

**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**



**CENTERS FOR DISEASE
CONTROL AND PREVENTION**

**Healthcare Infection Control Practices
Advisory Committee
November 13-14, 2006
Atlanta, Georgia**

DRAFT Record of the Proceedings

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ATTACHMENT 1

List of Participants

HICPAC Members

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Dr. Patchen Dellinger
Dr. Jeffrey Engel
Dr. Steven Gordon
Dr. Yvette McCarter
Ms. Denise Murphy
Mr. Russell Olmsted
Dr. David Pegues
Dr. Keith Ramsey
Dr. Nalini Singh
Dr. Philip Smith
Dr. Kurt Stevenson

Designated Federal Official

Dr. Michael Bell, Executive Secretary

Liaison and Ex-Officio Members

Dr. William Baine (Agency for
Healthcare Research and Quality)
Ms. Nancy Bjerke (Association of
Professionals of Infection Control
and Epidemiology, Inc.)
Ms. Joan Blanchard (Association of
periOperative Registered Nurses)
Dr. David Henderson
(National Institutes of Health)
Dr. Stephen Jencks (Centers for
Medicare and Medicaid Services)
Dr. Sheila Murphey
(Food and Drug Administration)
Ms. Kelly Podgorny (Joint Commission on
Accreditation of Healthcare
Organizations)
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. Michael Tapper (Society for
Healthcare Epidemiology of America)

CDC Representatives

Dr. Julie Gerberding, CDC Director
Dr. Denise Cardo, DHQP Director
Dr. Matthew Arduino
Ms. Amy Collins
Ms. Angela Deokar
Ms. Teresa Horan
Ms. Josephine Jones
Ms. Harriette Lynch
Mr. Glen Nowak
Dr. Daniel Pollock
Ms. Cathy Ramadei
Dr. Chesley Richards
Ms. Renee Ross
Dr. Lynne Schulster
Dr. Arjun Srinivasan

Members of the Public

Ms. Sandy Buhler (Kimberly-Clark)
Ms. Amber Hogan (Becton Dickinson &
Company)
Dr. Marion Kainer
(Tennessee Health Department)
Ms. Michele Marill
(Hospital Employee Health)
Ms. Michele Matezek (Public)
Dr. Suzanne Pear (Kimberly-Clark)
Ms. Jaime Ritter (Public)
Dr. Craig Umscheid (University of
Pennsylvania Health System)
Dr. Donald Williamson (Alabama
Department of Public Health)

EXECUTIVE SUMMARY

During the opening session of the meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on November 13-14, 2006 in Atlanta, Georgia, no voting members declared any new conflicts of interest for the record.

CDC oriented the new HICPAC members with presentations on the Federal Advisory Committee Act, financial disclosure and conflict of interest regulations, and the "Ethical Choice" video.

HICPAC's liaison and *ex-officio* members presented oral reports and distributed written summaries to outline current activities, priorities and future directions of their respective organizations: Advisory Council for the Elimination of Tuberculosis; Agency for Healthcare Research and Quality; American College of Occupational and Environmental Medicine; American Hospital Association; Association of periOperative Registered Nurses; Association of Professionals of Infection Control and Epidemiology; Board of Scientific Counselors; Centers for Medicare and Medicaid Services (CMS); Food and Drug Administration (FDA); Joint Commission on Accreditation of Healthcare Organizations; National Institutes of Health; and Society for Healthcare Epidemiology of America.

The update on public reporting included activities at both federal and state levels. At the federal level, Congress proposed new legislation for Medicare payment of healthcare-associated infections (HAIs) under the CMS Inpatient Prospective Payment System. CMS must make recommendations to Congress by February 2007 on the two conditions for which hospitals would no longer receive payment. Medicare would discontinue extra payments to hospitals for the selected conditions beginning in 2008. HICPAC agreed to designate a member to serve as a liaison to CMS in these activities.

The Division of Healthcare Quality Promotion (DHQP) is conducting numerous activities to assist states that have opted to use the National Healthcare Safety Network (NHSN) as the technical infrastructure to implement new public reporting legislation.

At the state level, New York will be the first state to use NHSN as the technical infrastructure in implementing mandatory public reporting requirements. The New York State Department of Health has conducted several activities in preparation of complying with this requirement. Pennsylvania will release hospital-specific data; cluster its hospitals into five peer groups for public reporting purposes; and report on manuscripts that would be published to validate methods.

The CDC Director joined the meeting to inform HICPAC about "National Influenza Vaccination Week" from November 27-December 4, 2006. HICPAC was asked to provide CDC with assistance and guidance on promoting 100% vaccination coverage and identifying effective strategies for CDC to implement in an environment in which the federal government does not own the market share of influenza vaccine.

The Electronic Health Records (EHR) Workgroup expects to draft and distribute a white paper on information technology (IT) to HICPAC for review and comment during the February 2007 meeting and finalize the document by the June 2007 meeting. The white paper would be used to empower healthcare professionals to use EHRs to improve patient safety and patient outcomes.

The white paper will include an introduction and overview of EHRs; evidence on the benefits of EHRs; functional requirements for infection prevention and control; the role of healthcare applications other than EHRs; and recommendations to influence the adoption of EHR and other IT solutions.

HICPAC members, liaisons and CDC staff described key outcomes from recent meetings of the National Quality Forum (NQF) Steering Committee and technical advisory panels (TAPs). The TAPs focused on public reporting definitions of HAIs for the pediatric population, intravascular catheter and bloodstream infections, surgical site infections, implementation and reporting, ventilator-associated pneumonias, and urinary tract infections.

The HICPAC Chair and DHQP agreed to discuss the most appropriate approach to involve HICPAC in NQF's consensus-based process to develop public reporting definitions. The suggestion for HICPAC to evaluate the implementation of public reporting measures at the state level would also be considered.

CDC is currently addressing two issues to finalize and release the sterilization and disinfection guideline. Language related to high-level disinfection of endoscopes using glutaraldehyde is being finalized. HICPAC and the primary author would be asked to review recommendations ranked in the IB versus II categories. CDC would distribute the entire guideline to HICPAC to facilitate the review.

The DHQP Director reported on DHQP's ongoing partnerships and collaborative efforts with CMS, other federal agencies and professional associations in public reporting legislation, Surgical Care Improvement Project measures, pay-for-performance issues, the Deficit Reduction Act, prevention of HAIs, and pandemic influenza preparedness. DHQP asked HICPAC to conduct a new activity to develop infection control practice guidance specifically for small hospitals.

CDC's update on pandemic influenza activities covered (1) guidance on HCW and community use of masks and respirators; (2) occupational guidelines for all other aspects of pandemic influenza; (3) funding to support several projects under a new pandemic influenza research agenda; (4) CDC's \$12 million request for proposals for pandemic influenza preparedness; and (5) pandemic influenza funding for DHQP to provide infection control training in Kenya and Thailand. HICPAC agreed to reconvene its Preparedness Workgroup with a new charge to identify HICPAC's role in CDC's ongoing pandemic influenza activities.

The update on the EpiCenters included a summary of projects that were approved for implementation in the first year of the current cycle. The research projects are focusing on the use of EHRs to improve the accuracy and efficiency of surveillance, strengthen infection control interventions, and prevent HAIs. HICPAC made a strong request for two EpiCenter investigators to present findings from research projects during each future meeting.

The HICPAC Chair provided several comments to support the need for a more evidence-based approach in the development of HICPAC guidelines. HICPAC's weighted scoring system to rank recommendations in guidelines is not clear or transparent. The semi-quantitative or qualitative approach weakens HICPAC's ability to defend recommendations. Healthcare professionals must wait anywhere from two to seven years before HICPAC guidelines are available for use in actual practice. HICPAC must be able to defend its guidance in light of the current environment of politics, payment reform, liability, public advocacy and consumer interest.

The Center for Evidence-Based Practice at the University of Pennsylvania Health System presented its step-wise approach to develop evidence-based guidelines. Issues of concern are evaluated and prioritized with input from medical and nursing leadership. Prioritized issues of concern are clearly defined based on the "patients, interventions, comparators and outcomes" model.

A task force of key stakeholders with appropriate expertise is convened to assist in reviewing data and developing evidence-based practice guidelines. A systematic literature review is performed that is guided by opinions of clinical experts in the field, a written research protocol, and well-established methods developed by national and international groups. Data are extracted and analyzed to include in the guideline.

Findings of the evaluation are presented to the task force to grade the quality of evidence for each outcome based on the "grading of recommendations, assessment, development and evaluation" model. Input is solicited from persons outside the task force. The risks and benefits of each outcome are balanced based on net benefits, harms, tradeoffs and uncertain tradeoffs. Recommendations are made on the issue of the concern.

HICPAC extensively discussed and made several suggestions to refine its process to develop guidelines. The HICPAC Chair confirmed that he would take several actions to advance this effort. A guidance document on the guidelines process would be drafted and circulated to HICPAC for review, discussion and comment. A letter would be drafted to DHQP summarizing HICPAC's comments and requesting that additional resources be considered in the next budget cycle. A conference call would be held with HICPAC to prioritize guidelines that need to be updated.

The HICPAC Chair led HICPAC in a review of the business items that were raised over the course of the meeting. These items included placing specific topics on the next meeting

agenda, disseminating materials to HICPAC, continuing to serve on workgroups, and contributing to the ongoing development of guidelines.

The dates of the next three HICPAC meetings are February 15-16, 2007; June 11-12, 2007; and November 12-13, 2007.

The Congressional intent of FACA is as follows. A new FAC would be established only when it was determined to be essential. The FAC would provide advice that is relevant, objective and open to the public. Standards and uniform procedures would be developed to govern the establishment, operation, administration and duration of the FAC. Congress and the public would have knowledge of the purpose, membership, activities and cost of the FAC. The FAC would be terminated after fulfilling the purpose for which it was established.

The role of FACs is to provide federal officials and the nation with advice on a broad range of issues affecting federal policies and programs. FACs provide the public with an opportunity to actively participate in the federal government decision-making process. Recommendations that are fully discussed and voted on by FACs can be circulated to the head of an agency, a department, the General Services Administration (GSA), the President of the United States and Congress.

The membership of a FAC must be fairly balanced to the fullest extent possible in terms of points of view represented and the functions to be performed. FACs can be represented by three types of members. Special government employees (SGEs) are private citizens who are appointed based on their individual expertise. SGEs are subject to standards of ethical conduct for employees of the Executive Branch.

