

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



**Healthcare Infection Control Practices
Advisory Committee
June 12-13, 2008
Atlanta, Georgia**

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ATTACHMENT 1

List of Participants

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Ms. Nancy Bjerke (Association of
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Ms. Joan Blanchard (Association of
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Dr. Lisa Maragakis (Society for
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Ms. Lisa McGiffert (Consumer's Union)
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Wei-Hui Chou (Taiwan CDC)

Beth Feldpush
(American Hospital Association)
[via conference call]
James Heilman (3M Health Care)
Tom Keaty (Sage Products)
Nicole Larsen (Medline Industries)
Grace Lee (Eastern Massachusetts
Prevention EpiCenter)
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Hollie Lewis (Cepheid)
James Liddell (Becton Dickinson
Microbiology Systems)
Michele Marill (Hospital Employee Health)

Richard Platt
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Jaime Ritter (CR Bard, Inc.)
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Wade Tetsuka (AirInSpace)
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Don Wright (Principal Deputy Assistant
Secretary for Health, HHS)

EXECUTIVE SUMMARY

During the opening session of the Healthcare Infection Control Practices Advisory Committee (HICPAC) meeting on June 12-13, 2008, no members declared any new conflicts of interest for the record that were pertinent to the current agenda.

The Division of Healthcare Quality Promotion (DHQP) highlighted results from four Prevention EpiCenters projects: (1) methods to enhance inpatient surgical site infection (SSI) surveillance; (2) the use of Medicare claims data to rank hospitals by SSI risk; (3) a multi-center comparison of electronic algorithms for central line-associated bloodstream infection (CLABSI) surveillance in intensive care units (ICUs); and (4) interventions to reduce infections by daily chlorhexidine bathing. A new EpiCenter project was proposed to prioritize recommended infection control and prevention practices in the United States.

HICPAC agreed to have further discussion on formulating guidance to advance electronic surveillance, piloting EpiCenter algorithms in National Healthcare Safety Network (NHSN) hospitals, and supporting the proposed EpiCenter project to prioritize infection control and prevention recommendations in the United States.

A panel of DHQP staff provided extensive updates on recent field investigations and community outreach campaigns conducted by the Prevention and Research Branch; ongoing efforts to address *C. difficile*-associated disease (CDAD); activities to improve ambulatory care, injection safety and basic infection control practices; and laboratory research projects conducted by the Clinical and Environmental Microbiology Branch.

HICPAC agreed to listen to additional presentations and have more substantive discussions during future meetings before taking formal action to address injection safety and basic infection control practices in outpatient facilities.

The Principal Deputy Assistant Secretary for Health at the Department of Health and Human Services (HHS) described a five-point strategy for HHS to respond to the Government Accountability Office report on healthcare-associated infections (HAIs). HICPAC was given a formal charge to assist HHS in reducing HAI rates.

HICPAC was asked to prioritize the list of recommended clinical practices and develop a global top 10 list across the entire gamut of HAIs. HICPAC was also asked to develop criteria for its guidance to be considered for inclusion in the Centers for Medicare and Medicaid *Conditions of Participation* as either “high-priority prevention interventions” or “high-priority HAIs.”

The HICPAC Chair proposed an approach to respond to the charge from HHS, including initial prioritization of the SSI, catheter-associated urinary tract infection (CA-UTI), and bloodstream infection guidelines. **None of the HICPAC members opposed the approach and all of the members made a commitment to meet HHS’s fall 2008 deadline.**

Updates were provided to describe progress that has been made since the previous meeting on HICPAC’s norovirus, disinfection, healthcare worker vaccination and CA-UTI guidelines. The updates also included a proposed concept for a new ambulatory care guideline; a description of HICPAC’s updated guideline methodology; and preliminary recommendations and grades for

the CA-UTI guideline. HICPAC made a number of suggestions for consideration in revising the preliminary recommendations for the CA-UTI guidelines.

The HICPAC workgroups reported on their respective activities since the previous meeting. The HAI Preventability Workgroup presented the "Mortality from Reasonably Preventable HAIs" document. The workgroup agreed to revise the document based on HICPAC's comments and suggestions. The Guideline Methods Workgroup described key sections of a companion paper that would be released with the CA-UTI guideline to summarize HICPAC's updated guideline methodology.

The Model Legislation Workgroup outlined its continued efforts to compile existing HAI legislation in each state and begin drafting a document to assist groups in writing new or adapting existing legislation. The National Patient Safety Goal (NPSG) Workgroup reviewed its letter that was sent to the Joint Commission in June 2008 to outline HICPAC's concerns with the NPSGs proposed for 2009.

HICPAC's liaison and *ex-officio* members submitted written reports on recently completed, ongoing and upcoming activities of their respective organizations and agencies.

The DHQP Surveillance Branch provided a comprehensive update on its ongoing research, particularly a study to (1) determine differences between the percentage of methicillin-resistant *Staphylococcus aureus* (MRSA) and MRSA incidence using CLABSIs as a candidate infection among ICU patients and (2) characterize actual trends and incidence of MRSA and methicillin-sensitive *Staphylococcus aureus* CLABSI rates by different ICU types.

DHQP's summarized its other activities, including a MRSA surveillance project through the Emerging Infections Network; efforts to respond to the tremendous growth of NHSN over the past year; and a new CDAD and multidrug-resistant organism module for facilities to report proxy measures that can be populated by electronic data sources.

HICPAC agreed to take several actions to respond to recommendations that were specifically directed to HICPAC during the External Peer Review of the DHQP Surveillance Branch in May 2008. HICPAC would develop a new surveillance guidance document in collaboration with a broad range of partners and stakeholders. HICPAC would create a risk assessment template for facility- and setting-based application.

The HICPAC Chair would draft a letter to express HICPAC's formal support for additional technical and financial resources for DHQP to respond to the tremendous growth of NHSN. HICPAC would explicitly endorse NHSN as the standard for HAI surveillance in the new surveillance guidance document.

Business items that were raised over the course of the meeting were reviewed, including HICPAC's future discussion on the evidence base for flash sterilization.

The next HICPAC meeting would be held on November 13-14, 2008 at the Georgetown Marriott Hotel in Washington, DC.

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**HEALTHCARE INFECTION CONTROL
PRACTICES ADVISORY COMMITTEE
June 12-13, 2008
Atlanta, Georgia**

Draft Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), National Center for Preparedness, Detection and Control of Infectious Diseases (NCPDCID), Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC). The proceedings were held on June 12-13, 2008 at CDC's Global Communications Center, Building 19, Auditorium B3, in Atlanta, Georgia.

Opening Session

Dr. Patrick Brennan, Chair of HICPAC, called the meeting to order at 9:07 a.m. on June 12, 2008. He welcomed the attendees to the proceedings and opened the floor for introductions. No members declared any new conflicts of interest for the record that were pertinent to the June 12-13, 2008 HICPAC agenda. The list of participants is appended to the minutes as Attachment 1.

Dr. Brennan announced that due to the volume of HICPAC's agendas, the meeting format would be revised to streamline oral reports by the liaison and *ex-officio* members. However, he confirmed that written reports submitted by the liaison and *ex-officio* members would continue to be a part of HICPAC's official record in their entirety.

Dr. Michael Bell, Designated Federal Official of HICPAC, was pleased to announce that Ms. Wendy Vance was recently appointed to serve as HICPAC's Committee Management Specialist on a full-time basis.

Update on the Prevention Epicenter Program

Dr. John Jernigan, of DHQP, explained that funding for the current EpiCenters was awarded in February 2006 to investigators at the University of Utah, Ohio State University, Washington University in St. Louis, Rush University Medical Center, and Harvard Pilgrim Health Care. He highlighted results of four EpiCenter projects.

Project 1 examined methods to enhance inpatient surgical site infection (SSI) surveillance. The premise of the study was that routinely collected inpatient pharmacy and discharge diagnosis codes could be used as a more sensitive and efficient method for detecting SSIs than traditional surveillance. The study focused on Surgical Care Improvement Project (SCIP) procedures.

The study design included the identification of all procedures with SSIs by routine surveillance and a random sample of 200 other procedures with no known SSI at each hospital. Medical records were retrospectively re-reviewed for antibiotic exposure and ICD-9 codes. National Healthcare Safety Network (NHSN) criteria were used to reassess SSI classifications.

Antibiotic duration during index hospital stay, discharge diagnosis codes, and readmission with antibiotics during 30 days were used as markers to identify SSIs in seven procedures: coronary artery bypass graft (CABG), craniotomy, hysterectomy, hip replacement, Caesarian section, knee replacement and breast surgery.

The study showed that routine surveillance failed to detect some SSIs. Enhanced surveillance in the smaller group of hospitals that met antibiotic exposure or discharge code criteria was more sensitive in detecting SSIs than routine surveillance. Enhanced surveillance most likely would require less effort than routine surveillance of all patients in many hospitals because fewer charts would need to be reviewed and more infections would be detected. Enhanced surveillance also would provide hospitals with a standardized approach to case finding.

Project 2 ranked hospitals by SSI risk using Medicare claims data. The study was conducted because traditional identification of SSIs is hospital-dependent, incomplete and non-uniform. Two key hypotheses guided the study. Medicare claims data can be used to standardize identification of possible SSIs following CABG surgery. Hospital-specific SSI rates based on Medicare claims can be used to rank hospitals. The EpiCenters developed claims-based indicators of SSIs to distinguish between hospitals with high and low SSI rates.

The study goals were to use selected claims codes and apply an algorithm to 2005 Medicare claims data to identify SSIs; identify hospital outliers with high SSI risk post-CABG; refine codes using EpiCenters as the test bed; and validate this approach in a national sample of U.S. hospitals. The Centers for Medicare and Medicaid Services (CMS) database showed that in 2005, 671 U.S. hospitals performed ≥ 80 CABGs in Medicare patients. Preliminary data showed that interventions could be beneficial because infection rates were higher in the 671 hospitals.

In the national validation phase of the study, CMS will request records from flagged patients in a sample of the 671 hospitals in both the top and bottom deciles. NHSN criteria will be used to

review and assess records to validate SSIs that were identified. The records also will be evaluated to determine differences between the percentage of validated SSIs in the top and bottom deciles. The review of 2,500 charts will begin in the summer of 2008.

Project 3 was a multi-center comparison of electronic algorithms for central line-associated bloodstream infection (CLABSI) surveillance in intensive care units (ICUs). The aim of the study was to determine whether electronic algorithms could be an acceptable surrogate for manual surveillance by infection control practitioners (ICPs) in measuring CLABSI rates.

During the 2004-2006 project period, 20 ICUs at four medical centers submitted data for 47 unit periods that included 311,602 patient-days and 210,684 central-line days. All units conducted prospective determinations of BSI rates using standard NHSN methods and ICPs. Electronic algorithms and definitions were applied retrospectively to identify BSIs.

Phase II of the BSI algorithm project will be launched because the electronic detection method appeared to identify more SSIs than ICPs. Three primary and secondary objectives have been established for Phase II of the study. Sources of variability between ICP and algorithmic CLABSI determinations will be assessed. A determination will be made on whether the second ICP review more often agreed with electronic or prior manual determinations. Results from the second ICP review will be extrapolated to the entire sample and unit-specific BSI rates will be calculated and compared to those determined by primary manual and electronic determinations.

To further analyze the tremendous variability between ICP and algorithmic determinations, a computer simulation was performed of hospitalized ICU patients who had catheters placed and removed, developed infections and had cultures drawn. Moreover, surveillance performance characteristics of individual ICPs were simulated. The model also used two methods to perform surveillance with simulated data after patient discharge: traditional or subjective criteria applied by simulated ICPs and automated or objective criteria.

