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

National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion

Healthcare Infection Control Practices Advisory Committee
February 11-12, 2010
Atlanta, Georgia

DRAFT Record of the Proceedings

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ATTACHMENT 1

List of Participants

[Note: Several HICPAC members, *ex-officios*, liaisons and members of the public were unable to attend the meeting in person due to inclement weather. Persons who attended the meeting via conference call are denoted with an asterisk.]

HICPAC Members

*Dr. Patrick Brennan, Chair
Ms. Lillian Burns
Dr. Alexis Elward
Dr. Susan Huang
Dr. Tammy Lundstrom
Dr. Yvette McCarter
*Mr. Russell Olmsted
*Dr. Stephen Ostroff
Dr. David Pegues
Ms. Barbara Soule

Designated Federal Official

Dr. Michael Bell,
Deputy Director, DHQP

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

*Dr. William Baine (Agency for Healthcare Research and Quality)
Dr. Elizabeth Bancroft (Council of State and Territorial Epidemiologists)
Ms. Joan Blanchard (Association of periOperative Registered Nurses)
Ms. Barbara DeBaun (Association of Professionals of Infection Control and Epidemiology, Inc.)
Ms. Lori Harmon (Society of Critical Care Medicine)
Ms. Nicole Haynes (Health Resources and Services Administration)
*Dr. David Henderson (National Institutes of Health)
Dr. Charles Huskins (Infectious Disease Society of America)
* Dr. Lisa Maragakis (Society for (Healthcare Epidemiology of America)
*Dr. Sheila Murphey (Food and Drug Administration)
Ms. Shirley Paton (Public Health Agency of Canada)
*Dr. Gary Roselle (Department of Veterans Affairs)
*Dr. Mark Russi (American College of Occupational and Environmental Medicine)
Dr. Sanjay Saint (Society of Hospital Medicine)
*Ms. Roslyn Schulman (American Hospital Association)
Ms. Rachel Stricof (Advisory Council for the Elimination of Tuberculosis)
Dr. Robert Wise (The Joint Commission)

CDC Representatives

Dr. Denise Cardo, DHQP Director
Matthew Arduino
Gregory Armstrong
Elise Beltrami
Peter Cegielski
Cecilia Curry
Susan Dolan
Natalie Greene (CDC Contractor)
Jeffrey Hageman
Rita Helfand
Martha Iwamoto
John Jernigan
Melanie Kaiser
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Michelle King
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Paul Malpiedi
Clifford McDonald
Shannon Oriola
Brian Panasuk
Marcia Patrick
Joseph Perz
Daniel Pollock
Cathy Rebmann
Cheri Rice
Elizabeth Ro[?] **LAST NAME?**

Arjun Srinivasan
Elizabeth Skillen
Dixie Snider
Jason Snow
Wendy Vance
Jackie Watkins
Heidi Williams
Tiffanee Woodard
Joni Young
Kim Zimmerman

Guest Presenters and
Members of the Public

*Russ Castioni (3M Company)
Kerry Edgar (Medegen, Inc.)
Hudson Garrett (PDI Healthcare)
Denise Graham (Association of Professionals of Infection Control and Epidemiology, Inc.)
Jane Kirk (GOJO Industries, Inc.)
Nancy Klinger (3M Company)
Michele Marill (Hospital Employee Health)
Naomi O'Grady (National Institutes of Health)
Patrick Parks (3M Company)
Jaime Ritter (C.R. Bard, Inc.)
Timothy Royer (Maximus Medical)
*Craig Umscheid (University of Pennsylvania Health System Center for Evidence-Based Practice)
Marcia Wise (BD Medical)
Cindy Winfrey (PDI Healthcare)

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 February 11-12, 2010 in Atlanta, Georgia. None of the HICPAC voting members declared any new conflicts of interest for the record that were pertinent to the published agenda for the February 11-12, 2010 meeting. The HICPAC Chair and several HICPAC members, *ex-officios*, liaisons and members of the public participated in the meeting via conference call due to inclement weather

The DHQP Director and a panel of DHQP leadership presented a series of updates on DHQP's recent healthcare quality and promotion activities in the following areas:

- The new process for CDC to report National Healthcare Safety Network data to the Centers for Medicare and Medicaid Services QualityNet database.
- The HHS/CDC policy on healthcare-associated infections (HAIs).
- The HAI American Reinvestment and Recovery Act (ARRA).
- Antimicrobial use improvement activities.
- Expansion of the CDC HAI Prevention Research and Evaluation Program in the new five-year funding cycle of 2011-2016.
- DHQP's expansion of its traditional focus on healthcare facilities to include state and local health departments.
- The President's proposed FY2011 budget for HHS/CDC to allocate ARRA funding for state and local health departments to continue to conduct HAI prevention, reduction and elimination activities.
- Personnel and organizational changes as a result of the consolidation of the National Center for Preparedness, Detection and Control of Infectious Diseases and the National Center for Zoonotic, Vector-Borne and Enteric Diseases into the new "National Center for Emerging and Zoonotic Infectious Diseases."

HICPAC made numerous comments and suggestions for DHQP to consider in refining and advancing these activities.

DHQP and HICPAC members reported on the current status of HICPAC guidelines and documents. The "Guideline for the Prevention and Management of Norovirus Gastroenteritis Outbreaks in Healthcare Settings" is currently undergoing clearance by DHQP and cross-clearance by gastroenteritis subject matter experts in the National Center for Immunization and Respiratory Diseases. The final revisions on "Guidance for Jurisdictions Considering Multidrug-Resistant Organism Legislation" were completed. The document would be published on the CDC website in the near future after review by the DHQP Director.

HICPAC made several comments and suggestions that should be considered in the ongoing development of the "Healthcare Personnel Infection Control Guideline," "Neonatal Intensive Care Unit Infection Prevention Guideline," and "Ambulatory Care Document." HICPAC provided thoughtful input in response to comments that were recently made to publish HICPAC guidelines in hard-copy journals and other formats beyond the CDC website.

The "Guideline for the Prevention of Intravascular Catheter-Related Bloodstream Infections" (CRBSI) was published in the *Federal Register* for a public comment period. HICPAC had an extensive discussion to resolve public comments that were submitted in the following areas:

- General Comments (*i.e.*, disclosure of conflicts of interest for all authors; revision of the categorization system for Category IB recommendations; and a recommendation of "zero infections" rather than facility-specific targets or benchmarks).
- Chlorhexidine-Impregnated Dressings
- Dialysis
- Needleless Connectors
- Site Selection
- Hand Hygiene
- Chlorhexidine for Skin Antisepsis
- Antimicrobial Prophylaxis
- Dressing Changes
- Administration Sets
- Replacement of Peripheral Catheters
- Catheter Securement Devices
- Peripheral Arterial Catheters
- Inclusion of Recommendations from the 1996 and 2002 CRBSI Guidelines

HICPAC reached consensus on the vast majority of public comments that were submitted, but a decision was made to table the formal vote on the draft CRBSI guideline. A conference call would be held before the June 2010 meeting to allow HICPAC to conduct a more rigorous decision-making process and thoroughly weigh the evidence of the recommendations.

CDC presented data to illustrate the implications of drug-resistant tuberculosis (DR-TB) globally on infection control in the United States. HICPAC noted that the emergence of highly DR-TB and the potential for transmission in U.S. healthcare settings would not require immediate changes to current infection control guidelines at this time. However, HICPAC agreed to periodically revisit this issue to determine whether guidelines should be updated at some point in the future.

HICPAC's liaison and e*x-officio* members submitted written reports and provided additional details during the meeting on recently completed, ongoing and upcoming activities of their organizations and agencies. The 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.

DHQP provided an overview of conflicts of interest (COI) to ensure that co-authors of HICPAC guidelines make disclosures in a systematic and transparent manner. DHQP drafted a standardized COI disclosure form that will be completed by all co-authors and included in all HICPAC guidelines in the future.

DHQP and HICPAC discussed the following issues during the business session:

- CDC's interim guidance on novel influenza A virus (H1N1).
- A brief description of HICPAC products. (This topic was added to the agenda for the benefit of the three new HICPAC members. Inclement weather caused the orientation session to be postponed until the June 2010 meeting.)

- A change in the meeting format to add public conference calls in the interim of February-June and June-November HICPAC meetings. (DHQP reached this decision because the lengthy gaps in time between these two meetings have caused HICPAC to delay progress in finalizing guidelines and conducting other activities.)

The HICPAC Chair led the members in a review of the action items that were raised over the course of the meeting. The next HICPAC meeting would be held on June 17-18, 2010 in Atlanta, Georgia.

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HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE
February 11-12, 2010
Atlanta, Georgia

DRAFT Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC). The proceedings were held on February 11-12, 2010 in Building 19 of the Tom Harkin Global Communications Center at the CDC Roybal Campus in Atlanta, Georgia.

Opening Session

Dr. Michael Bell is the Deputy Director of DHQP and the Designated Federal Official (DFO) for HICPAC. He called the meeting to order at 9:06 a.m. on February 11, 2010 and welcomed the attendees to the meeting. He announced three changes to the HICPAC meeting as a result of inclement weather.

First, the formal orientation session that was planned for the new HICPAC members during the current meeting would be postponed until the June 2010 meeting. Dr. Bell asked the participants to use the breaks and lunch period to informally introduce themselves to the three new HICPAC members: Dr. Dale Bratzler (Oklahoma Foundation for Medical Quality); Dr. Susan Huang (University of California-Irvine School of Medicine); and Dr. Stephen Ostroff (Pennsylvania Department of Health).

Second, Dr. Patrick Brennan, Chair of HICPAC, and Dr. Ostroff and Mr. Russell Olmsted, two voting members, would attend the meeting via conference call to complete HICPAC's quorum. A number of HICPAC *ex-officios*, liaisons and members of the public also would participate in the meeting via conference call. Third, the meeting would be adjourned earlier than the time on the published HICPAC agenda. Based on weather projections, hundreds of afternoon flights from the Atlanta airport were expected to be canceled on the following day.

Dr. Bell opened the floor for introductions. No voting members declared any new conflicts of interest for the record that were pertinent to the published agenda for the February 11-12, 2010 HICPAC meeting. However, Dr. Bell pointed out that a "Conflicts of Interest" overview would be

presented prior to HICPAC's formal votes on the following day. The list of participants is appended to the minutes as Attachment 1.

Update on DHQP Activities

A panel of DHQP leadership presented a series of updates on DHQP's recent healthcare quality and promotion activities.

***National Healthcare Safety Network (NHSN)/Centers for Medicare and Medicaid Services (CMS) Data Reporting*.** Dr. Daniel Pollock is the DHQP Surveillance Branch Chief. He reported that DHQP and the CMS Office of Clinical Standards and Quality are jointly developing a process to enable healthcare facilities to report NHSN data to CMS for purposes of quality measurement. NHSN data that will be reported to the CMS QualityNet database include central line-associated bloodstream infections (CLABSI) and surgical site infections (SSI). Facility-specific CLABSI and SSI data will be posted on Hospital Compare, a publicly facing website that is maintained by HHS.

Dr. Pollock described the three major components of the NHSN/CMS data reporting process. In the "pay for reporting" component, CLABSI and SSI will be reported to QualityNet as part of the CMS Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program. Based on Congressional approval, CMS will use its voluntary RHQDAPU Program to transition to a pay for performance program over time. In the "data submission" component, consideration is being given to using the NHSN Group Function or developing an NHSN reporting feature to submit data to the CMS QualityNet database.