Ex-officio members are federal officials with expertise in the subject matter. As government employees, *ex-officio* members must also comply with the standards and principles of conduct outlined in FACA. Liaison members represent special interest groups, organizations or affected populations and are not required to adhere to FACA regulations.

FACA outlines specific responsibilities for FACs. Most notably, Congress, the President of the United States, GSA, agency heads and committee management officers have authority to oversee, manage and determine the usefulness, activities, organizational structure and function of each FAC.

FACA defines two types of FACs that can be established. A "mandated" FAC is authorized by statute or the President through an Executive Order. A "discretionary" FAC is formed when the head of an agency determines the need for external advice and recommendations. HICPAC is a discretionary FAC. To formally establish a FAC, the agency must notify the public, file a charter, designate a federal officer (DFO), and appoint a chair and members.

FACA describes specific requirements to convene FAC meetings, including a notice to the public, the presence of a DFO, opportunities for public comments, detailed minutes that are available to the public, and maintenance of official records. FACs can form two types of subgroups to perform special tasks. Subcommittees must be represented by at least one member of the parent FAC, report directly to the parent FAC, and comply with FACA rules in accordance with CDC policy. The subcommittee must also present its recommendations to the parent FAC for deliberation.

Workgroups must be represented by at least two members of the parent FAC or subcommittee and report directly to the parent FAC or subcommittee. Workgroups conduct research, collect information and analyze issues related to the subject matter, but have no authority to make formal recommendations. Workgroups are not required to comply with FACA rules.

FAC members must adhere to financial disclosure and conflict of interest (COI) regulations while serving as SGEs. The Ethics Reform Act of 1989 requires each SGE to file a financial disclosure form upon appointment and annually thereafter. The committee management team, DFO of the FAC, and designated agency official review all financial disclosure forms submitted by SGEs. SGEs are prohibited from participating in any matter that would specifically and directly affect their financial interests.

Financial disclosure requirements were established for several reasons. SGEs and the agency would be protected. The FAC's activities would be performed without COIs or the appearance of COIs. The agency would be able to determine appropriate actions to take in the event a COI arises.

The law describes two major options for SGEs to remedy COIs. SGEs can publicly disclose their COIs and recuse themselves from participating in matters that affect their interests. SGEs can sign the agency's COI waiver that specifies requirements for recusal or participation in conflicting matters.

SGEs must also comply with other regulations in addition to COI rules. The bribery statute prohibits SGEs from seeking or accepting any item of value in return for being influenced during official government service. The representation statute prohibits SGEs from receiving compensation for representing an individual or an entity to the agency on any matter in which the SGE acted in an official capacity.

The post-employment statute imposes a lifetime ban on former SGEs representing an individual or entity to the government on any matter in which the former SGE personally and substantially participated during official government service. The Emoluments Clause of the U.S. Constitution prohibits federal employees from having a relationship with a foreign government or acting as an agent or lobbyist on behalf of a foreign entity without the consent of Congress.

The "Ethical Choice" video was developed by the U.S. Office of Government Ethics and was presented to HICPAC as a resource for the members to identify potential COIs or ethical issues. However, Ms. Jones and Ms. Ross emphasized that the HICPAC DFO or CDC Federal Advisory Committee Management Team would be available to provide members with guidance and assistance on determining COIs and identifying the most appropriate action to take. HICPAC members with questions on potential COIs should contact Dr.

Michael Bell, as the DFO, or the CDC Federal Advisory Committee Management Team at 404/498-0090.

Ms. Harriette Lynch, the HICPAC Committee Management Specialist, provided additional information to orient the new members to HICPAC. Members must complete and submit a travel request form with an itinerary to attend each HICPAC meeting. CDC will enter the request in the travel system and provide the members with their respective travel orders and other relevant information by e-mail.

Members must complete and submit travel worksheets and receipts to Ms. Lynch five days after each trip to obtain reimbursement. CDC will use this information to process and fax the voucher for signature. CDC will enter the signed voucher in the travel system for payment within seven to ten business days. Members should immediately notify Ms. Lynch by e-mail or telephone about problems with their travel vouchers.

Liaison and *Ex-Officio* Reports

Ms. Rachel Stricof and Dr. Jeffrey Engel reported on key issues the Advisory Council for the Elimination of Tuberculosis (ACET) is currently addressing. Tuberculosis (TB) was transmitted in the Hmong refugee camp in Thailand. TB cases in the United States were also detected in this population following the resettlement of ~15,000-16,000 Hmong refugees. A substantial proportion of the cases were multidrug-resistant TB (MDR-TB).

Of 53 TB cases in Hmong refugees who had resettled in the United States, only 14 were identified overseas. CDC is allocating ~\$700,000 to a three-year project to learn from the experience of the Hmong resettlement and prevent a reoccurrence of TB during the ongoing resettlement of ~150,000 Burmese refugees.

CDC's insufficient domestic budget for TB control in the United States continues to be a major concern. Most notably, a pending Congressional resolution would only provide level funding for TB. A transfer has been authorized for agencies to redirect 1% of funding to HHS. Cost of living increases would further impact the inadequate TB budget. CDC is extremely concerned that decreased TB funding and a reduction in the number of cases will result in a resurgence in the future. HICPAC should take an active role in ensuring the continuation of early detection, identification and appropriate treatment of TB in the absence of level funding.

The March 24, 2006 edition of the *Morbidity and Mortality Weekly Report (MMWR)* contained an article on the emergence of extensively drug-resistant TB (XDR-TB). The World Health Organization (WHO) recently held a meeting to agree on the following definition for "XDR-TB:" MDR-TB plus resistance to any fluoroquinolone and any injectable second-line drugs, including amikacin, kanamycin and capreomycin.

Dr. William Baine reported that the Agency for Healthcare Quality and Research (AHRQ) is supporting a task order to test techniques and use active case surveillance to radically reduce methicillin-resistant *Staphylococcus aureus* (MRSA) in hospitals. AHRQ is supporting grants for infection control in healthcare settings. AHRQ is awaiting feedback from the office of the HHS Secretary on the Patient Safety Act.

Dr. Mark Russi reported that the American College of Occupational and Environmental Medicine (ACOEM) held a two-day course on occupational exposures to healthcare workers (HCWs) during its meeting in October 2006. ACOEM is planning its 2007 meeting in conjunction with an international meeting on HCW safety in Vancouver, Canada.

ACOEM is continuing to participate in efforts to establish the Occupational Health Disaster Expert Network. The network of physicians and other employer-based healthcare practitioners throughout the country would serve as a resource to respond to disasters, exchange information prior to an event, and assist workplaces in preparing for incidents.

Ms. Roslyne Schulman reported that the American Hospital Association (AHA) is continuing to collaborate with Congress, federal agencies and AHA members on issues related to seasonal and pandemic influenza vaccination. AHA is supporting legislation to ensure that the supply of influenza vaccine and other anti-viral drugs is adequate. AHA is advocating for HCWs and emergency care workers to be prioritized in influenza vaccination and anti-viral drugs.

AHA provided testimony on pandemic influenza during a Congressional hearing in the summer of 2006. AHA administered a survey in July 2006 on hospital influenza prevention strategies and HCW vaccination practices. The submission of 556 completed surveys yielded a 55% response rate. The survey was designed to benchmark activities hospitals conduct to prevent influenza, determine the cost-effectiveness of various vaccination programs, and evaluate strategies hospitals use to implement HCW vaccination programs. CDC awarded a research contract to AHA to evaluate rapid HIV testing procedures in emergency departments. The project will be conducted through March 2008.

Ms. Joan Blanchard reported that the Association of periOperative Registered Nurses (AORN) recently released the *Perioperative Emergency Management Resource Manual*. The position statement on patients and HCWs with bloodborne diseases is being updated to reflect more recent data on percentages and rates of exposures. The mass casualty, triage and evacuation guidance statement is being revised for inclusion in the AORN standards book.

The AORN fire safety toolkit was completed and is now available to every operating room setting. The toolkit contains lessons learned from experts, family members of patients, professional organizations and hospitals that experienced fires in surgical settings. The toolkit also describes scenarios to assist groups in conducting fire drills and preparing for

fires in surgical settings. The sterilization standard by the Association for the Advancement of Medical Instrumentation (AAMI) was completed and will serve as the test standard for annual reviews and updates.

Dr. Denise Cardo, the DHQP Director, confirmed that DHQP would review the AAMI sterilization standard and HICPAC's disinfection and sterilization guideline to ensure consistency between the two documents.

Ms. Nancy Bjerke reported that the Association of Professionals of Infection Control and Epidemiology (APIC) launched a major campaign to control the spread of MRSA. A conference was held in August 2006 to discuss the latest strategies in controlling MRSA. A position statement was drafted in partnership with the Society for Healthcare Epidemiology of America (SHEA) and is expected to be released in November 2006. The purpose of the position statement is to respond to states that are considering legislating active surveillance cultures for MRSA and vancomycin-resistant enterococcus (VRE).

The first version of the APIC toolkit on essential elements to eliminate MRSA transmission in healthcare settings will be available at the end of November 2006. The APIC toolkit served as a model in designing web-based seminars that will be offered on this topic. Data from the MRSA prevalence study are currently being analyzed. Efforts are underway to publish results of the study in the January or February 2007 edition of the *American Journal of Infection Control*.

APIC will continue to emphasize prevention and promote zero tolerance for healthcare-associated infections (HAIs) and other adverse outcomes in the healthcare setting. APIC decreased its focus on benchmarking and asked infection control practitioners (ICPs) to aim for reducing HAI rates as low as possible rather than achieving a benchmark rate. APIC is making strong efforts to promote a healthcare culture in which providers would attempt to prevent as many HAIs as possible.

Dr. Brennan reported that the December 2006 meeting of the NCPDCID Board of Scientific Counselors (BSC) was canceled, but a conference call would be convened. The BSC has continued to emphasize HICPAC's importance and its ongoing value as a federal advisory committee.

Dr. Stephen Jencks reported that the Centers for Medicare and Medicaid Services (CMS) and CDC are jointly attempting to identify strategies to implement the Congressional requirement for CMS to discontinue payment for additional costs of preventable adverse events or infections. The second phase of the Institute for Healthcare Improvement (IHI) campaign would most likely include several topics of interest to HICPAC, such as MRSA; infectious and quasi-infectious measures under the Surgical Care Improvement Project (SCIP); and the interaction between heart failure and pulmonary disease.

