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

National Center for Preparedness, Detection and Control of Infectious Diseases
Division of Healthcare Quality Promotion





Healthcare Infection Control Practices Advisory Committee November 12-13, 2009 Washington, DC

Record of the Proceedings

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ATTACHMENT 1

List of Participants

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Dr. Yvette McCarter

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Mr. Russell Olmsted

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Ex-Officio and Liaison Members

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Healthcare Research and Quality)
Ms. Nancy Bjerke (Association of

Professionals of Infection Control and Epidemiology, Inc.)

Ms. Joan Blanchard (Association of periOperative Registered Nurses)

Dr. Charles Huskins (Infectious Disease Society of America)

Dr. Marion Kainer (Council of State and Territorial Epidemiologists)

Ms. Lisa McGiffert (Consumers Union)

Ms. Jeannie Miller (Centers for Medicare and Medicaid Services)

Dr. Sheila Murphey

(Food and Drug Administration)

Dr. Tara Palmore

(National Institutes of Health)

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(Department of Veterans Affairs)

Dr. Mark Russi (American College of Occupational and Environmental Medicine) [via conference call]

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Ms. Roslyn Schulman (American Hospital Association) Ms. Rachel Stricof (Advisory Council for the Elimination of Tuberculosis)

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Alex Kallen [via conference call]

LaKeyshia Alexander (CDC Contractor)

Fred Blosser (NIOSH)

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Cecilia Curry

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Jeffrey Hageman

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Tara MacCannell [via conference call]

Clifford McDonald

Leola Mitchell

Chesley Richards

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EXECUTIVE SUMMARY

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on November 12-13, 2009 in Washington, DC. None of the HICPAC voting members declared any new conflicts of interest for the record that were pertinent to the published agenda for the November 12-13, 2009 meeting.

The DHQP Director provided an update on several important developments that occurred after the last HICPAC meeting in June 2009:

- CDC's organizational changes will become effective in 2010.
- Healthcare-Associated Infections (HAIs) was topic for CDC's Grand Rounds in October 2009
- DHQP's FY2009 funding and activities to support the injection safety initiative.
- DHQP's new campaign to improve antimicrobial use.
- DHQP's collaborative efforts with partners to determine the role of National Healthcare Safety Network data in the Agency for Healthcare Research and Quality (AHRQ) Comprehensive Unit-Based Safety Program in decreasing the burden of data collection.
- DHQP's continued participation in CDC's Emerging Infections Program that funds ten states to conduct population-based surveillance.
- DHQP's ongoing vaccine safety initiatives.

The DHQP Deputy Director provided an extensive update on technical assistance, meetings and other support CDC provided to grantees who were awarded American Reinvestment and Recovery Act of 2009 (ARRA) funding to conduct HAI prevention activities over the next two vears.

Bill Munier from AHRQ described its strong partnerships with CDC and other HHS agencies to fund and conduct HAI activities since 2003. An overview was provided on the national rollout of the "Stop Bloodstream Infections" Program that is funded by AHRQ and conducted by Johns Hopkins University to eliminate central line-associated bloodstream infection and its associated costs.

In response to the AHRQ update, HICPAC discussed its potential role in shortening the time between gathering and translating evidence into practice by applying its expertise in developing and widely disseminating unambiguous, user-friendly and clear guidelines.

The DHQP Associate Director for Infection Control reported that CDC updated its interim guidance for 2009 H1N1 influenza. HICPAC was asked to provide input on three issues in this area: the potential implications of and the relationship between H1N1 and seasonal influenza guidance; aerosol-generating procedures; and respiratory protection equipment. HICPAC made a number of suggestions in response to DHQP's request for feedback, but agreement was reached for H1N1 guidance to be a recurring agenda item for all three HICPAC meetings in 2010.

DHQP and HICPAC reported the current status of HICPAC's guidelines and documents. The "Methods Paper for Guideline Production" and the "Guideline for Preventing Catheter-Associated Urinary Tract Infections" are now available on the CDC/HICPAC website

(www.cdc.gov/hicpac). "Guidance for Jurisdictions Considering MRSA Legislation" was recently cleared by CDC and would be posted on the CDC/HICPAC website in the near future after a few remaining revisions are made.

HICPAC provided comments, suggestions and clear direction to advance the development of the "Healthcare Personnel Infection Control Guideline" and establish a new workgroup that would write the "Pediatric Infection Prevention Guideline" that will focus on neonatal intensive care units.

HICPAC extensively discussed the draft "Guideline for the Prevention of Intravascular Catheter-Related Infections" and took formal action on eight specific issues in the document. HICPAC agreed to have a follow-up discussion after the guideline is revised in response to public comments. HICPAC unanimously passed a motion to tentatively approve the draft guideline.

HICPAC members agreed to submit comments on the "draft Norovirus Guideline" to the work group by the December 3, 2009 deadline. HICPAC's feedback particularly would focus on the summary of recommendations, implementation and audit, and future research sections. The workgroup hopes the draft norovirus guideline will be available for public comment no later than the spring of 2010.

HICPAC agreed that the next steps to advance the development of the "Ambulatory Care Document" would be to review HICPAC's existing guidelines and identify the most appropriate evidence-based recommendations to include in the document. A group of stakeholders would be identified to review the selected evidence-based recommendations and provide input..

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

The HICPAC Chair provided an update on the new National Quality Forum (NQF) process that is underway to identify the next set of serious reportable events and hospital-acquired conditions.

DHQP and a number of HICPAC members made suggestions and comments for HICPAC to be involved in improving guideline implementation at the bedside without primary responsibility. However, other members emphasized the critical need for HICPAC to take leadership or serve as a convener of guideline implementation in partnership with professional societies.

In terms of HICPAC's role in H1N1 preparedness activities, DHQP emphasized the critical need for HICPAC to deliberate on new evidence that is expected to become available over the next six months.

The HICPAC Chair led the members in a review of the business items that were raised over the course of the meeting. The next HICPAC meeting will be held on February 11-12, 2010 in Atlanta, Georgia.

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

National Center for Preparedness, Detection and Control of Infectious Diseases Division of Healthcare Quality Promotion

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE November 12-13, 2009 Washington, DC

Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), National Center for Preparedness, Detection and Control of Infectious Diseases (NCPDCID), Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC). The proceedings were held on November 12-13, 2009 at the Washington Marriott at the Metro Center Hotel in Washington, DC.

Opening Session

Dr. Patrick Brennan, Chair of HICPAC, called the meeting to order at 9:08 a.m. on November 12, 2009. He welcomed the attendees to the meeting and opened the floor for introductions. He particularly recognized the new liaisons: Drs. Charles Huskins (Infectious Diseases Society of America) and Sanjay Saint (Society of Hospital Medicine) as well as Dr. Mitchell Levy (Society of Critical Care Medicine) *in abstentia*.

Dr. Brennan announced that the newly appointed HICPAC members were not in attendance, but HICPAC was operating with a quorum for the current meeting. No members declared any new conflicts of interest for the record that were pertinent to the published agenda for the November 12-13, 2009 HICPAC meeting. The list of participants is appended to the minutes as Attachment 1.

Dr. Michael Bell is the Associate Director for Infection Control at DHQP and the Designated Federal Official for HICPAC. He announced that the HICPAC website was recently revised to capture more information about HICPAC and its activities. The updated website also is designed to provide helpful information on HICPAC documents other than formal guidelines. Dr. Bell asked HICPAC to review the updated website and provide feedback to CDC.

Ms. Denise Murphy is a HICPAC member. She provided an update on the formal orientation process that is being developed for new HICPAC members. An orientation packet is being created to describe the role, responsibilities and expectations of HICPAC members in terms of attendance at face-to-face meetings, participation on conference calls, development of

guidelines, relationships with partner organizations, and logistical information. Ms. Murphy confirmed that the packet of materials would be completed in time for the orientation session with the new HICPAC members during the February 2010 meeting.

DHQP Director's Report

Dr. Denise Cardo, Director of DHQP, covered the following areas in her update. Dr. Thomas Frieden, Director of CDC, proposed organizational changes that will become effective in 2010 pending HHS approval. Under the new organizational structure, Coordinating Centers would be eliminated. A new Center for Global Health and a new Office of Public Health Preparedness and Response would be established.

Dr. Frieden selected five important public health issues that would serve as topics for Grand Rounds sponsored by CDC. The first Grand Rounds focused on injuries and DHQP recently held the second Grand Rounds on HAIs in October 2009. The HAI Grand Rounds elevated DHQP's partnership with the Centers for Medicare and Medicaid Services (CMS) and its overall visibility to the level of the CDC Office of Director.

Dr. Cardo informed HICPAC of DHQP's recent meetings, collaborations and other activities with key partners. DHQP convened a meeting to provide its grantees with more detailed information on the American Reinvestment and Recovery Act of 2009 (ARRA). DHQP held a meeting with its funded Epicenters. The EpiCenter principal investigators emphasized the need for additional research for infections other than bloodstream infections (BSI) before checklists can be developed and implemented.

DHQP is partnering with the Society for Healthcare Epidemiology of America (SHEA) to develop a peer-reviewed paper and research agenda focusing on the need for healthcare epidemiologists to play a lead role in bridging the gap between basic research and the application of an infections checklist at a regional or national level. DHQP is continuing to collaborate with the HHS Steering Committee on the prevention of HAIs.

DHQP received FY2009 funding to focus on injection safety. DHQP is funding New York and Nevada to pilot the "Injection Safety Campaign" for clinicians and the public. DHQP and CMS created an interagency agreement to disseminate ARRA dollars to states for injection safety training.

DHQP has planned two meetings to further support the injection safety initiative. A meeting on December 3, 2009 in Atlanta, Georgia will focus on patient notification of best practices to assist states in informing patients of situations where infection control practices were not followed. A meeting in the spring of 2010 with industry partners will focus on engineering approaches to decrease and eliminate problems related to injection safety. The injection safety meetings will be designed to promote a national discussion, increase capacity in risk communications, and develop injection safety templates or other tools for states to use

DHQP launched a new campaign to improve antimicrobial use and is partnering with the CDC Foundation and the Institute for Healthcare Improvement (IHI) in this initiative. However, DHQP also would engage HICPAC in implementing the antimicrobial use campaign. DHQP is closely collaborating with CMS to improve surveillance by exploring strategies to use National Healthcare Safety Network (NHSN) data to strengthen the CMS Hospital Compare system.

DHQP is partnering with the Agency for Healthcare Research and Quality (AHRQ) and the Health Research and Educational Trust (HRET) to determine the role of NHSN data in AHRQ's Comprehensive Unit-Based Safety Program (CUSP) in decreasing the burden of data collection. DHQP formed a new collaboration with the Health Resources and Services Administration (HRSA) to develop a more tailored approach for critical access hospitals to collect data and improve infection control.