In the "data validation" component, validation of patient-level records will be a requirement for quality measurement reporting in accordance with RHQDAPU. DHQP and CMS are currently refining this component to determine specific data validation requirements. Most notably, both case-based and captured data will be validated. DHQP has informed CMS of several states that have provided leadership in developing data validation methodologies and also has emphasized the need to use these existing models in creating a data validation program within RHQDAPU for CLABSI and SSI. DHQP expects to initiate reporting to CMS of NHSN CLABSI data in 2010 and NHSN SSI data in 2011.

Dr. Pollock concluded that DHQP and CMS are making tremendous progress on the NHSN/CMS data reporting process, but specific details are being refined at this time. For example, efforts are underway to determine the role of states in this initiative. Healthcare facilities will have authority to establish timelines to report NHSN data to CMS. To the extent possible, reporting of NHSN CLABSI and SSI data to CMS will be harmonized with existing data collection and reporting requirements to decrease the burden on healthcare facilities.

DHQP will strengthen its existing relationships with states and the Council of State and Territorial Epidemiologists (CSTE) to establish a governance and decision-making process that will inform the development of national standards for case definitions and data requirements.

Overall, the NHSN/CMS data reporting process has the potential to influence the development of a *de facto* federal mandate for reporting of bloodstream infection (BSI) and SSI events.

HICPAC advised DHQP to be mindful of The Joint Commission's National Patient Safety Goal that requires accredited facilities to conduct institution-wide BSI surveillance.

***Healthcare-Associated Infection (HAI) Policy*.** Dr. Cecilia Curry is the DHQP Associate Director for Policy. She reported that HAIs are a high priority at several federal levels based on a number of initiatives proposed by the Administration and Legislative Branch; the introduction of multiple bills; strong interest by the White House, Congress, Office of Management of Budget, HHS and other federal agencies; and changes and increases in HAI funding.

Language on HAIs in terms of public reporting or pay for performance has been included in both the Senate and House versions of healthcare reform bills. In 2008-2009, three Congressional hearings on HAIs were held and the Government Accountability Office (GAO) launched four investigations on HAIs. In the spring of 2010, a Congressional hearing and a GAO investigation will be held on antimicrobial resistance.

At the state level, all states have complied with the legislative and FY2009 funding requirements to submit HAI Action Plans to HHS. CDC is currently analyzing the state plans and providing feedback to HHS and states. The state plans are consistent with the HHS National Action Plan for HAIs, include measurable five-year goals and interim milestones, and are linked to the HHS *Healthy People 2020* goals and targets.

As of February 5, 2010, 28 states passed public reporting legislation. Of these states, 21 require the use of NHSN for public reporting of HAIs. Of 21 states that mandate the use of NHSN for public reporting of HAIs, >50% issue public reports. The remaining states publicly report HAI data on their websites.

At the private-sector level, Consumers Union collects data from multiple sources to post hospital infection rates on its website at www.consumerreports.org. At this time, ~2,600 hospitals (or nearly 50% of hospitals in the United States) mandate the use of NHSN for public reporting of HAIs. Efforts have been initiated on developing a strategy for ambulatory care and long-term care facilities (LTCFs) to report HAI data under the HHS National Action Plan for HAIs.

An Ambulatory Surgical Center Workgroup and Dialysis Workgroup have been established to guide this initiative. Representation on the two workgroups is limited to HHS agencies at this time, but a stakeholder meeting will be held in 2010. The purpose of this meeting will be to obtain broader input from professional societies and other non-governmental organizations on overall progress in the HHS National Action Plan for HAIs and the development of new modules for LTCFs and ambulatory care facilities.

HAI American Reinvestment and Recovery Act (ARRA). Ms. Joni Young is the DHQP Senior Advisor for Program Integration. She reported that in February 2009, ARRA was passed with a $50 million appropriation to HHS to support state HAI prevention, reduction and elimination activities.

Of CDC's ARRA-HAI funding of ~$40 million, $35.8 million was allocated to 49 states, the District of Columbia and Puerto Rico for the development of state HAI programs, enhanced HAI surveillance through NHSN, HAI Prevention Collaboratives, and measurable outcomes in accordance with the HHS National Action Plan for HAIs. CDC allocated the remaining $4 million to ten states to develop HAI surveillance methods. CMS allocated its $10 million ARRA-HAI appropriation to state survey agencies to support the Ambulatory Surgical Center HAI Initiative. CDC is providing technical assistance to CMS in this effort.

CDC used its existing cooperative agreements under the Epidemiology and Laboratory Capacity (ELC) Program and Emerging Infections Program (EIP) to allocate ARRA-HAI funding to states. States with ELC cooperative agreements could apply for ARRA-HAI funding to conduct activities in three categories: (1) hire a state coordinator, develop a state HAI plan and convene a multidisciplinary advisory committee; (2) use NHSN to perform surveillance of HAIs; and (3) and establish an HAI Prevention Collaborative. CDC is providing technical assistance in both HHS regions and individual states.

The first quarter of the ARRA-HAI funding cycle was completed on December 31, 2009. Based on preliminary data from the first quarterly review of the performance of ELC grantees, all 51 grantees identified HAI coordinators; the grantees collectively enrolled 40 new hospitals in NHSN in the first quarter; and all 51 grantees submitted state HAI plans. The first quarterly review of EIP state health department grantees showed that NHSN user groups are being formed for data validation and methods development studies and timelines were established to administer the national HAI point prevalence survey.

CDC provided technical assistance to grantees in numerous formats after the ARRA-HAI funding awards were issued in September 2009. CDC convened a grantee meeting in October 2009 with representation by 28 states. To overcome travel restrictions placed on states, CDC also communicated with grantees through telephone calls, webinars and newsletters.

CDC has noted several successes with ARRA-HAI funding to date. A number of states are holding advisory committee meetings at the local level. CDC awarded non-ARRA funding to place nine CSTE Fellows in states to specifically focus on HAIs. Plans are underway to place an additional four CSTE Fellows in other states. CDC hopes that this effort will sustain state HAI prevention, reduction and elimination activities after ARRA funding is completed.

HICPAC commended CDC on developing an excellent process to evaluate applications and efficiently allocate ARRA-HAI funding to grantees in a timely manner.

***Antimicrobial Use Improvement Activities*.** Dr. Arjun Srinivasan is an epidemiologist in DHQP. He reported that DHQP is implementing several initiatives to improve antimicrobial use in U.S. healthcare facilities. DHQP launched the "Get Smart for Healthcare" Program in 2009 to improve antimicrobial use in inpatient healthcare settings. In developing the new program, DHQP used the existing brand and wide recognition of the "Get Smart: Know When Antibiotics Work" Program CDC initiated in 1995 that solely focused on improving antimicrobial use in

outpatient healthcare settings. The new program also is consistent with CDC's "Get Smart on the Farm" Program to improve antimicrobial use in agricultural settings.

DHQP and the Institute for Healthcare Improvement (IHI) are collaborating to place inpatient antimicrobial use on the "IHI Care Map." This tool will outline several processes of care IHI identified that need improvement in U.S. healthcare facilities. DHQP and IHI also are jointly developing a "change package" to support the development of interventions to improve inpatient antimicrobial use. The change package is being designed to identify drivers of both appropriate and inappropriate antimicrobial use.

DHQP and IHI consulted with a small group of experts in the field to discuss interventions that play a role in promoting good practices or improving bad practices. DHQP and IHI plan to disseminate the change package to obtain input from a broader group of experts in the fields of antimicrobial use, health systems, infectious diseases and nursing. The overarching goal of the change package will be to provide healthcare facilities with a series of interventions that are practical and usable across the full spectrum of healthcare facilities. DHQP is gathering a number of existing tools with demonstrated effectiveness in antimicrobial stewardship. These resources will be posted on a new CDC website to increase interest in improving antimicrobial use and facilitate implementation of the change package.

DHQP is refining existing systems and conducting other activities to better understand, measure and monitor the success of antimicrobial use interventions in U.S. healthcare facilities. Most notably, DHQP developed a component within the national HAI point prevalence survey that specifically focuses on antimicrobial use. DHQP hopes to pilot the antimicrobial use component in 2010 prior to national implementation of the full HAI point prevalence survey in 2011. Outcomes that will be measured include antimicrobial use itself, antimicrobial resistance and *Clostridium difficile* infection.

DHQP plans to launch a multi-center study to better understand and fill existing data gaps in the epidemiology of antimicrobial use. The study will be designed to identify the reasons clinicians choose to start, stop and change antibiotics. At this time, the peer-reviewed literature has a paucity of evidence on antimicrobial use, factors influencing antimicrobial use, and the overall decision-making process regarding antimicrobial use. The study also will analyze process measures, such as the percentage of orders accompanied by a culture and the percentage of orders with an indication or specific duration.

DHQP is collaborating with the NHSN Steering Committee to revise the "Antimicrobial Use and Resistance Module." Virtually no U.S. healthcare facilities use the module at this time due to its requirement of manual entry of antimicrobial use data. The NHSN information infrastructure and framework that are being developed will allow vendors to use the module to submit antimicrobial use data electronically. Electronic monitoring of antimicrobial use data will allow healthcare facilities to monitor the impact of interventions and create benchmarks to compare their performance in antimicrobial use with other institutions.

HICPAC applauded DHQP on its leadership in undertaking the important effort of improving antimicrobial use in U.S. healthcare facilities. The members made three suggestions for DHQP

to consider in further refining these activities. First, the "Get Smart for Healthcare" Program should be expanded beyond the acute care hospital setting. Most notably, the inclusion of LTCFs in the program will be critical.

Second, DHQP should broadly disseminate the change package to emergency department physicians. These clinicians will play an extremely important role in implementing interventions to improve inpatient antimicrobial use. Third, DHQP should consider two issues that will be important to efforts to improve antimicrobial use: direct examination of specimens, particularly gram staining, and the influence of the Stark legislation on moving hospital microbiology laboratories offsite.

***Expansion of the CDC HAI Prevention Research and Evaluation Program*.** Dr. John Jernigan, Deputy Branch Chief of the DHQP Prevention and Response Branch, described DHQP's proposed plan to expand the CDC HAI Prevention Research Program in the new 2011-2016 five-year funding cycle. He reported that the HHS Action Plan to Prevent HAIs called for a broadened research agenda to improve understanding of the basic science and epidemiology of HAIs; better quantify the efficacy of existing infection control practices; improve implementation of existing recommendations; and identify novel prevention strategies.

The Prevention Epicenters Program is CDC's only extramural research program that is dedicated to HAI prevention research. The annual budget of the Epicenters is $2 million with the current five-year funding cycle ending in February 2011. The new five-year funding cycle from 2011-2016 will provide DHQP with an opportunity to evaluate, improve and expand the Epicenters.

DHQP is using a contextual framework to better articulate CDC's role in HAI prevention research. The translational research and evaluation model is designed to move knowledge and discovery gained from basic and epidemiologic sciences to application in clinical and community settings. The five phases of translational research were published in *Genet Med* in 2007 and also are posted on the Institute of Translational Health Sciences website, but DHQP adapted this language to be more relevant to HAIs. The five "T-phases" of the translational research model as modified by DHQP are described below.