The simulated approach to CLABSI surveillance generated a number of benefits. Each surveillance method can be compared with a true gold standard rather than each other. The tradeoff between validity and reliability of the two methods can be examined. Performance in estimating true CLABSI rates can be analyzed and actual hospital rank order can be estimated. The preservation of rank order can be assessed using Kendall's Tau rank correlation method.

Overall, results of the simulated model suggested that objective criteria were less accurate than subjective criteria in estimating the true BSI rate of an individual facility. However, objective criteria appeared to provide more accurate estimates of true differences in BSI rates between institutions.

Project 4 analyzed interventions to reduce infections by daily chlorhexidine (CHG) bathing. The ICU-based intervention included daily skin cleansing with 2% CHG-impregnated cloths, no rinse and avoidance of CHG-incompatible lotions. The study outcomes included multidrug-resistant organism (MDRO) incidence, vancomycin-resistant *Enterococcus* (VRE) transmission and BSIs. Three trials were implemented in two hospitals with the following time series: pre-intervention

using soap and water, the actual intervention using CHG cloths, post-intervention using cloths without CHG, and post-intervention using soap and water.

The results showed major reductions in primary bacteremia, central venous catheter-associated bacteremia, and contaminated BSIs in medical ICUs. Decreases also were observed in VRE cross-transmission as well as clinical incidence of MDRO from VRE and methicillin-resistant *Staphylococcus aureus* (MRSA) clinical cultures in medical ICUs. No emergence of CHG resistance was detected in any of the trials.

In addition to the four projects Dr. Jernigan highlighted, he also described other EpiCenter studies that are underway: (1) a statewide *Clostridium difficile* (*C. difficile*) infection prevention collaborative in Ohio; (2) electronic alerts of MRSA carriage and unnecessary urinary catheter use; and (3) use of electronic data to measure *C. difficile* infection, quantify antimicrobial use, and measure ventilator-associated pneumonia (VAP) and other ventilator-associated morbidity.

Dr. Grace Lee, of the Eastern Massachusetts Prevention EpiCenter, described a potential EpiCenter project to prioritize recommended infection control and prevention practices in the United States. The EpiCenters are proposing this effort because CDC has released 13 guidelines and 1,200 recommended practices for hospitals on infection control and prevention.

CDC's guidelines focus on the strength of the evidence for each recommendation and strongly encourage 500 practices. However, prioritization is implicit in the guidelines and no further guidance is given on strategies to prioritize these practices. The lack of prioritization may hinder efforts to promote implementation of the guidelines. The goal of the proposed EpiCenter project is to provide decision-makers with a framework for prioritizing infection control and prevention recommendations in the United States.

A decision analysis framework would be the basis of one potential approach to the proposed project. A policy decision would be made to implement either "strategy A" with the status quo or "strategy B" with a new intervention. An HAI would have a more likely chance of occurring in strategy A compared to strategy B. However, potentially negative consequences would need to be considered in implementing both of the strategies.

A cost-effectiveness analysis (CEA) that is built on the field of decision analysis would be the basis of another potential approach. This strategy would incorporate probabilities, costs and utilities and also would measure the cost per case prevented and the cost per quality-adjusted life year (QALY) saved as outcomes. On the one hand, a strategy would not be adopted if health outcomes are worse with a new intervention. On the other hand, a strategy would be adopted if health outcomes are improved by a new intervention and cost less than current practices.

A CEA framework generates a number of benefits. Transparency can be promoted by explicitly stating assumptions that would be included in a model. Outcomes or health benefits associated with each strategy can be quantified. Hospitals can be advised on approaches to invest limited resources to maximize the health impact of their patient populations. Tradeoffs can be clarified when one strategy is implemented versus another.

A CEA framework also has several limitations. The quality of data that are used to inform model input will affect outcomes. A common metric is needed because all QALYs are not equal. Equity and value judgments are an important part of the decision-making process, but are not included in a CEA framework.

Institute of Medicine (IOM) Committees published two reports in 1985 and 2000 in an effort to prioritize infection control and prevention recommendations: (1) *New Vaccine Development: Establishing Priorities in the United States and Developing Countries* and (2) *Vaccines for the 21st Century: A Tool for Decision-Making*. Both reports used a quantitative model to prioritize vaccine development, but the 2000 report also used a CEA framework to prioritize vaccines that would warrant future investments to maximize the health of the U.S. population. Another IOM Committee is currently reviewing priorities in the HHS National Vaccine Plan.

In the EpiCenters proposed project, current guidance would be reviewed with an expert panel to particularly focus on the 500 practices that CDC strongly recommends. Evidence for the guidance would be assessed and the feasibility of using a CEA framework would be evaluated. Based on the quality and quantity of data, a core model would be developed to estimate the net health benefits and costs of each recommended intervention.

Probabilities, costs and utilities included in the model would be based on the published literature, empiric data to supplement unavailable published estimates and expert panel opinion. EpiCenter hospitals could serve as a potential source to fill data gaps in cost estimates, probability estimates or utilities.

The outcomes of the proposed project would include costs, health benefits, cost per case prevention, and cost per QALY saved. Sensitivity analyses would be performed to better understand changes in results of the model as key assumptions varied over plausible ranges. The project also could be designed to identify potential areas of future research.

Dr. Denise Cardo, Director of DHQP, made several remarks for HICPAC to consider in its discussion. The overarching goal of the EpiCenters is to improve and enhance the specificity of methods for detecting BSIs, SSIs and other healthcare-associated infections (HAIs). The application of EpiCenter data is a critical need at this time to minimize confusion in the field, avoid competition between ICPs and electronic algorithms, and address other unintended consequences or barriers.

Dr. Cardo asked HICPAC to provide formal recommendations or develop a new guideline to assist DHQP in applying current EpiCenter data to actual practice on a larger scale. HICPAC's advice could help DHQP to identify gaps to guide the development of future EpiCenter projects. She also requested HICPAC's leadership and expertise to support additional resources DHQP would need to meet the growing demand that is placed on NHSN. Most notably, the nation expects NHSN to improve surveillance through enhanced case detection, stronger data validation, and increased use of electronic algorithms.

HICPAC thanked the Prevention EpiCenter Principal Investigators for joining the meeting to answer questions and provide clarification on their innovative projects. Several HICPAC members made comments and suggestions to advance the research projects of the Prevention EpiCenter Program.

- EpiCenter algorithms and other methods should be piloted in a sample of NHSN hospitals due to the history of these institutions in collaborating with CDC and collecting HAI data. HICPAC could use outcomes from the pilot to determine whether EpiCenter methods could be applied nationally.
- The EpiCenter pilot should include institutions with solid experience in using electronic tools and data and should not be limited to NHSN hospitals. This strategy could address the disconnect between institutions that use electronic data and the broader infection control community. For example, ICPs in some states do not use discharge or coded data as a tool to assess hospital quality, ranking or comparisons. Other ICPs at the state level have limited knowledge or are unfamiliar with the role and function of NHSN.
- The EpiCenters should expedite the timeline to publish data from their studies in the peer-reviewed literature. This approach would assist HICPAC in providing evidence-based guidance to DHQP.
- The EpiCenters should explore the possibility of developing electronic or non-electronic algorithms for detection of catheter-associated urinary tract infections (CA-UTIs) as a future project. This effort would be extremely useful to HICPAC's development of the CA-UTI Guideline.
- The EpiCenters should strengthen their focus on children in future projects because the prevention of BSIs would result in enormous cost of life-years saved in the pediatric population.
- The EpiCenters should consider the possibility of incorporating a "value stream analysis" in a CEA framework. This approach ranks interventions based on those in which clinicians are most or least willing to fund.
- The EpiCenters should address issues that typically have not been the focus of CEAs. For example, the non-linearity of effects of infection control interventions have not been adequately addressed, such as the indirect impact on patients who do not receive interventions due to transmission of infectious diseases. Simulated models would play a significant role in better understanding non-linear dynamics and effects. Moreover, problems with estimating the cost-effectiveness of preventing infections have not been resolved to date due to tremendous flaws in traditional methods. The EpiCenters should attempt to address this issue in the proposed project to prioritize infection control and prevention recommendations in the United States.
- The EpiCenters should promote a stronger research agenda to implement guidance for the infection control and healthcare community.

Dr. Brennan confirmed that HICPAC would have further discussion on the suggestions for HICPAC to formulate recommendations to advance electronic surveillance, pilot EpiCenter algorithms in NHSN hospitals, and support the proposed EpiCenter project to prioritize infection control and prevention recommendations in the United States.

Update on DHQP Activities

Dr. Arjun Srinivasan, of DHQP, described recent field investigations and other ongoing activities conducted by the Prevention and Research Branch (PRB). PRB is evaluating infection control practices at ambulatory surgical centers (ASCs) in Oklahoma and also is investigating an outbreak of *Group A Streptococcus* infections in a long-term care facility (LTCF) in Nevada.

PRB investigated transmission of lymphocytic choriomeningitis virus to two recipients in Massachusetts from an organ donor that had neurologic abnormalities pre-mortem. The investigation resulted in discussions with the organ transplant community about developing guidelines for evaluating neurologic abnormalities in organ donors.

PRB investigated the sudden increase in cardiac arrests and severe adverse events at a dialysis center in Texas. Because the investigation raised the possibility of intentional wrongdoing by an employee, a criminal investigation is ongoing. PRB reviewed infection control practices at ASCs in Nevada.

PRB recently led a field investigation of bleeding deaths among dialysis patients in the District of Columbia, Maryland and Virginia. The investigation indicated issues with access failure and preceding access complications in some patients. PRB is attempting to determine potential risk factors to identify the types of patients who might be at risk for bleeding events.

PRB investigated anaphylactic reactions at a pediatric dialysis center in Missouri. The investigation found an association between adverse reactions and receipt of heparin; led to a national investigation by CDC and the Food and Drug Administration (FDA) that identified oversulphated chondroitin sulphate (OSCS) in multiple heparin products; and resulted in the development of a new screening test for OSCS. The contaminated heparin products have since been recalled.

PRB's investigation of a *Burkholderia cepacia* outbreak that was associated with contaminated mouthwash led to an initial national recall of one lot of product and subsequent market withdrawal of mouthwash made by the company. The investigation increased PRB's knowledge of a common misunderstanding in healthcare facilities about "voluntary recalls." PRB and FDA are collaborating to educate and better inform medical providers about voluntary recalls.

PRB is continuing to receive telephone calls and requests for assistance on investigations of outbreaks of multidrug-resistant *Acinetobacter*, cases and outbreaks of *Klebsiella pneumoniae* carbapenemase (KPC)-producing organisms, and cases of *C. difficile* and MRSA.

At the division level, DHQP is partnering with an advertising company to develop a community MRSA educational initiative to educate patients and providers on the recognition and management of MRSA skin and soft tissue infections (SSTIs). The national campaign will be targeted to mothers with lower socioeconomic status as the patient audience and primary care and emergency department physicians as the provider audience.

Two key messages will be delivered to the patient audience in the MRSA campaign. MRSA SSTIs are preventable and treatable. Patients should know the signs of an SSTI and obtain help early. Providers will be encouraged to consider MRSA as an important cause of SSTIs and appropriately diagnose and treat these infections. At this time, educational and advertising materials are being market tested and finalized. DHQP intends to launch the MRSA campaign nationally in the fall of 2008.

DHQP is leading the effort to revitalize a previous campaign that was designed to prevent antimicrobial resistance in healthcare settings. In the updated campaign, emphasis will be placed on four major strategies rather than 12 steps. The website will be revamped with descriptions of activities that have been successful in curtailing antimicrobial resistance. DHQP is increasing its efforts to improve antimicrobial use and is also closely collaborating with the "Get Smart" Program to coordinate activities. DHQP welcomes input from HICPAC on both the MRSA and antimicrobial resistance campaigns.