DHQP will take a number of actions in response to feedback that was submitted during the HHS stakeholder meetings regarding strategies to decrease the burden of NHSN data reporting requirements and increase usability of the system. DHQP will continue to rely on external input from the NHSN Steering Committee regarding technical and scientific issues of the system. DHQP will soon publish the *NHSN Annual Report* and is making efforts to release web-based versions of the report with additional data analyses in the future.

DHQP will continue to participate in the CDC Emerging Infections Program (EIP) that funds ten states to conduct population-based surveillance. The program was recently expanded from methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* (*C. difficile*) surveillance to more broadly focus on healthcare-related issues. The expansion of the program will strengthen DHQP's relationships with state health departments and hospitals in conducting population-based surveillance.

DHQP is continuing its strong focus on vaccine safety, particularly monitoring the safety of novel influenza A virus (H1N1) and seasonal influenza vaccines and also adverse drug events related to antiviral drugs. DHQP is continuing to fulfill its responsibilities at CDC for blood, tissue and organ safety and healthcare preparedness. Most notably, DHQP is developing tools and sponsoring exercises to assist the healthcare community in better preparing to respond to H1N1 and other emerging threats.

Dr. Brennan pointed out that Dr. Frieden's selection of HAIs as the second Grand Rounds speaks volumes about his interest and desire in not separating healthcare infection control from the public health domain. As a presenter at the HAI Grand Rounds, Dr. Brennan was impressed by the strong attendance at the Grand Rounds and CDC's electronic broadcast of this event to thousands of individuals.

Dr. Brennan advised DHQP to closely collaborate with the Department of Homeland Security and other federal partners to strengthen its role in healthcare preparedness. He noted that current experiences with H1N1 might inform other preparedness activities in the future. To support this effort, he raised the possibility of HICPAC members and liaisons describing lessons

learned in healthcare preparedness at their individual institutions and reviewing best practices in this area by other groups across the country.

Dr. Brennan suggested placing this item on the next meeting agenda to ensure that HICPAC does not duplicate completed or ongoing healthcare preparedness activities. He conveyed that Ms. Roslyne Schulman, the HICPAC liaison to the American Hospital Association (AHA), could assist in compiling best practices in healthcare preparedness at the national level.

Update on the American Recovery and Reinvestment Act (ARRA) of 2009

Dr. Chesley Richards, Deputy Director of DHQP, began his update by reminding HICPAC of the timeline of ARRA-HAI funding. In January 2009, HHS published the HAI Action Plan to clearly define the roles and responsibilities of federal agencies and outside experts in this initiative. In February 2009, ARRA was passed with a \$50 million appropriation to HHS. CDC was given \$40 million and CMS was given \$10 million to allocate to states to strengthen efforts in preventing HAIs. In March 2009, the FY2009 Omnibus Funding Bill was passed and required states to submit HAI prevention plans to HHS by January 1, 2010.

In April 2009, CDC considered the possibility of using its existing Epidemiology and Laboratory Capacity (ELC) Grant Program and EIP Program to distribute ARRA dollars. However, input from state partners emphasized the shortage of personnel and restrictions on hiring new staff at the state level. In May 2009, CDC released a funding opportunity announcement (FOA) to fund nine Council of State and Territorial Epidemiologists (CSTE) Fellows who would specifically focus on HAIs. Despite the fact that H1N1 was a top priority across the country, CDC was pleasantly surprised to receive 51 applications for ARRA-HAI funding from each state with the exception of Wyoming, the District of Columbia and Puerto Rico.

In September 2009, CDC made awards totaling \$39.8 million for states to conduct HAI prevention activities over the next two years. CDC created and distributed a template to assist states in developing HAI prevention plans. After the states submit their plans to HHS on January 1, 2010, HHS will forward the plans to CDC for a technical review to evaluate the ability of the plan in meeting all necessary items in the template, assess the strengths and weaknesses of the plan, and make recommendations to improve the plan. States will not be penalized for failing to submit a plan to HHS by January 1, 2010, but CDC has informed grantees that punitive measures could be enforced in the future based on the outcomes of health reform legislation.

CDC's competitive review of the ARRA-HAI applications resulted in the top scoring applications being funded at nearly the amount requested and funding at some level being awarded to all other states to establish HAI programs with surveillance and prevention activities. Of \$39.8 million that CDC awarded in ARRA funding for HAI prevention, \$35.8 million was allocated to ELC grantees and \$4 million was allocated to ten EIP state health departments and their academic partners to conduct additional projects related to analyzing and validating HAIs outside of hospital settings. CDC was required to award ARRA-HAI funds to states only.

CDC's decision to use the ELC Program to distribute the bulk of ARRA-HAI funds was based on its long history with state health departments in successfully addressing infectious disease issues. CDC established the ELC Program in 1995 to enhance epidemiologic capacity, strengthen laboratory practice, improve information systems, and develop and implement prevention and control strategies at the state level. CDC will use ARRA-HAI dollars in the ELC Program to obtain a better understanding of the epidemiology of HAIs through surveillance activities, improve the flow and utilization of data among state health departments, and strengthen the role of states in HAI prevention activities.

CDC informed ELC grantees of its expectations for ARRA-HAI dollars to be targeted to activities in three key areas. States would develop HAI programs by hiring coordinators, establishing multidisciplinary committees, and providing regular progress reports to CDC on meeting HAI reduction goals outlined in the HHS Action Plan. States would expand NHSN by providing expertise to participating hospitals and promoting better use of data at the local level. States would also develop Prevention Collaboratives that focus on two of the HHS HAI Action Plan targets.

CDC acknowledges that ARRA-HAI funding will produce a number of new opportunities. State-based efforts and expertise in HAI prevention will be rapidly developed and expanded to have national impact, particularly in state health departments with existing mandates. Interagency collaborations will be strengthened with AHRQ, CDC and CMS to ensure that efforts supported by ARRA-HAI funds are not duplicated. HAIs will be used as an example in developing a model to address challenges related to healthcare safety prevention at a population level. Infections will be prevented, deaths will be reduced, and cost-savings will be generated whenever possible in the current era of health reform.

At the division level, DHQP is extremely pleased with its exceptional partnership with the NCPDCID Division of Emerging Infections and Surveillance Services to award ARRA-HAI dollars to ELC grantees in an efficient manner. DHQP hired five experienced public health advisors to directly collaborate with state grantees in each HHS region on a daily basis to conduct activities supported by ARRA-HAI dollars. DHQP is in the process of recruiting and placing four more CSTE HAI Fellows in states in addition to the existing nine Fellows.

Based on its thorough review of smallpox, polio, tuberculosis and other elimination plans, DHQP identified activities in four major areas that are key to the elimination of HAIs. Data should be collected for persons to take concrete actions. Implementation of existing best practices, including HICPAC guidelines, should be improved. A scientific agenda should be developed and broadly implemented to fill existing gaps in knowledge. CDC should enhance its traditional role of identifying and responding to emerging threats.

DHQP has required ELC grantees to report progress in addressing at least two of the national five-year goals outlined in the HHS Action Plan because measurement and data reporting will play critical roles in the ARRA-HAI initiative. For example, a health reform bill was proposed in the House calling for mandatory national public reporting of HAIs from all hospitals to CDC. HAI prevention might be tied to Medicare/Medicaid payment in the future. CMS has already

implemented a program to reduce payment for HAIs and other hospital-acquired conditions. CMS has expressed an interest in including HAIs in its pay for reporting and performance program in the future.

DHQP will withdraw a portion of ARRA-HAI grant funding from states that do not comply with the measurement and data reporting requirements. Sustained data reporting over time will allow DHQP to determine whether states have reduced or eliminated HAIs. However, DHQP recognizes that tremendous variations in infection rates among healthcare settings, risk groups and interventions are the most significant challenge in this primary outcome measure. As a result, efforts are underway across DHQP to create simple metrics that can be used at unit, hospital, state and national levels.

A standardized infection ratio (SIR) is a summary measure used to compare HAI experiences among ≥1 groups of patients to those of a standard population. The SIR was included in the HHS Action Plan as the reported metric CDC would initially use and link to ARRA-HAI funding to ELC grantees. DHQP is closely collaborating with CSTE and the NHSN Steering Committee to refine the SIR and educate states on utilizing SIR data. SIR data will help DHQP to develop risk models. ELC grantees will be required to use the SIR to report HAI data to CDC beginning in January 2010. ARRA-HAI funds are not specifically targeted to information technology, but other parts of ARRA funding are supporting improvements in the utilization and expansion of electronic health records. CDC is currently developing applications and standards for these electronic systems.

To prepare states for the new data reporting requirements, DHQP convened a grantee meeting in October 2009 with representation by 28 states. The meeting focused on state HAI plans, NHSN, Prevention Collaboratives, and requirements for data reporting and ARRA funding. The presenters represented CDC, HHS, IHI, AHRQ and AHA. DHQP's other resources to educate states on the ARRA-HAI initiative include webinars, a website with up-to-date information for grantees, toolkits and other materials.

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To date, AHRQ, CMS, CSTE, the Association of State and Territorial Health Officials, NHSN Steering Committee, academia and a multitude of other partners have provided external advice to DHQP on state HAI plans, NHSN and HAI prevention. Potential roles for HICPAC in the ARRA-HAI initiative include providing DHQP with expert guidance on surveillance, NHSN, data reporting and ongoing prevention priorities as well as reviewing the state HAI plans. Mr. Russell Olmsted, as the HICPAC liaison to the NHSN Steering Committee, could serve as the communication conduit between the two groups.

Several HICPAC members made comments and suggestions for DHQP to consider in refining the data reporting requirements and other aspects of the ARRA-HAI initiative.

• DHQP should solicit guidance from HICPAC on developing a process to share best practices across states, such as a state that rapidly reduced HAIs.

- DHQP should ensure that a rigorous process is implemented to validate data submitted by states because misclassification of units can have a serious impact on state SIRs.
- DHQP should include an additional measure to account for the proportion of patient care hospitals actually provide regardless of the size of the institution.

Dr. Cardo was aware that some HICPAC members expressed concern with the SIR during the discussion. However, the ARRA-HAI initiative is an evolutionary process that would be improved over time. The initiative also could push states to collect and report better data on HAIs and improve prevention of HAIs. She further clarified that DHQP would conduct an annual assessment on progress among states in meeting metrics outlined in the HHS Action Plan. She asked HICPAC to consider a process to provide DHQP with ongoing input on the ARRA-HAI initiative and explore concrete strategies to resolve problems. In addition to Mr. Olmsted continuing to serve as the liaison to the NHSN Steering Committee, Dr. Cardo also suggested that HICPAC form a small workgroup to provide direct feedback to Dr. Richards and other DHQP staff.