- T_0 is characterized by the discovery of opportunities and approaches to health problems through technologic advances, surveillance, outbreak investigations and epidemiologic sciences.
- T_1 seeks to move discovery into the first application of candidate inteventions in healthcare settings and patient populations.
- T_2 assesses the value of candidate interventions leading to the development of evidence-based guidelines.
- T_3 attempts to move evidence-based guidelines into health practice through delivery, dissemination and diffusion research.
- T_4 seeks to evaluate "real world" health outcomes of population health practice.

DHQP recognizes the critical need for CDC to invest in HAI prevention research. Most notably, investments in T_0-T_2 translational research are critical for expediting broader implementation of

effective prevention strategies in the T_3-T_4 phases. Moreover, other federal agencies have not prioritized investments in T_0-T_2 HAI prevention research. DHQP also is aware of CDC's unique role in guiding and supporting translational prevention research. CDC has content expertise that is critical for effectively guiding research investments. Moreover, CDC contributes a strong public health perspective to HAI prevention research and bridges gaps between public health and academic research agendas.

DHQP's overarching goal in expanding the HAI Prevention Research and Evaluation Program will be to support CDC in fostering research that advances prevention and control of HAIs, antimicrobial resistance and other adverse healthcare events. DHQP is proposing to design the expanded program with four major components that are outlined below.

Component 1 is the "Academic Cooperative Agreement" that CDC will use to allocate research investments to the Epicenters and other academic partners. Component 1 will be similar to the current Prevention Epicenter Program. HAI prevention research will be conducted through investigator-initiated projects and prevention research emphasis projects that will provide grantees with additional funding opportunities intermittently over the five-year funding cycle.

DHQP will extensively consult with HICPAC in developing the subject, focus and content of funding opportunity announcements in component 1. Eligibility requirements for a five-year award in component 1 will include academic leadership, access to an integrated spectrum of healthcare settings, participation in NHSN and an existing informatics infrastructure. The research emphasis of component 1 will be T_0-T_2 to move from basic epidemiologic knowledge to new candidate interventions.

Component 2 is the "Health Department Cooperative Agreement" that CDC will use to allocate research investments to health departments. HAI prevention research and evaluation will be conducted from a distinct public health perspective. Component 2 will provide opportunities for health departments to implement projects beyond the scope of academic medical centers. Component 2 will be designed to enhance partnerships among health departments, healthcare institutions and academic centers at local and regional levels and also to support the roles of state and local health departments in HAI prevention. The research emphasis of component 2 will be T_0 and T_2-T_4.

Component 3 is the "Task Order System" that CDC will use to award research contracts to entities that are uniquely positioned to conduct HAI prevention research. Component 3 will serve as a flexible mechanism to allow for more rapid implementation of narrowly focused HAI prevention research studies that meet CDC's public health priorities, but might not be suitable for either the academic or health department cooperative agreements.

CDC will open an initial competitive process to select from a diverse pool of applicants with demonstrated experience and an existing infrastructure in implementing a wide range of HAI prevention studies. Examples of entities that might be awarded funding in component 3 include academic and non-academic research institutions as well as healthcare delivery organizations and networks. However, CDC is considering the possibility of opening the competitive process for health plans and private insurers to apply individually or in partnership with academic

medical centers and health departments. These entities could play an important role in component 3 due to their shared information systems and existing relationships with healthcare facilities that allow process and outcome measures to be evaluated.

Funding to health plans and private insurers also could facilitate a shift from the historical focus on location-based intervention research to a broader emphasis on the lives of patients who transfer across various healthcare settings. Entities that are awarded funding in the initial competitive process will be eligible to compete for new HAI prevention task order requests initiated by CDC over the five-year funding cycle. The research emphasis of component 3 will be T_0, T_2 and T_3.

Component 4 is "Interagency and Intergovernmental Agreements" that CDC will use to strengthen its existing relationships with federal partners and other organizations to conduct HAI prevention research on a broader scale. These groups include CMS, the Agency for Healthcare Research and Quality (AHRQ), Plexus Institute and Harvard Pilgrim HealthCare.

Dr. Jernigan concluded that the diversity of the four components of the expanded HAI Prevention Research and Evaluation Program will allow CDC to interact with a broad group of research partners to better address important gaps in the translational research pathway. CDC's expanded program also will serve as a mechanism to build the existing evidence base, advance current recommendations, and make more progress in achieving the goal of HAI elimination. Funding has not been identified at this time to support the expanded program, but DHQP hopes that additional resources will be leveraged to increase the number of Epicenters and engage a new cycle of Epicenters in each year of the five-year funding cycle.

For component 4, DHQP is aware of AHRQ's excellent track record in funding entities to conduct T_3 research projects. However, DHQP recognizes the critical need to initiate high-level discussions with federal partners to clearly define their roles and responsibilities in HAI prevention and evaluation. To publicize the expanded HAI Prevention Research and Evaluation Program, DHQP plans to convene a roundtable discussion on the role of state and local health departments in HAI prevention research during the CSTE meeting in June 2010.

Dr. Jernigan reiterated that DHQP is in the initial planning stage of developing CDC's expanded HAI Prevention Research and Evaluation Program. He welcomed input and expertise from HICPAC on refining the four components to ensure that appropriate entities would be recruited at the outset.

HICPAC fully supported DHQP's proposal to expand CDC's HAI Prevention Research and Evaluation Program. The members particularly commended DHQP on its initial efforts in clearly defining the roles and responsibilities of entities that would be awarded in components 1-3. Several HICPAC members made comments and suggestions for DHQP to consider while further developing this initiative.

- DHQP should create mechanisms to facilitate interaction and dialogue across the four components during the early stages of developing HAI prevention research and evaluation projects. For example, academic medical centers in component 1 should be

required to demonstrate an existing relationship with state or local health departments as a condition of grant funding. Health departments in component 2 should be required to establish strong partnerships with academic medical centers, small community hospitals and relevant professional societies to ensure that HAI prevention and evaluation research results are widely distributed to hospitals at the local level. Health departments can play a critical role in translating HAI prevention recommendations to increase implementation in LTCFs and small hospitals. DHQP should sponsor annual meetings with awardees in components 1-3 and federal partners in component 4 to review plans, preliminary results and interim progress in HAI prevention research and evaluation. Overall, integrated mechanisms across the four components would help to bridge silos, reduce redundancy and encourage the entities to share ideas.

- DHQP should explore the possibility of adding the T_3 research phase to the academic cooperative agreement in component 1. This change would provide Epicenters and other academic partners with an opportunity to develop implementation strategies and frameworks that are specifically focused on HAI prevention.
- A HICPAC member should volunteer to serve on AHRQ's National Advisory Council that is charged with reviewing research focus areas of various infection control projects funded by AHRQ. Representation by HICPAC could provide an opportunity for the Council to learn about infection control issues in the field that would be appropriate for AHRQ to address in collaboration with CDC.
- DHQP should ensure that health plans and private insurers have strong representation in the pool of applicants for the task order system in component 3. These entities have the most knowledge in the full spectrum of services that patients expect from healthcare facilities.

***DHQP Director's Report*.** Dr. Denise Cardo, Director of DHQP, reported on recent activities and developments in DHQP from the Office of Director level. DHQP broadened its traditional focus on healthcare facilities to give more attention to state and local health departments. The expansion was necessary due to the increase in public reporting and use of NHSN at the state level; ARRA funding awarded to states to conduct HAI prevention, reduction and elimination activities; the submission of state HAI plans to HHS; and CDC's expanded HAI Prevention Research and Evaluation Program that includes a component specifically targeted to health departments. CDC's leadership in public health and DHQP's solid experience and relationships with healthcare facilities will play critical roles in bridging health departments and healthcare facilities to make more progress in HAI elimination.

Dr. Cardo announced that the President's proposed FY2011 budget calls for HHS/CDC to allocate ARRA funding for state and local health departments to continue to conduct HAI prevention, reduction and elimination activities. DHQP will expand these initiatives by using CDC's existing mechanisms (*i.e.*, the ELC and EIP Programs) to incorporate a research component to gather more data on HAI prevention, surveillance and outbreaks. DHQP is closely collaborating with CSTE, the Association of State and Territorial Health Officials and other professional societies that have memberships of state and local health departments.

Dr. Cardo noted that some initiatives presented during the DHQP update (*i.e.*, the new NHSN/ CMS data reporting process) were developed as a direct result of HICPAC's previous input and

recommendations. Moreover, HICPAC's leadership in developing and publishing the guidance document on public reporting of HAIs five years ago was essential in CDC making advances in this area.

DHQP will continue its traditional partnerships with healthcare facilities, but a stronger focus on state and local health departments is necessary at this time. Public reporting mandates and ARRA funding have empowered states to provide more leadership, knowledge and expertise in encouraging healthcare facilities across the country to use NHSN and make other efforts to prevent HAIs. In the near future, DHQP plans to report on progress that has been made in HAI prevention, reduction and elimination since HICPAC's guidance document was published five years ago.

Dr. Cardo announced that DHQP was housed in the National Center for Preparedness, Detection and Control of Infectious Diseases (NCPDCID), but the name of the National Center was recently changed to the "National Center for Emerging and Zoonotic Infectious Diseases" (NCEZID). The new name reflects the consolidation of NCPDCID and the National Center for Zoonotic, Vector-Borne and Enteric Diseases.

The consolidation will not directly affect DHQP's overall mission and daily activities, but DHQP will indirectly benefit from three positive changes. First, DHQP will use HAIs to demonstrate a strong public health impact and bridge gaps between the public health and healthcare systems. Second, DHQP will obtain more support for its healthcare quality promotion activities from both the CDC and National Center levels. Third, DHQP will enhance its relationships with more infectious disease programs at CDC.

Dr. Cardo highlighted key personnel changes that have occurred as a result of the consolidation of the two National Centers. Dr. Chesley Richards was the Deputy Director of DHQP at the division level, but he accepted a new position as the Associate Director for Healthcare Quality in NCEZID at the National Center level. Dr. Richards also is devoting 50% of his time to providing leadership in addressing "prevention through healthcare." This issue was identified as one of the "critical functions" of the new CDC Associate Director for Policy.

As the former Deputy Director of DHQP, Dr. Richards will have a unique opportunity to use his knowledge and expertise to inform Dr. Thomas Frieden, Director of CDC, about the critical need for DHQP to strengthen its existing relationships with CMS, The Joint Commission and the National Quality Forum to make advances in HAI elimination.

Dr. Michael Bell was the Associate Director for Infection Control at DHQP and was recently named as the Deputy Director of DHQP to replace Dr. Richards. Due to his new position, Dr. Bell will no longer serve as the DFO for HICPAC. Mr. Jeffrey Hageman is an epidemiologist in DHQP and will replace Dr. Bell as the new DFO for HICPAC beginning with the next meeting. Ms. Joni Young was recently named as the first Senior Advisor for Program Integration in DHQP. In her new position, Ms. Young is responsible for managing DHQP's effective and systematic response to ARRA, novel influenza A virus (H1N1) and other emerging issues.

Recruitment efforts are underway to identify an individual who will be housed in the DHQP Office of the Director to manage, oversee and monitor all HAI elimination activities across the division and identify effective partnerships to improve data collection, validation and research in this area. Dr. Cardo confirmed that she would provide HICPAC with an organizational chart to illustrate the positions, roles and responsibilities of DHQP leadership in the Office of Blood, Organ and Other Tissue Safety; Healthcare Preparedness Activity; Antimicrobial Resistance Team; and Immunization Safety Office.