CMS is placing stronger emphasis on issues involved in the successful transition from hospitals to communities. The number of patients readmitted with various types of infections and medical conditions would serve as a measure of success. CMS welcomes HICPAC's participation and strategic guidance on the readmission initiative, particularly in the areas of immunization, unrecognized infections at the time of discharge, and discharge of Medicare patients.

Several HICPAC members made suggestions for CMS to consider in refining the readmission initiative.

- CMS should engage HICPAC and APIC representatives to provide ongoing guidance on a formal basis on infections, surveillance and other issues.
- CMS should include "admissions to hospitals from other providers" as another component in the readmission initiative.
- CMS should solicit HICPAC's expertise to accurately define "preventable" HAIs. This approach would play a key role in addressing system failures and eliminating the focus on punitive measures for HAIs.
- CMS should solicit HICPAC's guidance to determine whether 30 or 90 days should be used as the time period for readmission. For example, a wound infection that appeared on day 30 would be extremely different from pneumonia or a urinary tract infection (UTI) at the same time period.

Dr. Brennan confirmed that he would solicit a volunteer from HICPAC to serve as a formal liaison to CMS in the readmission initiative. He added that this topic would be placed on HICPAC's February 2007 agenda for a more extensive discussion.

Dr. Sheila Murphey reported that the Food and Drug Administration (FDA) is continuing to develop policy for the appropriate use of N95 respirators during pandemic influenza to ensure the safety, efficacy and proper labeling of these devices. FDA is discussing this issue with the CDC National Institute for Occupational Safety and Health (NIOSH). FDA hopes to release a guidance document on antimicrobial agents and medical devices for public comment in the near future. FDA will attempt to convene an expert panel to discuss this topic in early 2007.

FDA made a presentation to the Institute of Medicine's Committee on Personal Protective Equipment in the Workplace in October 2006 on the current regulation of all personal protective equipment. FDA issued a caution to hospitals about using rapid tests for detecting influenza A virus. FDA disseminated this guidance to remind HCWs about the proper use and limitations of these assays; emphasize the need for appropriate specimens; and reinforce the importance of confirming results when influenza activity is low in the community.

FDA announced the 2006-2007 vaccine strains for seasonal influenza vaccines in August 2006. FDA released new guidance on developing cell-based viral vaccines to assist in the

development of new types of influenza vaccines. FDA published a final rule in the *Federal Register* in October 2006: "Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With or Otherwise Containing Material from Cattle."

The FDA Transmissible Spongiform Encephalopathy (TSE) Committee held a meeting in September 2006 to review comments that were submitted on developing candidate donor screening tests for variant Creutzfeldt-Jakob disease and other TSEs. The committee did not vote or attempt to reach consensus on any of the issues presented during the meeting. Agendas, minutes, full transcripts and copies of presentations of each committee meeting are available to the public on the FDA web site.

Ms. Kelly Podgorny reported that the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) will publish an international handbook on infection control best practices in October 2006 and the second edition of a book on TB in December 2006. JCAHO, APIC and the Joint Commission Resources co-sponsored the 2nd Annual Infection Control Conference in August 2006 that focused on a call to action to manage MRSA.

JCAHO proposed new performance elements to address the administration of influenza and pneumococcal polysaccharide vaccines under its standard modification for medication management. The standard proposed administration of these vaccines through medical order or as permitted by law or regulation through a physician-approved protocol.

Dr. David Henderson reported that the National Institutes of Health (NIH) is conducting three major activities under the Bethesda Hospital Emergency Preparedness Partnership (BHEPP). A community disaster drill will be held in December 2006. An abstract on BHEPP's key projects was presented during a national meeting. Department of Defense funding in the amount of \$4.3 million will be used to procure equipment and supplies and commission a transportation feasibility study to support BHEPP.

The NIH Clinical Center has a 250-bed contingency station to provide internal surge capacity for 300-350 patients. NIH is continuing to fund research on an H5N1 influenza vaccine that was found to be both immunogenic and protective in a mouse model. NIH is also supporting research for other influenza vaccine studies. The NIH Clinical Center underwent an unannounced JCAHO accreditation visit in September 2006.

Dr. Michael Tapper reported that SHEA is collaborating with IHI on its new campaign to decrease MRSA, VRE and other gram-positive microorganisms. SHEA is partnering with the Veterans Health Administration (VHA) to compile best practices in limiting hospital infections. SHEA and the Infectious Disease Society of America (IDSA) attended a Department of Homeland Security (DHS) Council meeting in September 2006 to address comments the two organizations submitted in response to the DHS pandemic strategic plan. The DHS Council asked SHEA and IDSA to provide more input and attend future meetings to address the comments in more details.

The SHEA/CDC training courses on hospital epidemiology in September 2006 were well represented by 263 participants. SHEA will convene its annual meeting on April 14-17, 2007 in Baltimore, Maryland. Efforts are underway to recruit a new editor for the SHEA *Infection Control and Hospital Epidemiology* journal. SHEA, APIC, CDC, and the Council for State and Territorial Epidemiologists (CSTE) completed a translational toolkit that provides guidance on uniform methodologies and comparable approaches to public reporting of HAIs to governmental agencies. The toolkit is expected to be published in the near future.

The SHEA Public Policy and Governmental Affairs Committee has continued to receive outstanding input from CDC, APIC, CSTE and IDSA during its monthly conference calls. SHEA and APIC administered a survey under a joint cooperative agreement with CDC to build healthcare capacity both domestically and internationally. Input was solicited from members of the two organizations to identify strategies to establish an emergency contact system for infection control needs. SHEA will soon publish two position papers on the economic impact of infection control in healthcare settings and various aspects of the duties of hospital epidemiologist.

Update on Public Reporting

Dr. Chesley Richards, of DHQP, announced that Congress proposed new legislation for Medicare payment of HAIs under the Inpatient Prospective Payment System (IPPS). CMS uses the IPPS to pay hospitals for a given diagnosis or procedure based on diagnosis-related groups (DRGs). However, infections and certain other complications acquired in the hospital could trigger higher payments from the IPPS based on (1) a \$23,000 loss to the hospital if the patient's admission was an outlier condition or (2) the presence or absence of a complication or co-morbidity in accordance with 121 sets of DRGs.

Key language in the Congressional legislation is summarized as follows. The HHS Secretary will identify at least two infections or conditions that are high cost, high volume or both by October 1, 2007. Infections or conditions that are presented as a secondary diagnosis will result in assigning the case to a DRG with a higher payment. The infections or conditions could have been "reasonably" prevented through the application of evidence-based guidelines. The legislation will be enacted in FY'07, but Medicare payments to hospitals will not be affected until FY'08.

Several critical issues will need to be addressed in implementing the legislation: (1) distinguishing between infections that are present on admission (POA) versus those acquired during hospitalization; (2) clearly defining "high-volume" and "high-cost" infections or conditions; (3) determining measurement and preventability issues; and (4) resolving differences in terminology for HAIs. For example, the public health community uses "bloodstream infections" (BSIs), while organizations that group ICD-9 codes for diagnoses

use “sepsis” or “septicemia.” CMS is engaged in dialogue with policymakers to explore the possibility of including non-infectious conditions in the legislation. Falls and pressure ulcers are being considered in these discussions.

Dr. Richards described other outcomes of the legislation. A new POA data element was approved for inclusion in uniform billing sheets beginning in 2007. Health plans and data clearinghouses must implement the POA variable beginning in March 2007. All submitters must code the POA variable by the end of May 2007. All institutional paper claims must use Uniform Bill 2004 with the POA variable by May 23, 2007.

Dr. Richards outlined unintended consequences of the legislation. The practice of coding HAIs as a POA variable might increase, particularly for patients with a high risk for nosocomial infections. More patients might be transferred to other settings based on age, race or gender. The hospital would then attempt to recoup the costs of treating HAIs in transferred patients from receiving facilities. Significant changes will be made in coding conditions. Risk adjustment issues will need to be addressed.

Dr. Richards conveyed that in preparation of implementing the legislation, CDC collected data to estimate annual hospital costs of HAIs. Preliminary results of the data analysis are as follows. Catheter-associated UTIs represented ~500,000 infections per year. Central line-associated BSIs resulted in ~\$9 billion in additional costs each year. Ventilator-associated pneumonias (VAPs) were the cause of the most deaths each year.

Efforts are underway to remove catheter-associated UTIs from the complication list because these HAIs do not result in significant extra costs. Post-surgical infections and *Clostridium difficile* (*C. difficile*) have specific ICD-9 codes, but these HAIs have been underestimated based on the use of ICD-9 codes for primary diagnoses. A number of complex issues have not been resolved to date, such as translating BSIs into sepsis or septicemia for coding purposes and combining pneumonia, mechanical ventilation and POA codes.

Dr. Richards noted that several opportunities would be available despite the challenges in implementing the legislation. Most notably, payment might place more emphasis on prevention and prevention behaviors. Development of a focused and specific set of DRGs and complication codes might facilitate the integration of solid data and situations with a prevention impact. A strong case could be made to link the legislation to payment for prevention initiatives through either pay-for-performance or SCIP. However, any of these potential scenarios would need to be piloted over the next year before payments to hospitals are affected in 2008.

Dr. Richards described the timeline for implementation of the legislation. CMS must make recommendations to Congress by February 2007 on the two conditions for which hospitals would no longer receive payment. Data collection issues must be addressed by the fall of 2007 because data on the POA variable and the two selected conditions would begin to be

gathered at the national level at that time. Medicare would discontinue extra payments to hospitals for the selected conditions beginning in 2008.

Dr. Richards concluded that the implementation of the legislation presents a tremendous opportunity for HICPAC, APIC and SHEA to provide additional guidance on preventing HAIs. For example, a recommendation could be made to reward hospitals that participate in prevention initiatives.

Dr. Daniel Pollock, of DHQP, described DHQP's recent activities to support the implementation of public reporting legislation. DHQP outreached to states that have opted to use the National Healthcare Safety Network (NHSN) as the technical infrastructure to implement new public reporting legislation. Most notably, five of these states attended DHQP's training session on NHSN in August 2006. For states and other enrollees that were unable to attend the training session, DHQP will offer web-based educational courses and a distance-based learning initiative on using NHSN for public reporting purposes.