Dr. Brennan reminded HICPAC that 2010 would be the five-year anniversary of the publication of its guidance document on public reporting of HAIs. He raised the possibility of HICPAC conducting a follow-up assessment to determine whether public reporting in states has reduced the incidence of HAIs over the past five years. Dr. Brennan confirmed that he would have an offline discussion with DHQP leadership to determine the best process for HICPAC to provide ongoing advice on the ARRA-HAI initiative.

Update on Agency for Healthcare Research and Quality (AHRQ) HAI Activities

Dr. William Munier is the Director of the Center for Quality Improvement and Patient Safety at AHRQ. He reported that AHRQ receives an annual Congressional appropriation of ~\$400 million to fulfill its mission to improve care by effectively applying science. The Michigan Health and Hospital Association Keystone Center was awarded \$454,000 to conduct AHRQ's first major HAI project in 2003. The project was successful in reducing central-line infections in intensive care unit (ICUs) in Michigan. AHRQ awarded contracts totaling \$2 million in 2007 under its "Accelerating Change and Transformation in Organizations and Networks" initiative for organizations to examine facilitators, barriers and challenges to implementing known effective practices in infection control.

AHRQ received a \$5 million Congressional appropriation in 2008 that was specifically earmarked for HAIs. AHRQ coordinated this initiative with CDC and CMS to fund six projects, such as the implementation of MRSA-reducing practices; contributions of community and long-term care facilities to the rising occurrence of MRSA in hospital patients; development of rapid-cycle state and national estimates of MRSA; and creation of strategies to better understand MRSA reservoirs. AHRQ included an additional \$3 million to the \$5 million appropriation to expand the Michigan Keystone ICU Project to ten additional states.

AHRQ received a \$17 million appropriation in 2009 to fund eight MRSA projects with \$9 million and CUSP with \$8 million. The MRSA I and II projects focused on MRSA among inpatients and outpatients. Based on CDC's concept, AHRQ also funded the MRSA III project as a cluster-randomized trial to compare the clinical effectiveness of targeted or general approaches to MRSA screening. Of the \$8 million appropriation for CUSP, \$6 million was allocated to HRET in collaboration with Johns Hopkins University (JHU) to further expand the Michigan Keystone ICU Project to 22 additional states, the District of Columbia and Puerto Rico.

These funds also were used to broaden the project beyond ICUs to include ambulatory care settings using the CUSP central line-associated blood stream infections (CLABSI) methodology. JHU's successful efforts in leveraging more funds from private sources allowed the CUSP/CLABSI Project to be implemented in all 50 states. Both AHRQ and CDC have revised their contract language to emphasize strong collaboration at the state level in reducing HAIs.

At this time, AHRQ is modifying the CUSP protocol and materials to be applied to catheter-associated urinary tract infections and hemodialysis patients. AHRQ has allocated \$1 million to both of these projects. AHRQ expects that its FY2009 \$17 million appropriation for HAIs will remain the same in the FY2010 Congressional budget. AHRQ will use its FY2010 appropriation to expand and strengthen statewide collaboratives with units, hospitals and other settings to reduce HAIs; broaden efforts to eliminate HAIs in ambulatory settings, including dialysis centers, outpatient clinics, surgery centers and nursing homes; and fund investigator-initiated research aimed at identifying new interventions to reduce HAIs.

AHRQ received 52 submissions from the Interagency HAI Workgroup and outside contractors on potential HAI projects to fund in FY2010. AHRQ will decrease the 52 proposed submissions and forward ~12 potential projects to the Interagency HAI Workgroup for review and to AHRQ senior leadership for final approval. Projects will be reviewed and selected based on the following criteria: alignment with the HHS HAI National Plan Tiers I-III priorities, strong scientific merit, ability to be generalized across the country, and consistency with existing AHRQ-funded HAI projects. AHRQ hopes to release an FOA in a full, open and competitive process outside of its existing contracting networks.

AHRQ's future plans are to assure continued alignment of its funded projects with the HHS Action Plan; continue the national rollout of the CLABSI project to demonstrate the impact of AHRQ-funded projects; promote best practices and research findings via proven techniques; and collaborate with CDC to align HAI efforts with those of patient safety organizations that collect data on adverse events using AHRQ's "Common Formats."

Dr. Peter Pronovost is a HICPAC member and Director of the Johns Hopkins Quality and Safety Research Group. He provided an overview of the national rollout of the "Stop BSI" Program that is funded by AHRQ and conducted by JHU. The overarching goal of the program is to eliminate CLABSI and its associated costs. The program also will build on the success of the Michigan Keystone ICU Project to achieve national impact.

Several objectives have been established for consortia to achieve the goal of the program: reduce the mean CLABSI rate to <1%, decrease the median rate of CLABSI to 0%, improve a

safety culture in hospitals, and help clinicians learn from their past mistakes. At the federal level, HHS, CDC, AHRQ and CMS provide national leadership of the program. At the state level, statewide collaboratives were formed with representation by AHA, HRET, JHU, Michigan, state hospital associations, state health departments, quality improvement organizations, state infection control practitioners (ICPs), and teams from individual hospitals. The technical aspects of the program have been centralized based on CDC's measures and evidence to reduce HAIs, but the hospital teams modify certain aspects to address specific needs or unique barriers at the local level.

The program is based on the guiding principles of CUSP: use robust measurements, apply evidence to actual practice, identify local barriers to applying evidence, measure performance, and ensure all patients receive the evidence. Separate "Translating Evidence into Practice" checklists were created as resources for hospital leadership, staff and advisory boards. Efforts are underway to create a similar checklist for ICPs.

The checklists are designed to assure accountability by front-line clinicians who actually insert catheters, but a culture change must be promoted in hospitals to eliminate CLABSI. Several actions are taken in this effort. Hospital staff is educated on the science of safety, including key principles of teamwork and standardized designs. Staff is asked to identify defects by describing potential harm to patients in the future. Senior executives are partnered with local unit-based teams. Staff is encouraged to learn from one defect each quarter. Hospital teams are asked to implement teamwork tools to improve the safety culture.

The Michigan Keystone ICU Project published its 18-month data in the *New England Journal of Medicine* in 2006 that showed the project resulted in the rapid, near elimination and sustainbility of catheter-related bloodstream infections in 103 ICUs over the past five years. The Michigan project also sustained its 70% reduction in ventilator-associated pneumonia (VAP). The enormous and mature body of evidence and robust measurements generated by CDC, AHRQ and the National Institutes of Health (NIH) played a significant role in the success of the Michigan project.

JHU is currently addressing a number of challenges in implementing the Stop BSI Program: recruiting physicians who are willing to focus on actual results rather than efforts; ensuring that the technical aspects of the program are accurate; advancing the science of implementing a culture change; assuring data quality, completeness and effectiveness; and inviting various groups to participate in the program (*i.e.*, the infection control, public health, local quality improvement and payment policy communities) to align incentives and benefit from the strengths of diversity.

The Stop BSI Program can serve as a solid model for large-scale quality improvement of HAIs if forces are aligned to build capacity. However, several actions will need to be taken to achieve this goal. The HHS Secretary should provide leadership and the HHS agencies should closely coordinate efforts. A public health model should be aligned with a quality improvement model. Regulatory or national efforts should be shifted to the level of the community or bedside.

Consumers should be extensively engaged in efforts to eliminate HAIs. A culture change should be strongly promoted in which the medical community would view HAIs as "preventable" rather than "inevitable." Research should be conducted to better understand the epidemiology, measurements and effectiveness of HAI interventions before building a pipeline of new HAI elimination programs across the country. HAI elimination should serve as the "polio eradication campaign" of the current generation.

Some HICPAC members emphasized the need to strike a balance between research and science in the literature versus performance improvement and application of evidence at the bedside. The HICPAC members raised the possibility of applying the success with CLABSI reduction to VAP in a shorter period of time. The HICPAC members noted that additional research might not be needed in this area because a number of institutions across the country already have achieved and sustained a 0% VAP rate by replicating checklists or other components from the CLABSI initiative.

Based on HICPAC's comments, Dr. Pronovost pointed out that HICPAC's potential role in shortening the time between gathering and translating evidence into practice could be to apply its expertise in developing and widely disseminating unambiguous, user-friendly and clear guidelines. The guidelines could serve as a technical resource for institutions with an interest in implementing HAI elimination best practices. HICPAC's three-step process in this effort could be to summarize and rate the evidence on measures, launch a pilot test, and broadly implement the HAI best practices.

Dr. Cardo added that another potential role for HICPAC could be to develop a table to illustrate the current status of individual infections in building the pipeline of new HAI elimination programs. The table could guide the HHS agencies in targeting new investments in HAI research, help HICPAC to select topics for future guidelines, and complement the SHEA research agenda.

Dr. Cardo reported that efforts are underway at DHQP to develop a VAP definition. Clinicians are extensively engaged in this initiative to assure endorsement and use of the definition in healthcare facilities.

Update on CDC Interim Guidance for 2009 H1N1 Influenza

Dr. Bell reported that CDC updated its interim guidance for 2009 H1N1 influenza. Although CDC does not expect to change the guidance in the near future, he asked for HICPAC's input on three additional issues. Issue 1 is the potential implications of and the relationship between H1N1 and seasonal influenza guidance.

Issue 2 is aerosol-generating procedures. DHQP and the National Institute for Occupational Safety and Health (NIOSH) are now discussing this issue because the current guidance is based on limited evidence. CDC expects that data will be collected in the future to conduct a quantitative assessment on the difficulties associated with open suctioning or sputum induction versus administration of nebulized treatment.

Several proposals describe approaches to measure the amount of material released from each aerosol-generating procedure, the radius of released material, and the use of live virus-type assays to eliminate the need to solely rely on polymerase chain reaction techniques that do not provide useful information.

Issue 3 is new and better equipment because none of the currently available devices are ideally suited to deliver medical care. NIOSH's current research agenda includes next-generation respiratory protection. Pilot projects of respiratory protection by other groups are underway as well.

HICPAC's suggestions and comments in response to Dr. Bell's request for input are outlined below.