Dr. Brennan congratulated Dr. Bell, Mr. Hageman, Dr. Richards and Ms. Young on their new roles at CDC and wished them well in these positions. He also commended Dr. Cardo on her outstanding leadership in leveraging additional resources and developing new partnerships for DHQP over the past few years. He questioned whether HICPAC's scope of work should be expanded to include the issue of patient safety to support the parts of CDC's new organizational structure that are relevant to DHQP.

In response to Dr. Brennan's question, Dr. Cardo was not in favor of expanding HICPAC's scope of work at this time. Her position was that HICPAC should continue to primarily focus on HAIs due to the complexity of this issue. Moreover, HHS and its agencies outside of CDC (particularly AHRQ and CMS) heavily rely on HICPAC's expertise in HAIs. However, Dr. Cardo was open to discussing the expansion of HICPAC's scope of work in the near future. For example, HICPAC could play a critical role in providing specific guidance to the DHQP Office of Blood, Organ and Other Tissue Safety on issues related to infection control and prevention practices.

Status Report on HICPAC Guidelines and Documents: SESSION 1

Reports on the current status of HICPAC guidelines and documents are outlined below.

***Guideline for the Prevention and Management of Norovirus Gastroenteritis Outbreaks in Healthcare Settings*.** Dr. Tara MacCannell, of DHQP, is the CDC technical resource to the HICPAC workgroup that developed the norovirus guideline. She reminded HICPAC of the three key research questions the workgroup identified to guide the development of the 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?

Following the November 2009 HICPAC meeting, the workgroup completed the expert review process by integrating comments submitted by HICPAC members and the external expert review panel into the norovirus guideline. Recommendations in the guideline cover 11 topics:

1. Patient cohorting and isolation precautions
2. Hand hygiene
3. Indirect patient care staff/food handlers
4. Diagnostics
5. Personal protective equipment (PPE)
6. Environmental cleaning
7. Staff leave and management
8. Visitors
9. Education
10. Active case findings
11. Communication and notification

The "case management" guidance was removed because the workgroup found only one supporting recommendation in the literature, but the text was retained in the evidence summary of the guideline. The "leave policies" guidance was renamed to "staff leave and management." The "communication activities" guidance was renamed to "communication and notification."

The workgroup amended the norovirus guideline in several major areas based on HICPAC's comments and suggestions. The Tier 1 and 2 definitions were changed. Category IA-IC recommendations in Tier 1 are "strong recommendations that should be implemented during outbreaks of norovirus gastroenteritis." Category II recommendations in Tier 2 are "weak recommendations that are not supported by strong evidence, but should be considered (particularly during outbreaks with uncontrolled transmission)."

Explicit language was added to clarify HICPAC's position on the use of alcohol hand rubs versus handwashing. The original recommendation stated: "Consider FDA-approved alcohol-based hand sanitizers as an adjunct method of hand hygiene during outbreaks or norovirus gastroenteritis when hands are not visibly soiled and have not been in contact with diarrheal patients, blood or other body fluids." The following new language was added to the end of the paragraph: "During outbreaks, use of soap and water is the preferred method of hand hygiene." (Category II)

The following recommendation on case management was removed: "Consider monitoring for signs of hypovolemia or renal dysfunction in those with symptomatic norovirus infection and comorbid conditions, such as underlying renal or cardiovascular disease, immunosuppression, or renal transplants, and institute appropriate medical therapy where appropriate. (Category II) Table 5, *Measures of Prevention and Control of Norovirus Outbreaks in the Published Literature*, was removed from the guideline because some of the interventions were inconsistent with HICPAC's evidence-based recommendations.

Dr. MacCannell described the final steps in publishing the norovirus guideline. The document was submitted for clearance by DHQP and cross-clearance by gastroenteritis subject matter experts in the National Center for Immunization and Respiratory Diseases. After this clearance process, the document will be published in the *Federal Register* and re-revised based on comments submitted. The final version will be distributed to HICPAC for a formal vote and then

submitted to the CDC agency-wide clearance process. The document will be posted on the CDC website, but Dr. MacCannell has not been given a definite date for website publication.

HICPAC agreed with the workgroup's decision to remove Table 5 from the guideline overall, but several members emphasized the need to develop a summary of key recommendations and place the new table in the executive summary or immediately behind the recommendation tiers. The members pointed out that the table would serve as a useful tool for clinicians and infection preventionists. Dr. Brennan advised the workgroup to reconcile differences between Table 5 and HICPAC's evidence-based recommendations.

HICPAC also advised the workgroup to revise the recommendation in the "communication and notification" section with stronger language for healthcare facilities to report norovirus outbreaks to state or local health departments upon "initial detection" rather than at the end of an outbreak.

***Journal Publication of HICPAC Guidelines*.** Dr. Bell reported that this topic was placed on the agenda as a result of recent e-mail communications indicating an interest in publishing HICPAC guidelines in hard-copy journals and other formats beyond the CDC website. His position was that HICPAC should not devote its time to discussing publication strategies because documents posted on the CDC website are in the public domain and are free to be reproduced by a journal, organization or individual.

Dr. Bell was in favor of HICPAC being aware of and having limited involvement in the process to publish guidelines in peer-reviewed journals. However, the core writing group should decide on potential journals to submit HICPAC guidelines and spearhead the publication process. Dr. Bell emphasized that DHQP also could assist the authors in facilitating a process to more broadly disseminate HICPAC guidelines to target audiences.

Dr. Brennan added that HICPAC adopted the methods process to publish guidelines on the CDC website in a timelier manner. However, this process has presented a challenge because hard-copy journals typically have no interest in publishing documents that have been posted on a website. He planned to place this issue on a future agenda for HICPAC to explore strategies to address this challenge. Dr. Brennan stated for the record that HICPAC has no preference in publishing its guidelines in either one of the two major U.S. infection control journals.

Dr. Craig Umscheid is the Director of the University of Pennsylvania Health System Center for Evidence-Based Practice and an external expert and technical consultant to several writing groups of HICPAC guidelines. He announced that *Infection Control and Hospital Epidemiology* (*ICHE*) agreed to publish the Urinary Tract Infection Guideline recommendations and the *American Journal of Infection Control* accepted HICPAC's Methods Paper for Guideline Production for publication. The journal editors were informed of the rigorous peer review and clearance process for both documents to ensure that no revisions were made to the content.

Dr. Umscheid emphasized the importance of publishing HICPAC guidelines in the peer-reviewed literature for both dissemination and indexing purposes. This strategy would allow other researchers to locate or build on HICPAC's systematic review of the evidence. Overall, Dr. Umscheid's position was that publication in peer-reviewed journals should be a routine part

of the publication process for HICPAC guidelines. However, he agreed with Dr. Bell that the authors rather than HICPAC should lead this effort.

***Guidance for Jurisdictions Considering Multidrug-Resistant Organism Legislation*.** Dr. Tammy Lundstrom is a HICPAC member who chaired this workgroup. She reported that during the clearance process, CDC recommended changes to the guidance document. These revisions included editorial changes and the addition of more references from the literature on potential unintended consequences of isolation. Dr. Lundstrom recently revised the document based on CDC's comments and submitted the most recent version to Dr. Cardo for review.

Dr. Cardo added that the changes CDC recommended were not substantive and did not modify the content of the document. She would review Dr. Lundstrom's final draft, circulate this version to HICPAC, and distribute the document for review by the NCEZID Office of the Director due to its influential nature. The document would then be posted on the CDC website.

***Healthcare Personnel (HCP) Infection Control Guideline*.** Dr. Lundstrom is the chair of the workgroup. She reported that the remaining members include three other HICPAC members, a technical resource from CDC/DHQP who will be named in the near future, and external experts from four professional societies: the Association of Professionals of Infection Control and Epidemiology, Inc. (APIC), American College of Occupational and Environmental Medicine (ACOEM), Infectious Diseases Society of America (IDSA) (to be named in the future), and Society for Healthcare Epidemiology of America (SHEA).

The workgroup immediately recognized the need to organize the guideline due to its large size and inclusion of information from multiple documents. Based on HICPAC's suggestions during the previous meeting, the workgroup agreed to structure the guideline in three sections. The "Baseline and Routine Practices" section will cover pre-employment immunizations, annual testing, booster and annual immunizations, and education. The "Special Populations" section will cover pregnant and immunocompromised HCP. The "Specific Infectious Diseases" section will cover TB, meningitis and pertussis.

The "Appendices" will cover travel issues with links to the *Yellow Book* and recommendations on post-return surveillance of U.S. HCP who might return with extensively drug-resistant TB or viral infections due to their work in high-risk international settings with no infection prevention and control measures. The appendices also will discuss the need for PPE among vaccinees and those having natural infection.

Other links that will be provided in the appendices include recommendations by the Advisory Committee on Immunization Practices (ACIP), HICPAC's norovirus guideline and guidance on bloodborne pathogens. To ensure consistency between two different HCP guidelines that are being updated by two different CDC advisory committees, all infection control information will be deleted from ACIP's updated guideline on HCP immunization. The link to the ACIP guideline in the HICPAC guideline will be specifically for HCP immunization.

The workgroup noted that the tables in the 1998 HCP infection control guideline were well utilized and extremely useful to the occupational health, infection control and healthcare

epidemiology communities. Most tables focused on vaccine-specific issues or prophylaxis for specific infectious diseases. The workgroup intends to reproduce these tables in the updated guideline.

The workgroup is currently refining research questions that will guide the development of the updated guideline and has proposed five potential topics in this effort:

1. Respiratory protection for infections transmitted by the airborne route.
2. The best method for TB screening (*i.e.*, purified protein derivative, QuantiFERON® or a combination of both tests).
3. Evidence-based best practices for pregnant or other immunocompromised HCP.
4. Best practices for influenza immunization. (The workgroup noted that this issue most likely would be covered by a link to ACIP recommendations and would not serve as a specific research question.)
5. Methicillin-resistant *Staphylococcus aureus* (MRSA) and HCP (*i.e.*, the appropriate time to test and evidence-based strategies to test, decolonize and follow-up.)

Dr. Lundstrom concluded that the workgroup's next steps will be to fully identify its core members and external experts; search medical databases and websites to locate relevant guidelines and narrative reviews for inclusion in the guideline; and continue to refine the research questions to begin the literature search with the University of Pennsylvania Health System Center for Evidence-Based Practice.

In terms of publication, Dr. Lundstrom reminded HICPAC that an informal survey showed ACOEM members preferred a single compilation of the HCP infection control guideline due to the extensive use of the document in the occupational medicine field. Dr. Mark Russi is the HICPAC liaison to ACOEM and an external consultant to the workgroup. He added that the *Journal of Occupational and Environmental Medicine* most likely would be interested in publishing the guideline.

The HICPAC members made three key suggestions for the workgroup to consider in its ongoing efforts to develop the HCP infection control guideline. First, the "Special Populations" section should contain a link to the new guideline that describes high-risk procedures and potential limitations on HCP who perform high-risk procedures. The guideline highlights certain situations that make HCP or patients more vulnerable, such as specific viral infections, cystic fibrosis/anesthesiology, and some dermatologic issues.