In collaboration with CSTE, DHQP formed a user group of states that intend to use NHSN for public reporting purposes. DHQP will participate in a breakout session on public reporting and its implications during CSTE's annual meeting in June 2007. DHQP initiated dialogue with CSTE, the National Association of Health Data Organizations, and the National Organization of Hospital Discharge Data Systems to discuss concerns about public reporting. DHQP and these groups are exploring the possibility of engaging APIC and SHEA to focus on cross-cutting public reporting issues.

DHQP attended several meetings to solicit input from infection control surveillance vendors. The vendors emphasized the need for their customers to use NHSN for public reporting purposes after the legislation has been implemented. DHQP is collaborating with vendors and application developers to develop standards-based solutions to enable each healthcare facility to use its individual product for public reporting through NHSN. DHQP offered to collaborate with organizations in Pennsylvania to enhance knowledge of the comparative yield of different approaches to collecting and reporting data for public reporting purposes.

Ms. Stricof informed HICPAC that New York will be the first state to use NHSN as the technical infrastructure in implementing mandatory public reporting requirements. She described activities the New York State Department of Health (NYSDOH) has conducted to date in preparation of complying with this requirement. NYSDOH conducted seven of the nine NHSN training sessions across the state. Efforts are underway to enroll all state hospitals in NHSN by January 2007. Wide promotion of initiatives to control, reduce and eliminate HAIs played a key role in the acceptance of public reporting mandates throughout the state.

NYSDOH will perform a case control study in its mandatory requirement to audit and validate HAIs. In this initiative, all HAIs in the state will be matched by size and type of hospital, duration of surgery and other controls. These data will be analyzed to document

rates of infections, identify factors that caused patients to develop or not develop HAIs, and determine the need for further risk adjustments. NYSDOH will create a web site to provide the public with information on infection rates by hospital and individual risk based on the patient's age, underlying medical conditions and other factors. NYSDOH expects to complete these activities over the next year.

Dr. Brennan provided an update on public reporting activities in Pennsylvania. Hospital-specific data would be released on the following day. "Cases" would be defined as hospital admissions or discharges and would serve as the denominator. The hospital-specific data would include (1) hospital reports of HAIs gathered from ICPS; (2) actual numbers of BSIs, pneumonias, UTIs and surgical site infections (SSIs); (3) rates of multiple sites based on all cases; (4) a mortality rate for patients who had specific infections; and (5) charge data reported.

Pennsylvania hospitals would be clustered into five peer groups based on trauma centers or heart surgery, transplant or trauma programs. During a national press conference on November 21, 2006 in Washington, DC, the Pennsylvania Health Care Cost Containment Council (PHC4), its data vendor and associates would report on manuscripts that would be published to validate methods. One of these methods would indicate that risk adjustment is not necessary for public reporting data. The last draft of the PHC4 report suggested that public reporting data should not be used for inter-hospital comparisons at this time.

Dr. Cardo described HICPAC's potential role in implementation of the Congressional legislation. CMS is reviewing and considering comments on the proposed Medicare rules submitted by HICPAC, APIC and SHEA. However, HICPAC and other groups should provide additional guidance to CMS to more effectively promote prevention. For example, recommendations could be provided to CMS to address unintended consequences of the legislation, such as changing ICD-9 codes or transferring high-risk patients to other settings. Dr. Cardo asked HICPAC to provide additional guidance to CMS on two specific levels: (1) the two conditions for which hospitals would no longer receive payment and (2) strategies to promote adherence to the recommendations.

The HICPAC members made two suggestions for CDC to consider in its ongoing discussions with CMS about the Congressional legislation. First, CDC should collect data on the role of race in HAIs because hospitals might perceive this variable as a higher risk for certain complications. Second, CDC should collect and disseminate denominator data to allow hospitals to more easily make risk adjustments.

Dr. Brennan confirmed that HICPAC would have a more extensive discussion on its next steps in public reporting at a later time during the meeting.

Late Breaking Issue

Dr. Julie Gerberding, the CDC Director, joined the meeting to inform HICPAC about "National Influenza Vaccination Week" that will be launched from November 27-December 4, 2006 to encourage ongoing influenza vaccination. Manufacturers have projected the availability of 110-115 million doses in FY'07. This amount will far exceed the maximum of 83 million doses that were previously distributed. However, the supply and distribution of influenza vaccine are still not matched and a gap still exists between the demand and need for influenza vaccine by 210 million persons.

CDC has no authority to address private-sector market issues, but efforts will be made throughout the agency to widely publicize the supply to avoid wasting vaccine and discourage manufacturers from decreasing production in the next influenza season. CDC will communicate several key messages in this effort. Influenza typically does not peak until after January. Multiple influenza strains could be circulating at the same time. No time in the season is "too late" to be vaccinated against influenza. CDC will also focus on extending the current immunization season.

Due to the important role of HICPAC and the broader infection control community in vaccination programs for HCWs, Dr. Gerberding requested HICPAC's assistance and guidance in two areas. Vaccination coverage of 100% should be promoted. Effective strategies for CDC to implement in an environment in which the federal government does not own the market share of influenza vaccine should be identified. For example, the extended influenza season, availability of the vaccine supply, and vaccination as a quality indicator for patient safety could serve as critical messages to achieve ubiquitous coverage among HCWs and increase coverage in the next season.

Dr. Gerberding was confident that HICPAC's strong influence in the infection control community and its role as respected opinion leaders would greatly contribute to CDC's efforts to achieve 100% vaccination coverage. She confirmed that CDC would forward press materials to HICPAC for wider distribution to individual members, publications and web sites of professional organizations. She thanked HICPAC for its ongoing and diligent efforts to provide CDC with expert advice.

Update by the Electronic Health Records (EHR) Workgroup

Dr. Seven Gordon, a HICPAC member and the EHR Workgroup Chair, reported on activities that were conducted following the previous meeting. The workgroup hopes to draft and distribute a white paper on EHRs to HICPAC for review and comment during the February 2007 meeting and finalize the document by the June 2007 meeting. The purpose of the white paper will be to empower ICPs and hospital epidemiologists to use EHRs to improve patient safety and patient outcomes.

The workgroup identified several factors that called for the development of the white paper. Timely and accurate information is the cornerstone for empowering decision-making. Efforts are underway to promote value in the healthcare setting by focusing on outcomes, raising standards and establishing pay-for-performance. All healthcare is local.

Dr. Gordon announced that CDC contracted Dr. Ashish Atreja, of the Cleveland Clinic Foundation, to serve as the first author of the white paper. Dr. Atreja is an internist with expertise in informatics. Input would be solicited from HICPAC on an ongoing basis in developing and finalizing the white paper because the document would be released as a HICPAC product.

Dr. Gordon summarized six sections that the workgroup proposed to include in the white paper. Section 1 will serve as the introduction. The important role of EHRs and other information technology (IT) in infection control will be emphasized. Current, short-term and long-term implications of EHRs will be described, including economic and quality of care perspectives. The need for a high-level set of EHR and IT requirements will be outlined from an infection control perspective.

Section 2 will provide an overview of EHRs. The importance of EHRs in patient-centered healthcare with persons, a process and IT for solutions will be highlighted. The language will note that EHRs are not a panacea. EHRs will be clearly defined. Functional blocks of EHRs will be described with electronic patient data at the base of the block and population-based research genomics and personal health records at the top of the block. Five core care processes will be identified: patient care delivery, patient care management, patient care support processes, financial and other processes, and patient self-management. The Health Level Seven EHR functional model will be illustrated.

Section 3 will provide evidence that EHRs yield benefits for infection control and quality of care. Several evidence-based models that have been used to improve patient safety will be described: (1) computerized antimicrobial decision support to decrease mortality; (2) clinical decision-support system and appropriate antibiotics for acute respiratory tract in the community; (3) automated surveillance systems for infection control; (4) use of the Intranet and measurement of influenza vaccination among HCWs; and (5) anesthesia records and measurement of timing of antibiotic prophylaxis before surgery.

Section 4 will outline functional requirements for infection prevention and control. Several examples will be highlighted. A knowledge base, data and technical standards would be needed to (1) detect HAIs in index hospitalization or post-discharge time intervals; (2) optimize antimicrobial choices and avoid adverse events; (3) automate rapid detection of adverse events to the fullest extent possible; and (4) embed process-of-care guidelines in EHR systems and automate process measurement and feedback.

Section 5 will define the role of healthcare applications other than EHRs. Admission, discharge, transfer, laboratory and pharmacy applications can provide source data for infection control. As EHRs continue to develop, these application databases in the healthcare setting can yield data for specific purposes. For some purposes, further development would be needed to improve the yield across care sites. For example, wider use of standard terminology in laboratory and pharmacy systems could be fostered. For other purposes, such as the use of coded discharge data to identify and enumerate HAIs, additional research would be needed to better define the usefulness and limitations for infection control purposes.

Section 6 will include recommendations to influence the adoption of EHR and other IT solutions. Strategies will be described for ICPs to help shape the use of technology as EHRs and other advances in technology are integrated into the mainstream of clinical practice. Guidance will be provided for ICPs to help guide policy and purchasing decisions about particular EHRs and IT solutions. For example, differential reimbursement for systems could be an important short-term opportunity to help guide the use of technology.

To advance the development of the white paper, Dr. Gordon asked HICPAC to assist the workgroup in addressing several unresolved issues. Should certain components of surveillance be mandated? What are the uniform and pragmatic elements for EHRs regardless of the size or type of facility? What variables should be used to distinguish risk? What actions could all healthcare settings take in implementing EHRs with a minimal amount of resources? What measurements should be included in EHRs for infection control practices, such as hand hygiene or *C. difficile*?

Several HICPAC members made suggestions for the workgroup to consider in its ongoing efforts to develop the EHR white paper.

- The white paper should describe strategies for hospital epidemiologists and ICPs to incorporate EHRs into existing infection prevention and surveillance activities.
- The white paper should include standard definitions for HAIs in specific categories. The CSTE model should be reviewed in this effort.
- The white paper should provide education on the appropriateness of hand hygiene.
- The white paper should emphasize the need for accountability when guidelines, policies, procedures or recommendations are not followed. This language should note that a disconnect occurs between patient outcomes and actions when persons are not held accountable.
- The white paper should highlight best practices and tools that have been effective in integrating EHRs into infection control practices.
- The white paper should include a glossary of IT terms.

Update on National Quality Forum (NQF) Public Reporting Activities

HICPAC members, liaisons and CDC staff described key outcomes of meetings the NQF technical advisory panels (TAPs) recently held to review and make recommendations on public reporting definitions of HAIs.