- Respiratory protection guidance should be streamlined because front-line providers are confused by the multitude of recommendations for droplet precautions and special respiratory precautions. Guidance should be issued to clearly articulate the appropriate types of respiratory protection equipment healthcare personnel (HCP) should wear in certain situations.
- Efforts should be made to analyze the pattern of disease transmission and clearly
 distinguish between true healthcare-associated transmission and the proportion of
 disease that appears to be acquired outside the healthcare setting. This analysis would
 be helpful in providing hospitals with a clear perspective during seasonal influenza
 season.
- Hospitals should be advised to implement different infection control strategies based on the significant proportion of H1N1 patients who will be afebrile, the insensitivity of rapid tests, and the possibility of three to four days passing before viral cultures become positive. Potential infection control strategies for hospitals to address these issues include changing empiric isolation precautions based on the type of virus that is circulating. Hospitals should evaluate the effectiveness of these changes. Universal masking should be enforced for all HCP who provide direct patient care until persons are vaccinated because up to 50% of the population will be vulnerable. All patients with respiratory symptoms presenting to the emergency department should be masked until placed in a room. The feasibility and implications of the N95 recommendations should be considered in light of these potential infection control strategies.
- A survey should be administered to compare experiences between institutions that are implementing the N95 recommendations or enforcing the use of surgical masks.
- A study should be conducted to determine whether hospital restrictions on the number and age of visitors to patients have an impact on the rate of transmission within a facility.

Dr. Brennan was in favor of compiling and disseminating HICPAC's suggestions for proposed studies on influenza to professional societies for consideration. He also asked Dr. Bell to provide the list of proposed studies to the CDC Influenza Division.

Status Report on HICPAC Guidelines and Documents: SESSION 1

Dr. Bell and a series of HICPAC members reported the current status of HICPAC's guidelines and documents.

Methods Paper for Guideline Production. Dr. Bell reported that the methods paper is now available on the CDC/HICPAC website. CDC is currently exploring strategies to publish the paper in the literature for referencing purposes.

Guideline for Preventing Catheter-Associated Urinary Tract Infections (CAUTI). Dr. Bell reported that the CAUTI guideline is now available on the CDC/HICPAC website.

Guidance for Jurisdictions Considering MRSA Legislation. Dr. Bell reported that CDC recently cleared this guidance document. Dr. Tammy Lundstrom is a HICPAC member who chaired this workgroup. She is currently revising the document in response to a few remaining comments CDC submitted. The document will be posted on the CDC/HICPAC website in the near future after Dr. Lundstrom completes these revisions. Dr. Lundstrom and CDC will explore strategies to publish the document in a journal.

Healthcare Personnel (HCP) Infection Control Guideline. Dr. Lundstrom is a HICPAC member and chair of the workgroup. She reported that the current membership of the workgroup includes representatives from HICPAC, SHEA, the Association of Professionals of Infection Control and Epidemiology, Inc. (APIC) and the American College of Occupational and Environmental Medicine (ACOEM). A new member representing the Infectious Diseases Society of America (IDSA) and a technical resource from CDC are expected to be named in the near future.

The workgroup has held several conference calls to discuss strategies to update the 1998 HCP infection control guideline. The workgroup agreed that the guideline should be updated in its entirety at some point due to its broad use in the field. For example, an informal survey administered to ACOEM members showed that this group prefers a comprehensive document as a single source.

The workgroup identified several areas in the guideline that need to be updated. The introduction describes the objectives and elements of a comprehensive personnel health program in the context of infection prevention and control as well as the epidemiology of selected infections that are transmitted between HCP and patients. The workgroup will update the following selected infections:

- Bloodborne pathogens.
- Gastrointestinal infections (with a reference to HICPAC's new norovirus guideline).
- Measles, meningococcal disease, mumps and pertussis (with new language on the combined tetanus, diphtheria and pertussis vaccine that was licensed in 2005).
- Rabies.
- Rubella.
- Scabies.

- Staphylococcus aureus infection in carriage in HCP.
- Tuberculosis (with new language on extensively drug-resistant TB).
- Varicella (with a reference to the new immunization recommendations).
- Viral respiratory infections (with new language on H1N1 and severe acute respiratory syndrome).

The next section of the guideline focuses on special populations, including pregnant, laboratory and emergency response personnel. The workgroup agreed to significantly minimize the large section devoted to latex hypersensitivity. The guideline describes the American with Disabilities Act in the context of infection prevention in infected HCP, prevention of transmission of selected infections and special issues. The workgroup will update recommendations and tables on HCP protection, immunization and prophylaxis.

The workgroup identified several companion documents that could be referenced to inform the update of the HCP infection control guideline. The Advisory Committee on Immunization Practices (ACIP) is currently updating guidelines for immunization of HCP. SHEA will soon publish updated guidance on HCP infected with bloodborne pathogens.

The workgroup agreed to produce a single document, but update three sections of the HCP infection control guideline in the following sequence: (1) elements of a comprehensive personnel health program from an infection control perspective, (2) selected infections, and (3) specific populations. The workgroup also discussed the possibility of organizing the pathogens section by transmission category. The workgroup's next steps will be to convene a conference call to refine the research questions and narrow the scope of the guideline.

Dr. Bell advised the workgroup to include website links to recommendations that are subject to frequent changes or regular updates, such as guidance on post-exposure prophylaxis or vaccination.

Dr. Craig Umscheid is the Director of the University of Pennsylvania Health System Center for Evidence-Based Practice. He conveyed that several methods exist to refine the scope of the guideline. For example, a common set of research questions could be developed for each pathogen. The methods section could clarify that some recommendations were not linked to a key research question. The most significant issues in infection control of HCP could be identified and addressed in the guideline. Dr. Umscheid's position was that the best approach would be to prioritize the most critical infection prevention and control issues in the guideline.

The HICPAC members made two suggestions for the workgroup to consider in its ongoing efforts to update the HCP infection control guideline. First, the workgroup should not organize the pathogens section by transmission category. This approach would be particularly confusing for pathogens that are transmitted by multiple modes.

Second, the workgroup should include an additional section in the guideline or develop a new companion document focusing on U.S. HCP who work in high-risk international settings with no infection prevention and control measures. This guidance should be limited to vaccination, post-exposure prophylaxis, post-return surveillance and other issues for which HCP would

consult with an occupational health professional. The guidance also should include key questions for healthcare trainees to pose to the overseas receiving organization.

Guideline for the Prevention of Intravascular Catheter-Related Infections. Dr. Brennan reported that recommendations in the draft guideline for the prevention of intravascular catheter-related BSI (CRBSI) were distributed to HICPAC for review. The entire guideline was circulated to HICPAC prior to the meeting and was recently published in the Federal Register for public comments.

Ms. Lillian Burns is a HICPAC member and serves on the workgroup that is updating the CRBSI quideline. She reviewed major changes between the 2002 and 2009 versions of the guideline.

- New language was added to the "education, training and staffing" recommendation:
 - Observational studies suggest a ratio of 2:1 in ICUs where nurses are managing patients with CVCs. (Category IB)
- New language was added to the "site selection" recommendations:
 - In pediatric patients, the upper or lower extremities or the scalp can be used as the catheter insertion site. (Category II)
 - Use a midline catheter or peripherally inserted central catheter (PICC), instead of a short peripheral catheter, when the duration of IV therapy will likely exceed six days. (Category IB)
- The "maximal sterile barrier precautions" recommendations were changed from Category IA to IB.
- New language was added to the "skin preparation" recommendations:
 - Prepare clean site with a 2% chlorhexidine-based preparation before central venous catheter insertion and during dressing changes. If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives. (Category IA)
 - The antibacterial properties of chlorhexidine work on contact, and chlorhexidine does not require a minimum 2-minute drying time before proceeding. Catheter insertion may begin as soon as the chlorhexidine is dry. (Category IB)
- The "catheter site dressing regimens" recommendations were changed as follows:
 - This language was removed: "... which is preferable to a transparent or semipermeable dressing."
 - This recommendation was changed from Category IA to IB: "Do not use topical antibiotic ointment or creams on insertion sites, except for dialysis catheters, because of their potential to promote fungal infections and antimicrobial resistance."
 - New language was added: "Use a chlorhexidine-impregnated sponge dressing for temporary short-term catheters in patients older than 2 months of age, if the CRBSI rate is higher than the institutional goal, despite adherence to basic CRBSI

prevention measures, including education and training, use of chlorhexidine for skin antisepsis, and MSB." (Category IB).

- A new "patient cleansing" recommendation was added:
 - Use a 2% chlorhexidine wash daily to reduce CRBSI. (Category II)
- A new "catheter securement devices" recommendation was added:
 - Use a sutureless securement device to reduce the risk of infection for PICCs. (Category II)
- The "antimicrobial/antiseptic impregnated catheters and cuffs" recommendation was changed from Category IB to IA.
- New language was added to the "antibiotic lock prophylaxis, antimicrobial catheter flush and catheter lock prophylaxis" recommendation:
 - "Use prophylactic antimicrobial lock solution in patients with long term catheters who have a history of multiple CRBSI despite optimal maximal adherence to aseptic technique. (Category II)
- The "antibiotic/antiseptic ointments" recommendation was changed from Category II to IB.
- New language was added to the "anticoagulants" recommendation:
 - Do not routinely use anticoagulant therapy to reduce the risk of catheter-related infection in general patient populations. (Category II)
- New language was added to the "replacement of peripheral and midline catheters" recommendations:
 - Replace peripheral catheters in children only when clinically indicated. (Category IB)
 - Replace midline catheters only when there is a specific indication. (Category II)
- New language was added to the "replacement of CVCs, including PICCs and hemodialysis catheters" recommendation:
 - Do not use guidewire exchanges routinely for non-tunneled catheters to prevent infection. (Category IB)
- New language was added to the "peripheral arterial catheters and pressure monitoring devices for adult and pediatric patients" recommendations:
 - In adults, use of the radial, brachial or dorsalis pedis sites is preferred over the femoral or axillary sites of insertion to reduce the risk of infection. (Category IB)
 - In children, the brachial site should not be used. The radial, dorsalis pedis, and posterior tibial sites are preferred over the femoral or axillary sites of insertion. (Category II)
 - A cap, mask, sterile gloves and a large sterile fenestrated drape should be used during peripheral arterial catheter insertion. (Category IB)

- During axillary or femoral artery catheter insertion, maximal sterile barriers precautions should be used. (Category II)
- Replace arterial catheters only when there is a clinical indication. (Category II)
- Use disposable, rather than reusable, transducer assemblies when possible. (Category IB)
- New language was added to the "replacement of administration sets" recommendations:
 - In patients not receiving blood, blood products or lipid emulsions, replace administration sets, including secondary sets and add-on devices, no more frequently than at 96-hour intervals, but at least every 7 days. (Category IA)
 - Replace tubing used to administer propofol infusions every 6 or 12 hours, when the vial is changed, per the manufacturer's recommendation (FDA website Medwatch). (Category IA)
- New language was added to the "needleless intravascular catheter systems" recommendations:
 - There is no benefit to changing these more frequently every 72 hours. (Category II)
 - Change caps no more frequently than every 72 hours "for the purpose of reduced infection rates" or according to manufacturers' recommendations. (Category II)
 - Minimize contamination risk by wiping the access port with an appropriate antiseptic "(chlorhexidine preferred)" and accessing the port only with sterile devices. (Category IA)
 - Use a needless system to access IV tubing. (Category IC)
 - When needleless systems are used, the split septum valve is preferred over the mechanical valve due to increased risk of infection. (Category II)
- New language was added to the "multidose parenteral medication vials and parenteral fluids" recommendations:
 - All multidose vials should be dated when 1st used and thereafter not used beyond the manufacturer's stated expiration period. (Category IC)
 - Use the needle and syringe to access the multidose vial only once and then discard both safely. This applies to each and every dose withdrawn from the vial. (Category IA)
- The "performance improvement" recommendation was revised:
 - Use hospital-specific or collaborative-based performance improvement initiatives in which multifaceted strategies are "bundled" together to improve compliance with evidence-based recommended practices. (Category IC)
- The surveillance section was removed, but certain language from this section was relocated in the text of the guideline. Surveillance is only referenced in the discussion section of the 2009 guideline with no specific recommendations.
- The following recommendations were removed:
 - Catheter insertion: "Do not routinely use arterial venous cutdowns."