Dr. Clifford McDonald, of DHQP, described DHQP's continued efforts to address *C. difficile*-associated disease (CDAD). The Agency for Healthcare Research and Quality (AHRQ) recently published a national inpatient sample of hospital discharges that showed a marked increase in the total number of hospital discharge diagnoses of *C. difficile* since 2000. Data collected in 2006 showed that *C. difficile* is continuing to increase.

At the state level, Ohio mandated public reporting of all *C. difficile* cases in hospitals and nursing home in 2006. Of 14,000 cases reported in the state since that time, >50% occurred in nursing home settings. A review of death certificates in Ohio showed a sharp increase in the number of deaths with *C. difficile* listed as the primary cause of death.

DHQP extrapolated Ohio data to the U.S. population and estimated the national burden of *C. difficile* to be 475,000 cases and 23,000 deaths in hospitals or nursing homes after adjusting for missing data. However, DHQP recognizes that the onset of *C. difficile* in hospitals and nursing homes most likely accounts for only 50% of the total burden.

DHQP also acknowledges that better data are needed on the actual costs and outcomes of *C. difficile* to prioritize recommendations for this infection. To support this effort, the St. Louis Prevention EpiCenter analyzed *C. difficile* in a hospital-based endemic setting over one year. Based on index hospitalization or 180 days as markers, the study showed excess costs of \$5,000 per case or a total of >\$1 billion in excess healthcare costs from *C. difficile* alone. The study also found that *C. difficile* accounted for ~6% of attributable mortality in an endemic setting and 15,000-30,000 excess deaths.

DHQP recently investigated a *C. difficile* outbreak in a Baltimore hospital. Because traditional infection control measures were not effective, the hospital consulted with DHQP and removed all fluoroquinolones from its formulary. This approach led to a decrease in *C. difficile* cases. The investigation indicated unnecessary antimicrobial use in many hospitals because antibiotic usage is one of the most important drivers for *C. difficile* in healthcare settings.

In addition to healthcare settings, *C. difficile* is also causing problems in unique populations. DHQP recently reported on ten cases in pregnant women of which six were hospitalized in ICUs for toxic megacolon, five required colectomies, three died, and three lost their babies.

To address the burden of *C. difficile*, DHQP published recommendations in 2008 on conducting surveillance of this infection. Data from six hospitals that applied the *C. difficile* guidance showed 50%-60% of all cases were healthcare-onset and 44% were community-onset. Connecticut published data in April 2008 on statewide community-associated cases and found that ~30% of cases had no previous antibiotic use in the three months preceding symptom onset and ~30% of cases had no underlying conditions.

Data from DHQP, Connecticut and hospitals confirmed that community-associated disease represents a small proportion of the total burden. The most critical control point for the majority of *C. difficile* cases continues to be the interruption of transmission and control of antibiotic use in healthcare settings.

DHQP is partnering with veterinary researchers to analyze the incidence of *C. difficile* in food-producing animals. An epidemic strain that was commonly found in pigs and cattle is now increasingly being detected in humans in the community. Typing data suggested possible migration of *C. difficile* from food-producing animals to humans. A survey that was administered to collect and characterize 92 isolates from nine states showed a larger variation in community strains than hospital strains.

Overall, the continued increase in *C. difficile* rates, mortality and costs is primarily associated with a human epidemic strain. The increase is more notable in previously low-risk populations, such as community residents and pregnant women. Ecological evidence indicates the potential for transmission of virulent strains of *C. difficile* from food-producing animals to humans, but this migration accounts for an extremely small proportion of all human *C. difficile* disease. Human-to-human transmission still accounts for the vast majority of *C. difficile* disease in humans.

Dr. Joseph Perz, of DHQP, reported on DHQP's activities to improve ambulatory care, injection safety and basic infection control practices. Outpatient care has grown to ~1.2 billion outpatient visits per year in the United States. In 2005, 4,755 dialysis centers and 4,445 ASCs were operating in the United States. These numbers represent increases of 65% and 210%, respectively, in the growth of these facilities since 1996. Outpatient facilities account for significant infection-related morbidity and mortality and serve as important settings in terms of the emergence of antibiotic-resistant patterns.

Healthcare delivery has shifted from acute care settings to ambulatory care, long-term care and free-standing specialty care sites. However, these settings often lack infection control oversight and present an emerging threat to patient safety. Outbreaks associated with unsafe injection practices and breakdowns in basic control practices are increasing in outpatient facilities.

In January 2008, a cluster of three acute hepatitis C virus (HCV) cases was identified in an endoscopy clinic in Las Vegas. All three patients underwent procedures at the same clinic during the incubation period. The clinic performed 50-60 upper and lower endoscopies per day.

A review of surveillance records, laboratory records and a physician report identified three additional cases associated with the clinic.

The investigation showed that unsafe injection practices most likely led to HCV transmission in the endoscopy clinic. Some providers used old syringes with new needles to draw more anesthesia and also used medication remaining in the vial to sedate the next patient. This practice was a major breach in infection control because the vials were labeled for single rather than multiple use. The endoscopy clinic was immediately advised to stop unsafe injection practice, but the clinic was eventually closed after its license was revoked.

The investigation also found that some clinic staff had commonly used unsafe practices for at least four years. Due to this period of time, the local health department began notifying ~40,000 patients and recommending HCV, HIV and hepatitis B virus (HBV) screening. CDC and its partners assisted Nevada in performing rapid assessments of infection control practices at all licensed ASCs in the state.

In 2007-2008, three incidents of syringe reuse that occurred in a variety of outpatient settings in New York City, Michigan and Long Island, New York resulted in notification to and testing of patients for HBV, HCV and HIV. Administration of anesthesia during outpatient procedures was the common factor in all of the outbreaks. Additional incidents included syringe reuse during influenza vaccination and kidney failure in three patients subjected to unsafe cosmetic injections. All of the outbreaks have received intense press coverage and legislative interest.

In the *2007 Isolation Precaution Guideline*, CDC acknowledged the transition of healthcare delivery from primarily acute care hospitals to outpatient settings. CDC also reaffirmed its 1996 standard precautions as the foundation for preventing transmission of infectious agents in all healthcare settings. CDC cited HBV and HCV outbreaks in ambulatory settings as a strong evidence base for the need to reiterate safe injection practice recommendations as part of standard precautions.

At this time, CDC is making stronger efforts to disseminate its previous guidance to assure that all healthcare workers consistently adhere to and implement basic infection control practices. For example, CDC is collaborating with CMS and state licensing and certification agencies. CDC's tool that was used to administer special surveys to ASCs in Nevada will be replicated in three other states to more heavily focus on injection safety and other basic infection control practices.

CDC is continuing its dialogue on this issue with FDA and professional groups, developing and disseminating educational materials, and conducting outreach. CDC is also participating in a pilot campaign targeted to patients and providers on injection safety and basic infection control practices.

Dr. Roberta Carey, of DHQP, provided an update on ongoing laboratory activities conducted by the Clinical and Environmental Microbiology Branch (CEMB). From 2007-2008, CEMB has played an integral role in >41 outbreaks involving >1,900 specimens. Intrinsic contamination of

healthcare items has contributed to transmission of infection through heparin pre-filled syringes, alcohol-free mouthwash, fentanyl chloride, packed red cells, pooled platelets and infant formula.

Contaminated healthcare items have resulted in transmission of *Serratia marcescens*, Group C *Streptococcus*, *Burkholderia vanimaris*, *Sphingomonas paucimobilis*, *Yersinia enterocolitica*, and *Enterobacter sakazakii*. Reuse of syringes, needles, multi-dose vials of drug products and other lapses in infection control practices during healthcare delivery have contributed to transmission of infection from extrinsic contamination.

CEMB develops and evaluates sampling and processing methods for recovery of emerging pathogens from environmental surfaces. This effort has led to CEMB detecting environmental infection, including *C. difficile* and *Acinetobacter baumannii* transmission from contaminated portable x-ray machines, intravenous poles, bedrails, sinks and counters.

CEMB developed genetic typing databases to characterize emerging pathogens, such as *Burkholderia* in mouthwash. CEMB is currently developing and evaluating disinfection protocols to enhance intervention strategies, including disinfection of healthcare environmental surfaces and chlorine and mono-chloramine disinfection of nontuberculous mycobacteria biofilms.

CEMB is continuing to address KPC. KPC is a class A β -lactamase that confers resistance to all β -lactams, such as extended-spectrum cephalosporins and carbapenems. KPC is most common in *Klebsiella pneumoniae*, but has also been reported in *Klebsiella oxytoca*, *Serratia*, *Citrobacter freundii*, *Enterobacter*, *Salmonella*, *Escherichia coli*, and *Pseudomonas aeruginosa* in Colombia and Puerto Rico.

KPC isolates most frequently have been detected in Delaware, Long Island, New Jersey and Pennsylvania, but sporadic isolates have been observed in other parts of the country and sent to CEMB for characterization and validation. Risks for an infection with KPC include hospitalized patients with an increased number of co-morbid conditions, frequent or prolonged hospitalization, invasive devices or antimicrobial exposure. Carbapenemase-producers are most frequently isolated from urine or blood.

CEMB's methods focus on sensitivity and specificity to detect KPC in the laboratory and inform clinicians and ICPs of a problem. With imipenem, sensitivity ranges from 42%-94% and specificity ranges from 93%-28%. With meropenem, sensitivity ranges from 48%-94% and specificity ranges from 96%-100%. With ertapenem, sensitivity ranges from 90%-100% and specificity ranges from 81%-93%.

KPC should be considered with *Enterobacteriaceae*, particularly *Klebsiella pneumoniae* that are resistant to extended-spectrum cephalosporins. However, a more detailed examination should be performed with a carbapenem minimum inhibitory concentration of 2 or 4 $\mu\text{g}/\text{mL}$. A disk diffusion also can be performed with ertapenem or meropenem to determine whether the zone of inhibition range decreases to ≤ 22 mm. Although imipenem is most commonly tested, the drug is a poor predictor of KPC.

After KPC is detected, molecular testing should be performed to confirm the presence of the organism. Because CEMB is not equipped to handle the numerous flood of requests for molecular testing across the country, clinical laboratories should confirm KPC with a modified Hodge test.

CEMB is also focusing on nine vancomycin-resistant *Staphylococcus aureus* (VRSA) cases. Of these nine cases, seven unique VRSA isolates were detected in Michigan. The outcomes of the Michigan VRSA cases were that *S. aureus* maintained VRE *vanA* plasmid and TN1546-like elements integrated into *S. aureus* plasmid. CEMB also found that a unique Inc18-like *vanA* plasmid was associated with five of the seven Michigan VRSA isolates, more often found in the Michigan VRE cases than other geographical locations, and more frequently observed in *Enterococcus faecalis* than other VRE species.

CEMB analyzed 1,034 isolates from the Active Bacterial Core Surveillance System that were found in invasive disease to examine pulse field types. USA100 and USA500 strains are most common in HAIs. The analysis showed that >91% of these infections occurred in healthcare settings or community settings with a healthcare background. The majority of USA300 strains occurred in community settings, but 11% occurred in hospitals. Only three USA300 pulse field types accounted for 84% of all USA300 patterns, while multiple USA100 pulse field types caused infections in hospital settings.

CEMB is partnering with Emory University to conduct a MRSA carriage study in an HIV-positive population. The study design includes nares and groin screening of methicillin-sensitive *Staphylococcus Aureus* (MSSA) among 601 patients enrolled at their routine clinic visits as the baseline; follow-up screening at six- and 12-month intervals; and a comparison of the sensitivity between direct plating and broth enrichment.

