

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



**CENTERS FOR DISEASE
CONTROL AND PREVENTION**

**Healthcare Infection Control Practices
Advisory Committee
November 13-14, 2007
Washington, DC**

DRAFT Record of the Proceedings

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ATTACHMENT 1

List of Participants

[Attendees joined the meeting in person or by conference call]

HICPAC Members

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

Designated Federal Official

Dr. Michael Bell, Executive Secretary

Ex-Officio and Liaison Members

Ms. Nancy Bjerke (Association of Professionals of Infection Control and Epidemiology, Inc.)
Dr. William Baine (Agency for Healthcare Research and Quality)
Ms. Joan Blanchard (Association of periOperative Registered Nurses)
Ms. Marion Kainer (Council of State and Territorial Epidemiologists)
Ms. Louise Kuhny (Joint Commission)
Dr. Lisa Maragakis (Society for Healthcare Epidemiology of America)
Ms. Lisa McGiffert (Consumer's Union)

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

CDC Representatives

Dr. Denise Cardo, DHQP Director
Scott Fridkin
Carolyn Gould
John Jernigan
Chesley Richards
Benjamin Schwartz
Angela Scott

Guest Presenters and Members of the Public

Rajender Agarwall (University of Pennsylvania Health System Center for Evidence-Based Practice)
Ashish Atreja (Cleveland Clinic)
Dale Bratzler (Oklahoma Foundation for Medical Quality)
Gretchen Kuntz (University of Pennsylvania Health System Center for Evidence-Based Practice)
Craig Umscheid (University of Pennsylvania Health System Center for Evidence-Based Practice)

EXECUTIVE SUMMARY

During the opening session of the Healthcare Infection Control Practices Advisory Committee (HICPAC) meeting on November 13-14, 2007, no members declared any new conflicts of interest for the record.

A HICPAC workgroup provided a progress report on the "HICPAC/APIC Surveillance Definitions for Home Health Care and Home Hospice Infections." HICPAC commended the workgroup on developing a succinct and extremely impressive document. HICPAC made several suggestions for the workgroup to consider in further revising the definitions.

HICPAC **unanimously approved** two consensus recommendations on the home healthcare definitions. All of the "common skin containment" text in 2(b) and 3(b) would be deleted from the laboratory-confirmed bloodstream infections definition. The clinical sepsis definition would be retained, but "a patient aged <1 year" would be changed to "children <1 year of age."

HICPAC **unanimously approved** adoption of the sections of the home healthcare definitions that did not require revision. HICPAC would call for a subsequent vote on the final iteration of the document after the clinical sepsis and bloodstream infection (BSI) sections were revised.

A HICPAC workgroup provided a progress report on the catheter-associated urinary tract infection guideline. The update included the workgroup's three key questions to guide the development of the document; search strategy to review databases; results of the database search; exclusion criteria; evidence tables; and timeline and targets.

HICPAC commended the workgroup on conducting an invaluable literature review and completing a tremendous amount of work since its initial conference call in May 2007. However, HICPAC was extremely concerned that its annual budget does not include specific funds to update guidelines. HICPAC made several suggestions for the workgroup to consider in further refining the literature review.

A HICPAC workgroup provided a progress report on the norovirus guideline. The update included the workgroup's five key questions to guide the development of the document, results of the guideline search, and next steps. HICPAC commended the workgroup on its outstanding efforts to date. HICPAC made several suggestions for the workgroup to consider in further refining the norovirus guideline. HICPAC **unanimously approved** the workgroup's five key questions, but with a revision to question 3.

CDC provided an update on the Prevention EpiCenters Program. A summary was provided on five major EpiCenter projects: (1) automated detection of BSIs; (2) automated detection of *Clostridium difficile*-associated disease; (3) electronic measures of hospital antimicrobial utilization; (4) use of Medicare claims to identify hospitals with high rates of surgical site infections (SSIs) following cardiac surgery; and (5) alternative approaches to inpatient SSI surveillance.

The Oklahoma Foundation for Medical Quality provided an extensive overview of process measures for HICPAC to consider in incorporating into guidelines and recommendations in the future. To guide the decision-making process, HICPAC was urged to be mindful of the challenges and limitations associated with process measures, such as information technology and programming costs for ongoing maintenance of process measures, rapidly changing science, and the timeline to modify process measures.

A HICPAC workgroup provided a progress report on the multidrug-resistant organism (MDRO) document. The update included the purpose and scope of the MDRO document; issues that were considered and discussed; and the workgroup's recommendations. HICPAC commended the workgroup on developing a document to assist infection control practitioners in creating MDRO profiles for their respective facilities and identifying appropriate measurements for assessments. HICPAC made several suggestions for the workgroup to consider in the final revisions of the MDRO document.