- Catheter site care: "Do not apply organic solvents to the skin before insertion of catheters or during dressing changes."
- Catheter site dressing regimens: "Change dressings at least weekly for adult and adolescent patients."
- Recommendations were removed from the "selection and replacement of intravascular catheters" section regarding selected catheter insertion techniques, the inability to assure adherence to aseptic techniques, and the use of clinical judgment to determine when to replace a catheter that could be a source of infection.
- Recommendations were removed from the "peripheral venous catheters" section" regarding daily evaluation of the catheter insertion site by palpitation through the dressing and removal of peripheral venous catheters if the patient develops signs of phlebitis.
- The following recommendation was removed from the "catheter site care" section: "Do
 not routinely apply prophylactic topical antimicrobial or antiseptic ointment or creams to
 the insertion site."
- The following recommendations were removed from the "surveillance" section:
 - Conduct surveillance in the ICUs.
 - Express ICU data as the number of catheter-associated BSIs.
 - Investigate events leading to unexpected, life threatening or fatal outcomes.
- The following "general principles" were removed:
 - No recommendation can be made for the use of impregnated catheters in children.
 - Use totally implantable access devices for patients who require long-term intermittent vascular access.
 - Use cuffs, CVCs for dialysis if the period of temporary access is anticipated to be prolonged.
 - Use a fistula or graft instead of a CVC for permanent access for dialysis.
- Resolution has not yet been reached on the recommendation regarding the length of time to scrub cleaning hubs with chlorhexidine or alcohol due to the paucity of data.
- The evidence categories in the 2009 guideline were not significantly changed from the 2002 guideline.

Following HICPAC's discussion and suggestions on the CRBSI guideline, Dr. Brennan led the voting members in a review of eight issues in the document that would require their formal action. HICPAC's resolution of these eight issues is set forth below.

1. Recommendation 3 (lines 287-289) and recommendation 5 (lines 292-294) on page 13 should be thoroughly reviewed to ensure that the references are aligned with and

- support the guidance. *HICPAC general agreement*: The workgroup would resolve this issue in the next iteration of the guideline.
- 2. The following recommendation (page 18, lines 401-403) should be clarified: "Use maximal sterile barrier precautions, including the use of a cap, mask, sterile gown, sterile gloves, and a large sterile full body drape, for the insertion of CVCs, PICCs, or guidewire exchange." (Category IB) HICPAC general agreement: "A large drape, such as a half-sheet" would replace "a large sterile full body drape." Specific dimensions would be given.
- 3. HICPAC should reach consensus on whether to retain recommendations 6 and 7 (page 21, lines 472-477): "Replace dressings used on short-term CVC sites every 2 days for gauze dressings and at least every 7 days for transparent dressings, except in those pediatric patients in which the risk for dislodging the catheter may outweigh the benefit of changing the dressing." (Category IB) "Replace dressings used on tunneled or implanted CVC sites no more than once per week, until the insertion site has healed." (Category IB) HICPAC formal vote: 8 opposed to retaining the recommendations, 0 in favor, 1 abstention. HICPAC would vote on new wording for recommendations 6 and 7 during the business session on the following day or take an electronic vote after the meeting.
- 4. HICPAC should reach consensus on whether to retain the following recommendation (page 25, lines 561-568): "Use a chlorhexidine/silver sulfadiazine or minocycline/rifampin-impregnated CVC in adults whose catheter is expected to remain in place >5 days if, after successful implementation of a comprehensive strategy to reduce rates of CRBSI, the CRBSI rate remains above the goal set by the individual institution based on benchmark rates (<u>Tables 2 and 3</u>) and local factors. The comprehensive strategy should include at least the following three components: educating persons who insert and maintain catheters, use of maximal sterile barrier precautions, and a 2% chlorhexidine preparation for skin antisepsis during CVC insertion." (Category IA) HICPAC formal vote: unanimously passed to retain the recommendation.
- 5. HICPAC should reach consensus on whether the following language (page 31, lines 710-712) should remain a Category II recommendation and if evidence exists to support the recommendation for persons other than those who have multiple CRBSIs: "Use prophylactic antimicrobial lock solution in patients with long term catheters who have a history of multiple CRBSI despite optimal maximal adherence to aseptic technique." HICPAC formal vote: unanimously passed to retain the language as a Category II recommendation.
- 6. The recommendation on hemodialysis catheters (page 40, lines 910-912) references outdated guidelines that were published in the *American Journal of Kidney Diseases* in 2000. The recommendation should reference the 2006 updated guidelines that stated uncuffed dialysis catheters should only be used for hospitalized patients and should be used for less than one week. *HICPAC general agreement*: The workgroup will update the reference.

- 7. HICPAC should reach consensus on the following recommendation (page 44, lines 994-995): "A cap, mask, sterile gloves and a large sterile fenestrated drape should be used during peripheral arterial catheter insertion." (Category IB) HICPAC formal vote: unanimously passed to revise the recommendation and category: "A cap, mask, sterile gloves and a sterile fenestrated drape should be used during peripheral arterial catheter insertion." (Category II) The following sentence (page 45, lines 1025-1027) will be deleted: "Unlike CVCs, use of full barrier precautions during arterial cannulation does not appear to reduce the risk of arterial CRBSI."
- 8. HICPAC should reach consensus on whether to change the following Category IA recommendations to Category IC: "Sterilize reusable transducers according to the manufacturers' instructions if the use of disposable transducers is not feasible" (page 45, lines 1018-1019). "Replace tubing used to administer propofol infusions every 6 or 12 hours, when the vial is changed, per the manufacturer's recommendation (FDA website Medwatch)" (page 46, lines 1050-1052). HICPAC formal vote: unanimously passed to change both recommendations to Category IC.

Dr. Bell explained that the next steps in the CRBSI guideline would be for CDC and the workgroup to collate, review and respond to the public comments submitted on the document and make revisions as appropriate. HICPAC would take a preliminary vote on the guideline on the following day.

Norovirus Guideline. Dr. Kurt Stevenson, of Ohio State University, College of Medicine, is a former HICPAC member who chaired the workgroup that developed the norovirus guideline. He joined the meeting by conference call and yielded the floor to Dr. Umscheid to provide the status report on the document.

Dr. Umscheid reminded HICPAC that the workgroup identified three key questions to guide its research and activities to develop the norovirus guideline:

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

The workgroup created an analytic framework to answer the three key research questions for the norovirus guideline based on determining risk factors for a sporadic infection or outbreak, diagnosing an infection or outbreak, and preventing a sporadic infection from spreading to an outbreak or containing an existing outbreak.

From September 2007-June 2009, the workgroup reviewed existing norovirus guidelines from national and international databases, developed the key research questions, conducted an exhaustive literature search, completed the abstract and full-text screening process, extracted

and synthesized data for articles that would be included in the norovirus guideline, completed the evidence and "Grading of Recommendations, Assessment, Development and Evaluation" (GRADE) tables, summarized the evidence, and drafted the recommendations.

Searches of Medline and other databases resulted in the workgroup identifying 3,702 potentially relevant studies. Based on the title and abstract screening process, the workgroup initially included 379 studies for full-text evaluation. The final number of studies included for data extraction was 146 because 233 additional studies were further excluded based on exclusion criteria.

Since June 2009, the workgroup has completed the background section of the norovirus guideline; updated the methodology section; drafted new "summary of recommendations" and "implementation and audit" sections; distributed the draft guideline to internal and external reviewers; and revised the document based on in-depth comments by the reviewers. The most recent version of the draft guideline was distributed to HICPAC prior to the current meeting.

Dr. Umscheid highlighted major changes the workgroup made to the draft norovirus guideline since the June 2009 HICPAC meeting. The workgroup developed two new sections to ensure that the guideline is as usable to front-line ICPs as possible. In the "summary of recommendations" section, guidance associated with key questions from the evidence review were reorganized according to their best use to providers. "Tier 1" guidance is strong Category IA-IC recommendations that provide advice on infection control activities for norovirus clusters or outbreaks with epidemiologic or laboratory evidence of local patient or staff transmission.

"Tier 2" guidance is weaker Category II recommendations that provide advice on activities to consider during periods of uncontrolled norovirus outbreaks with evidence of continued patient or staff transmission. Recommendations in both tiers are grouped in the following categories: patient cohorting and isolation precautions, hand hygiene, indirect patient care staff, diagnostics, personal protective equipment (PPE), environmental cleaning, staff leave and policies, visitors, education, active case finding, communication activities, patient transfers, ward closure and case management.

In the "implementation and audit" section, the highest priority recommendations and measures of success are outlined. The workgroup agreed to place the following priority recommendations in this section.

- Avoid exposure to vomitus or diarrhea by instituting contact precautions for patients who
 exhibit symptoms consistent with a norovirus gastroenteritis cluster or outbreak.
 Sporadic cases of norovirus can be managed under standard precautions with
 necessary provisions to reduce staff, visitor and patient exposure to vomitus or diarrhea.
 (Category IB)
- In the absence of clinical laboratory diagnostics or delay in obtaining laboratory findings, use Kaplan's clinical and epidemiologic criteria as a tool to raise the index of suspicion of a norovirus outbreak to help institute appropriate infection control measures in a timely fashion. (Category IA)

- Facilities should develop policies that address provisions for staff leave among those who develop symptoms consistent with norovirus. All affected staff should be excluded from work until a minimum of 48 hours after the resolution of symptoms. Once staff returns, strict adherence to hand hygiene must be maintained.
- Protocols for staff cohorting should be established in the event of a norovirus outbreak
 where staff cares for one patient cohort on their ward. (For example, staff cares for
 exposed symptomatic patients, exposed asymptomatic patients or unexposed patients.)
- Appropriate local and state health departments should be notified if an outbreak of norovirus is expected.
- The frequency of cleaning and disinfection of patient care areas and high-touch surfaces should be increased during norovirus outbreaks. Ward level cleaning should be increased up to twice daily with high-touch surfaces cleaned and disinfected up to three times daily.