Dr. Nalini Singh reported that the Pediatric TAP solicited consensus on a comprehensive set of national standards for public reporting of HAIs in the U.S. pediatric population. The Pediatric TAP considered all HAIs in its discussion of the following issues. BSI rates would apply to children 1-12 years of age. Negative staphylococcus in blood cultures is extremely important for the pediatric population, particularly younger children in neonatal intensive care units (NICUs). Emphasis should be placed on whether therapy is maintained. The Pediatric TAP ranked this recommendation with a "B" grade due to the need to revise the current definitions.

The Pediatric TAP identified several issues that should be resolved before public reporting definitions for children are developed. Definitions have not been developed for HAIs in children <1 year of age and children with hypertension, instability of vital signs and glucose instability. The current definition for "central lines" is unclear in children because no distinction has been made between surgically placed lines and pick lines. The major role of gram-negative microorganisms has not been fully discussed.

The current definition for "VAP" is unclear in children because no distinction has been made between progressive and persistent pneumonia. A determination has not been made on whether two x-rays should be obtained to diagnose VAP. Strategies have not been created to address specific pediatric subgroups with a potentially higher risk for HAIs, such as children with cystic fibrosis, severe control pneumonia, special needs or dependence on a device. No SCIP measures have been developed for SSIs in the pediatric population.

The Vermont/Oxford Network defines "low birth weight infants" as <1,500 grams, but this definition is different than NHSN language. Definitions for low birth weight infants should be reviewed for consistency between the two groups. Existing guidelines for cutaneous antisepsis in children have not been updated to reflect current practice or recent data. Some states have instituted public reporting of MRSA in NICUs and *C. difficile*, but reporting of these HAIs should be prioritized at the national level. Most notably, a resurgence of *C. difficile* has been observed in children.

Dr. Singh announced that the Pediatric TAP would submit a report of its deliberations to the NQF Steering Committee. The report would contain a strong recommendation for NQF to address the unresolved issues during its process of establishing public reporting definitions for children. Dr. Singh also asked HICPAC to consider these issues to determine whether the pediatric definitions should be revised.

Dr. Tapper reported that the NQF Steering Committee extensively discussed process versus outcome measures for VAP during its previous meeting. Several consumer advocates strongly supported outcome measures for VAP, while infection control experts were more in favor of process measures.

From November-December 2006, the NQF Steering Committee would hold a second public meeting to revisit outstanding issues, collect reports from all TAPs, and forward consensus draft reports for members and the public to review. From January-March 2007, the NQF Steering Committee would review and revise the TAP reports and submit the final drafts to the NQF Board and Member Councils for a formal vote. Dr. Tapper encouraged HICPAC to provide him with comments or suggestions to present during the next NQF meeting on November 17, 2006.

Dr. Gordon reported that the Intravascular Catheter and Bloodstream Infections TAP primarily discussed definitions for these HAIs during its meeting. However, the deliberations did not focus on the use of electronic data sources to detect infections.

Dr. Patchen Dellinger reported that the SSI TAP extensively discussed SSI rates, but the deliberations primarily focused on nine potential public reporting measures and whether these data were valid and reliable. The overarching position of the SSI TAP was that the proposed measures could be beneficial for hospital quality assurance programs, but would not be useful for public reporting purposes. The SSI TAP was not willing to endorse any measures that would discontinue surveillance when patients were discharged from the hospital because most SSIs are detected after discharge.

The SSI TAP fully endorsed three of the proposed public reporting measures: (1) the selection of antibiotics; (2) antibiotics administered within one hour of surgery; and (3) discontinuation of prophylactic antibiotics within 24 hours after surgery. The SSI TAP endorsed the 6:00 a.m. post-operative glucose measure for cardiac surgery with reservations because a single post-operative dose is inconsistent with published studies. The literature supports serum glucose lower than 200.

The SSI TAP did not endorse the post-operative normothermia measure for colorectal patients. Another TAP endorsed the deep sternal wound infection rate, but the SSI TAP communicated its disagreement with this recommendation. The SSI TAP revisited and took a new vote on the proper hair removal measure, but the result of the new vote is not known. The SSI TAP noted that repeat dosing was not included in any of the current measures.

Ms. Teresa Horan, of DHQP, reported that the Implementation and Reporting (IR) TAP reviewed and ranked public reporting measures graded by the other TAPs. The measures were ranked as "A," "B" or "C" based on the feasibility of collecting public reporting data, the usefulness of the data to consumers, and accessibility of the data to consumers. The NQF Steering Committee has not made a decision on the grades the IR TAP gave to the public reporting measures.

Two IR TAP members were dissatisfied with the public reporting measures overall and made the following comments for the record. Efforts to establish public reporting measures at this time are premature because no measures have been developed with the exception of those used in Pennsylvania and Florida. Implementation of public reporting measures should be studied for at least five years at the state level before national recommendations are made. Research needs and unresolved issues should be identified and addressed before NQF recommends a set of national public reporting measures. Representatives of PHC4 and a consumer organization supported the position of the two IR TAP members.

Ms. Horan reported on the outcomes of two other TAP meetings. The VAP TAP raised concerns about the public reporting definitions overall, but proposed changes and reached consensus on a few process measures. The UTI TAP identified several issues for future research and recommended pilot studies for prevention processes and standing orders to remove catheters. However, the UTI TAP did not endorse any outcome measures and noted that no definition has been established for "public reporting of UTIs."

Dr. Cardo reported that she recently received a letter from NQF announcing the completion of all TAP activities. The NQF Steering Committee would consider CDC's proposed changes on the public reporting definitions during the consensus-based process. On the one hand, NQF acknowledged that CDC would need to pilot studies to revise some of the definitions and evaluate the impact of these changes.

On the other hand, NQF was aware that CDC could easily implement other definitions. For example, the SSI definitions would require no further actions because no outcome measures were proposed. However, Dr. Cardo clarified that CDC's primary concerns are actual implementation of the public reporting definitions by states and dissemination of solid information to minimize confusion about public reporting in states.

Dr. Cardo added that NQF also asked CDC to participate in a conference call to discuss the proposed changes on the public reporting definitions submitted by the TAPs. However, she was extremely interested in including broader input from sources other than CDC in this discussion. Most notably, NQF informed CDC of its strong interest in engaging HICPAC in the consensus-based process to establish public reporting definitions due to its expertise in the healthcare infection control field.

Dr. Cardo proposed strategies for HICPAC to participate in CDC's future communications with NQF. HICPAC could form a subgroup to participate on the conference call with NQF, convey concerns about the proposed measures, and recommend options to strengthen the public reporting definitions. HICPAC could assist CDC in gathering input from APIC, CSTE and SHEA and conveying this feedback to NQF.

Several HICPAC members agreed that the development of public reporting measures was premature at this time because the proposed timeline is unrealistic and NQF's efforts to

date have been disorganized. The HICPAC members made three suggestions that should be considered in NQF's consensus-based process to establish public reporting definitions.

- CDC should explore the possibility of using subsets of its existing public reporting definitions to eliminate superficial HAIs and focus on HAIs during admission and readmission.
- CDC and HICPAC should provide NQF with specific and realistic deliverable dates to implement the public reporting measures.
- HICPAC should conduct evaluation studies of the implementation of public reporting measures at the state level. States could provide data to HICPAC to facilitate this effort in a short period of time.

Dr. Brennan confirmed that he would engage Drs. Bell and Cardo in a discussion about the most appropriate approach to involve HICPAC in NQF's consensus-based process to develop public reporting definitions. The suggestion for HICPAC to evaluate the implementation of public reporting measures at the state level would also be considered.

Update on the Sterilization and Disinfection (S&D) Guideline

Dr. Bell reported that two issues are delaying CDC's efforts to finalize and release the S&D guideline. To address the first issue, CDC and FDA are continuing communications to finalize language related to high-level disinfection of endoscopes using glutaraldehyde. The original recommendation contained the term "at the very least," but this language undermined FDA's officially cleared label claim that should be followed to achieve high-level disinfection.

CDC changed the language to emphasize that the FDA label claim should be followed. The revised recommendation also notes that several other studies are available on high-level disinfection of endoscopes using glutaraldehyde. CDC would provide HICPAC and the primary author with the revised language for review. CDC would also redistribute the entire S&D guideline to particularly provide new HICPAC members with an opportunity to review the full document.

To address the second issue, CDC would circulate recommendations ranked in the IB versus II categories. HICPAC and the primary author would be asked to rapidly complete the review and approval process within the next three days. CDC would take this approach due to several reasons. The IB and II categories in the S&D guideline are different than those in other environmental infection control guidance. Some of the IB recommendations in the S&D guideline are more "common sense" than evidence-based. HICPAC's current system to rank recommendations is outdated. A clear distinction has not been made between the IB and II categories.

Dr. Bell reminded HICPAC of the current categories that are used to rank its recommendations in guidelines:

- IA (prospective controlled trials that are solid and supported by strong evidence).
- IB (less strong evidence, but sound clinical opinion).
- IC (regulatory requirements).
- II (no data, but an appropriate action to take based on "common sense.")

Dr. Cardo made several remarks in response to the S&D guideline. The endoscope recommendation should be ranked as "IC" due to the guidance to follow the FDA label claim. The parenthetical language should be removed. HICPAC should submit comments on the revised endoscope language and the IB/II recommendations as soon as possible because the D&I guideline has already been published in the *MMWR*. HICPAC's input on the IB/II recommendations should be limited to the actual categories because the content of this guidance would not be changed.

Dr. Brennan announced that an extensive discussion on HICPAC's guidelines process was scheduled on the agenda for the following day.

Report by the DHQP Director

Dr. Cardo covered the following areas in her report. DHQP is closely collaborating with CSTE and states that are using NHSN to implement public reporting mandates. However, DHQP is also providing guidance to states that are not using NHSN for public reporting purposes. DHQP sponsored a meeting with APIC, IHI, SHEA, VHA and several groups in Pennsylvania to identify the best strategies to prevent and measure the impact of MRSA and multidrug-resistant organisms (MDROs) in hospitals.

DHQP is continuing its strong partnership with CMS on SCIP measures, pay-for-performance issues, the Deficit Reduction Act, and prevention of HAIs. DHQP recently briefed Congressional staff on joint efforts by CDC, HICPAC, CMS and JCAHO to address influenza vaccination of HCWs and hospital infections. DHQP acknowledged the critical need to continue to educate Congress to more widely promote prevention of infections in hospitals. Most notably, Congress has engaged a physician with knowledge of HICPAC's recommendations and other ongoing initiatives to prevent HAIs.