CDC provided a briefing on the August 2007 partners consultation that was held to discuss the healthcare-associated infection (HAI) elimination effort. The update included key recommendations that were raised during the consultation; actions CDC has taken to date to respond to feedback; and opportunities, challenges and next steps in the HAI elimination effort.

HICPAC was extremely pleased that CDC shifted the focus from "zero tolerance" to "elimination" of HAIs. HICPAC made several suggestions for CDC to consider in the ongoing HAI elimination effort. HICPAC **tabled** a motion to compile and submit evidence to the Joint Commission on standards on processes to address three HAIs: ventilator-assisted pneumonia, SSIs and catheter-based BSIs.

CDC proposed a new process in which HICPAC would establish workgroups to develop and disseminate one- to two-page public policy documents to address important issues that have an impact on health policy. HICPAC extensively discussed the proposed process and agreed to establish two new workgroups with the following charges: develop a public policy memorandum advocating for the HAI elimination effort and create model legislation for methicillin-resistant *Staphylococcus aureus*.

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

CDC provided a comprehensive overview of the shared responsibility for influenza preparedness. The presentation included an extensive summary of CDC's guidance on prioritization for pandemic influenza vaccine.

HICPAC made several suggestions on the guidance and **unanimously approved** the following language: "HICPAC endorses the recommendations for antiviral prophylaxis of healthcare workers (HCWs) as outlined in the guidance. However, HICPAC recognizes the need for further study and discussion to determine if the principle of shared responsibility can effectively ensure protection for HCWs and the critical infrastructure. Any approach must compliment a strategy of vaccination, production, distribution and administration."

A HICPAC workgroup provided a progress report on the most recent version of the electronic health record (EHR) white paper. HICPAC commended the workgroup on developing an outstanding document despite the lack of rigorous, peer-reviewed and published studies on EHRs. HICPAC did not formally endorse the EHR white paper based on concerns raised by several members.

The workgroup agreed to make the following revisions based on input by HICPAC and the Division of Healthcare Quality Promotion. An introductory paragraph would be added before the background section to describe the nature of the document; emphasize the lack of evidence to make prescriptive recommendations; and clearly state that the document is not an evidence-based guideline. Broad recommendations would be added to the conclusions section in either narrative or tabular form.

A progress report was provided on development of the Infectious Disease Society of America (IDSA)/Society for Healthcare Epidemiology of America (SHEA) guidelines. The guidelines were developed to address relevant device-associated infections and multidrug-resistant pathogens.

HICPAC was in favor of supporting rather than formally endorsing the IDSA/SHEA guidelines. HICPAC **unanimously approved** the following motion: HICPAC would ask the IDSA/SHEA HAI Guideline Committee to (1) allow HICPAC to formally review the next iteration of the draft guidelines; (2) provide feedback within a two-week period; (3) offer a brief editorial to accompany the publication of the guidelines in *Infection Control and Hospital Epidemiology (ICHE)*; and (4) submit a one-page commentary to explain the role of the IDSA/SHEA guidelines into existing guidelines. Following the motion, HICPAC agreed to direct its one-page commentary to *ICHE* rather than IDSA and SHEA.

HICPAC reviewed its business items that were raised over the course of the meeting. The next HICPAC meeting will be held on February 11-12, 2008 in Atlanta, Georgia.

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PRACTICES ADVISORY COMMITTEE
November 13-14, 2007
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Draft Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) National Center for Preparedness, Detection and Control of Infectious Diseases (NCPDCID), Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC). The proceedings were held in Washington, DC at the Hubert Humphrey Building on November 13, 2007 and at the Residence Inn Marriott on November 14, 2007.

Opening Session

Dr. Patrick Brennan, Chair of HICPAC, called the meeting to order at 9:06 a.m. on November 13, 2007. He welcomed the attendees to the proceedings and opened the floor for introductions. No members declared any new conflicts of interest for the record. The list of participants is appended to the minutes as Attachment 1.

Dr. Brennan clarified that several updates would be presented on HICPAC's documents and other activities on day 1 of the meeting. However, issues requiring formal action by HICPAC would be called for a vote on the following day.

Update on the Home Healthcare Definitions

Ms. Nancy Bjerke, HICPAC's liaison to the Association for Professionals in Infection Control and Epidemiology (APIC), pointed out that Draft D of the "HICPAC/APIC Surveillance Definitions for Home Health Care and Home Hospice Infections" was distributed to HICPAC for review. She noted key changes in the most recent version of the definitions.

The workgroup that was formed to lead this effort agreed to use CDC's published and shorter "home healthcare" definition. Agreement was reached to change "hospice care" to "home hospice care." Agreement was reached to define "fever" as a patient's temperature that is 2.4°F greater than the baseline temperature. However, one workgroup member supported the use of the McGeer definition of fever of 38°C/100.4°F. The "homebound" definition was removed because most patients are out of the home for appointments and other forms of care.