Second, a list of persons, organizations and healthcare institutions that routinely utilize the guideline should be maintained. The list should be used to efficiently notify users each time a chapter in the guideline is updated and provide links to updated sections. Third, the workgroup should invite Dr. David Webber to serve as an expert reviewer of the HICPAC infection control guideline. Dr. Webber is leading the effort to update the ACIP guideline on HCP immunization and has expressed an interest in participating in HICPAC's guideline development process.

Guideline for the Prevention of Intravascular Catheter-Related Bloodstream Infections (CRBSI). Dr. Alexander Kallen is a Medical Officer in DHQP. He reported that the publication

of the draft CRBSI guideline in the *Federal Register* resulted in 293 individual comments and >1,100 individual suggestions. He noted that several comments submitted during the public comment period require discussion and consensus by HICPAC in order for the workgroup to move forward in finalizing the document for publication. Dr. Kallen's summary of the public comments that HICPAC needs to resolve is outlined below.

General Comments

1. Conflicts of interest of all authors should be included in the guideline.
2. The level of evidence does not appear to support the "Grading of Recommendations, Assessment, Development and Evaluation" (GRADE) scheme in some areas. This situation is usually when the recommendation is standard practice. The categorization system for Category IB recommendations should be revised to be similar to the new modified GRADE system in the Guideline for Preventing Catheter-Associated Urinary Tract Infections (CAUTI). This approach would allow for standard practices that are unlikely to be studied, but are strongly recommended for implementation.
3. Pages 7-8: The use of zero infections (similar to CLABSI) should be recommended as a goal rather than facility-specific targets or benchmarks.

Chlorhexidine-Impregnated Dressings (pages 21-23)

1. A decision should be made on whether to use the term "chlorhexidine-impregnated sponge" (a specific product) versus "chlorhexidine-impregnated dressing" throughout the document.
2. Recommendation 11 states: "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) The recommendation should be re-categorized as Category IA.

Dialysis-Specific Comment

1. The previous recommendation against the use of catheters should be added to the guideline (potentially on page 40). This language stated: "Use a fistula or graft instead of a CVC for permanent access for dialysis."

Needleless Connectors (pages 47-48)

1. Recommendation 1 states: "Change the needleless components at least as frequently as the administration set. There is no benefit to changing these more frequently than every 72 hours." (Category II) This recommendation might conflict with some manufacturer recommendations that often are based on the number of accesses rather than times. Consideration should be given to revising the recommendation to include guidance on changing the hub if contaminated with blood.
2. Recommendation 6 states: "When needleless systems are used, the split septum valve is preferred over the mechanical valve due to increased risk of infection." (Category II) Concerns were expressed that a generalization of four observational trials to a general recommendation against mechanical valve needleless connectors is "unwarranted." Moreover, large differences between these devices appear to argue against a general recommendation against mechanical valve needleless connectors.

Site Selection (page 13)

1. Recommendation 7 states: "Use a subclavian site, rather than a jugular or a femoral site, in adult patients to minimize infection risk for nontunneled CVC placement. (Category IA) This language should be modified to avoid the femoral site rather than the subclavian site that is preferentially used for nontunneled CVCs in adults.
2. Recommendation 9 states: "Place catheters used for hemodialysis and pheresis in a jugular or femoral vein, rather than a subclavian vein, to avoid venous stenosis." (Category IA) "Pheresis" should be removed from this recommendation. To avoid the subclavian site in hemodialysis patients, "… and patients with advanced kidney disease" should be added to the recommendation.

Hand Hygiene (pages 16-17)

1. Recommendation 1 states: "Perform hand hygiene procedures, either by washing hands with conventional antiseptic containing soap and water or with waterless alcohol-based hand rubs (ABHR). Hand hygiene should be performed before and after palpating catheter insertion sites as well as before and after inserting, replacing, accessing, repairing or dressing an intravascular catheter. Palpation of the insertion site should not be performed after the application of antiseptic, unless aseptic technique is maintained." (Category IA) The recommendation should be re-categorized as Category IB. The term "removing conventional antiseptic containing" should be deleted.
2. Recommendation 2 states: "Maintain aseptic technique for the insertion and care of intravascular catheters." (Category IA) The recommendation should be re-categorized as Category IB.

Chlorhexidine for Skin Antisepsis (pages 19, 48)

1. Recommendation 1 states: "Prepare clean skin with 70% alcohol before peripheral venous catheter insertion." (Category IA) Chlorhexidine for peripheral IV insertion should be recommended.
2. Recommendation 2 states: "Prepare clean skin 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) Lower concentrations of chlorhexidine (*i.e.*, 0.5%) with alcohol as alternatives for skin antisepsis for CVC maintenance and insertion should be recommended. Only alcohol-based chlorhexidine preparation for skin antisepsis surrounding CVC insertion and maintenance should be recommended.
3. Recommendation 4 states: "Minimize contamination risk by wiping the access port with an appropriate antiseptic (chlorhexidine preferred) and accessing the port only with sterile devices." (Category IA) "Chlorhexidine preferred" should be removed. The duration and technique for required disinfection of a port should be added. The use of the word "scrub" should be considered.

Antimicrobial Prophylaxis (page 28)

1. The recommendation states: "Do not administer systemic antimicrobial prophylaxis routinely before insertion or during use of an intravascular catheter to prevent catheter

colonization or CRBSI." (Category IA) "Prophylactic antimicrobials prior to CVC insertion" should not be included in the recommendation. The recommendation should be re-categorized as Category IB.

Dressing Changes (page 21)

1. Recommendation 5 states: "Do not submerge the catheter or catheter site in water. Showering should be permitted if precautions can be taken to reduce the likelihood of introducing organisms into the catheter (*e.g.*, if the catheter and connecting device are protected with an impermeable cover during the shower)." (Category II) The recommendation should be re-categorized as Category IB. The basis of this public comment is a study published in *ICHE* in 2008 with a cohort of pulmonary hypertension patients with Dunbar IV that showed decreased rates of catheter-associated BSI when the hub connection was properly protected.
2. Recommendation 6 states: "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) Recommendation 7 states: "Replace dressings used on tunneled or implanted CVC sites no more than once per week until the insertion site has healed." (Category IB) "Gauze" should be separated from "transparent dressings" in recommendation 6. The collection of adequate data to support "2 days" in recommendation 6 is questionable. Recommendation 6 should be re-categorized as Category II. Recommendations 6 and 7 should be synchronized for "transparent dressings." "Transparent" might need to be inserted before "dressings" in recommendation 7 to account for soiled or loose dressing.

Administration Sets (page 46)

1. Recommendation 1 states: "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) The recommendation should specify its focus on continuously used administration sets. A second recommendation should be added to emphasize that the frequency for changing intermittently used sets is an unresolved issue.

Replacement of Peripheral Catheters (page 36)

1. Recommendation 1 states: "Replace peripheral catheters every 72-96 hours to reduce risk of infection and phlebitis in adults." (Category IB) The recommendation should be re-categorized as either Category II or an unresolved issue. Some evidence found no difference in rates of phlebitis and failure when two different strategies were used (*i.e.*, "planned removal" versus "as needed removal").

Catheter Securement Devices (page 24)

1. The recommendation states: "Use a sutureless securement device to reduce the risk of infection for PICCs." (Category II) Catheter securement devices should be recommended for all catheters. The recommendation should be revised to clarify its application in adults.

Peripheral Arterial Catheters (page 44)

1. Recommendation 3 states: "A cap, mask, sterile gloves and a large sterile fenestrated drape should be used during peripheral arterial catheter insertion. (Category IB) Based on a randomized trial, the recommendation should be revised as follows: "a minimum of sterile gloves and a small fenestrated drape."

Inclusion of Recommendations from the 1996 and 2002 CRBSI Guidelines

Several suggestions were made during the public comment period to add the following recommendations from the 1996 and 2002 CRBSI guidelines to the updated guideline.

1. Surveillance A and B, recommendation II. "Monitor site regularly and encourage patients to report changes to HCP."
2. Catheter-site dressing changes, recommendation VIII E: "Replace catheter when aseptic technique not adhered to."
3. Peripheral catheter section, recommendations II, C, 1 & 2: "Evaluate daily and remove if phlebitis, cord or tenderness is present."
4. CVC section, recommendations II, A & D: "Use CVC with a minimum number of ports and designate knowledgeable people to supervise trainees."
5. CVC section, recommendations II, H: "Do not use dialysis port to draw blood."
6. CVC section, recommendations VI, A: "Designate a specific port for TPN."

HICPAC extensively discussed the public comments that were made on the CRBSI guideline. **The discussion resulted in HICPAC's consensus on the following public comments.**

General Comments

- #1: HICPAC agreed to include conflicts of interest of all authors of the CRBSI guideline in the document.
- #2: HICPAC agreed to adopt the following language for the categorization system for Category IB recommendations: "Strongly recommended for implementation, and supported by some experimental, clinical or epidemiologic studies, and a strong theoretical rationale or an accepted practice (*e.g.*, aseptic technique) supported by low to very low quality evidence."
- #3: HICPAC agreed to add language to the introduction to emphasize the goal of moving toward "zero infections" or "elimination of infections." For the three specific tier 2 interventions (*i.e.*, chlorhexidine patches, antimicrobial impregnated catheters and chlorhexidine baths), HICPAC agreed on the following language. "Use antibiotic or antiseptic impregnated catheters after implementing standard strategies if infections have not been sufficiently eliminated or if rates have not decreased or been sustained at very low levels."

Chlorhexidine-Impregnated Dressings

- #1: HICPAC agreed to maintain both terms in the document, but use a tiered approach to make a clearer distinction of the level of evidence. The Category IA recommendation would be "chlorhexidine-impregnated sponge." The Category IB recommendation would be "chlorhexidine-impregnated dressing."
- #2: HICPAC agreed to re-categorize recommendation 11 as Category IA provided that evidence supports implementing the interventions on a per facility basis or in a tiered

approach if infection rates are decreasing. Corresponding language in the background section would be revised to be consistent with the new Category IA recommendation.

Dialysis-Specific Comment

- #1: HICPAC agreed to include the previous recommendation against the use of catheters: "Use a fistula or graft instead of a CVC for permanent access for dialysis."

Needleless Connectors

- #1: HICPAC agreed to revise recommendation 1 on page 47 as follows: "Change the needleless components at least as frequently as the administration set or according to manufacturer recommendations. There is no benefit to changing these more frequently than every 72 hours or if recommended by the manufacturer."
- #2: HICPAC agreed to revise recommendation 6 on page 48 as follows: "When needleless systems are used, the split septum valve might be preferable over the mechanical valve due to increased risk for infection with some mechanical valves."

Site Selection

- #1: HICPAC agreed to revise recommendation 7 on page 13 to show two levels of the quality of evidence. The Category IA recommendation would be to "avoid the femoral site." The Category IB recommendation would emphasize that the "subclavian site is preferred over the jugular or femoral site."
- #2: HICPAC agreed to revise recommendation 9 on page 13 as follows: "Place catheters used for hemodialysis in a jugular or femoral vein, rather than a subclavian vein, and in patients with chronic kidney disease to avoid venous stenosis."

Hand Hygiene

- #1: HICPAC agreed to re-categorize recommendation 1 on page 16 as Category IB. HICPAC agreed to delete the term "removing conventional antiseptic containing" from the recommendation.
- #2: HICPAC agreed to re-categorize recommendation 2 on page 17 as Category IB.