DHQP's responsibility for infection control of pandemic influenza was recently expanded to include healthcare preparedness. CDC allocated additional funding and full-time equivalents to DHQP to support new tasks in this area. DHQP is closely collaborating with AHRQ and the Health Resources and Services Administration on its new role in healthcare preparedness.

Dr. Cardo noted that HICPAC's agreement to conduct a new activity would be extremely beneficial to DHQP. Existing recommendations to guide surveillance, risk adjustment, public reporting and other infection control issues are targeted to mid-size and large hospitals. However, guidance in these areas should be specifically developed for small hospitals.

HICPAC agreed with Dr. Cardo on the need to formulate infection control guidance specifically for small hospitals. Several members made suggestions that should be considered if HICPAC agreed to undertake this effort.

- Future communications with NQF should explore the possibility of developing minimum public reporting criteria for small hospitals.
- Minimum criteria should be established for small hospitals in the following areas: patient transfers; isolation capacity and controls while waiting for patient transfers; and screening and containment procedures to identify patients who should be transferred.
- The successful track record of small hospitals in taking a "zero tolerance" approach to infection prevention should be highlighted as a best practice or model in the guidance.

With no further discussion or business brought before HICPAC, Dr. Brennan recessed the meeting at 5:10 p.m. on November 13, 2006.

Update on Pandemic Influenza Activities

Dr. Brennan reconvened the HICPAC meeting at 8:30 a.m. on November 14, 2006 and yielded the floor to the first presenter. Dr. Bell reported that DHQP is involved in pandemic influenza planning in terms of infection control and preparedness, but has no role in issues related to vaccine or antiviral drugs. DHQP and several other CDC entities formed a small workgroup to focus on non-pharmaceutical public health interventions and broad community measures in pandemic influenza, such as school closures, cancellation of public events, and the use of masks and respirators.

CDC is also addressing concerns about a pandemic influenza strain that might have different transmissibility characteristics. Most notably, the H5N1 strain has manifested in infectious material in diarrhea in children. Overall, CDC's planning guidance for pandemic influenza is designed to identify the most potentially important factors that healthcare facilities and HCWs should consider. However, the recommendations are not clearly defined or concrete due to the hypothetical nature of pandemic influenza.

Dr. Bell described three sets of ongoing pandemic influenza guidance. Guidance for HCWs on the use of masks or respirators during pandemic influenza was recently posted on the DHS web site at www.pandemicflu.gov with the following recommendations.

Respirators should be used for high-risk procedures, such as suctioning and bronchoscopy. The use of respirators would be "prudent" if the HCW is face-to-face with an infectious patient. This language was incorporated to resolve uncertainties about whether three feet, six feet or another range should be used as the distance for droplet transmission of influenza. The language also provides facilities with flexibility to make decisions based on local characteristics and populations.

Guidance on negative pressure isolation rooms and respirators was separated to ensure that hospitals did not incur costs to add unnecessary rooms. In addition to background information and recommendations specifically targeted to HCWs, the guidance also includes appendices on different types of respirators and masks, an explanation of particle dynamics, and NIOSH's rationale for the guidance.

The pandemic influenza guidance for HCWs was vetted through a broad range of federal agencies, state and local health departments, professional organizations and unions. The partners were divided on whether respirators or surgical masks should be recommended for pandemic influenza. However, the guidance will be refined and corrected over time as more surveillance data are collected on different viral strains and the transmissibility of these strains.

HHS asked CDC to develop guidance on community use of masks and respirators during pandemic influenza. CDC will submit the draft guidance to HHS and other federal partners for the government clearance process prior to its release on the web site. The document contains three key messages for the public to avoid exposures, contain exposure sources, and limit exposures. This approach was taken for the public to consider actual sources of infectious materials during a pandemic, particularly infected persons.

The community guidance recommends the use of surgical masks rather than respirators for members of the general public during pandemic influenza. The document makes several key points to support the recommendation. Existing guidelines on respiratory etiquette and hand hygiene are emphasized. Surgical masks are more comfortable than respirators and provide a splash barrier to a large proportion of influenza virus transmission.

The average member of the public would have difficulty breathing through a respirator, particularly in the absence of occupational resources for fit testing and respiratory testing. Community members with chronic lung disease or other respiratory conditions would be unable to wear a respirator for an extended period of time. However, the document recommends respirators for community use in situations where an individual would be in contact with an infected patient for a brief period of time.

CDC is not actively involved in the third set of guidance for pandemic influenza. The Department of Labor (DOL) is developing occupational guidelines for all other aspects of pandemic influenza. Efforts are being made to incorporate risk stratifications to maintain the focus on "realistic" rather than "imagined" sources of risk. This guidance will consider input from various sources on retaining nuclear power plant staff, air traffic controllers and other critical personnel in fixed industries during pandemic influenza. CDC has asked DOL to also consider housekeeping staff and other contractors in these facilities during pandemic influenza.

Dr. Bell was pleased to announce that funding was allocated to support a pandemic influenza research agenda. The resources are expected to facilitate the production of more evidence-based guidance on pandemic influenza in the future. Dr. Bell's summary of these studies is outlined below.

- The NIOSH comprehensive multi-year study is refining its previous research on particulate matter to include an infectivity component. The study is also focusing on a personal sampler that was designed to identify specific HCWs who would be at risk and need occupational health protection.
- A study by the CDC Division of Migration and Quarantine is focusing on influenza particles transmitted from persons breathing, speaking or coughing without the need for a tube. The focus of the research project on viable virus particles will provide a solid basis of comparison to the NIOSH study.
- A case-control study in multiple dormitories in Berkeley, California is focusing on the impact of interventions. Cases will be given hand hygiene gels or respirators during a routine influenza season, while controls will not be provided with any interventions.
- A community study in New York is focusing on the impact of interventions. Certain households will use surgical masks, respirators or hand hygiene gels, while other households will use no interventions.
- A study in Virginia is focusing on the impact of interventions. Seronegative students will be exposed to live rhinovirus in an aerobiology chamber with no protection; eye protection alone; eye, nose and mouth protection; a mask; or respirator.

Dr. Bell described DHQP's pandemic influenza preparedness activities. The CDC Office for Terrorism, Preparedness and Emergency Response (COTPER) released a \$12 million request for proposals for pandemic influenza preparedness. In response to COTPER's request, DHQP recommended several tasks that should be included in the awarded projects.

"Essential services" during pandemic influenza should be clearly defined, such as births, myocardial infarctions, strokes and severe trauma. Minimum staffing levels should be determined to continue to deliver limited services during a pandemic. Additional staff should be identified for patients with pandemic influenza who would require triage, routine

care or intensive care. Licensure, credentialing, liability and other legal issues should be addressed to engage HCWs from other states and encourage healthcare facilities to continue to conduct business during a pandemic.

HHS allocated pandemic influenza dollars to DHQP to provide infection control training in Nairobi, Kenya and Bangkok, Thailand. During the two-year project in Thailand, DHQP will partner with WHO to provide respiratory hygiene training and distribute educational materials to Southeast Asian countries with the greatest burden of respiratory illness.

During the three-year project in Kenya, retired nurses will be hired to create an infection control workforce. Activities of the new workforce will include visiting eight provincial hospitals three or four times per month, performing baseline assessments, providing training, reinforcing infection control, and serving as an onsite resource. DHQP will attempt to leverage resources from partners to expand the initiative to other areas after the three-year project period.

Dr. Bell asked HICPAC to provide guidance on CDC's pandemic influenza activities in specific rather than broad areas, such as parameters for a more optimal mask or respirator, a systematic approach to protect environmental healthcare facilities, or strategies to address sick children during pandemic influenza. He also asked HICPAC to explore the possibility of developing a white paper on the role of the community in healthcare.

Several HICPAC members made suggestions for CDC to consider in its ongoing pandemic influenza planning and preparedness activities.

- CDC should closely collaborate with CMS to address reimbursement issues for hospitals and ensure continuity of care during pandemic influenza.
- CDC should consider the current ethical consensus in which society must provide the best known protection to personnel who are expected to report to work during an event. CDC's recommendation on the use of N95 respirators to protect HCWs during pandemic influenza should be supported by a strong ethical basis.
- CDC should use fit testing and medical checks of N95 respirators as an opportunity to reinforce infection control training for front-line HCWs.
- CDC's pandemic influenza guidance should place more emphasis on the community aspect of transmission.
- CDC should redesign the pandemic influenza research projects to focus on the spectrum of disease, patient source and containment measures. Serologic studies that were conducted in homes and other previous research on these issue should be reviewed in this effort.
- CDC's pandemic influenza studies should be supported by solid evidence and a scientific approach on the mode of transmission for influenza virus and the viability of the organism.

- CDC should solicit guidance from HICPAC on the allocation of funds under the pandemic influenza research agenda to ensure that the studies are designed to answer relevant infection control questions.
- CDC and its federal partners should conduct studies, disseminate solid evidence and allocate resources to support its recommendation on HCW use of respirators during pandemic influenza. All healthcare facilities do not have funds to purchase respirators, comply with fit-testing requirements, and maintain respirator programs on an ongoing basis for theoretical risks from a pandemic.
- CDC and HICPAC should develop a white paper on infection control practices in the healthcare setting for pandemic influenza planning and preparedness.
- CDC and HICPAC should engage the American Academy of Pediatrics in developing guidance for the care of sick children during pandemic influenza.

Dr. Brennan confirmed that he would collaborate with DHQP staff to reconvene the Preparedness Workgroup. The workgroup's new charge would be to identify HICPAC's role in CDC's ongoing pandemic influenza activities.

Update on the Prevention EpiCenter Program

Dr. Kurt Stevenson is a HICPAC member and an EpiCenter investigator. He reported that CDC launched the Epidemiologic Centers for the Prevention of Healthcare-Associated Infections Program in 1997 as a mechanism to directly collaborate with academic partners. CDC funded the EpiCenters to address important scientific questions on the prevention of HAIs, antibiotic resistance and other healthcare-associated adverse events.