Agreement was reached on providing the full set of site definitions for institutions or infection control practitioners (ICPs) to determine those that would be appropriate for their designed surveillance systems. The definitions further recommended the selection of only those site definitions that could be solely attributed to the patient in either the home or hospice setting. Infections that could be acquired from or transmitted by healthcare workers (HCWs), such as influenza, were excluded from this definition.

Lower respiratory infections (LRIs), such as pneumonia and bronchitis, were combined into one definition under respiratory tract infections. The definitions note that patients who meet the criteria for LRI and have chest x-rays interpreted as pneumonia, probable pneumonia or the presence of an infiltrate are counted as pneumonia.

Laboratory-confirmed bloodstream infections (LCBSIs) were changed to clarify that patients must meet one of three criteria and additional laboratory information as outlined in the definitions. The LCBSI definitions contain the following language. Two coagulase-negative staphylococci that are drawn at different times and are not the same as evidenced by totally different susceptibility results might lead to overcalling infections simply because of their presence or the need for physicians to cover themselves.

Surgical site infections (SSIs) were retained in the document, but the statement was modified in the text and repeated in the site definitions. The workgroup recognized that the multiple categories and criteria for intravascular-associated infections were included in skin and soft tissue infections (SSTIs) and one definition would be sufficient.

The home healthcare definitions contain broad statements regarding surveillance activities, but the workgroup emphasized the need for clearer guidance to accompany the document. For example, APIC's updated "Recommended Surveillance Practices" were published in 2007 in the *American Journal of Infection Control (AJIC)*. The workgroup emphasized the need to resolve a number of details regarding the home healthcare definitions, including authorship, publication venues and dates, and the clearance process.

HICPAC commended Ms. Bjerke and the other workgroup members on developing a succinct and extremely impressive document. Several members made suggestions for the workgroup to consider in further revising the definitions.

- All of the "common skin containment" text in 2(b) and 3(b) should be deleted from the LCBSI definition. **[HICPAC CONSENSUS]**
- "Patient aged <1 year" should be changed to "children."
- Efforts should not be made to align the home health population with reporting requirements for the acute care setting.
- The clinical sepsis definition should be retained, but "a patient aged <1 year" should be changed to "children <1 year of age." A new clinical sepsis definition should be added for adolescent and adult populations. **[HICPAC CONSENSUS]**
- "Pathogen cultured" should be replaced with "pathogen protected" in the LCBSI definition.
- A footnote should be added to the LCBSI definition stating that "patients are encouraged to have two blood cultures." Ms. Teresa Horan, of DHQP, should be consulted to obtain appropriate language for the footnote.
- Text under "fever" in the clinical definition for sepsis should be changed to "or >38°C."
- The conversion factor in the National Healthcare Safety Network (NHSN) definitions should be included in the home healthcare definitions. This formula is used to calculate temperatures that are taken orally, rectally or from other sites.
- The definitions in the SSTI section should be clarified with the following header: "localized IV-associated infection."
- Catheter-associated infections should be specified with the following text: "(including the IV site of infections that do not have an associated bloodstream infection)."
- The definitions should give helpful guidance on the evaluation or readmission for sepsis to paraprofessionals who provide home health care. For example, explicit language could be included stating that "patients with these clinical signs and symptoms of sepsis should be taken to the hospital." This approach might play a significant role in ensuring that patients do not die at home with unrecognized sepsis.

Dr. Denise Cardo, Director of DHQP, clarified that HICPAC is not obligated to use the NHSN definitions in developing the home healthcare definitions. She urged HICPAC to consider the best criteria that would improve and strengthen the definitions. This approach might lead to an opportunity for HICPAC to assist DHQP in advancing the NHSN definitions.

Dr. Michael Bell, Executive Secretary of HICPAC, explained that final decisions have not been made at this point on the authorship, publication and availability of the home healthcare definitions. He confirmed that these issues would be discussed in more detail on the following day.

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

Dr. David Pegues, a HICPAC member, is leading the workgroup that was formed to update HICPAC's 1981 CA-UTI guideline. He covered the following areas in his update. The workgroup finalized three key questions after the June 2007 HICPAC meeting:

1. Who should and should not receive urinary catheters? The populations that were considered in this question included persons who would receive the most benefit from urinary catheters and persons at highest risk of UTIs or morbidity and mortality.
2. For persons who might require urinary catheters, what practices decrease their risk of infection? Issues considered for this question included catheter systems, antimicrobial impregnated catheters and management technologies to decrease the risk of infections associated with catheter site tear or catheter insertion. System changes to decrease the frequency of catheterization or increase earlier removal of these devices were discussed as well.
3. What are the best methods to manage CA-UTI complications?