Chlorhexidine for Skin Antisepsis

- #1: HICPAC agreed not to revise recommendation 1 on page 19. No evidence supports the public comment to recommend chlorhexidine for peripheral IV insertion.
- #2: HICPAC agreed to revise recommendation 2 on page 19 as follows: "Prepare clean skin site with a chlorhexidine-based preparation of 2% or higher…".
- #3: HICPAC agreed to delete "chlorhexidine preferred" from recommendation 4 on page 48 and highlight options for the use of chlorhexidine in the background section. A sub-bullet would be added to recommendation 4 to emphasize that 3-5 seconds of wiping the access port have been demonstrated to be inadequate based on the evidence. Although 15 seconds of wiping are being used as a more appropriate duration for cleaning in many instances, the optimal duration is an unresolved issue.

Antimicrobial Prophylaxis

- #1: HICPAC agreed to re-categorize the recommendation on page 28 as Category IB.

Dressing Changes

- #1: HICPAC agreed to re-categorize recommendation 5 on page 21 as Category IB. The study published in 2008 in *ICHE* that served as the basis of this public comment would be referenced in the CRBSI guideline.
- #2: HICPAC agreed to separate "gauze" (Category II) and "transparent dressings" (Category IB) in recommendation 6 on page 21. Recommendations 6 and 7 would be synchronized with the same language: "… replace transparent dressings at least every 7 days."

Administration Sets

- #1: **HICPAC did not reach consensus on resolving the "administration sets" public comments for recommendation 1 on page 46.** Some HICPAC members were not aware of data that showed administration sets used more intermittently might need to have a different frequency. Other HICPAC members were in favor of specifying "continuously used administration sets" and not addressing "intermittently used sets." Several HICPAC members were uncertain whether the quality of evidence supported a Category IA recommendation for the "administration sets" language. Dr. Kallen confirmed that the workgroup would re-review the literature to facilitate HICPAC's decision-making process on the public comments for this recommendation.

Replacement of Peripheral Catheters

- #1: HICPAC agreed to re-categorize recommendation 1 on page 36 as either Category II or an unresolved issue. HICPAC also agreed to update the recommendation to reflect new data as appropriate.

Catheter Securement Devices

- #1: HICPAC agreed to add a sub-bullet to the recommendation on page 24 to emphasize that evidence to support extending securement devices to other catheter types is currently lacking.

Peripheral Arterial Catheters

- #1: HICPAC agreed not to change recommendation 3 on page 44 and maintain the same language: "A cap, mask, sterile gloves and a large sterile fenestrated drape should be used during peripheral arterial catheter insertion." (Category IB)

Inclusion of Recommendations from the 1996 and 2002 CRBSI Guidelines

- HICPAC agreed to include all six recommendations from the 1996 and 2002 CRBSI guidelines in the updated guideline as Category IB. HICPAC acknowledged that the inclusion of these recommendations in the updated guideline would serve as a reminder for healthcare facilities to implement these standard practices.

Ms. Kerry Edgar is the Vice President of Marketing of Medegen, Inc. She made comments in response to HICPAC's consensus to revise recommendation 6 on page 48 with the following language: "When needleless systems are used, the split septum valve might be preferable over the mechanical valve due to increased risk for infection with some mechanical valves."

Ms. Edgar clarified that two types of split septum technologies are currently on the market: the Blunt Plastic Cannula and Luer Access Split Septum. Because a recall is underway for the Luer product, HICPAC's generic language on a "split septum valve" might cause healthcare facilities to use a product that is not supported by evidence. The guidance also might have an unintended consequence of being viewed as HICPAC's endorsement of a particular product, particularly since one company manufactures 80% of split septum connectors in the world.

Based on Ms. Edgar's comments, Dr. Bell agreed on the need to further revise HICPAC's "split septum" recommendation with more specificity. He confirmed that CDC and HICPAC would resolve this issue during an offline discussion.

Update on Drug-Resistant Tuberculosis (DR-TB)

Dr. Peter Cegielski is the Team Leader for Drug-Resistant TB in the CDC Division of TB Elimination. He provided an update on the implications of DR-TB globally on infection control in the United States. An outbreak of DR-TB occurred in South Africa in 2006 followed by a patient with highly DR-TB who boarded an international flight in Atlanta in 2007.

Anti-TB drugs are grouped into ten major classes. Drug-susceptible TB is treated with first-line drugs in four classes, while DR-TB is treated with second-line drugs in six classes. Second-line drugs are less effective, more toxic and expensive than first-line drugs. Second-line drugs also are irrelevant for drug-susceptible TB.

With both multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB), patients are resistant to the two most important classes of first-line drugs (isoniazid and rifampicin), but resistance to pyrazinamide and ethambutol is possible or likely. XDR-TB is a subset of MDR-TB. XDR-TB patients also are resistant to the three most important classes of second-line drugs (aminoglycosides, capreomycin and quinolones), but resistance to thioamides, cycloserine and PAS is possible or likely.

The Green Light Committee (GLC) was established to scale up access to second-line drug treatment to curtail the spread of MDR-TB globally and prevent the development of additional resistance. From 2000-2009, GLC approved 115 projects in 72 countries that demonstrated capacity to administer quality assured drugs in accordance with published criteria. To date, 64,447 patients have received treatment under the GLC program. Despite this progress, however, the 2006 Nathanson, *et al*. study reported second-line drug resistance in virtually all of the GLC sites.

To determine the global prevalence of MDR-/XDR-TB, CDC analyzed data submitted by laboratory directors in the Supranational TB Reference Laboratory Network. Of 17,690 isolates tested for second-line drug resistance from 2000-2004, 3,520 (or 20%) had MDR-TB. Of the isolates with MDR-TB, 347 (or 10%) also had XDR-TB. CDC's data analysis demonstrated that

XDR-TB is a global phenomenon. CDC published these data in the March 24, 2006 edition of *Morbidity and Mortality Weekly Report*.

The 2006 Gandhi and Moll, *et al.* study showed that of 1,539 patients with isolates submitted from a hospital in KwaZulu-Natal, South Africa, 544 (or 35%) were culture-positive for *Mycobacterium tuberculosis* (*M.tb*). Of the culture-positive patients, 221 (or 41%) had MDR-TB based on resistance to isoniazid and rifampicin. Of the MDR-TB patients, 53 (or 24% of MDR-TB patients and 10% of culture-positive patients) had XDR-TB based on resistance to all tested drugs.

The mortality of XDR-TB in South Africa was extraordinary with deaths in 52 of 53 patients (or 98%). After sputum collection, the median survival time was 16 days with a range of 2-210 days. Of the 53 XDR-TB patients, 51% had no prior TB treatment, 64% were previously hospitalized, and the majority had an identical *M.tb* spoligotype. All 44 XDR-TB patients who were tested for HIV were positive. The South African experience was similar to HIV-related MDR-TB outbreaks that occurred in the early 1990s in the United States. With the exception of one hospital, mortality ranged from 72%-93% with a median survival time of 4-16 weeks after diagnosis.

The World Health Organization and the International Union Against Tuberculosis and Lung Disease published a report in 2008 on the estimated annual incidence of MDR-TB based on 274,000 cases tested in 116 countries. The data showed that MDR-TB accounted for ~5% (or 489,139 cases per year) of the global TB burden from 1994-2006. The 2006 Zignol, *et al.* study showed that China and India accounted for the highest incidence of MDR-TB (or >500,000 cases) due to the large populations of these countries.

The global incidence of MDR-TB reflects a similar trend in the United States. The number of TB cases in U.S.-born persons steadily declined from 1993-2008, but increased in foreign-born persons (FBP) in the United States over the same period. FBP currently account for >50% of TB cases in the United States and also have much higher proportions of primary isoniazid resistance and primary MDR-TB than U.S.-born persons. CDC data have not shown a significant downward trend of XDR-TB (as defined by initial drug susceptibility tests) in the United States after 1993.

Hmong refugees who were newly resettled from Thailand in 2004-2005 were directly linked to the diagnosis of five MDR-TB cases in California. Based on this outbreak, CDC revised its overseas TB screening guidelines for all immigrants and refugees who apply for U.S. immigration.

CDC recently completed an investigation of a TB outbreak in 2008-2009 among residents and staff in an assisted living facility for mentally handicapped persons in Duval County, Florida. The outbreak emphasized that despite the tremendous success of screening guidelines for the prevention of TB, the risk for transmission in U.S. healthcare settings continues to be a problem. CDC is continuing to lead TB prevention efforts at the national level by publishing supplemental information, frequently asked questions and a TB risk assessment worksheet.

Dr. Cegielski concluded his update by thanking HICPAC and the broader infection control community for applying vigorous infection control practices. These interventions have played a tremendous role in markedly decreasing institutional transmission of TB and TB incidence in the United States. However, highly DR-TB that has emerged as a global public health threat is reflected in the United States among visitors, immigrants and refugees. The potential for transmission in healthcare settings requires continued vigilance.

In preparation of responding to an outbreak of highly DR-TB in the United States, Dr. Cegielski urged HICPAC to support ongoing efforts to make rapid molecular diagnostic tests for DR-TB more widely available. He explained that these tests can rapidly produce drug susceptibility results in <24 hours rather than the one-month turnaround time with liquid culture. At this time, only a few laboratories offer rapid molecular diagnostic testing services within their states because the Food and Drug Administration has not approved these methods for use nationally.

Dr. Bell's position was that the emergence of highly DR-TB and the potential for transmission in U.S. healthcare settings would not require immediate changes to current infection control guidelines at this time. However, he emphasized that HICPAC would periodically revisit this issue to determine whether guidelines should be updated at some point in the future.

Dr. Bell further noted that CDC and HICPAC would need to be prepared with an appropriate and expeditious response if an outbreak of highly DR-TB caused deaths in a U.S. healthcare facility. He confirmed that Dr. Cegielski's slides would be distributed to HICPAC in preparation of future discussions on this issue.

HICPAC thanked Dr. Cegielski for presenting his important update on DR-TB. The members agreed that persistent vigilance and continued monitoring of the incidence and epidemiologic characteristics of TB patients in U.S. healthcare facilities are critical.

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 February 11-12, 2010 meeting:

- Joan Blanchard, RN, BSN, MSS, CNOR, CIC (Association of periOperative Registered Nurses) (AORN)
- Barbara DeBaun, MSN, RN, CIC (Association of Professionals of Infection Control and Epidemiology, Inc.) (APIC)
- Shirley Paton, RN, MN (Public Health Agency of Canada) (PHAC)
- Sanjay Saint, MD, MPH (Society of Hospital Medicine) (SHM)
- Rachel Stricof, MPH, CIC (Advisory Council for the Elimination of Tuberculosis) (ACET)
- Charles Huskins, MD, MSc (Infectious Diseases Society of America) (IDSA)
- Lori Harmon, RRT, MBA (Society of Critical Care Medicine) (SCCM)
- Elizabeth Bancroft, MD (Council of State and Territorial Epidemiologists) (CSTE)
- Alexis Elward, MD (Advisory Committee on Immunization Practices) (ACIP)

- William Baine, MD (Agency for Healthcare Research and Quality)
- Gary Roselle, MD (Department of Veterans Affairs) (VA)
- Mark Russi, MD, MPH (American College of Occupational and Environmental Medicine) (ACOEM)
- Lisa McGiffert (Consumers Union)
- Sheila Murphey, MD (Food and Drug Administration) (FDA)
- Robert Wise, MD (The Joint Commission)

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

- Ms. Blanchard reported that AORN continues to be concerned about the lack of infection control information disseminated to ambulatory surgical centers. To address this issue, AORN is convening workshops, broadcasting webinars and continuing its discussions with these facilities. AORN updated the *AORN Syntegrity: A Standardized Perioperative Framework* brochure with the following materials: (1) 2010 Surgical Care Improvement Project measures and associated documentation values; (2) 2010 perioperative criteria required by The Joint Commission and other accreditation organizations that are relevant to Standardized Perioperative Framework (SPF) data values; and (3) new CMS data released in 2010. The fifth phase of care in SPF will be a 30-day follow-up of patients post-operatively for infection control. AORN will publish the 3rd edition of its Perioperative Nursing Data Set in March 2010.