The first cycle of EpiCenters used funding to (1) develop strategies to reduce transmission of antibiotic resistance and organisms in intensive care units; (2) analyze novel approaches to skin antisepsis; (3) evaluate the role of administrative and pharmacy data in simpler and more accurate surveillance of SSIs; (4) examine post-prescription reviews as a method of promoting rationale antibiotic use; and (5) focus on transmission and the role of active surveillance culturing. The CDC web site contains references on the first cycle of EpiCenter research projects.

The current cycle of EpiCenters represents ~50 affiliated hospitals and healthcare plans that are electronically linked. A steering committee of principal investigators of the five funded projects, CDC staff, HICPAC members, representatives of professional organizations and other stakeholders oversees EpiCenter activities. The following tasks have been completed to date. All projects proposed by the EpiCenters were reviewed and approved. Collaborations were developed for studies to be conducted across multiple hospitals and all EpiCenters. Approval of the EpiCenter projects from CDC and local

Institutional Review Boards has been obtained or is pending. Efforts will be made in the future to form an advisory committee to the steering committee.

The current cycle of EpiCenters initiated activities in February 2006 focusing on the use of EHRs to improve the accuracy and efficiency of surveillance, strengthen infection control interventions, and prevent HAIs. Projects approved by the steering committee for the first year of the current cycle include:

- The role of various algorithms as surveillance tools for catheter-associated BSIs.
- Detection of SSIs.
- The role of CMS administrative data as a surveillance tool for SSIs.
- The capacity of various electronic sources to generate accurate data on antimicrobial use.
- Surveillance of *C. difficile*.
- The role of chlorhexidine soaps in the prevention of infections.
- The role of electronic infection control alerts in identifying high-risk patients for MRSA and removing urinary catheters to prevent UTIs.

Dr. Gordon is HICPAC's liaison to the EpiCenters. He emphasized the critical need to formally engage EpiCenter investigators in HICPAC meetings on a regular basis to provide updates on findings from the research projects. He pointed out that the EpiCenter studies could play an important role in HICPAC's deliberations, development of future guidelines, and other infection control activities. Moreover, the EpiCenter research projects have made tremendous contributions to the scientific literature.

Other HICPAC members asked CDC to explore the possibility of using the EpiCenters to evaluate HICPAC's criteria to rank recommendations in guidelines. For example, the EpiCenters could systematically review references that support HICPAC's recommendations to determine whether the ranking criteria have been met or should be revised.

Dr. Brennan proposed that two EpiCenter investigators present findings from research projects during each future HICPAC meeting. This model would allow HICPAC to learn about all of the EpiCenter studies on an annual basis. However, he realized that the investigators might be concerned about this approach. Presentations in a public forum on preliminary data or research protocols that were developed by and are the property of outside investigators might jeopardize the publication of these data in peer-reviewed journals in the future.

Despite this concern, however, Dr. Brennan was confident the EpiCenter investigators could present data to HICPAC without revealing proprietary or confidential information. He emphasized the need to eliminate silos among HICPAC, the EpiCenters and DHQP.

Update on the HICPAC Guidelines Process

Dr. Brennan informed the new members that this agenda item was a follow-up to HICPAC's previous discussion on an appropriate process to conduct business. During a previous meeting, several members did not support HICPAC endorsing or co-authoring guidelines developed by other groups. At that time, CDC also reviewed HICPAC's charge to provide advice to the HHS Secretary, CDC Director and DHQP. To a lesser degree, HICPAC also provides guidance to the broader infection control and prevention community and high levels of the U.S. public health infrastructure.

Dr. Brennan summarized HICPAC's major areas of focus over the past few years: (1) public reporting document; (2) MDRO and isolation guidelines; (3) guidance on pertussis and influenza vaccination of HCWs; (4) EHR white paper; and (5) policy statements to CMS on the interpretative guidelines and IPPS. At this time, 14 guidelines are posted on the HICPAC web site, but some of these documents are in critical need of an update. For example, one of the 14 guidelines was released in 1983.

Dr. Brennan has been soliciting volunteers to take responsibility for reviewing and updating specific guidelines over the past few months, but HICPAC has not been very enthusiastic about this process. He was aware of several reasons that have contributed to HICPAC's lack of interest in this activity. The reality in the field is to rapidly change guidance, evidence and knowledge to inform CDC, CMS and other agencies.

A lengthy amount of time and an enormous commitment are needed for HICPAC and CDC to develop, review, revise, approve, clear and publish guidelines. For example, efforts were initiated on the isolation guideline seven years ago, but the document has still not been placed in the public domain. The terms of all federal advisory committee members are established for a specific time period. As a result, new HICPAC members might feel uncomfortable endorsing a document that was developed by the previous membership.

Dr. Brennan asked the members to review HICPAC's current process to conduct business and identify strategies to fulfill its charge in a more evidence-based manner. Most notably, HICPAC's weighted scoring system to rank recommendations in guidelines is not clear or transparent. The semi-quantitative or qualitative approach weakens HICPAC's ability to defend the recommendations.

Dr. Brennan also asked HICPAC to focus on specific issues during the discussion. DHQP should allocate additional resources for HICPAC to produce more evidence-based guidelines and update the documents on a more rapid cycle in light of three meetings per year. HICPAC's activities should be clearly defined in terms of developing policy statements, guidelines or both.

Although HICPAC is viewed as an expert and a leader in developing guidance for healthcare infection control practices, this role is not being fulfilled if ICPs, hospital epidemiologists and other healthcare professionals must wait two to seven years before guidelines are available for use in actual practice. HICPAC might need a narrower focus at this time to answer specific research questions.

Overall, Dr. Brennan emphasized the need for HICPAC to take a different approach in developing guidelines. Unlike the climate when HICPAC was initially established, the current environment is strongly influenced by politics, payment reform, liability, public advocacy and consumer interest. HICPAC must be able to defend its guidance in light of these realities. For example, many stakeholders view HICPAC's guidelines as an exhaustive compilation and summary of the published literature that is not supported by evidence-based methods or a clear framework.

Dr. Craig Umscheid, of the Center for Evidence-Based Practice (CEP) at the University of Pennsylvania Health System (UPHS), presented CEP's model of developing evidence-based guidelines for HICPAC to consider during its discussion. CEP's mission is to support patient care, quality and safety through the practice of evidence-based medicine. To produce a guideline for UPHS, CEP performs a systematic review and considers key stakeholder issues when a clinical issue arises in UPHS that requires evaluation of a drug, device or process of care.

CEP developed a step-wise process to produce evidence-based guidelines. One, CEP evaluates and prioritizes issues of concern based on referrals from chief medical officers and committees on pharmacy and therapeutics, technology, and clinical effectiveness and quality improvement at UPHS hospitals. Dr. Brennan, as the UPHS Chief Medical Officer, can also refer issues to CEP for evaluation.

CEP solicits input from UPHS medical and nursing leadership in prioritizing issues of concern. CEP applies its established impact criteria to guide the prioritization process, including the potential to affect a large number of patients, relationship to a national or local quality measure, and potential risk to UPHS.

Two, CEP clearly defines the prioritized issue of concern based on the "patients, interventions, comparators and outcomes" (PICO) approach.

Three, CEP convenes a task force of key stakeholders with appropriate expertise to assist in reviewing data and developing evidence-based practice guidelines. Potential task force members are asked to disclose financial conflicts for the manufacturer of the technology and its competitors over the past year, such as research funding, intellectual property rights, stock ownership and honorarium in certain situations. Task force members with significant financial conflicts can participate in the development process, but cannot vote on the final guideline.

Four, CEP performs a systematic literature review that is guided by opinions of clinical experts in the field, a written research protocol, and well-established methods developed by national and international groups. CEP organizes the systematic literature review into aims, background and methods sections to develop inclusion and exclusion criteria for studies; identify databases and other data collection methods; determine an approach to judge the quality of studies; and select a quantitative, qualitative or other type of analysis.

CEP agreed on a systematic approach to increase the transparency and validity of the evaluation process, provide more opportunities to replicate the review, and identify areas of uncertainty and future research needs. CEP was aware that a narrative literature review has no protocol to include or exclude studies and could lead to a more biased evaluation.

Five, CEP extracts and analyzes data to include in the guideline.

Six, CEP presents the findings of the evaluation to the task force to grade the quality of evidence for each outcome. The "grading of recommendations, assessment, development and evaluation" (GRADE) approach is used in this effort. Several national and international groups have adopted the GRADE model and are engaged in ongoing activities to develop one worldwide system to grade evidence and recommendations.

The GRADE model includes a review of four factors that inform outcomes of interest: the study design, individual study quality, consistency of effects across studies, and directness of the study results to the target population. Results of the GRADE review are used to rank the overall quality of the evidence in four categories.

A "high" grade means further research is very unlikely to change confidence in the estimate of the effect. A "moderate" grade means further research is likely to impact confidence in the estimate and might change the estimate. A "low" grade means further research is very likely to impact confidence in the estimate and is likely to change the estimate. A "very low" grade means any estimate of effect is very uncertain. Some groups have combined the third and fourth GRADE categories into one "low" category due to the difficulty in distinguishing between these two groups.

Seven, CEP solicits input from persons outside the task force.

Eight, CEP balances the risks and benefits of each outcome based on net benefits, harms, tradeoffs and uncertain tradeoffs.

Nine, CEP makes recommendations on the issue of the concern. A "strong" recommendation means actions should definitely be taken to achieve net benefits or actions should definitely not be taken to avoid net harms. A "weak" recommendation means actions should probably or probably not be taken depending on the tradeoffs. Clinical judgment and patient preferences are extremely important factors in making a weak recommendation. A

“future research” recommendation means the tradeoffs are too uncertain to provide clear guidance.

Dr. Umscheid described an actual situation at UPHS in which CEP piloted its step-wise process and developed an evidence-based practice guideline over a period of ~4 months. In step 1, Dr. Brennan referred the issue of “continued use of aprotinin” to CEP for evaluation in response to concerns expressed by UPHS cardiac anesthesiologists. Aprotinin is a hemostatic agent that is used to prevent blood loss during cardiac surgery. CEP prioritized the issue based on recent publications of several clinical trials that suggested aprotinin was associated with renal failure. FDA subsequently released an advisory about the potential relationship between aprotinin and renal failure.

In step 2, the PICO model was applied for the aprotinin evaluation. The patients were adult cardiac surgery recipients. The intervention was aprotinin. The comparators were any drug alternatives to aprotinin. The outcomes were the six most important factors in an aprotinin evaluation identified by the cardiac anesthesiologists.