Preliminary results showed that 31% of patients had MSSA with nares of 27% and groin positivity of 18%. These findings were similar to nasal carriage data from the National Health and Nutrition Examination Survey (NHANES). The study also showed that 13.5% of patients had MRSA with nares of 11% and groin-positivity of 8%. These findings were nearly ten times higher in the study population of HIV patients than healthy adults in NHANES. The inclusion of groin cultures in the study led to the detection of an additional 3% of positive patients. The inclusion of enrichment broth led to the detection of an additional 15% of positive nasal cultures and an additional 29% of positive groin cultures.

HICPAC thanked the panel of presenters for providing comprehensive updates on DHQP's ongoing field investigations, community outreach activities, research projects and laboratory studies. Several members suggested next steps that HICPAC and CDC should consider to improve healthcare infection control practices.

- HICPAC should formulate guidance to emphasize the critical need for outpatient facilities to designate a staff member to oversee injection safety and basic infection control practices on a full-time basis.
- CDC should partner with the Joint Commission, American College of Surgeons and other organizations to use the recent syringe reuse incidents as an opportunity to create

a professional organizational structure and culture for outpatient facilities. This strategy could promote more effective implementation of policies in these settings.

- HICPAC should engage and solicit input from outpatient facilities in the development of future guidelines. For example, ASCs and other outpatient settings do not believe that HICPAC guidelines apply to their facilities.
- HICPAC should recommend the development of training and education initiatives to assure competencies in safe injection practices for physicians, physician assistants and mid-level practitioners. HICPAC's guidance in this area also should emphasize the need to incorporate basic infection control practices into medical school curricula.
- CDC should attempt to link to ongoing efforts in some states that require ASCs to report infections.

Dr. Brennan explained that HICPAC would take no formal action at this time on injection safety and basic infection control practices in outpatient facilities due to the tremendous magnitude and scope of the problem. He advised HICPAC to carefully review and consider the information that was presented during the meeting. He confirmed that additional presentations and more substantive discussions would be placed on future agendas. Dr. Brennan also pointed out that during its business session on the following day, HICPAC would discuss the development of a new ambulatory care guideline.

Dr. Bell agreed with Dr. Brennan's approach for HICPAC to address this complex issue in a step-wise process over time. Most notably, HICPAC would need to engage a number of interest groups and stakeholders in its discussions, including organizations representing surgeons, nurse anesthetists, gastroenterologists, peri-operative registered nurses, epidemiologists and ICPs. Dr. Bell also noted that HICPAC's guidance would need to address flaws in professional education at all levels, retention of institutional accreditation and professional requirements.

Overview of HHS's Role in Reducing HAI Rates

Dr. Don Wright is the Principal Deputy Assistant Secretary for Health at HHS. He reminded HICPAC that the Government Accountability Office (GAO) issued its report on HAIs in March 2008 with a focus on three key areas: (1) CDC's preventive guidelines and activities supported by HHS to promote implementation of the recommendations; (2) accreditation efforts to reduce HAIs; and (3) identification, integration and interoperability of HHS's data collection systems.

GAO made a number of recommendations to HHS based on its in-depth study of HAIs. CDC's recommended clinical practices should be prioritized to promote implementation of high-priority practices and assure compliance in hospitals. The prioritized recommendations should be considered for inclusion in CMS's *Conditions for Participation*. Consistency, compatibility and interoperability of data collected across HHS should be enhanced to increase the reliability and robustness of national estimates of HAIs.

In April 2008, Dr. Wright provided HHS's formal response to the GAO report during testimony before the House Oversight and Reform Committee. He focused his remarks on four major

areas: (1) HHS's successful efforts in the prevention of HAIs, including the development of outstanding guidelines by HICPAC and CDC; (2) improved quality and robustness of monitoring and surveillance through HAI reporting to NHSN by nearly 1,500 hospitals; (3) value-based purchasing to create incentives and pay for healthcare quality rather than quantity; and (4) regulatory approaches to facilitate quality improvement research.

After the Congressional testimony, the Deputy Secretary of HHS charged Dr. Wright with developing a plan to address flaws and areas of improvement outlined in the GAO report. In response to this directive, Dr. Wright created a five-point strategy that will be implemented over the next few months.

Strategy 1 is the establishment of a new "HHS Steering Committee on HAI Reduction." The membership of the Steering Committee will be limited to representatives of HHS agencies with no outside participation. The Steering Committee will be charged with developing national goals for reducing HAIs, such as "decreasing HAIs by 60% in five years." The national goals and strategies will be transparent to CDC, AHRQ, CMS, FDA and other HHS operating divisions.

The Steering Committee will be responsible for creating benchmarks, tracking progress and measuring success in reducing HAIs at three intervals: 1-2 years for short-term goals, 3-5 years for mid-term goals, and 5-10 years for long-term goals. For example, interoperability of information technology, computer systems and data sets across HHS agencies most likely would be a long-term goal. The Steering Committee also will develop approaches to coordinate and leverage HHS resources to accelerate and maximize impact.

Strategy 2 is the prioritization of recommended clinical practices and will be implemented in partnership with HICPAC. HICPAC will be charged with prioritizing the existing 1,200 recommended infection control and prevention practices and developing two top 10 lists. The "global" top 10 list will cover the entire gamut of HAIs rather than a single class of HAIs and will serve as the platform for a National Prevention Campaign to raise awareness throughout the country of the importance of lowering HAI rates.

The global list will also help to guide the administration of CMS hospital surveys; incorporate an infection control perspective into the hospital accreditation process; and assist CDC and AHRQ in translating recommendations into practice programs. The "secondary" top 10 list will prioritize and bundle individual classes or anatomic locations of HAIs, such as catheter-induced BSIs. This list will be distributed to hospitals to assist in decreasing the incidence of HAIs.

The top 10 lists will not be intended to minimize the importance of the other recommended clinical practices. Instead, the top ten lists will serve as a mechanism for hospitals to focus on the most critical recommendations. Moreover, the top 10 lists might change as new data emerge and research gaps are filled over time.

Strategy 3 is the improvement of hospital regulatory oversight and compliance and will be implemented in partnership with CMS, the Joint Commission and the American Osteopathic Association. The partners will administer infection control practice surveys as a part of their

routine surveillance processes. Trade associations, professional societies and other groups with similar missions will be engaged as needed.

The possibility of including recommended infection control practices in the *Conditions for Participation* will be explored with CMS. DHQP will be asked to collaborate with its partners to provide technical assistance to hospitals with deficient infection control programs to assist in lowering HAI rates in these institutions.

Strategy 4 is the improvement and expansion of HAI surveillance. Alignment of definitions across HHS data systems will be assured. Standardized measures will be developed to enhance compatibility and comparability of HAI rates across HHS agencies. Reporting of HAIs through NHSN will be encouraged. At this time, 25% of U.S. hospitals participate in NHSN.

Strategy 5 is the direct link between value-driven healthcare and reduced HAI rates. The HHS Secretary believes that public reporting of HAIs and other patient measures empower consumers to make informed choices and result in improved overall quality of care. Studies have demonstrated that provider feedback plays an effective role in reducing HAIs. Incentives for prevention may increase prevention efforts.

Dr. Wright outlined HICPAC's formal charge to assist HHS in reducing HAI rates. First, HICPAC would prioritize the list of recommended clinical practices and develop a global top 10 list across the entire gamut of HAIs to help focus rapid implementation efforts. The global top 10 list would serve as a platform for a National Prevention Campaign. HICPAC would develop a secondary top 10 list of other major classes of HAIs, such as catheter-induced BSIs and VAP, that would be distributed to hospitals and accrediting bodies.

Second, HICPAC would develop criteria for its recommendations to be considered for inclusion in CMS's Medicare *Conditions of Participation* as either "high-priority prevention interventions" or "high-priority HAIs." HICPAC would create the criteria with input from CMS and AHRQ *ex-officios*. The criteria would reflect affected populations, the magnitude of the problem, strength of evidence, economic impact and feasibility.

Dr. Wright announced that he recently obtained support and endorsement from CMS leadership for HICPAC to undertake this effort. However, CMS expressed an interest in HICPAC creating HAI criteria for its other tools and resources beyond the *Conditions of Participation*, such as pay-for-performance for reporting SSIs.

Dr. Wright explained that the majority of tasks for HHS's strategy to reduce HAIs would be completed by the Steering Committee during monthly meetings and by five workgroups during meetings twice per month. The five workgroups would be charged with addressing the following issues: (1) prevention guidelines and implementation, (2) regulatory oversight and incentives, (3) outreach and messaging, (4) research gaps and future directions, and (5) the role of information technology in reducing HAI rates.

HICPAC would provide ongoing input to the Steering Committee, but its primary focus and involvement would be in the Prevention Guidelines and Implementation Workgroup and the

Regulatory Oversight Workgroup. However, HICPAC's charge would be directly linked to activities of all five workgroups.

Dr. Wright emphasized that a short timeline has been established for this initiative because the Deputy Secretary of HHS has expressed a strong interest in finalizing HHS's HAI plan by the end of the current Administration. HHS hopes to receive an initial draft report in the fall of 2008 and present the preliminary "National Policy on Lowering HAIs" to HICPAC during its next meeting for review and comment. The National Policy will serve as HHS's strategic plan for reducing HAIs over the next ten years.

The initial draft will be revised based on input from HICPAC and other internal sources and then published in the *Federal Register* for public comment. HHS will also solicit feedback from the Association of Professionals of Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA) and other professional societies.

Dr. Wright clarified that no additional resources have been allocated to date to support the planning phase of the National Policy. However, he realized that HHS would need to closely examine and prioritize resources in the future, particularly to implement recommendations from the Research Gaps and Future Directions Workgroup.

Dr. Wright concluded his overview by informing HICPAC that he is a career employee and not a political appointee. As a result, he would continue to serve as the Principal Deputy Assistant Secretary for Health regardless of the changes in the new Administration. He planned to provide consistent leadership in implementing the National Policy over time.

Dr. Brennan emphasized that attention to HICPAC's guidelines at Dr. Wright's level is extremely gratifying. His position was that HHS's leadership and support would elevate HICPAC's previous efforts of collaborating with the Joint Commission, CMS and professional organizations to translate HICPAC recommendations into accreditation processes and *Conditions of Participation*.

On behalf of HICPAC, Dr. Brennan accepted the charge as outlined by Dr. Wright. He confirmed that HICPAC welcomed the opportunity to partner with HHS in developing the National Policy. He noted that HICPAC would discuss its charge in more detail during the business session on the following day. He concluded that the National Policy is tremendous in its potential impact and would serve as a major opportunity for HHS, DHQP, HICPAC and the public to reduce HAIs across the nation.

Based on HICPAC's acceptance of the charge, Dr. Cardo conveyed that CDC would continue to explore options to provide personnel, resources and outside experts to support HICPAC's participation in developing HHS's National Policy.

Update on the HICPAC Guidelines

Dr. Kurt Stevenson provided an update on the *Guideline for the Prevention and Management of Norovirus in Healthcare Settings*. He reminded HICPAC that five key questions the workgroup developed to inform the development of the norovirus guideline were presented during the November 2007 and February 2008 meetings and have not changed.

The workgroup also created an analytic framework to answer research questions for the norovirus guideline based on evaluating patients at baseline, identifying sporadic infections and outbreaks, preventing transmission of an outbreak, and focusing on environmental cleaning.

From September 2007-February 2008, the workgroup reviewed existing guidelines, developed the five key questions and conducted a literature search. Screening of titles and abstracts and a review of full-text studies are underway to determine papers that will be used to support the evidence of the norovirus guideline.

Searches of Medline and other databases led to the workgroup identifying 3,702 studies to include in the title and abstract screening process. This process also excluded 3,323 studies based on the following criteria. The study was not in English. The study contained a meeting abstract only with no publication of full text. The study was not relevant to one of the five key questions.