The workgroup described two performance measures in the implementation and audit section: (1) Evaluate fluctuations in the incidence of norovirus in healthcare settings using the National Outbreak Reporting System. This system monitors the reporting of waterborne, foodborne, enteric, person-to-person and animal contact associated disease outbreaks to CDC by state and territorial public health agencies. (2) CDC is currently implementing a national surveillance system for genetic sequences of noroviruses that may also be used to measure changes in healthcare-associated norovirus epidemiology.

The "future research" section provides general and specific recommendations to improve future research on norovirus.

- Conduct more primary analytic research with the use of controls in both clinical and laboratory settings, with comparisons between surrogate and human norovirus strains, and with consideration of healthcare-focused risk factors. The analytic research should be statistically powered in order to find differences between groups if they exist. Studies should evaluate clinically relevant outcomes. Studies should particularly focus on infection control interventions in associated outcomes.
- Assess the benefit of using Kaplan's criteria as an early detection tool for norovirus outbreaks in healthcare settings. Examine whether Kaplan's criteria are more predictive for select strains of norovirus and correlate between prolonged shedding of norovirus after symptoms have subsided and the likelihood of secondary transmission of norovirus transmission. Identify an ideal animal model for surrogate testing of norovirus properties and pathogenesis. Translate laboratory findings into practical infection prevention strategies.
- Evaluate the contribution of norovirus-contaminated water sources in healthcare settings.
- Quantify the effectiveness of cleaning and disinfecting agents against norovirus.
- Evaluate the effectiveness and reliability of fogging, UV radiation and ozone mist to reduce norovirus environmental contamination.
- Evaluate the utility of medications that may attenuate the duration and severity of norovirus illness.

- Evaluate the effectiveness of FDA-approved hand sanitizers against norovirus and the role of non-alcohol-based products.
- Develop methods to evaluate norovirus persistence in the environment with a focus on enduring infectivity.
- Evaluate the role of asymptomatic shedding, duration of protective immunity and other protective host factors.

The workgroup developed a table summarizing measures for prevention and control of norovirus outbreaks that are described in the published literature. However, the efficacy of these interventions in actually containing or preventing norovirus outbreaks is limited because no tests have been performed in analytic studies.

After the draft guideline is revised based on HICPAC's feedback, the document will be published in the *Federal Register*, re-revised in response to public comments, distributed to HICPAC for a formal vote, submitted to the CDC clearance process, and posted on the CDC/HICPAC website. The workgroup hopes the final norovirus guideline will be released no later than the spring of 2011.

HICPAC would submit specific comments on the norovirus guideline by the December 3, 2009 deadline, but some members asked the workgroup to consider two key suggestions in the interim.

First, the terms "infection prevention," "infection control," and "infection prevention and control" should be consistently used throughout the document and aligned with other guidelines. Second, consideration should be given on whether to retain, revise or remove the table of available interventions to prevent or contain norovirus outbreaks. The workgroup has already acknowledged that some of these interventions are not supported by rigorous evidence and might be confusing to ICPs.

Liaison and Ex-Officio Reports

The following liaison and *ex-officio* members presented verbal reports or submitted written reports into the official HICPAC record for the November 12-13, 2009 meeting:

- Rachel Stricof, MPH, CIC (Advisory Council for the Elimination of Tuberculosis) (ACET)
- Alexis Elward, MD (Advisory Committee on Immunization Practices) (ACIP)
- William Baine, MD (Agency for Healthcare Research and Quality)
- Mark Russi, MD, MPH (American College of Occupational and Environmental Medicine) (ACOEM)
- Roslyne Schulman, MHA, MBA (American Hospital Association) (AHA)
- Joan Blanchard, RN, BSN, MSS, CNOR, CIC (Association of periOperative Registered Nurses) (AORN)

- Nancy Bjerke, BSN, RN, MPH, CIC (Association of Professionals of Infection Control and Epidemiology, Inc.) (APIC)
- Lisa McGiffert (Consumers Union)
- Marion Kainer, MD, MPH (Council of State and Territorial Epidemiologists) (CSTE)
- Sheila Murphey, MD (Food and Drug Administration) (FDA)
- Charles Huskins, MD, MSc (Infectious Diseases Society of America) (IDSA)
- Robert Wise, MD (The Joint Commission)
- Tara Palmore, MD (National Institutes of Health) (NIH)
- Sanjay Saint, MD, MPH (Society of Hospital Medicine) (SHM)
- Gary Roselle, MD (Department of Veterans Affairs) (VA)
- Lisa Maragakis, MD, MPH (Society for Healthcare Epidemiology of America) (SHEA)

Additional details by the liaison and *ex-officio* members on recent activities of their organizations and agencies are highlighted below.

- Ms. Stricof reported that ACET has expanded the focus of its BCG guidance document with a broader scope: "TB Prevention and Control Measures for U.S. Health Care Workers and Volunteers Serving in High-Risk Settings for Exposure to *Mycobacterium Tuberculosis*." ACET is continuing to provide guidance on CDC's new TB technical instructions to improve overseas screening methods for immigrants and refugees entering the United States.
- Dr. Elward reported that ACIP published two official position statements in 2009: prevention and control of seasonal influenza with vaccine in July 2009 and use of H1N1 2009 monovalent vaccine in August 2009. ACIP approved several of its provisional recommendations since the June 2009 meeting. Most notably, ACIP will clarify HCP who cannot receive the live attenuated influenza virus vaccine. ACIP's provisional recommendations for measles-mumps-rubella vaccine evidence of immunity requirements for HCP were posted on the CDC website. ACIP's campaigns and related activities primarily have focused on H1N1 vaccine distribution. ACIP has been involved in CDC's regular press conferences regarding the H1N1 vaccine supply. ACIP has deferred activities of its Pertussis Workgroup due to the need to focus on H1N1 at this time, but vaccination of HCP against pertussis will be addressed in the future. The ACIP Hepatitis Workgroup is reviewing data on hepatitis B among residents of long-term care facilities, reviewing vaccine efficacy data in patients >60 years of age, and considering options of various groups to vaccinate.
- Ms. Blanchard reported that AORN published the AORN Syntegrity: A Standardized Perioperative Framework brochure. The brochure is aligned with AORN standards and recommended practices as well as accreditation, regulatory and mandatory reporting requirements for tracking infections. The brochure also provides other information that is critical to patient outcomes in the perioperative setting. The first phase of the framework is being piloted at this time. In the future, the framework will be available to hospitals after vendors purchase the license. The brochure was distributed to HICPAC for review. AORN and APIC issued joint press releases during "International Infection Prevention

- Week." AORN is providing training to ambulatory surgery centers on meeting CMS's required conditions for coverage in infection prevention and control.
- Ms. Bjerke reported that APIC, ACOEM, IDSA and SHEA issued a joint position statement on "Healthcare Personnel at High Risk for Severe Influenza Illness: Care of Patients with Suspected or Confirmed Novel H1N1 Influenza A." APIC released position statements on the essential role of surveillance technologies in HAI prevention and the role of safe infection, infusion and medication vial practices in saving lives. APIC, AORN and SHEA encouraged manufacturers to seek Food and Drug Administration approval of pediatric-sized facemasks for the national stockpile. APIC conducted educational programs, developed tools, and distributed other materials and resources for H1N1 and seasonal influenza. APIC will convene the "HAI: The Changing Legal and Regulatory Landscape" Conference with a live webcast on November 19, 2009. APIC was pleased to announce that Mr. Russell Olmsted, a HICPAC member, won the Carole DeMille Achievement Award. APIC is collaborating with CSTE and SHEA on the HAI elimination white paper.
- Ms. McGiffert reported that Consumers Union will host a patient safety forum with a live webcast on December 17, 2009. Following the forum, the *Money Driven Medicine* film will be presented that focuses on using more evidence-based care. The Consumers Union is continuing to repackage CMS data on surgical site infection (SSI) prevention strategies on its "Stop Hospital Infections" website to ensure consumers fully understand this information.
- Dr. Kainer reported that CSTE is continuing its extensive focus on H1N1 surveillance and vaccine distribution. CSTE is continuing to assist states in developing and submitting HAI prevention plans to HHS by January 1, 2010. CSTE convened a meeting with ELC grantees in October 2009 to provide guidance on ARRA-HAI funding. CDC awarded funds to place nine CSTE Fellows in states to specifically focus on HAIs.
- Dr. Murphey reported that FDA is continuing its extensive focus on influenza activities. The first investigational IV neuraminidase inhibitor was granted and is available through CDC. FDA is continuing to clear lots of H1N1 vaccine produced by four manufacturers. A number of H1N1 vaccine clinical trials for special populations are underway. FDA licensed and approved seasonal influenza vaccine produced by six manufacturers. FDA approved seven diagnostic kits and issued guidance for other manufacturers with an interest in submitting requests for diagnostic kits. However, the effectiveness of the diagnostic kits in identifying 2009 H1N1 novel strains at the bedside is limited. FDA recently announced its "Safe Use Initiative for Medications" to compliment CDC's ongoing activities in this area. To support this initiative, FDA will convene a series of public meetings and open a docket for public comment. Key areas of the initiative will focus on contamination of multi-use vials and avoidance of operating room fires due to alcohol-based skin preparations. FDA recently published a major update of the food code and will collaborate with the U.S. Department of Agriculture on developing traceability systems for all foods to more rapidly identify problems and prevent outbreaks earlier.

