outbreak investigations and the rise in the number of healthcare facilities that are scheduled to participate in NHSN by November 2008.
- Dr. Bell will place the following presentations on the June 2008 HICPAC agenda: an overview by the National Surgical Quality Improvement Project and an update by CDC on new influenza vaccine technologies.

- Dr. Bell will facilitate a conference call with HICPAC to assist CDC in crafting talking points in preparation of the GAO hearing in the spring of 2008.
- Dr. Bell will facilitate a conference call with HICPAC to obtain an update on the development of recommendations for the measurement of MDROs in healthcare settings because this item could not be accommodated on the February 2008 agenda.
- Ms. Vance will provide HICPAC with copies of all PowerPoint slides that were presented during the meeting.
- The HICPAC members and liaisons will participate in the following ongoing or new activities:
  - Further development of the CA-UTI guideline.
  - Further development of the norovirus guideline.
  - Further development of recommendations on the measurement of MDROs in healthcare settings.
  - Development of HICPAC's formal response to the Joint Commission's field review of the NPSGs.
  - Development of HICPAC's framework for model legislation of MRSA.
  - Regular updates to HICPAC on activities by the CSTE Surveillance Policy Group.
  - Leadership of the May 2008 external peer review of DHQP's surveillance activities.
  - Development of HICPAC's response to CMS on HAIs selected for the DRA.
  - Collaboration with DHQP to compile and distribute lessons learned to front-line providers on CDC's outbreak investigations.

### **Closing Session**

The next HICPAC meeting was scheduled for June 12-13, 2008 in Atlanta, Georgia. However, Dr. Brennan expressed concern with this date because four of HICPAC's 14 voting members would be unable to attend due to a conflict with the APIC Board meeting. However, he realized that logistical arrangements DHQP has made to date for the June 2008 meeting would be virtually impossible to change at this point.

To address the potential loss of HICPAC's quorum, Drs. Bell and Brennan agreed to notify the absent voting members of specific times to call into the meeting to discuss and vote on important issues.

With no further discussion or business brought before HICPAC, Dr. Brennan adjourned the meeting at 11:40 a.m. on February 12, 2008.

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

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Date

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