The study could not be characterized as “primary analytic research,” such as systematic reviews of analytic research; economic and meta-analyses; interventional studies; and prospective and retrospective observational studies, *i.e.*, cohort, case-control or analytic cross-sectional studies. The full text of the study was published, but was not available for review. Of 379 studies that were considered for the full-text review, 129 were not included based on the exclusion criteria.

The workgroup has now identified 250 full-text studies to be included in the data extraction process. By the November 2008 HICPAC meeting, the workgroup expects to extract data from the 250 studies into evidence tables, assess the quality of each study, apply the “Grading of Recommendations, Assessment, Development and Evaluation” (GRADE) system to weigh the strength of the evidence, and formulate draft recommendations.

The workgroup will address four major issues before drafting the preliminary recommendations: (1) the level of sensitivity and specificity of the norovirus search, such as combining viral gastroenteritis terms with more specific terms; (2) use of basic science and *in vitro* studies, particularly for key questions 3 and 5; (3) use of uncontrolled studies; and (4) use of non-systematic reviews.

Dr. Bell informed HICPAC that the *Disinfection Guideline* was submitted to the *Morbidity and Mortality Weekly Report (MMWR)* and is in the queue to receive editorial input. Issues regarding inactivation of prion-contaminated material were removed from the disinfection guideline because a decision was made that this topic could be addressed in separate publications. The original authors of the prion section are currently exploring the possibility of

revisiting this issue in a separate APIC/SHEA document. After the *MMWR* editorial process is complete, Dr. Bell would circulate the publication date to HICPAC.

Dr. Brennan confirmed that HICPAC and CDC would take Ms. Stricof's suggestion under advisement to make the disinfection guideline available electronically since the infection control community is eagerly anticipating the release of the document.

Dr. Robert Wise, HICPAC's liaison to the Joint Commission, announced that an organization's sole use of flash sterilization for outpatient eye surgery was rather controversial. The Joint Commission cited HICPAC's disinfection guideline to make strong case against the use of flash sterilization for eye surgery. Because the guideline was developed in 1999, several large outpatient surgical centers emphasized that the recommendations were outdated and inconsistent with current industry practice throughout the country.

Dr. Wise pointed out that the Joint Commission heavily relies on HICPAC's evidence-based guidelines to support its accreditation process, but the recommendations must be up-to-date due to the magnitude and scope of the infection control industry. He asked HICPAC to review, update and release the disinfection guideline and other outdated recommendations as quickly as possible to inform the field and reflect current practice.

Dr. Steven Gordon provided an update on the *Healthcare Worker (HCW) Vaccination Guideline* that HICPAC and the CDC Advisory Committee on Immunization Practices (ACIP) are jointly developing. The guideline is targeted to occupational health personnel and HCWs. The workgroup is continuing its review of BCG and other vaccines to inform the development of the recommendations. The workgroup hopes to present the draft HCW vaccination guideline to HICPAC in the first quarter of 2009 for review, comment and a formal vote.

The overarching purpose of the guideline is to update the joint ACIP/HICPAC HCW vaccination recommendations that were developed ~10 years ago; address previously unresolved issues; and present the recommendations in a more streamlined and user-friendlier format. Because no new vaccines will be recommended, the updated guideline is not expected to result in any controversy.

During the presentation of the updated guideline in 2009, the authors will ask HICPAC to pay particular attention to new recommendations on the evidence of immunity in HCWs with the measles, mumps and rubella vaccine (MMR). Updated guidance for the MMR vaccine will exclude year of birth and self-reported history of disease.

Dr. Bell provided an overview on the concept for a new *Ambulatory Care Guideline for Infection Prevention*. The guideline should be modeled on the streamlined format of the norovirus and CA-UTI guidelines and should not be developed as a voluminous document on ambulatory care practices.

The guideline potentially could focus on the following areas: (1) injection safety and basic infection control practices due to current legislative interest in these issues; (2) strategies to

examine ASCs; (3) requirements to update continuing medical education or related educational activities; and (4) prevention of transmission of respiratory infections in ASCs.

The fourth area of focus would compliment national attention to pandemic influenza prevention and resources that are allocated to DHQP in this area. This set of recommendations could address architectural innovations, displacement ventilation, the organization of patients in waiting areas, environmental controls for frequently touched surfaces, and other approaches to decrease the risk of exposure to respiratory infections in healthcare facilities. Dr. Bell asked HICPAC to consider the concept of the new ambulatory care guideline overnight in preparation for a discussion of this issue during the business session on the following day.

Dr. Craig Umscheid described guideline methods that were used to develop the *CA-UTI Prevention Guideline*. The goal of this process was to conduct a targeted systematic review based on the best available evidence with explicit links between the literature reviewed and the final recommendations. The workgroup achieved this goal in a multi-step process.

A search was conducted of national and international guidelines to develop key questions and design search strategies. A literature search was performed to answer the key questions. An abstract and full-text screening process was implemented for studies that were identified during the literature search. Data were extracted into evidence tables to evaluate the quality of each study. GRADE tables were created to weigh the strength of the evidence. Outcomes from the GRADE tables were used as the basis to formulate preliminary recommendations.

A comparison of condom versus indwelling urethral catheters is one example of applying the guideline methods. The critical outcomes in this model would include symptomatic UTI, bacteriuria, bacteremia and patient satisfaction. The quantity and type of evidence would include randomized controlled trials (RCTs) and observational studies. The findings would include decreased risk, no difference or increased patient satisfaction.

To grade the evidence, an RCT would be initially graded as “high.” However, the RCT grade could be decreased to “moderate” or “low” based on the quality and consistency of data, directness and precision of the evidence, and publication bias. An observational study would be initially graded as “low,” but could be increased to “moderate” or “high” if the data demonstrated a strong association. The overall grade of condom versus indwelling urethral catheters would be “moderate” after applying the GRADE System because the lowest and highest quality evidence would be compared to the most critical outcomes.

The overall evidence grades are divided into four categories. A “high” grade means that further research is very unlikely to change confidence in the estimate of effect. A “moderate” grade means that further research is likely to impact confidence in the estimate of effect and may change the estimate. A “low” grade means that further research is very likely to impact confidence in the estimate of effect and is likely to change the estimate. A “very low” grade means that any estimate of effect is very uncertain.

Three factors must be considered in applying overall evidence grades and formulating recommendations: (1) values and preferences used to determine critical outcomes; (2) net

benefits, net harms or tradeoffs from weighing critical outcomes; and (3) the overall GRADE of the evidence for critical outcomes.

Category I recommendations are strong. For example, most patients would desire the recommended course of action and only a small proportion would not. Patients should request discussion if the physician does not offer an intervention. Clinicians should provide most patients with the recommended course of action. For policymakers, recommendations can be adopted as policy in most situations.

Category II recommendations are weak. For example, most patients would desire the recommended course of action, but many would not. Clinicians should recognize that different choices would be appropriate for various patients. Patients would need help to arrive at management decisions consistent with their values and preferences. For policymakers, policymaking would require substantial debate and involvement of many stakeholders.

A “strong” GRADE recommendation would be equivalent to HICPAC’s Category IA, IB and IC recommendations in which the net benefits and net harms would be weighed. A “weak” GRADE recommendation would be equivalent to HICPAC’s Category II recommendations in which tradeoffs would be weighed. A GRADE recommendation of “further research” would be equivalent to HICPAC’s “no recommendation” in which tradeoffs would be uncertain. The workgroup will clarify in the CA-UTI guideline that Category IA, IB and IC recommendations are equally strong and should be “implemented” rather than “considered.”

Dr. Carolyn Gould explained that the workgroup formulated three key questions and multiple sub-questions to inform the development of the *CA-UTI Prevention Guideline*. The workgroup also defined “symptomatic UTI,” “bacteriuria” and “bacteriuria/unspecified UTI” as CA-UTI outcome categories in the GRADE tables. The workgroup’s preliminary recommendations and grades for the key questions and sub-questions of the CA-UTI guideline are outlined below.

QUESTION 1 focused on populations that should receive urinary catheters. Sub-question 1A: Is urinary catheterization necessary in certain populations? Urinary catheters in operative patients should be used only as necessary rather than routinely. The risks of infection, risks of urinary retention, and the need for intraoperative catheterization should be weighed. (Category II) Urinary catheterization of patients and nursing home residents should be avoided for management of incontinence. (Category II)

Further study is needed on periodic use of condom catheters in this population and the use of catheters to prevent skin breakdown. (No recommendation/unresolved issue) Further study is needed on the benefit of using a urethral stent as an alternative to an indwelling catheter in selecting patients with bladder outlet obstruction. (No recommendation/unresolved issue)

Alternative urinary drainage strategies for chronic indwelling urinary catheters should be used in spinal cord injury patients whenever possible. (Category II) Clean intermittent catheterization should be used in children with myelomeningocele and neurogenic bladder to reduce the risk of urinary tract deterioration. (Category II)

Question 1B: What are the risk factors for CA-UTI? A sterile and continuously closed drainage system should be maintained. (Category IA) The catheter and urinary drainage system should not be disconnected unless the catheter must be irrigated. (Category IA) Catheters should be left in place only as long as needed for appropriate indications. (Category IA)

Urinary catheter use and duration of use should be minimized in patients at higher risk for CA-UTI, such as women, elderly persons, and patients with impaired immunity, higher severity of illness, diabetes, renal dysfunction and incontinence. (Category II) Only properly trained personnel should insert urinary catheters using correct aseptic techniques. (Category II)

Question 1C: What populations are at highest risk of mortality from catheters? Urinary catheter use and duration of use should be minimized in patients who might be at higher risk for mortality due to catheterization, such as elderly persons and patients with higher severity of illness. (Category II)

QUESTION 2 focused on the best practices to decrease the risk of infection for persons who might require urinary catheters. Sub-question 2A: What are the risks and benefits associated with different approaches to catheterization? Condom catheter drainage is preferable to an indwelling urethral catheter in cooperative male patients without urinary retention or bladder outlet obstruction. (Category IB)

Intermittent catheterization is preferable to an indwelling urethral or suprapubic catheter in selected patients with bladder emptying dysfunction. (Category II) Intermittent catheterization should be performed at regular intervals to prevent urinary retention. (Category II) For operative patients who have an indication for an indwelling catheter, the catheter should be removed as soon as possible post-operatively, preferably within 24 hours. (Category II)

Further study is needed on the risks and benefits of suprapubic catheters as an alternative to indwelling urethral catheters in selected patients requiring short- or long-term catheterization, particularly with respect to patient preference and complications related to catheter insertion or the catheter site. (No recommendation/unresolved issue) Clean intermittent catheterization is an acceptable and more practical alternative to sterile intermittent catheterization for patients requiring chronic intermittent catheterization. (Category IB)

Question 2B: What are the risk and benefits associated with different catheters or collecting systems? Further study is needed on the benefit of antimicrobial silver alloy or antibiotic-coated catheters compared to standard silicone-based catheters in reducing the risk of clinically significant CA-UTI events. (No recommendation/unresolved issue) Hydrophilic catheters are preferable to standard catheters for patients requiring intermittent catheterization. (Category II) A sterile and continuously closed drainage system should be maintained. (Category IA)

Complex urinary drainage systems are not needed as a routine prevention measure for CA-UTI. (Category II) The use of urinary catheters with pre-connected sealed junctions is a useful adjunct measure to reduce the risk of disconnection of the sterile and closed drainage system. (Category II) Further study is needed to clarify the benefit of catheter valves in reducing the risk

of CA-UTI and other urinary complications and also to identify the appropriate patient population for this device. (No recommendation/unresolved issue)

Question 2C: What are the risks and benefits associated with different catheter management techniques? The workgroup is continuing to review the evidence to answer this question for the following techniques: antibiotic prophylaxis, bladder irrigation, antiseptic instillation in drainage bags, local skin care, frequency of catheter or bag change, catheter lubricants, secured devices, bacterial interference, clamping versus free drainage, duration of catheterization for short-term drainage, portable ultrasound to assess bladder volume, and catheter cleansing procedures.