- Dr. Huskins reported that IDSA endorsed the SHEA position statement on interim guidance of infection control precautions for H1N1 in healthcare facilities. IDSA, APIC and SHEA sent a joint letter to President Obama in November 2009 to convey significant concerns with federal guidance that was issued regarding PPE. The organizations advised the Administration to modify the federal PPE guidance to reflect the best available evidence and institute an immediate moratorium on enforcement of the Occupational Safety and Health Administration requirement for healthcare facilities to use N-95 respirators in relation to H1N1 influenza. IDSA collaborated with partners to produce other position statements focusing on the reassignment of HCP due to 2009 H1N1 influenza and a policy on mandatory immunization of HCP against seasonal and 2009 H1N1 influenza. IDSA's legislative activities include active participation in healthcare reform efforts, infectious disease funding, and passage of the "Strategies to Address Antimicrobial Resistance Act." IDSA advocated for the Interagency Task Force on Antimicrobial Resistance to publish the revised "Action Plan to Combat Antimicrobial Resistance" in a timely manner. IDSA attended the "Innovative Incentives for Effective Antibacterials" Conference in September 2009.
- Dr. Palmore reported that NIH is collaborating with a number of federal partners on basic and clinical influenza studies, including H1N1 vaccine research. NIH is conducting clinical studies on the natural history and treatment of H1N1 in immunocompromised patients. NIH has enforced mandatory vaccination of its HCP with H1N1 and seasonal influenza.
- Dr. Saint reported that SHM partnered with CDC to develop a quality improvement toolkit entitled "Implementing a Quality Improvement Project to Reduce Hospital Acquired Infections and Antimicrobial Resistance." CDC staff authored and co-authored publications for SHM in the *Journal of Hospital Medicine* and *The Hospitalist*.
- Dr. Roselle reported that the VA is continuing to distribute a wealth of printed and web-based materials on H1N1. The VA is continuing its strong focus on HAIs due to 60 million outpatient visits per year in 150 VA hospitals and 800 outpatient clinics. The VA is continuing to implement its MRSA program and expects to release results of this initiative in the near future. The VA plans to expand the MRSA program to improve non-organism-based prevention. The VA is continuing to implement and will expand its BSI, SSI and VAP programs to focus on infections outside of ICUs. The VA is continuing to focus on HAIs in long-term care facilities and will soon administer its third national point prevalence survey with coverage of ~14,000 patients. The VA is continuing to make efforts to translate data to guidance that actually can be implemented at the bedside.
- Dr. Maragakis reported that SHEA was disappointed by the federal guidance on respiratory protection and is partnering with APIC and IDSA to advocate for more evidence-based guidance through position papers and a letter to President Obama. SHEA's other position statements focused on reassignment of high-risk HCP and infection control practices for multidrug-resistant gram-negative organisms. SHEA will soon convene a writing group to revise its mandatory influenza vaccination paper to

address specific implementation issues. The SHEA Pediatric Special Interest Group sent letters in July 2009 asking face mask manufacturers to apply for formal FDA clearance and testing of pediatric surgical face masks and increase production of these masks in response to shortages as a result of the H1N1 pandemic. The deadline for submitting abstracts for SHEA's 5th Decennial International Conference on HAIs is November 16, 2009.

With no further discussion or business brought before HICPAC, Dr. Brennan recessed the meeting at 5:19 p.m. on November 12, 2009.

Status Report on HICPAC Guidelines and Documents: SESSION 2

Dr. Brennan reconvened the HICPAC meeting at 9:05 a.m. on November 13, 2009 and yielded the floor for status reports on HICPAC's remaining two documents.

Pediatric Infection Prevention Guideline. Dr. Alexis Elward is a HICPAC member and will chair the new workgroup that will develop the pediatric infection prevention guideline for neonatal ICUs (NICUs). She reminded HICPAC that this effort is being undertaken due to major gaps in the pediatric infection prevention literature in several areas: the epidemiology of pediatric HAIs in terms of denominators and knowledge of the entire at-risk population; attributable mortality and other pediatric outcomes; preventability of CLABSI in select pediatric subpopulations, particularly NICUs; benchmarks and risk stratification for pediatric SSI; management of MRSA colonization in NICUs; family/patient education and family-centered care; and management of viral infections in NICUs.

To assist HICPAC in determining next steps in developing the guideline, Dr. Elward obtained input on pediatric infection prevention issues in NICUs from three key stakeholder groups. The SHEA Pediatric Special Interest Group (PSIG) strongly supported the development of a formal white paper as a research gap analysis rather than a NICU-centered guideline. PSIG expressed concern that with the exception of NICUs, the paucity of data would not support developing a rigorous pediatric guideline as a separate document.

The Child Health Corporation of America's Children's Hospital Neonatal Consortium (CHNC) expressed a great deal of enthusiasm for the development of an infection prevention guideline specific to NICUs. CHNC's position is consistent with outcomes of the "Compendium of Strategies to Prevent HAIs in NICUs" Symposium that the Society for Pediatric Research held in May 2009.

The American Academy of Pediatrics (AAP) has placed the development of a NICU infection prevention statement on its next meeting agenda. However, HICPAC's next steps in this area could influence the depth and breadth of AAP's document. AAP has expressed a strong interest in collaborating with HICPAC on developing and releasing a joint NICU infection prevention guideline.

Dr. Elward's literature review revealed a paucity of studies that have tested and evaluated the effectiveness of interventions for CLABSI, MRSA and *Candida* in pediatric patients. Most notably, randomized controlled trials have only been performed for *Candida*. As a result, the majority of recommendations in the NICU infection prevention guideline would be Category IB (standard accepted practice) or Category II (observational study designs).

Since the June 2009 HICPAC meeting, Dr. Elward refined key research questions in four areas that are important to infection prevention in NICUs. For "viral infections" in NICUs, effective strategies to prevent, detect and control outbreaks should be grouped in three categories: primary prevention (*i.e.*, visitation policies and vaccination of parents and children >6 months of age); secondary prevention (*i.e.*, definition and isolation of "exposed infants" and criteria to remove exposed infants); and specific issues (*i.e.*, Synagis® prophylaxis for NICU patients exposed to respiratory syncytial virus or other specific pathogens).

For "CLABSI," no recommendation can be made on the safety and efficacy of chlorhexidine in infants <2 months of age due to the lack of data. Because chlorhexidine is widely used in infants <2 months of age, however, a statement should be incorporated into the guideline on the body of available evidence regarding the safety of chlorhexidine in this population. A formal gap analysis or data needs section should be included in the guideline on current standard practices as well as safe and effective interventions that are being studied or implemented at this time. These interventions include silver coated catheters, closed flush medication systems, and two-person teams clothed in sterile garb for tubing changes.

For "MRSA," data should be collected to answer key research questions in the following areas: patient and environmental characteristics associated with MRSA colonization in NICU patients; the most effective surveillance strategies; the best control measures for parents and multiple patients in NICUs; management of multiple patients with discordant MRSA colonization status; and management of pediatric patients whose mothers are colonized with a drug-resistant organism.

For "invasive Candidal infections," data should be collected to answer key research questions in the following areas: patient characteristics associated with invasive Candidal infections and the most effective prevention strategies. Because randomized controlled trials have been conducted on *Candida* in the pediatric population, the guideline could be supported by Category IA recommendations in this area.

Dr. Elward described the next steps to advance the NICU infection prevention guideline. Representatives of AAP, CHNC, PSIG and other relevant neonatology stakeholder groups will be identified and extensively engaged in the development of the guideline. Diverse input and strong endorsement of the document from the field will be extremely important in terms of implementation because most of the guidance will be standard practice or consensus-based Category II recommendations.

After the workgroup is officially convened, the members will hold monthly conference calls, conduct a comprehensive literature review, review existing HICPAC guidelines to cite relevant references and ensure consistency, collect additional data to provide more information where necessary, and draft specific sections

Dr. Elward requested HICPAC's feedback on whether a formal guideline, gap analysis or a combination of both documents should be produced. She reiterated the critical need for the document to include a research needs section and rank the current status of NICU infection prevention metrics and interventions as Phase 1, 2 or 3. She also asked HICPAC to consider whether the NICU infection prevention guideline should be released as an official HICPAC document or a joint statement with AAP.

HICPAC made three suggestions that should be considered in establishing the new workgroup and clearly defining its charge.

- The survey should include the RAND appropriateness method. Clinicians can use this
 tool to provide input on the validity, feasibility and level of confidence of their current
 practices and outcomes. The RAND appropriateness method has been extremely useful
 in collecting information in the absence of empiric evidence.
- The workgroup should closely coordinate and collaborate with the NHSN Steering Committee in ranking NICU infection prevention measures to ensure consistency with the NHSN definitions.

Dr. Bell encouraged the new workgroup to use non-governmental organizations rather than HICPAC to administer a survey on priority areas and research gaps in pediatric infection control issues. He explained that as a federal advisory committee, HICPAC is required to obtain approval from the Office of Management and Budget to collect information from more than nine respondents. This process typically requires more than one year to complete.

Dr. Brennan closed the discussion by describing the next steps in this initiative. The preliminary charge of the new workgroup will be to develop a NICU infection prevention guideline rather than a gap analysis. A research needs section on infection prevention interventions in NICUs will be a major emphasis of the document.

Dr. Brennan will inform Dr. Umscheid of the workgroup's interest in the University of Pennsylvania Health System Center for Evidence-Based Practice providing research support and expertise on the methods section of the guideline. CDC will coordinate initial collaborations and communications between the workgroup and AAP. Dr. Bell will identify a DHQP staff member to serve as a technical resource to the workgroup and also will ensure that CDC's maternal and child health experts are extensively engaged at the outset of developing the guideline.

Ambulatory Care Document. Dr. Bell reminded HICPAC that this effort is being undertaken due to the need to issue recommendations to improve infection control practices in ambulatory care settings. Because "ambulatory care" covers a broad range of specialties (*i.e.*, infectious disease physicians, obstetricians, oncologists and other providers in private practice), a single guidance document most likely would be inadequate.

Dr. Bell proposed two options to narrow the scope of developing an ambulatory care guidance document. Option 1 would be guidance that broadly focuses on infrastructure issues, such as resources an ambulatory care facility would need on a daily basis for outpatients. The

advantage of option 1 is that more issues in ambulatory care settings would be covered. Option 2 would be guidance that discretely focuses on ambulatory surgery centers or another specific ambulatory care setting. The advantage of option 2 is that more evidence would be available to support the recommendations.

Dr. Cardo's position was that the best approach to developing the ambulatory care guidance document would be to extract and repackage evidence-based recommendations from HICPAC's published guidelines in a useful, simple and helpful format for ambulatory care settings. The guidance document also could provide additional information on issues that were not addressed in previous HICPAC guidelines. Dr. Cardo noted that HICPAC's guidance document could play a critical role in increasing adherence to CMS requirements among ambulatory care facilities.

HICPAC agreed with Dr. Cardo's suggestion to repackage existing evidence-based guidance for ambulatory care settings rather than attempting to develop an entirely new document. The HICPAC members proposed a number of next steps to advance the development of the ambulatory care guidance document.