- Ms. DeBaun reported that APIC administered an economic survey in the spring of 2009 with responses by ~2,000 members. The survey showed that 41% of respondents experienced budget cuts in their organizations in the previous 18 months. These decreases particularly affected the ability of APIC members to travel to important conferences and participate in continuing education activities. In an effort to address this issue, APIC is developing "APIC Anywhere" to provide onsite virtual learning courses for practitioners who are unable to travel due to budget constraints.

- Ms. Paton reported that PHAC is developing a new TB guideline to facilitate Canada's response to emerging TB-related issues. PHAC recently launched a new initiative on antimicrobial resistance. PHAC's H1N1 activities have resulted in the development of a point-of-care risk assessment that is designed to assist persons in making decisions on appropriate situations to use masks and respirators.

- Dr. Saint reported that SHM is continuing to collect data on hospital medicine trends. The number of hospitalists in the United States dramatically increased from ~500 in 1996 to >30,000 in February 2010. The proportion of U.S. hospitals that have hospital medicine groups also significantly increased from <5% in 1996 to ~68% at this time. SHM is continuing to promote its role as a facilitator in effectively implementing evidence on inpatient practices.

- Ms. Stricof reported that during the next ACET meeting on March 2-3, 2010, an update would be presented on guidelines for "TB Prevention and Control Measures for U.S. Health Care Workers and Volunteers Serving in High-Risk Settings for Exposure to *Mycobacterium Tuberculosis*." Because ACET's guideline would be linked to HICPAC's HCP Infection Control Guideline, ACET would welcome input from HICPAC on key issues for this subpopulation, such as pre-travel screening and education, approaches to minimize risk while overseas, and post-travel interventions. Based on HICPAC's agreement, Ms. Stricof confirmed that she would share an early draft of ACET's guideline with HICPAC.

- Dr. Huskins reported that Dr. Stanley Deresinski, Chair of the IDSA Standards and Practice Guidelines Committee, and other IDSA leadership participated in a conference call with Drs. Bell and Brennan in December 2009. The purpose of the conference call was to improve and streamline interactions between IDSA and HICPAC on guidelines of mutual interest. The plan that was drafted to clarify IDSA's participation in HICPAC's guideline development process would be distributed to HICPAC for review and comment.

- Ms. Harmon reported that SCCM's "Surviving Sepsis Campaign" guidelines are now in a two-year revision process. The Guidelines Committee met during the SCCM Annual Congress in January 2010 to determine whether changes should be made to bundles. To date, ~21 organizations have expressed strong interest and support in either endorsing the guidelines or collaborating with the SCCM Guidelines Committee.

- Dr. Bancroft reported that CSTE would convene its annual conference in Portland, Oregon on June 6-10, 2010 with a strong focus on HAIs. The role of state and local health departments in preventing and tracking HAIs would be a key topic during the conference as well. The *Epidemiology Capacity Assessment Report* that was recently published showed a 10% decrease in the workforce of local epidemiologists in state and local health departments over the three-year time period of 2006-2009. Despite ARRA funding and support, additional budget cuts in the future would further limit the capacity of state and local health departments to respond to hospitalists.

- Dr. Elward reported that the ACIP Pertussis Workgroup would hold discussions with HICPAC members and liaisons regarding post-exposure prophylaxis of HCP who have been vaccinated against pertussis. The ACIP Hepatitis Workgroup would present an update to HICPAC on hepatitis B vaccination of adults at a future meeting. The update would include ACIP's cost-effectiveness analysis that supports specific populations to vaccinate. ACIP would provide HICPAC with its updated guidance on immunization of HCP.

- Dr. Roselle reported that the VA primarily would focus on antimicrobial stewardship activities in 2010. The VA would sponsor three meetings across the country to launch the education phase of this initiative. The VA is continuing to implement its MRSA program and plans to expand this effort in the near future to include *Clostridium difficile*.

The VA Secretary has prioritized HAIs as one of the VA's most prominent areas in its "Transition Initiatives for the 21st Century."

In preparation of the business session on the following day, Dr. Bell asked the HICPAC members to remain in the meeting room for a brief offline discussion with Dr. Brennan. With no further discussion or business brought before HICPAC, Dr. Bell recessed the meeting at 4:35 p.m. on February 11, 2010.

Status Report on HICPAC Guidelines and Documents: SESSION 2

Dr. Bell reconvened the HICPAC meeting at 8:58 a.m. on February 12, 2010 and yielded the floor for status reports on HICPAC's remaining two documents.

***Neonatal Intensive Care Unit (NICU) Infection Prevention Guideline*.** Dr. Alexis Elward is a HICPAC member and chair of the workgroup. She reported that the core writing group is represented by HICPAC, CDC, the University of Pennsylvania Health System Center for Evidence-Based Practice, and a neonatologist who will be named in the near future.

Dr. Elward outlined the roles and responsibilities of the workgroup. The core writing group will have primary responsibility for reviewing the literature and abstracts and extracting data into evidence tables. Renowned neonatologists and other experts from professional societies will be engaged in the future to conduct an independent review of the guideline.

A neonatologist will be identified to serve as a co-author on the core writing group. This expert will lend credibility to the HICPAC guideline; help to co-brand the HICPAC guideline with the NICU infection prevention position paper that is currently being developed by the American Academy of Pediatrics (AAP); and promote the HICPAC guideline as a practical and feasible document for use by neonatologists. AAP is assisting the workgroup in identifying the neonatologist who will serve as a co-author.

Dr. Elward informed HICPAC of the progress the workgroup has made since the November 2009 meeting. The workgroup focused its efforts in three major areas: (1) consulting with AAP to understand the scope and methodology of its position paper on NICU infection prevention; (2) identifying members of the workgroup; and (3) and revising the timeline to produce the HICPAC guideline.

The workgroup drafted key research questions for the guideline based on literature reviews, abstracts presented at a Pediatric Academic Society meeting, a survey administered by the SHEA Pediatric Special Interest Group, and discussions with neonatologists who are members of the Child Health Corporation of America's Children's Hospital Neonatal Consortium. The workgroup distributed its key research questions to AAP members who are writing the NICU infection prevention position paper for the AAP Infectious Diseases Committee and the Fetus and Newborn Committee.

The workgroup grouped the key research questions into four categories. The key research questions for "viral infections" are: (1) What are the most effectives strategies to prevent respiratory viral infections in NICU patients? (2) What are the best methods for detection of an outbreak of respiratory viral pathogens in NICUs? (3) What are the best methods for control of respiratory viral pathogens in NICUs?

The key research questions for "MRSA" are: (1) What are the patient and environmental characteristics associated with MRSA colonization in NICU patients? (2) What are the most effective surveillance strategies? (3) What are the most effective control measures? The workgroup is currently developing key research questions for the categories of "CLABSI prevention" and "invasive candidal infection prevention."

Dr. Elward noted that similar to the HICPAC guideline, the AAP NICU infection prevention position paper also is being developed in an evidence-based review process. However, the scope and content of the AAP position paper will be different from the HICPAC guideline in some areas. For example, the AAP position paper will not address viral infections or MRSA colonization, but will include guidance on CLABSI prevention, hand hygiene, *Clostridium difficile* and antibiotic use. The methodology of the two papers also will be different because the HICPAC document will be based on the CAUTI guideline. The workgroup is continuing its efforts to co-brand the AAP and HICPAC documents for the two groups to produce a joint guideline.

Dr. Elward highlighted two issues in the guideline that possibly would need special attention by HICPAC during the discussion, review and approval process. First, HCP who work while sick most likely would be a contentious issue. Strong evidence from randomized controlled trials or well-designed studies is lacking to support a Category IA recommendation in this area. The workgroup has acknowledged the need to reconcile this section with HICPAC's HCP Infection Control Guideline. Second, contact precautions and appropriate interactions for colonized family members who visit infants in NICUs would be another controversial topic.

Dr. Elward concluded her update by presenting the workgroup's revised timeline to draft the NICU infection prevention guideline. In April 2010, the guideline team members would be confirmed and given writing assignments. In June-July, 2010, the key research questions would be finalized and circulated to the guideline team. The literature search would be initiated.

In September 2010, the abstract and full text review would be completed. In November 2010, data would be extracted into initial evidence tables. In February 2011, the data extraction process would be finalized and initial narrative summaries would be written. In June 2011, the narrative summaries would be finalized and recommendations would be drafted. In November 2011, the recommendations would be finalized and presented for a formal HICPAC vote.

HICPAC commended the workgroup on the tremendous progress that has been made since the November 2009 meeting on the NICU infection prevention guideline. The members advised the workgroup to consult with and use Dr. Rachel Gorwitz as a resource in its ongoing efforts to develop the guideline. Dr. Gorwitz conducted a study on the incidence of MRSA in NICUs.

***Ambulatory Care Document*.** Dr. Bell began his update by reminding HICPAC of the reasons to develop a well-organized ambulatory care guidance document. A rigorous evidence-based guideline would fill existing data gaps in the ambulatory care setting. Multiple outbreaks related to incorrect injection practices demonstrate the critical need to provide ambulatory care settings with solid recommendations. The number of ambulatory care facilities is rapidly increasing. CDC has strengthened its partnership with the Health Resources and Services Administration to address infection control practices in ambulatory care settings at the national level.

Dr. Bell reported that DHQP drafted a preliminary outline to guide the development of the ambulatory care document. DHQP used the CMS survey tool that was created for ambulatory surgical clinics as a model in drafting the outline. The CMS survey tool is a well-focused compilation of existing guidelines that emphasizes standard precautions to use for care in all settings (*i.e.*, hand hygiene, appropriate glove use, safe infection practices, respiratory hygiene cough etiquette, disinfection and sterilization, and environmental hygiene).

Dr. Bell explained that the ambulatory care document would be based on existing guidelines to provide physicians' offices, ambulatory surgical centers and other users with a list of evidence-based recommendations. However, these guidelines would be cited in the ambulatory care document for users to review the background, supporting data and references. Dr. Bell asked for HICPAC's input on the usefulness and appropriateness of DHQP's proposed approach to develop the ambulatory care document. He confirmed that the draft outline would be distributed to HICPAC prior to the next meeting.

HICPAC fully supported DHQP's proposed approach to develop the ambulatory care document. The members agreed that distilling existing recommendations into one source would tremendously benefit the field. The HICPAC members made several suggestions to DHQP on the actual content of the document.