Question 2D: What are the risks and benefits associated with different systems changes? The workgroup is continuing to review the evidence to answer this question in the following areas: reminders, bacteriologic monitoring, mixed infection control and quality improvement programs, hand hygiene, isolation, catheter teams, feedback, and nurse-directed catheter removal.

For QUESTION 3, the workgroup is continuing to review the evidence to determine whether management of an obstructed urinary catheter is the best method to manage urinary catheter-associated complications. The other sections of the CA-UTI guideline the workgroup is still developing focus on implementation and audit and recommendations for further research. In the final draft, the workgroup plans to list all the recommendations at the beginning of the document and also in each of the relevant sections.

HICPAC commended all of the workgroups for their tremendous progress in refining the guidelines since the previous meeting. Several members made suggestions for the CA-UTI workgroup to consider in revising its preliminary recommendations.

- The language of “increased risk of urinary retention or **re-catheterization** in patients not receiving catheters” should be changed to **catheterization** because these patients never received catheters for surgery.
- Caution should be taken in providing too much detail in the recommendations. For example, a description of surgical indications for catheters in the recommendations might lead to confusion.
- A list of indications for catheterization should be developed for clinicians and included in the guideline.
- The recommendation should be changed to “minimize urinary catheter use and duration of use in all patients at higher risk for CA-UTI, particularly women, elderly persons, and patients with impaired immunity, higher severity of illness, diabetes, renal dysfunction and incontinence.”
- A footnote should be added to the recommendation to “ensure that only properly trained personnel insert urinary catheters using correct aseptic techniques.” Because the recommendation is graded as Category II or “suggested” for implementation, untrained personnel could be used.
- The guideline should emphasize that Category IA, IB and IC recommendations are all strong and should be equally implemented. The guideline should further clarify that the only difference among the three categories is the quality of the evidence.

- The language of “in operative patients, there was low-quality evidence to suggest a benefit of **not using urinary catheters routinely**” should be changed to “**avoiding urinary catheterization when possible.**”
- New text should be included to provide guidance on appropriate times to perform urine culturing. The guideline focuses on prevention and not treatment, but this language would be important in the current era of pay-for-performance.
- New text should be included on the use of antimicrobial catheters. This language should be supported by primary studies.
- Innovation, surgical intervention at earlier stages and evaluation of incontinence in certain populations should be described in the “further research” section to highlight gaps in knowledge, opportunities for improvement and the need for funded studies in the future.

HICPAC Workgroup Reports

HAI Preventability Workgroup. Dr. Brennan reported that the “Mortality from Reasonably Preventable HAIs” document was distributed to HICPAC for review. SHEA drafted the document in response to a Congressional request in March 2008 to make estimates on the extent to which mortality from HAIs is preventable. The document was circulated during the hearing of the House Oversight and Reform Committee in April 2008.

Dr. Umscheid explained that the purpose of the document was to estimate the number of annual deaths in U.S. hospitals from reasonably-preventable cases of HAIs. To estimate the number of HAIs and resulting mortality, the best available evidence was gathered from the National Nosocomial Infections Surveillance System (NNIS), National Hospital Discharge Summary, and American Hospital Association (AHA). To estimate the proportion of HAIs that could be prevented, HAI risk reduction data resulting from quality improvement strategies were extracted from a recent AHRQ report.

Of ~1.7 million HAIs that occurred in 2002, 98,987 resulted in deaths and accounted for 5.7% of fatal infections. UTI prevention studies reviewed by AHRQ suggested a 17%-69% reduction in UTIs depending on the intervention and population examined. Five studies of good or moderate quality conducted over the past ten years were included in the review.

Based on these data sources, the following estimates were made on the number of preventable infections: (1) 44,762-203,916 from BSIs; (2) 95,078-177,646 from VAP; (3) 95,483-387,550 from UTIs; and (4) 75,526-156-862 from SSIs. The following estimates were made on the number of preventable deaths: (1) 5,520-25,145 from BSIs; (2) 13,667-25,537 from VAP; (3) 2,225-9,031 from UTIs; and (4) 2,133-4,431 from SSIs.

Because the estimates will be used to inform policy discussions regarding the reduction of HAIs in hospitals, the uncertainty and limitations of the analysis are explicitly outlined in the document. Survey data on the number of deaths caused by HAIs were collected more than five

years ago and do not reflect improvements in infection control practice since that time. A method has not been developed to date to definitively attribute deaths to HAIs.

The quality of available HAI reduction studies is limited, none of the studies are randomized, and only a few studies are controlled. Some published studies were conducted ten years ago. The validity of reported risk reductions is uncertain and might be exaggerated due to limitations of the data sources. Preventable deaths were not estimated from studies that directly measured death as an outcome. An assumption was made that rates of preventable deaths and infections were the same.

An appendix is included in the document that estimated the cost of reasonably-preventable HAIs to be \$1.8-\$9.4 billion. Four cost studies on catheter-related BSIs in the United States conducted in 1999-2006 were used as data sources to develop the cost estimates.

The HICPAC members made a number of comments and suggestions on the HAI preventability document.

- The public might view the document as broad “guesstimates” with flawed data and a waste of resources. Consumer advocates most likely would rank the implementation of proven infection control practices for hospitals to reduce HAIs and save lives as a much higher priority than studies to estimate the number of preventable HAIs.
- The summary of the document should include more information on the decline of HAIs based on improvements in infection control practice.
- Billing code data should be gathered to correlate HAIs to the diagnosis-related group of septicemia.
- The term of “attributable to and mortality from HAIs” should be clarified because this language is inconsistent with NHSN definitions.
- The additional focus of the document on preventable deaths from HAIs should be reconsidered due to the ongoing effort to develop a National HAI Elimination Plan.
- Pediatric studies should be included in the document to estimate the number of preventable HAIs in children.

Dr. Brennan asked HICPAC to submit additional comments on the HAI preventability document in writing to Dr. Umscheid. The document would be revised and redistributed to HICPAC for further review and comment. He hoped to publish the paper as a joint document by SHEA, HICPAC, APIC and other groups to address language in the CMS regulations about the extent to which HAIs are reasonably preventable.

Guideline Methods Workgroup. Dr. Umscheid reported that a companion paper would be released with the CA-UTI guideline to summarize HICPAC’s updated guideline methodology. Key sections of the companion paper are outlined as follows. HICPAC’s role and function in producing evidence-based guidelines on healthcare infection control practices will be described.

Details will be provided on methods and processes that were used to develop HICPAC’s recent guidelines. Organizational changes that were made to update HICPAC’s guideline methodology will be specified. For example, DHQP staff and HICPAC members were assigned to develop

key questions for guidelines, screen abstracts and full-text studies for inclusion in the guidelines, write or review evidence summaries and recommendations, and share bibliographies and draft guidelines with outside experts.

Dr. Umscheid and other methodology consultants at the University of Pennsylvania Health System Center for Evidence-Based Practice were engaged to develop and maintain methods for the guidelines, establish timelines, build evidence and GRADE tables, design search strategies, manage references, and review and integrate all aspects of the development process.

Challenges in producing HICPAC guidelines will be highlighted in the companion document, such as the rapidly growing evidence base, increased attention on HAIs, emerging infectious diseases, and prioritization and communication of guidelines to providers.

Other issues will be noted as challenges or future opportunities, such as continued development of clinically-relevant and targeted key questions; judgments of studies to include in guidelines; the complexity of systematic reviews; use of meta-analyses in light of the heterogeneity of the evidence; adaptation of the GRADE System to the HICPAC ranking scheme; the role of cost analyses in HICPAC guidelines; the need to sufficiently balance content and method expertise; and opportunities to direct future research.

To support HICPAC's updated guideline methodology, the workgroup acknowledged that capacity will be needed to (1) rapidly develop and update guidelines; (2) rapidly respond to emerging needs; (3) address key clinical questions of infection control providers and personnel; (4) use available evidence to answer questions; and (5) provide unbiased and transparent guidance.

The workgroup will take several actions to achieve these goals. Emerging methods and evidence-based medicine will be used in developing guidelines. A targeted systematic review process will be developed based on the best available evidence with explicit links between the evidence and HICPAC's recommendations. A rapid, unbiased, transparent and evidence-based review process will be implemented and efficiently updated to address key questions of providers.

The HICPAC members made two key suggestions on the companion paper to the CA-UTI guideline. First, the identification of gaps in current knowledge is an important outcome of the document and should serve as a foundation to develop a hospital epidemiology research agenda for the next ten years. Second, the companion paper should be consistent with the National Quality Forum process because this effort led to the identification of infection reporting research that should be conducted.

Dr. Brennan asked HICPAC to submit additional comments on the companion paper in writing to Dr. Umscheid. He noted that the document would need to be vetted, cleared and released in parallel with the CA-UTI guideline to inform the professional community of HICPAC's updated methodology.

Model Legislation Workgroup. Dr. Bell reported that the workgroup is currently developing a table to capture existing HAI legislation in each state. The workgroup will also draft an outline to describe the rationale, potential benefits and unintended consequences of HAI legislation. The workgroup will use the draft outline as the basis to develop a concise and succinct document with no more than 2.5 pages.

The document will contain language in bullet form to help groups in writing new or adapting existing legislation to address local needs. Cautionary language on the potential consequences of misinterpreting HAI legislation will be included in the document as well. The workgroup will convene a conference call after the outline is drafted.

National Patient Safety Goal (NPSG) Workgroup. Mr. Russell Olmsted reported that on June 4, 2008, the workgroup sent HICPAC's comprehensive letter to the Joint Commission on the proposed 2009 NPSGs. The letter outlined HICPAC's concerns in several general areas. A number of the proposed NPSGs were based on draft documents that were unpublished, not vetted and had untested measures. HICPAC emphasized the need to validate these measures before their establishment as NPSGs.

The proposed NPSGs were prescriptive and appeared to negate the current Joint Commission standard that requires each facility to perform an annual risk assessment. Pathogen-specific goals related to MRSA and *C. difficile* were narrow and appeared to divert attention from other emerging problems in hospitals. The term "best practices" in the proposed NPSGs appeared to be subjective and might not be effective across the spectrum of acute care delivery. The workgroup also made comments that were specific to individual NPSGs.

Although the workgroup did not receive a formal response to the letter, Dr. Brennan announced that the Joint Commission gave serious consideration to comments and input by HICPAC and SHEA.

Liaison and *Ex-Officio* Reports

Ms. Rachel Stricof submitted a written report on key outcomes of the meeting of the Advisory Council for the Elimination of Tuberculosis that was held in March 2008. The presentations focused on the budget of the Surveillance, Epidemiology and Outbreak Evaluation Branch; TB public health laws; nucleic acid amplification testing guidelines; and the 2007 technical instructions for overseas screening of TB. Ms. Stricof also submitted a copy of a presentation that was given during the meeting on the role of BCG vaccine in the prevention of TB for HCWs in high-risk situations overseas.

Dr. William Baine submitted a written report on AHRQ's \$5 million MRSA initiative. AHRQ is partnering with CDC and CMS to fund six projects under the special initiative.

Dr. Mark Russi submitted a written report on recent activities by the American College of Occupational and Environmental Medicine, including key outcomes from its annual spring

meeting in April 2008; an updated online guidance document for delivery of occupational health services in medical center settings; an extensive update of its evidence-based practice guidelines; and revisions and updates to its position statements on influenza vaccination and HIV in the workplace.