- The guidance document should be developed based on a stratification of the level of invasive procedures performed in ambulatory care settings. In this scenario, ambulatory surgery centers would be prioritized.
- The guidance document should be specifically targeted to unregulated ambulatory care settings that are not regularly surveyed or are not mandated to comply with any standards or requirements.
- The guidance document should address general rather than specific infection control issues. Although ambulatory care settings serve disparate patient populations and perform different practices than hospital settings, safe injection practices in terms of administration of medication as well as sterilization, disinfection and hand hygiene procedures should be universal. Moreover, the guidance document should highlight HICPAC's existing infection control recommendations on training, documentation and accountability to raise standards in ambulatory care settings. A general document would be more applicable to all procedure-based medical facilities.
- Professional societies with "broad" rather than "specialty" memberships should be recruited to co-author the ambulatory care guidance document with HICPAC. These groups include the American Medical Association, American Nurses Association, APIC Ambulatory Care Workgroup, American Society for Gastrointestinal Endoscopy, AORN, and other organizations with memberships of anesthesiologists, ophthalmologists and plastic surgeons.
- The guidance document should be developed in a tiered approach focusing on issues in three major categories for ambulatory care settings: surgical procedures, endoscopy procedures and pain management. Professional societies should be engaged to assist HICPAC in writing the sections and implementing the recommendations in the three categories.
- The ambulatory care guidance document and all other HICPAC guidelines should be written with clear language for providers to appropriately conduct infection control practices 100% of the time. To support this effort, a separate implementation and

sustainability checklist should be developed for practitioners in ambulatory care settings to evaluate and monitor their performance in adhering to the guideline at baseline and on daily, weekly and long-term bases. DNV Healthcare, Inc. is the first hospital accreditation program in the United States that integrates the ISO 9001 Quality Management System with the CMS "Conditions of Participation." DNV also is the only hospital accreditation program that requires continual quality improvement and should play a key role in the development of HICPAC's implementation/sustainability checklist. DNV's quality system review process evaluates the ability of hospitals to assess and sustain their progress over time. HICPAC also should engage diverse stakeholder groups in creating the checklist to ensure issues related to the feasibility, benefits and ease of implementing the recommendations are captured.

- The guidance document should include an audit tool or an assessment of barriers to implementing infection control recommendations in ambulatory care settings. These issues should be grouped in three categories: provider barriers due to lack of knowledge; guideline barriers due to unclear recommendations; or system barriers due to the inability to implement recommendations in a specific institution.
- The guidance document should include recommendations from the SHEA "Compendium
 of Strategies to Prevent HAIs" in addition to those from HICPAC guidelines. SHEA also
 should be asked to develop a companion compendium to HICPAC's ambulatory care
 quidance document.
- HICPAC should establish a standing workgroup to create a formal implementation plan at the time that guidelines are developed. The workgroup also should be charged with identifying evidence-based recommendations or interventions to include in pilot projects or the implementation/sustainability checklist.

Dr. Brennan closed the discussion by describing the next steps in this initiative. DHQP staff would review HICPAC's existing guidelines and identify the most appropriate evidence-based recommendations to reproduce in the ambulatory care document. DHQP would present the findings from its review during the February 2010 HICPAC meeting.

With support from DHQP, Dr. Brennan would take the lead in identifying a large group of diverse stakeholders before the next HICPAC meeting. He would draft a letter to the stakeholder groups describing the background, purpose, intent and expected outcomes of the ambulatory care guidance document. The letter also would inform the stakeholders that a conference call would be held in the near future to reach consensus on the evidence-based recommendations DHQP selected and provide input on developing an implementation and sustainability checklist to measure progress in infection control practices in ambulatory care settings.

Update on the New National Quality Forum (NQF) Process

Dr. Brennan reported that a new NQF process is underway to identify the next set of serious reportable events (SREs) and hospital-acquired conditions (HACs). Background documents on the new NQF process have indicated an interest in extending the SREs and HACs beyond acute care settings to include long-term care and dialysis facilities, home health and nursing homes. The review of HICPAC's existing guidelines to identify the most appropriate evidence-based recommendations to reproduce in the ambulatory care document could inform the new NQF process.

In the new NQF process, existing SREs and HACs will be reviewed for their validity and utility, future settings will be considered, and several technical advisory panels will be established for settings of care, including an Ambulatory Panel, Inpatient Hospital Panel, Nursing Home Panel, Hospice Panel and Home Health Panel. Dr. Brennan was nominated by IDSA and SHEA to serve on the NQF Steering Committee and would attend the first meeting the following week.

Several HICPAC members agreed with Dr. Cardo's suggestion for HICPAC to have formal representation in the new NQF process. The members noted that a number of NQF committees make recommendations on infection control practices and would greatly benefit from HICPAC's expertise in this area.

Dr. Richards was concerned about the suggestions to expand HICPAC's current role and charge to include developing user-friendly and simplified versions of HICPAC's evidence-based guidelines, creating implementation toolkits as companion documents to guidelines, and providing expertise on NQF measures in a formal manner. He noted that HICPAC is already challenged by reviewing the evidence, developing guidelines, and obtaining clearance and final approval in a timely manner. These new roles would be labor- and resource-intensive and could have a significant impact on HICPAC's charge to produce evidence-based guidance. Dr. Richards' position was that neither HICPAC nor DHQP is adequately staffed or resourced to undertake these new efforts.

If HICPAC decides to expand its existing charge with these new competencies, Dr. Richards advised the members to seriously consider the potential implications (*i.e.*, changing the current HICPAC membership in order for NQF and representatives of other groups to serve as new liaison members, forming necessary workgroups, leveraging technical expertise and other resources from CDC and other groups to support these efforts, and assuring available communication channels between HICPAC and NQF).

Dr. Brennan fully agreed with Dr. Richards' comments and concerns. Professional societies whose members represent the infection control community in the field, rather than HICPAC, should continue to develop implementation tools. However, HICPAC should serve as a key partner to professional societies in this effort. HICPAC's primary role and area of expertise should continue to be reviewing evidence and creating the science to support infection control practices in the field. If HICPAC decides to expand its role with an implementation arm, the current membership must change and DHQP must be more richly resourced.

Dr. Brennan's position was that HICPAC should focus on refining its guideline development process and should not undertake a new implementation role at this time. However, refined guidelines in which recommendations would be placed in the same format that care is delivered might indirectly result in improving implementation at the bedside.

Dr. Bell, Dr. Cardo and Ms. Murphy were in favor of HICPAC formalizing a plan and clearly defining the role of liaison members in improving guideline implementation at the bedside. After a guideline is published, for example, HICPAC could formally charge specific liaison members with creating an implementation strategy for the field. The liaison members could engage other professional societies that are not represented on HICPAC as necessary. Implementation at the bedside also might increase if representatives of professional societies had a larger role in co-authoring HICPAC guidelines.

The HICPAC members made two suggestions on improving guideline implementation at the bedside. First, professional societies should be asked to develop implementation plans that would be released as companion documents when HICPAC guidelines are published. HICPAC could adopt this process as a standardized approach when each guideline is released.

Second, HICPAC should use its methods paper as a model in developing an implementation guidance document that would summarize existing evidence on translational research. Professional societies could use HICPAC's implementation guidance document as an evidence-based template in creating a plan to implement guidelines at the bedside. In an effort to eliminate divergent or competitive guidelines by multiple groups, HICPAC should take leadership or serve as a convener of guideline implementation in partnership with professional societies.

HICPAC Business Session

Dr. Brennan entertained a motion for HICPAC to tentatively approve the draft "Guideline for the Prevention of Intravascular Catheter-Related Infections." A motion was properly placed on the floor by Drs. Pronovost and Schecter, respectively. **HICPAC unanimously approved the motion.** Dr. Brennan confirmed that HICPAC would have a follow-up discussion after the document is revised in response to HICPAC's recommendations on the previous day and public comments.

Dr. Bell announced that HHS charged CDC with prioritizing guideline recommendations in a more quantitative manner. To fulfill its charge, CDC awarded a contract to RTI to analyze the potential costs and benefits of each recommendation in the CAUTI guideline and determine the interaction between the recommendations. The analysis of the CAUTI guideline would be used a model for prioritizing recommendations in other guidelines in the future. Discussions have been held on using the BSI guideline as a model in conducting a retrospective analysis of guideline recommendations. Dr. Bell would provide a more detailed update on this initiative during upcoming meetings.

In response to HICPAC's role in H1N1 preparedness activities, Dr. Bell emphasized the critical need for HICPAC to deliberate on new evidence that is expected to become available over the next six months. He agreed with Dr. Brennan's suggestions for the HICPAC members to report their H1N1 preparedness activities and experiences at their respective institutions and for the Influenza Division to make a presentation during the February 2010 meeting.

In response to Ms. Stricof's comments, Dr. Brennan confirmed that HICPAC would have a broader discussion on problems associated with the current prioritization scheme for influenza vaccination in the field. During the next meeting, HICPAC also would revisit its current position of not recommending mandatory influenza vaccination of HCP.

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

- Dr. Brennan will begin developing the follow-up paper five years after the publication of HICPAC's guidance document on public reporting of HAIs.
- Dr. Brennan will coordinate communications between Drs. Elward and Umscheid for the University of Pennsylvania Health System Center for Evidence-Based Practice to begin developing the NICU infection prevention guideline.
- Dr. Brennan will initiate discussions with Dr. Pronovost on conducting an assessment of measures.
- DHQP staff will review HICPAC's existing guidelines and identify the most appropriate evidence-based recommendations to reproduce in the ambulatory care document in advance of the next meeting. Dr. Brennan will collaborate with DHQP to identify stakeholders to provide feedback on the selected recommendations.
- The HICPAC members will participate in the following ongoing or new activities:
 - Finalize the guidance document for jurisdictions considering MRSA legislation. [Dr. Lundstrom]
 - Participate on the next conference call with the workgroup that is updating the HCP Infection Control Guideline. [Drs. Lundstrom and McCarter, Ms. Murphy]
 - Assist Dr. Brennan in writing the five-year follow-up document on public reporting of HAIs. [Ms. Burns, Dr. Lundstrom]
 - Initiate the development of a template for professional societies to implement HICPAC guidelines at the bedside. [Drs. Pegues and Pronovost, Ms. Murphy]
 - Initiate the development of the NICU infection prevention guideline and determine whether the guideline will be a sole HICPAC or joint HICPAC/AAP document. [Dr. Elward]
 - Revise the Guideline for the Prevention of Intravascular Catheter-Related Infections in response to HICPAC's recommendations and public comments. [Ms. Burns]
 - Serve as a conduit between HICPAC and the NHSN Steering Committee and provide regular updates to both groups. [Mr. Olmsted]

- Finalize and distribute the orientation packet to the new HICPAC members during the February 2010 meeting. [Ms. Murphy]

Closing Session

The next HICPAC meeting would be held on February 11-12, 2010 in Atlanta, Georgia.

With no further discussion or business brought before HICPAC, Dr. Brennan adjourned the meeting at 11:12 a.m. on November 13, 2009.

> I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete. Patrick J. Brennan, M.D.

Date

Chair, Healthcare Infection Control **Practices Advisory Committee**