- The ambulatory care document should describe minimum standards for education, training and staff competency in sterilization and disinfection as well as other key areas. The document also should be developed with a companion assessment tool to evaluate the performance of ambulatory care settings in meeting the minimum standards. Due to differences among outpatient settings in terms of the equipment, instruments, products and methods used, the assessment tool should be designed as a template for facilities to tailor in meeting their specific needs. Resources that should be utilized in developing the minimum standards and assessment tool include Multi-Society Guidelines, FDA Public Health Alerts and the VA guidance document.
- For practical purposes, the ambulatory care document should be developed as a position paper rather than a formal HICPAC guideline with the GRADE system. HICPAC would be challenged in developing minimum standards for the ambulatory care setting because the literature does not provide clear evidence in this area. The position paper should be accompanied by helpful toolkits and include HICPAC's expert opinions, guidance and experience in inpatient settings for areas that are not supported by robust studies.
- HICPAC's existing evidence-based recommendations with the GRADE system for healthcare facilities should be included in the ambulatory care document because most

of these recommendations are applicable to all healthcare settings. This approach would hold ambulatory care settings accountable to implementing standard practices.

- The target audiences should be clearly defined because these groups will influence the content of the ambulatory care document and toolkits. On the one hand, states and professional societies would understand HICPAC's recommendations with the GRADE system and the supporting evidence for this guidance. On the other hand, the average practicing physician in an outpatient setting would have no knowledge of the GRADE system and would require a simpler document that clearly describes and emphasizes hand hygiene, disinfection and sterilization, and other standard practices. Different versions of the document and toolkits should be repackaged based on the two groups of target audiences (*i.e.*, regulators and investigators versus end-users who direct ambulatory surgical clinics).
- The ambulatory care document should contain guidance on employee health issues, particularly to help employees in protecting themselves against bloodborne pathogens and respiratory viruses.
- Basic guidelines developed by AORN and APIC should be used as key resources in developing the ambulatory care document because this guidance applies to both hospital-based settings and freestanding ambulatory surgical centers.
- After the ambulatory care document is drafted, DHQP should convene representatives of medical boards and key stakeholder groups in the field to explore effective strategies to ensure implementation of the recommendations. Engagement of medical boards will be critical for implementation of the document because these groups are the only governing body or regulatory authority for the vast majority of physicians' offices and outpatient clinics. Moreover, many physicians in outpatient settings have no affiliation with professional societies, but have regular contact with and are respectful of guidance from medical boards to change practices.

Dr. Bell made several remarks in follow-up to HICPAC's comments and suggestions. The ambulatory care document would contain a list of basic components that should be present in all outpatient settings. Professional societies and other organizations outside of HICPAC would develop the implementation tools, but the ambulatory care document would serve as the basis in creating these resources.

Dr. Bell agreed with HICPAC's suggestion for the ambulatory care document and toolkits to be designed as companion materials that DHQP and professional societies would release at the same time. He explained that DHQP would continue developing the ambulatory care document and would provide an update to HICPAC on a conference call. He noted that DHQP's goal is to complete the first draft of the document by the June 2010 HICPAC meeting.

Overview of Conflicts of Interest (COIs)

Mr. Jeffrey Hageman is an epidemiologist in DHQP and would begin serving as the new HICPAC DFO at the next meeting. He conveyed that due to HICPAC's tremendous progress in improving its guideline development process, other CDC entities outside of DHQP most likely

would adopt this methodology. CDC has acknowledged that a systematic approach with the same level of transparency would improve the development of guidelines across the agency.

Mr. Hageman noted that although transparency in the methodology for HICPAC guidelines has vastly improved, COI disclosures has not been as transparent to the same degree. Core writing groups of HICPAC guidelines typically include HICPAC members, CDC staff and external experts. However, a systematic approach has not been created to capture COI disclosures for co-authors of guidelines in a transparent manner.

As a starting point in improving this area, DHQP reviewed the uniform disclosure format developed by the International Committee on Medical Journal Editors and other COI models created by the National Academy of Sciences and federal agencies. DHQP adapted specific components of these tools to draft a standardized COI disclosure form for co-authors of HICPAC guidelines.

Mr. Hageman confirmed that he would share DHQP's draft standardized COI disclosure form for HICPAC co-authors prior to the next meeting. He announced that similar to the methodology for HICPAC guidelines, the COI form most likely would be adopted by other CDC entities outside of DHQP as well.

Dr. Bell provided additional details on COIs from two different perspectives. From a public meeting perspective, HICPAC members should consider their potential COIs on a point-by-point basis as topics are introduced for formal votes. The members should publicly state any real or perceived COIs for the record and recuse themselves from participating in those discussions or voting on those issues.

From a guideline perspective, COIs must be addressed before members of professional societies or other external experts are invited to serve as co-authors. COI disclosures by co-authors will be a part of HICPAC guidelines and will be particularly scrutinized when documents are published in the *Federal Register* for public comments. As a result, COIs must be transparent to ensure credibility of HICPAC guidelines.

HICPAC Business Session

***H1N1 Influenza*.** Dr. Bell reported that CDC is developing a process to reevaluate its existing interim guidance on H1N1 influenza, but he was asked whether HICPAC should undertake this effort. DHQP explained that HICPAC is on record with its position regarding H1N1 influenza. As a result, CDC confirmed that HICPAC's recommendations would be considered in the reevaluation process. Dr. Bell would continue to provide regular updates to HICPAC as CDC moves forward in reevaluating its interim guidance on H1N1 influenza.

***Abbreviated Orientation Session*.** Dr. Bell described the range of HICPAC products for the benefit of the three new members. One, HICPAC's evidence-based guidelines are created based on a systematic review of the literature. The guidelines are published in the public

domain and can be reproduced. HICPAC adopted the GRADE system to increase the level of rigor for federal guidelines. DHQP has an existing relationship with the University of Pennsylvania Health System Center for Evidence-Based Practice to support the development of guidelines with the GRADE system.

Two, HICPAC's guidance documents are created based on expert opinion due to the absence of a rigorous evidence basis. HICPAC engages in thoughtful discussion to state its position. An example of this product was HICPAC's thorough review of the available evidence on H1N1 and the release of a position statement on this issue.

Three, HICPAC's "utility tools" are created based on the positions and experiences of HICPAC members. These resources are designed to provide a contextual framework and background to avoid negative consequences in the field. For example, HICPAC's guidance document on public reporting of HAIs and MDRO legislation document describe issues to consider in these areas and outline potential unintended consequences to avoid. HICPAC's tools have been extremely valuable in helping states and local jurisdictions to develop products in a uniform manner for their specific needs.

Dr. Bell noted that HICPAC is continuing to address the challenge of striking a balance between developing detailed recommendations for the field and responding to requests from HHS to identify the most important infection control issues nationally based on a review of the evidence. He pointed out that HICPAC's close relationships with professional societies and other colleagues would continue to be critical in developing effective implementation tools for the field.

Dr. Brennan emphasized the importance of explicitly stating that methods must be appropriate to HICPAC when professional societies and other stakeholders express an interest in HICPAC's involvement in developing or endorsing guidelines. He raised this point due to the difficulties in using the current GRADE system to update the previous CRBSI guideline. Dr. Cardo fully agreed with Dr. Brennan's comments. She raised the possibility of developing written criteria and requirements for HICPAC to accept invitations to be involved in outside guideline activities.

***HICPAC Votes*.** Dr. Brennan conveyed that based on his offline discussion with HICPAC members after the meeting on the previous day, agreement was reached to table the formal vote on the draft CRBSI guideline. He pointed out that the document is completed for the most part and should be finalized within the next month. Dr. Brennan was pleased that during the extensive discussion on the previous day, HICPAC reached consensus on the vast majority of public comments submitted. However, he emphasized the need for additional time for HICPAC to further discuss and refine the recommendations.

Dr. Brennan noted that participation in the meeting via conference call by the HICPAC Chair and several members, liaisons and *ex-officios* did not provide an adequate opportunity for HICPAC to conduct a rigorous decision-making process and thoroughly weigh the evidence of the recommendations. Moreover, HICPAC was uniquely challenged by the CRBSI guideline due to the difficulties in using the current GRADE system to update a document that was developed under the old categorization system. As a result, HICPAC must give strong attention

to public comments that were submitted regarding omitted references, unresolved issues and the process to weigh the evidence.

Dr. Brennan was well aware that tabling HICPAC's formal vote on the CRBSI guideline would delay dissemination of the document to the field. However, his position was that additional time for a more thorough review would be in the best interest of the overall guideline production process. This approach also would allow HICPAC to release an evidence-based guideline that would generate confidence in the recommendations by the infection control community and the public at large.

Dr. Brennan announced that during a conference call earlier in the day, DHQP leadership supported his proposal to table HICPAC's formal vote on the CRBSI guideline. However, he confirmed that HICPAC's formal vote would be taken prior to the next meeting in June 2010.

Dr. Bell explained that the decision to table HICPAC's formal vote did not reflect the outstanding efforts of the writing group or the quality of the draft CRBSI guideline. He clarified that additional time would allow HICPAC to adhere to its charter of producing an evidence-based guideline, particularly for contentious issues.

***Meeting Format*.** Dr. Bell reported that the lengthy gaps in time between the February-June and June-November meetings have caused HICPAC to delay progress in finalizing guidelines and conducting other activities. As a result, DHQP is discussing the possibility of holding interim conference calls between the two meetings. Similar to face-to-face HICPAC meetings, the conference calls would be announced in the *Federal Register* and open to the public. Dr. Bell would update HICPAC on DHQP's progress in this area in the near future.

***Summary of Action Items*.** Dr. Brennan led HICPAC in a review of the action items that were raised over the course of the meeting.

- Dr. Brennan will meet with Dr. Umscheid to address the unresolved issues related to the public comments submitted on the CRBSI guideline. Dr. Brennan will convey these findings to Dr. Bell and Mr. Hageman during a conference call in February or March 2010.

- Dr. Brennan will participate in a conference call with Mr. Hageman to discuss the completion of the standardized COI disclosure form for co-authors of HICPAC guidelines. The COI form will be included in the packet of materials that will be given to the three new HICPAC members during the orientation session in June 2010.

- Dr. Brennan will participate in planning activities with Dr. Bell and Mr. Hageman to address logistical issues related to convening HICPAC's public conference call prior to the June 2010 meeting.

- Dr. Bell and Mr. Hageman will draft the background section of the ambulatory care guidance document for review and discussion by HICPAC.

- The HICPAC members will participate in the following ongoing or new activities:
  - — Continue to update the HCP Infection Control Guideline. [Drs. Lundstrom and McCarter, Mr. Olmsted]
  - — Attend the orientation session for new HICPAC members and review background materials. [Drs. Bratzler, Huang and Ostroff]
  - — Develop a toolkit for professional societies to implement HICPAC guidelines at the bedside (beginning with the CAUTI Guideline). [Dr. Pegues]
  - — Assist DHQP in developing the ambulatory care guidance document. [Drs. Bratzler and Pegues]
  - — Continue to revise the CRBSI Guideline in response to public comments submitted. [Ms. Burns]
  - — Continue to develop the NICU Infection Prevention Guideline. [Dr. Elward]

Closing Session

The next HICPAC meeting would be held on June 17-18, 2010 in Atlanta, Georgia. Dr. Bell thanked the HICPAC members, *ex-officios*, liaisons and members of the public who participated in the meeting via conference call for their patience with the technical difficulties.

With no further discussion or business brought before HICPAC, Dr. Bell adjourned the meeting at 10:05 a.m. on February 12, 2010.

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

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Date

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