Dr. Brennan conveyed that AHA's written report covered its comments on the FY'09 Medicare Inpatient Prospective Payment System; case studies focusing on the reduction of HAIs as part of an AHA quality improvement initiative; and continued communications with policymakers to focus resources and efforts on decreasing HAIs.

Ms. Joan Blanchard submitted a written report on recent activities by the Association of periOperative Registered Nurses (AORN), including development of its electronic standardized peri-operative record; the Executive Symposium that will be held in July 2008 in Colorado; the "Smoke Evacuation Toolkit" to assist peri-operative teams in implementing the AORN *Position Statement on Surgical Smoke and Bioaerosols*; the successful 2008 AORN Congress in California; and the 13th Conference on Infectious Disease.

Ms. Nancy Bjerke submitted a written report on APIC's recent activities, including the release of the *APIC/HICPAC Surveillance Definitions for Home Health Care and Home Hospice Infections* on the APIC web site; the Annual APIC International Conference in June 2008 in Colorado; the first "National U.S. Inpatient Healthcare Facility *Clostridium difficile* Prevalence Study"; the premiere of the quarterly *Prevention Strategist* publication in April 2008 to replace *APIC News*; APIC's testimony before Congress on HAIs; and the "Mastering the New CMS Regulations: Implications for Infection Prevention Control Conference" in September 2008 in Virginia.

Dr. Nalini Singh submitted PowerPoint slides with key outcomes of the most recent NCPDCID Board of Scientific Workgroup meeting. The workgroup discussed and provided input to NCPDCID on NHSN, the Epidemiology and Laboratory Capacity Grant Program, the GeoSentinel Surveillance System, and the Early Aberration Reporting System.

Ms. Lisa McGiffert submitted a written report of hospital infection stories that the Consumer's Union has compiled. The stories were accompanied by photographs of affected patients across the country.

Ms. Marion Kainer submitted a written report of recent activities by the Council of State and Territorial Epidemiologists (CSTE), including its annual conference in June 2008 in Denver; feedback on the Durbin Bill; position statement on NHSN; input on AHRQ's proposed patient safety organizations; and HAI Workgroup.

Dr. Sheila Murphey submitted a written report on FDA's recent activities, including the release of its *Sentinel Initiative: A National Strategy for Monitoring Medical Product Safety* white paper; redesign of its web site; publication of draft guidance on *Certifications to Accompany Drug, Biological Product and Device Applications and Submissions*; web link to CMS's final rule on the Medicare Part D Claims Data Rule; and release of recommendations to manufacturers seeking to develop plasmodium species antigen detection assays.

Dr. Brennan conveyed that the Joint Commission's written report described its Standards Improvement Initiative; continued participation on the HAI Allied Task Force; and ongoing efforts to gather data on major clinical issues related to flash sterilization.

Dr. David Henderson submitted a written report describing the National Institute of Health's continued focus and activities related to emergency preparedness; multidrug-resistant *Acinetobacter baumannii* infections; influenza immunization of healthcare providers; and an outbreak of nosocomial pneumonia due to a *Legionella pneumophila* serogroup 1 case cluster.

Dr. Lisa Maragakis submitted a written report on SHEA's recent activities, including its successful 18th Annual Scientific Meeting in April 2008 in Orlando; HAI guidelines that were developed in partnership with the Infectious Disease Society of America and approved for publication; educational initiatives; a briefing to Senate staffers on HAIs in the context of NHSN and public reporting; and public policy responses to a number of documents and issues.

Dr. Stephen Kralovic submitted a written report on the Veterans Administration's (VA) MRSA Prevention Initiative that directs all VA acute care facilities in the United States to initiate a MRSA prevention program. The VA is continuing its performance-based management process to achieve quality healthcare outcomes as well as its award-winning "Infection: Don't Pass It On" public health campaign. The VA will hire and deploy a high-level epidemiologist to DHQP to explore strategies to link NHSN and the VA surveillance system.

With no further discussion or business brought before HICPAC, Dr. Brennan recessed the meeting at 5:47 p.m. on June 12, 2008.

Update by the DHQP Surveillance Branch

Dr. Brennan reconvened the HICPAC meeting at 9:12 a.m. on June 13, 2008 and yielded the floor to the first presenter.

Dr. Scott Fridkin, Deputy Chief of the Surveillance Branch, explained that DHQP made a number of changes in transforming NNIS to NHSN. Surveillance data are collected from non-ICU units and smaller hospitals. Pathogen and susceptibility data are gathered. Hospital areas are categorized differently to collect information from bone marrow transplant wards and other specialty care areas.

NNIS allowed data on any nosocomial infection from an ICU, but NHSN's data on pathogens are limited to device-associated and post-procedure infections. An influx of NHSN facilities was observed in 2007 due to open enrollment and state-based mandates. Due to these differences, comparisons between NNIS and NHSN are difficult without a specialized evaluation or analysis.

Data submitted to infection control and hospital epidemiology departments as part of the first *NHSN Antibiotic Resistance Report* showed that 28,000 HAIs were reported. Of reported HAIs,

CLABSIs accounted for 35% and post-procedure infections accounted for 19%. Of 23,000 device-associated infections, 13% were from non-ICU areas. The proportion of smaller hospitals that reported ≥ 1 HAI to NHSN increased to 32%.

Of 33,000 pathogens that were associated with the 28,000 HAIs reported to NHSN, gram-positive organisms accounted for the majority of BSIs and gram-negative organisms accounted for the majority of VAP. An analysis of the percentage of pooled mean resistance of all organisms tested in a particular species showed that SSI resistance was 50% and CA-UTI resistance was 65%.

Data collected from NNIS in 2003 showed that 29% of any type of *Enterococci* was vancomycin-resistant and ~60% of *S. aureus* was methicillin-resistant. Because data collected from NHSN in 2006 showed a slight increase in VRE and a slight decrease in MRSA, DHQP conducted a study to (1) determine differences between the percentage of MRSA and MRSA incidence using CLABSIs as a candidate infection among ICU patients and (2) characterize actual trends and incidence of MRSA and MSSA CLABSI rates by different ICU types.

Over the past 10 years, 1,600 units have reported ~2,500 MSRA CLABSIs and ~1,600 MSSA CLABSIs to NNIS or NHSN. The study showed a significant increase in the percentage of MRSA from ~50% to ~65% over the past 10 years. An increase in the incidence of MRSA CLABSIs per 1,000 central-line days was observed in the first part of the study period, but a significant decrease was seen in this rate in 2000-2001. An overall reduction of ~50% was seen in the MRSA CLABSI rate at the end of the study period compared to the beginning. A steady decrease of ~70% was seen in the MSSA CLABSI rate over the entire study period.

DHQP performed the same analysis for each major ICU type, including surgical ICUs (SICUs), medical ICUs, and medical/surgical units in both major and non-major teaching facilities. In SICUs, for example, no significant trends in the percentage of MRSA were seen. An impressive increase of ~102% that was seen in the incidence of MRSA in SICUs in the first few years of the study period was followed by a marked decline of ~62% throughout the remainder of the study period. A steady decrease in MSSA CLABSIs was observed in all ICU types.

DHQP made a number of conclusions based on results of the study. MRSA provides an incomplete picture of the changes in the magnitude of the MRSA problem over time. MRSA incidence might be a better metric of MRSA burden, but is dependent on specific issues that are addressed, such as the impact of prevention efforts or guidance for empiric therapy. MRSA CLABSI rates are declining in some, but not all ICU types. Additional studies are needed to understand the influence and cause of inflection points in ICUs, such as MRSA-specific efforts or the impact of CLABSI infection prevention practices.

DHQP is collaborating with state health departments to conduct another MRSA surveillance project through the Emerging Infections Network (EIN). The number of invasive MRSA cases classified as "nosocomial" reported to EIN was ~1,500 in 2005 and ~1,400 in 2006. DHQP will use EIN to launch a *C. difficile* surveillance system in 2009.

In addition to surveillance of HAIs, DHQP is also focusing on the tremendous growth of NHSN over the past year. Of ~491 facilities enrolled in NHSN in April 2007, 24% were moderate size with 200-500 beds, 80% were general acute care hospitals, and 40% were non-major teaching hospitals. Of 1,470 facilities enrolled in NHSN in May 2008, 56% had <200 beds, 91% were general acute care hospitals, and 61% were non-major teaching hospitals.

At this time, >1,000 hospitals actively report data to NHSN and 17 states now use or plan to use NHSN for mandatory reporting. DHQP's recent analysis showed that mandatory reporting only accounted for ~50% of NHSN's growth, while voluntary reporting accounted for the remainder of the growth. Most states with reporting requirements are focusing on CLABSIs, but four states are considering the use of the MDRO and CDAD module.

DHQP plans to launch a new MDRO and CDAD module in August 2008 for facilities to report proxy measures that can be populated by electronic data sources. DHQP will use laboratory identification event reporting to calculate the number of hospital-onset MRSA cases, BSI isolates or nosocomial cultures per 1,000 patient days. Proxy measures in the MDRO and CDAD module will be consistent with the HICPAC/SHEA position paper on evaluating and measuring MDROs in the context of prevention efforts.

Although the proxy measures in the MDRO and CDAD module will be based on the approved HICPAC/SHEA MDRO metric document, Dr. Brennan pointed out that HICPAC would need to take a formal vote to officially agree on editorial changes. A conference call would be convened within the next 10 days for HICPAC to vote on the revised MDRO metric paper.

Mr. Olmsted served as the chair and represented HICPAC on the External Peer Review of the Surveillance Branch that was convened in May 2008. The Panel was charged with evaluating NHSN in the context of its other capabilities and initiatives. The Panel was also asked to assess DHQP's other surveillance activities, including electronic HAI surveillance, adverse drug event surveillance; population-based surveillance of MRSA and CDAD; and use of the National Hospital Discharge Survey or National Inpatient Sample.

DHQP described the purpose of NHSN to guide the Panel's discussion. NHSN provide facilities with risk-adjusted data that can be used for inter-facility comparisons and local quality improvement activities. NHSN is based on the NNIS paradigm in which voluntary confidential data reporters provide high-quality data if the data are useful to them and no penalties are imposed for reporting the truth.

DHQP presented detailed information to the Panel on all aspects of NHSN, including the Patient Safety Component; a new Biovigilance Component, eSurveillance Initiative and Special Pathogens Module; device-associated procedures; tremendous growth over the past year; and the recent influx of smaller hospitals.

DHQP informed the Panel of the three categories of the current landscape of HAI surveillance. The "scientific" landscape covers MDROs, CDAD, HAIs in non-hospital settings, algorithmic detection of HAIs, surrogate measures of HAIs, and adherence to HAI prevention guidelines in clinical practice.

The “technical” landscape covers technical solutions that capitalize on the availability of healthcare data in an electronic format and reduce or obviate the need for manual data collection and data entry. The “policy” landscape covers mandatory reporting by providers to public health agencies; public reporting of hospital-specific rates; and renewed interest in validating HAI reporting, linking federal data systems, and estimating the national scope and cost of HAIs.

The Panel discussed the strong business case for conducting HAI surveillance, including the need to protect patients and hospital personnel in the most cost-effective manner, increased scrutiny on HAIs, demands for transparency and disclosure of HAIs for patients to make informed decisions, value-based purchasing, assurance of effective prevention practices, and solid surveillance programs and infrastructures to manage data.

The Panel agreed with a study that concluded NHSN’s methods for expression of infection rates and risk adjustment have become a national and international standard for categorizing and benchmarking HAI rates. The Panel also noted that many other countries have adopted NNIS or NHSN principles and methodologies for HAI surveillance. The Panel’s overall impression was that NHSN is CDC’s “crown jewel” in terms of surveillance.