In step 3, members of the task force for the aprotinin evaluation were identified and convened.

In step 4, a systematic literature review was performed that identified 72 recent and high-quality randomized control trials and reviews of aprotinin for each exposure outcome combination.

In step 5, an evidence table was created for the aprotinin evaluation that listed characteristics of each study: formal name, author, design, quality score, target population, total number of patients, total number of patients who received aprotinin or a placebo and required transfusion, relative risks, and upper and lower confidence intervals. A meta-analysis of two randomized control trials was also performed. The meta-analysis showed that aprotinin was significantly associated with a reduced number of transfusions in patients receiving off-pump cardiac surgery.

In step 6, the aprotinin data were reviewed with the task force. No serious limitations in the quality of the studies, important consistencies, or significant barriers to the directness of the studies were identified. Each outcome in the aprotinin evaluation was given a “high” grade.

In step 8, tradeoffs were identified between the benefits and harms of using aprotinin, such as reduced transfusions, re-operations for bleeding and strokes versus increased renal dysfunction.

In step 9, a “weak” recommendation was made in which the use of aprotinin was supported in patients at high risk for bleeding and stroke and discouraged in patients at high risk for renal dysfunction.

Dr. Umscheid announced that CEP is now applying its step-wise process to produce evidence-based guidelines for four other issues of concern. However, CEP is making efforts to refine the pilot to complete these guidelines in two to three months.

Dr. Umscheid compared the HICPAC and GRADE systems to rank recommendations in guidelines. The key similarities between the two systems are "strong," "weak" and "future research" categories and evidence ranging from very low to low quality to support a future research recommendation. The key difference between the two systems is the quality of evidence used to support strong and weak recommendations.

On the one hand, HICPAC supports a strong recommendation with evidence ranging from very low to high quality and supports a weak recommendation with evidence ranging from very low to moderate quality. On the other hand, GRADE supports a strong recommendation with evidence ranging from moderate to high quality to demonstrate obvious net benefits or net harms and supports a weak recommendation with evidence ranging from low to high quality to balance benefits and risks of each outcome.

Several HICPAC members made suggestions to refine and advance HICPAC's guideline development process.

- CEP's systematic and objective review process should be adopted for HICPAC to develop evidence-based guidelines.
- CEP's process should be tailored to meet HICPAC's charge to provide infection control guidance.
- Evidence-based approaches other than CEP should be reviewed and considered because this process has only been piloted for a specific issue.
- A clearly defined format and system should be developed to select and prioritize the literature that would be used to support HICPAC's recommendations.
- A guidance document with methods, rules and a detailed description of the systematic review process should be created to guide the development of HICPAC guidelines. The guidance document should be institutionalized and given to all new HICPAC members.
- DHQP should identify external resources that might be available to support HICPAC's guideline development process. For example, new and existing relationships with schools of public health and professional societies could be established and strengthened to leverage personnel and other resources to develop and update HICPAC guidelines.
- HICPAC should play an "oversight" role in guidelines by other groups instead of actually developing guidelines.
- Best practice guidance that could serve as "soft" criteria for HICPAC to provide references should be developed.
- A firm quantitative/qualitative approach should be taken in HICPAC's guideline development process.

- HICPAC's guideline development process should not attempt to impose conformity in areas of uncertainty with no supporting evidence. HICPAC guidelines should provide healthcare facilities with flexibility to make local decisions in these areas.
- Research priorities should be identified for areas of uncertainty. EpiCenters, industry and other groups should be engaged to assist HICPAC in this effort.
- A guideline should be developed on rigorous study designs and methods to assist HICPAC in overcoming barriers to poor or no data.
- HICPAC's current criteria to rank recommendations in guidelines should not be changed because other professional societies use the same system.
- HICPAC should continue its role as an expert and leader in the development of healthcare infection control practices guidelines because the guidance is tremendously important to both national and international organizations.
- DHQP should allocate a specific budget and internal resources for HICPAC to develop and update guidelines.
- Liaisons should keep HICPAC informed of guidelines developed by their respective organizations. This approach should be used to engage HICPAC early in the process when a request is made for formal HICPAC endorsement of guidelines that are developed by other groups.
- Each liaison should provide DHQP with a written list of guidelines their respective organizations are currently developing or updating for discussion at the next HICPAC meeting.

Dr. Bell made several observations on HICPAC's guideline development process in response to some of the suggestions. DHQP is interested in assigning more staff to develop and update HICPAC guidelines, but the creation of a "CEP-type" institution in DHQP would be highly unlikely. However, several options are available and should be considered. Specific components from CEP and other systems could be extracted and compiled to develop a new process for HICPAC guidelines. HICPAC could narrow its focus on future guidelines, such as one aspect of SSIs. HICPAC could develop surveillance definitions. HICPAC's new system could be piloted with a small guideline.

Dr. Bell fully supported the suggestion to create a guidance document on HICPAC's guideline development process. He noted that the document would be extremely helpful to DHQP staff and would also facilitate consistency in ranking recommendations as HICPAC memberships changed over time.

Dr. Brennan confirmed that he would take several actions to advance HICPAC's guideline development process. He and Dr. Umscheid would draft a white paper with HICPAC's suggestions, specific components of the CEP system, and appropriate aims, research questions and approaches for HICPAC guidelines. The draft would be circulated to HICPAC for review, discussion and comment during a conference call or the next meeting.

Dr. Brennan would draft a letter to DHQP summarizing HICPAC's comments and requesting that additional resources be considered in the next budget cycle. In particular, more resources would be needed for HICPAC to undertake the major effort of developing surveillance definitions. Dr. Brennan would convene a conference call with HICPAC to prioritize guidelines that need to be updated.

HICPAC Business

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

1. Drs. Brennan and Bell will review the list of liaisons that were previously proposed and the web sites of these potential liaisons.
2. Drs. Brennan and Bell will collaborate with Ms. Bjerke and Ms. Horan to identify new DHQP staff and other internal resources to assist in finalizing APIC's home health definitions.
3. Dr. Brennan will collaborate with Drs. Jencks and Richards to address upcoming changes in IPPS payments to hospitals and the CMS discharge planning initiative. Dr. Brennan will ask a HICPAC member to serve as a liaison to this effort.
4. Drs. Brennan and Bell will place the following items on the agenda for the February 2007 HICPAC meeting:
 - Presentation by the EHR Workgroup on the draft IT white paper.
 - Extensive discussion with CMS on the discharge planning initiative.
 - Two 30-minute presentations by EpiCenter investigators at each future HICPAC meeting. [Dr. Brennan will ensure that the presentations are designed to assist HICPAC in creating a framework for developing infection control practices guidance in the future.]
 - Brief overviews by each liaison on guidelines their respective organizations are developing or updating that would be relevant to or have a potential impact on HICPAC.
5. Dr. Cardo will follow-up with the NQF Steering Committee to propose a process for developing definitions for public reporting outcomes and formally involving a subgroup of HICPAC and DHQP representatives in this effort.
6. Dr. Bell will solicit HICPAC's vote by e-mail on the revised language in the S&D guideline on high-level disinfection of endoscopes using glutaraldehyde.

7. Dr. Brennan will collaborate with Dr. Umscheid in drafting a white paper on HICPAC's guideline development process and distribute the document to each member for review and comment.
8. Dr. Bell or Ms. Lynch will e-mail the following materials to HICPAC:
 - Written instructions for the members to complete and submit travel request forms and worksheets.
 - Dr. Richards' slides on IPPS.
 - Influenza materials generated by the CDC Press Office for further distribution to other professional organizations.
 - The IB/IC recommendations in the S&D guideline along with the entire document.
9. DHQP will correct the MDRO guideline to reconcile the table and text and list the actual HICPAC membership at the time the document was developed.
10. Dr. Brennan, Dr. Bell and Ms. Lynch will collaborate to reconvene the Preparedness Workgroup. Discussion topics on the conference call will include CDC's pandemic influenza research agenda, infection control issues in the community, and the most appropriate areas where HICPAC should provide input. Dr. Smith will continue to chair the workgroup; Drs. Henderson, Ramsey and Stevenson will serve as members.
11. Dr. Brennan will remind Dr. Jernigan of Dr. Gordon's role as HICPAC's liaison to the EpiCenters.
12. Dr. Brennan will draft an advisory letter to Dr. Cardo based on HICPAC's discussion of its infrastructure and resource needs for the guideline development process.
13. Dr. Brennan will follow-up with Dr. Naomi O'Grady, of NIH, on her leadership role in updating the BSI guideline.
14. The HICPAC members will take the following actions:
 - Dr. Gordon will (1) participate on the CMS discharge planning initiative; (2) present the draft EHR white paper for HICPAC's review, discussion and comment during the February 2007 meeting; and (3) continue to serve as a liaison to the EpiCenters.
 - Dr. Singh will provide guidance on pediatric issues in terms of CDC's pandemic influenza activities and NQF's public reporting definitions.
 - Dr. Stevenson will (1) serve as a Preparedness Workgroup member; (2) convey HICPAC's request to receive regular reports from EpiCenter investigators; and (3) compile recent studies on epidemiologic methods for infection control performance improvement.

- Dr. Engel will provide HICPAC with regular updates on CSTE's experiences and lessons learned in collaborating with CDC to develop definitions for community-acquired infections.
- Dr. Pegues will (1) clarify methodologies for reviewing the literature and ranking the strength of evidence and (2) represent HICPAC in IDSA's efforts to revise the UTI guideline.
- Dr. Ramsey will serve as a Preparedness Workgroup member and work on the healthcare vaccination guideline.
- Dr. Smith will serve as the Preparedness Workgroup Chair and collaborate with Drs. Brennan and Bell to develop an agenda for the workgroup's next conference call.
- Ms. Murphy will collaborate with and obtain input from other members to develop a "HICPAC orientation packet" of guidelines that have been developed, are of highest priority, or are being addressed by other professional societies.
- Mr. Olmsted will assist in developing the architecture for an evidence-based approach in the guideline development process and work on the BSI guideline.
- Ms. Burns will work on the UTI guideline.
- Dr. Dellinger will work on the SSI guideline.

Closing Session

The dates of the next three HICPAC meetings are February 15-16, 2007; June 11-12, 2007; and November 12-13, 2007.

With no further discussion or business brought before HICPAC, Dr. Brennan adjourned the meeting at 12:45 p.m. on November 14, 2006.

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

Date

Patrick J. Brennan, M.D.
HICPAC Chair