The Panel reviewed results of a survey that was recently administered to ~800 ICPs throughout the country. The survey showed that surveillance was one of the greatest challenges for ICPs. ICPs expressed an interest in a better, timelier and more efficient system to track HAIs in the entire hospital population in both acute care facilities and non-hospital settings. ICPs also cited MDROs, hand hygiene and state-based mandates as significant challenges.

The Panel formulated recommendations in response to three key questions posed by DHQP. One, did the Surveillance Branch’s presentations omit important scientific, technical or policy features of the current landscape of HAI surveillance in the United States, including antimicrobial resistance?

- The Surveillance Branch provided an excellent discussion on the scientific, technical and public policy landscape of HAI surveillance.
- NHSN should broaden its focus beyond acute care hospitals to more accurately reflect the direction of care delivery outside of this traditional setting.
- HICPAC and DHQP should jointly develop a risk assessment template for facility- and setting-based application. HICPAC also should create a surveillance guideline to assist providers in the field in identifying key areas to measure. The risk assessment template and surveillance guideline should be linked. APIC’s recently published *Recommended Practices for Surveillance* should be reviewed and expanded in this effort.

Two, are the Surveillance Branch’s current capacity, priorities and plans for NHSN adequate with respect to the current landscape of HAI surveillance?

- The Surveillance Branch’s activities and plans for NHSN are appropriate, but its technical and financial capacity is not sufficient at this time to implement these plans.

Most notably, NHSN is entirely supported by discretionary funds and has no dedicated line item. The potential loss of the NHSN infrastructure would compromise capacity in the field to advance and expand prevention. HICPAC should make a recommendation on the critical need to allocate additional resources to DHQP for NHSN.

- CDC should view NHSN as a pivotal area and a priority to address patient safety and provide necessary data to control and prevent HAIs. An appropriate level of resources should be allocated to DHQP to ensure data and other aspects of NHSN are not compromised as the demand on the system continues to increase.
- CDC should fully embrace partnerships with other HHS agencies, particularly AHRQ and CMS, to meet the growing demand for NHSN services. Collaborations with CSTE and the Joint Commission should be strengthened in this effort as well.
- HAIs should be viewed as a public health problem beyond hospitals.

Three, what directions, strategies and steps are most important for the Surveillance Branch to meet new opportunities and challenges in HAI surveillance?

- HICPAC should explicitly endorse NHSN as the standard for HAI surveillance and reinforce its endorsement in all relevant guidelines and other communications that are developed in the future.
- HICPAC should assist DHQP and the HHS Secretary by playing a proactive role in determining appropriate actions to take when existing surveillance data are inconsistent or conflicting. For example, HICPAC should establish a position on the value and efficacy of active surveillance and detection of MDROs.
- HICPAC and DHQP should jointly establish linkages between NHSN and evidence-based guidelines, new contributions to the literature, and information generated by other parts of CDC and other HHS agencies.
- CDC should build a constituency of partners to support the aims and goals of NHSN as the premiere source of data on epidemiologic trends, new findings and other aspects of HAIs.
- CDC should encourage and promote the use of NHSN data by outside researchers, but sound policies should be developed on the use of these data.
- CDC should launch a marketing campaign to broadly share success stories that showcase the efficacy and value of NHSN.
- CDC should take a multifaceted approach to improve the communication and timely output of NHSN data while increasing the visibility of NHSN analytic products. CDC should use innovative communication mechanisms to disseminate data to the public, such as developing and releasing a consumer version of NHSN and posting user-friendly information on web sites.

HICPAC commended Mr. Olmsted and the other Panel members for conducting an excellent and comprehensive peer review of the DHQP Surveillance Branch. Several HICPAC members made suggestions to advance the Panel's recommendations.

- The recommendation for HICPAC and DHQP to jointly develop a risk assessment template for facility- and setting-based application should take advantage of the current

opportunity to create a risk adjustment tool to prospectively collect data on SSIs. HICPAC and DHQP should link their epidemiological expertise to the wound and SSI expertise in the Surgical Infection Society to develop and apply a clinically-relevant tool. This effort could be tested in NHSN's research and development component.

- A cost analysis should be performed to determine resources that DHQP would need to implement the Panel's recommendations.
- HICPAC should not wait until DHQP develops a strategic plan for national surveillance before creating a surveillance guideline. These efforts can be conducted in parallel to ensure that both activities inform each other.

Dr. Bell's position was that HICPAC should develop a new surveillance guidance document rather than a guideline. He explained that a "guideline" involves an extensive evidence review and a transparent assessment of the quality of evidence using the updated methodology for the norovirus and CA-UTI guidelines. A "guidance document" captures the experience, wisdom and expert opinion of a broad group of constituents upfront rather than using these consultants as reviewers after a document is developed. Concise guidance documents are also developed more rapidly than guidelines.

Dr. Brennan reviewed next steps for HICPAC to begin developing the new surveillance guidance document. A conference call would be convened to identify the membership of the new workgroup, such as APIC, SHEA, the Joint Commission, Prevention EpiCenters and health departments. Due to the broad range of partners and stakeholders that would be engaged upfront, subgroups might need to be established as well. The workgroup also would develop the risk assessment template in parallel with the surveillance guidance document.

Dr. Brennan turned to the Panel's recommendation for HICPAC to endorse additional technical and financial resources DHQP would need to respond to the tremendous growth of NHSN. He would draft a letter on this issue and circulate the document to HICPAC for review and comment. In terms of the Panel's recommendation for HICPAC to explicitly endorse NHSN as the standard for HAI surveillance, a formal statement would be embedded in the new surveillance guidance document.

HICPAC Business Session

Dr. Brennan announced that the terms of Drs. Steven Gordon and Nalini Singh would expire after the current meeting. He emphasized that both of the outgoing members have made significant contributions to HICPAC, particularly the leadership of Dr. Gordon in developing the electronic health records white paper and the expertise and strong advocacy of Dr. Singh for the pediatric population.

Dr. Brennan presented plaques and certificates of appreciation to Drs. Gordon and Singh. The participants applauded the outstanding service of the two outgoing members.

Dr. Wright reviewed next steps for HICPAC to respond to its charge from HHS. HICPAC would identify four or five guidelines that should be prioritized and provide HHS with a timeline for this deliverable. HICPAC would use the prioritized guidelines to develop a top 10 list for HHS's National Policy on Lowering HAIs.

The top 10 list primarily would be targeted to healthcare providers, but the Joint Commission and other accrediting bodies also would use the list during their routine hospital surveys. The HHS Steering Committee would establish short-, mid- and long-term benchmarks to track progress with the top 10 list.

Dr. Wright emphasized that the development of the National Policy over the next six to eight months should not be overly comprehensive and delay the process. Instead, the National Policy would be an ongoing process over time with evaluations at specific intervals similar to HHS's *Healthy People* initiatives.

Dr. Wright reiterated that HICPAC would also develop a global top 10 list as the foundation for HHS's National Prevention Campaign. This list would be targeted to the general public with important strategies to lower the incidence of HAIs in healthcare settings.

The HICPAC members made a number of suggestions in response to the charge from HHS.

- The hand hygiene, SSI, CLABSI, CA-UTI, VAP, MDRO, isolation, and disinfection and sterilization guidelines should be prioritized.
- HICPAC's disease- or procedure-specific guidelines should serve as the basis for developing the top 10 list for healthcare providers in the National Policy.
- HICPAC should create an "Infection Control Bill of Rights for Patients" as the top 10 list for the public in the National Prevention Campaign. The Consumer's Union should serve as a key liaison in this effort.
- The "universal precautions" section should be extracted from the isolation guideline and used as the basis for developing the global top 10 list of HAIs.
- A new ambulatory and office-based surgery guideline should be created and prioritized. The guideline could provide advice and education on implementing important infection control practices to address the growing shift in care from acute care settings to outpatient facilities.
- HICPAC should create a short checklist for each guideline of the five most important infection control practices that should be implemented.

Dr. Chesley Richards, Deputy Director of DHQP, noted that the new Medicare policy on non-payment or reduced payment for HAIs should be considered as an additional factor in prioritizing HICPAC's guidelines. He explained that CA-UTIs, a specific SSI and BSIs will be implemented under the new Medicare policy beginning in October 2008. He also pointed out that MRSA, *C. difficile* and VAP have been released for public comment and are being considered for possible implementation in 2009.

Drs. Brennan and Cardo conveyed that DHQP could develop a new tool for facilities to report process measures to NHSN on the prioritized HAIs. For example, SCIP process measures

could be incorporated into NHSN to efficiently collect both process and outcome data. This strategy also would respond to the GAO recommendation for data systems to be aligned across HHS agencies. CMS would capture process-related HAIs and CDC would capture present-on-admission (POA) indicators through NHSN.

Based on the comments and suggestions by HICPAC and DHQP leadership, Dr. Brennan proposed the following process for HICPAC to respond to its charge from HHS. HICPAC would convene a conference call by the end of June 2008 to begin formalizing action steps. The CA-UTI, SSI and BSI guidelines would be initially prioritized because these three infections will be implemented under the new Medicare policy in October 2008.

This approach would ensure that HICPAC's efforts are aligned with CMS's POA indicators to avoid the perception of competing interests within HHS. However, HICPAC would re-review the prioritization of the initial three guidelines in the future since CMS is considering implementation of different HAIs in 2009. Workgroups with current and former HICPAC members, DHQP staff and external subject matter experts would conduct activities over the summer to meet HHS's deadline of developing the global top 10 list of priorities by the fall of 2008.

None of the HICPAC members opposed Dr. Brennan's proposed approach and all of the members made a commitment to meet HHS's fall 2008 deadline.

Dr. Bell returned to the new ambulatory care guideline and suggested the development of a top 10 list for this document. Because no new data have been generated on outpatient infection control, information on basic practices could be extracted from other guidelines and repackaged for ASCs. This short-term activity could be rapidly conducted and embedded into HICPAC's response to its charge from HHS.

Dr. Bell noted that HICPAC's development of a guideline on the prevention of acute respiratory infections in ASCs obviously would require much more time. As a result, he proposed tabling discussions to plan this effort until the November 2008 meeting.

Dr. Bell pointed out that HICPAC's examination of the evidence base for flash sterilization to determine the advantages and disadvantages of this procedure also would need to be discussed during the November 2008 meeting. HICPAC would submit the outcomes of its analysis to the Joint Commission.

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

- Dr. Bell will distribute the proposed dates for the 2009 and 2010 meetings to ensure that HICPAC members have no scheduling conflicts with other events.
- Drs. Bell and Brennan will identify a CMS representative to serve on HICPAC's new "HHS Prioritization Workgroup."

- Drs. Bell and Brennan will convene a conference call by the end of June 2008 for HICPAC to discuss four major topics: (1) the response to HICPAC’s specific questions during the May 2008 conference call regarding the MDRO metrics paper; (2) the framework to develop the HHS priorities for HAIs and the “Infection Control Bill of Rights for Patients;” (3) the membership of the new Surveillance Guidance Workgroup; and (4) next steps on the ambulatory care guideline.
- The HICPAC members and liaisons will participate in the following ongoing or new activities:
 - Further revisions to finalize the joint ACIP/HICPAC HCW vaccination, CA-UTI, MDRO and norovirus guidelines.
 - Participation on the new HHS Prioritization Workgroup.
 - Participation on the new Surveillance Guidance Workgroup, including the development of a new risk assessment tool for SSIs.
 - Completion of the MDRO metrics paper.

Closing Session

The next HICPAC meeting would be held on November 13-14, 2008 at the Georgetown Marriott Hotel in Washington, DC. With no further discussion or business brought before HICPAC, Dr. Brennan adjourned the meeting at 11:28 a.m. on June 13, 2008.

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

Date

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