The workgroup developed a search strategy to review the MEDLINE database. Search terms for "catheterization" were combined with search terms for "infection and obstruction" or "diagnostics and interventions." After duplicates were excluded, the analysis yielded 8,065 search results from MEDLINE and three other databases.

Of 8,065 potentially relevant studies, 6,976 were excluded based on title and abstract screening. Of 1,089 studies that were included for full text evaluation, 817 were retrieved and reviewed as of November 8, 2007. Based on the November 2007 review, 522 additional studies were excluded for the following reasons:

- The data were not in English.
- The data contained a meeting abstract only with no publication of full text.
- The data were not primary analytic research.
- The data were not relevant to one of the three key questions.
- The full text was published, but was not available for review.

The workgroup slightly modified the exclusion criteria by excluding *in vitro* studies, antimicrobial susceptibility studies and observational studies with no valid comparison from the analysis. Of ~170 studies that have been retrieved, reviewed and included in the analysis, data have been extracted from 129 studies. At this point, ~120 studies need further review and ~270 references are old and difficult to locate.

The workgroup created evidence tables to answer the three key questions, such as the impact of mental care for question 2. The workgroup intends to place all the included references in the evidence tables and use HICPAC's grade criteria to rate the quality of the evidence. The workgroup will then create data tables.

In terms of its timeline and targets, the workgroup is aiming to present the data to external experts for review, grade the strength of the evidence, and draft preliminary recommendations for presentation during the February 2008 HICPAC meeting. The workgroup is also hoping to finalize the recommendations and submit the updated CA-UTI guideline for publication in June 2008.

Dr. Pegues encouraged other HICPAC members to assist the workgroup in the labor-intensive process of reviewing all of the evidence tables and assigning formal evidence grades. He raised the possibility of the workgroup holding a face-to-face meeting with other HICPAC members and the external reviewers to conduct this activity.

Dr. Pegues concluded his update by acknowledging the outstanding efforts of the other workgroup members: Dr. Carolyn Gould of DHQP and Dr. Rajender Agarwall, Ms. Gretchen Kuntz and Dr. Craig Umscheid of the University of Pennsylvania Health System (UPHS) Center for Evidence-Based Practice.

Dr. Gould made two observations for HICPAC to consider in updating future guidelines. Additional resources should be allocated to locate and compile references because this activity will be the most time-intensive. The key questions, protocol and strategy to revise a guideline might need to be modified as references are located.

HICPAC commended the workgroup on conducting an invaluable literature review and completing a tremendous amount of work since its initial conference call in May 2007. However, several members were extremely concerned that HICPAC's annual budget does not include specific funds to update guidelines. A number of members made suggestions for the workgroup to consider in further refining the literature review.

- The workgroup's excellent literature review should be posted on the CDC web site for access by the public to ensure transparency. The availability of this information would provide a rationale and evidence base for the grading scheme of the recommendations.
- HICPAC should be mindful that the ranking scheme might be used to guide practice organizations.
- Detailed tables, a description of the rationale for the ranking scheme, and other additional evidence should be placed in an electronic appendix because several organizations would find this information to be extremely valuable.
- The literature review should be posted on a Cochrane wide site for wider access by the public.

- HICPAC should explore the possibility of collaborating with other evidence-based practice centers in the future that conduct systematic reviews for Medicaid and Medicare issues.

Update on the Norovirus Guideline

Dr. Kurt Stevenson, a HICPAC member, is leading the workgroup that was formed to develop HICPAC's norovirus guideline. He covered the following areas in his update. The rationale for developing the guideline is to respond to the high demand for this information from states and individual healthcare facilities and also to address the quality of the literature on norovirus.

The CA-UTI and Norovirus Workgroups are similar in two key areas. First, both workgroups are using a rapid and more streamlined approach to answer clinically focused questions and grade the quality of evidence. Second, both workgroups are using the valuable expertise of DHQP and UPHS staff in their activities.

The workgroup has held several conference calls to formulate its key questions, evaluate existing guidelines and review a number of academic databases. The workgroup agreed to structure the guideline with an introduction to provide a context for norovirus as a pathogen, its epidemiology, overall burden and economic implications.

The workgroup performed a guideline search and located 13 published practice guidelines on norovirus, including its public health consequences and outbreak management. Guidelines for cruise ships focusing on environmental management and in-house outbreak management of norovirus were located as well. Moreover, several emerging themes were identified during the guideline search for the workgroup to construct an analytical framework. However, the workgroup determined that none of the guidelines were based on systematic reviews of the literature.

Dr. Stevenson requested HICPAC's input on the workgroup's five key questions that are outlined below:

1. What patient characteristics increase or decrease the risk of norovirus infection in healthcare settings? The workgroup is focusing on several issues for this question, including asymptomatic shedding, post-infection immunity, specific populations at risk, infection prevention policies, education strategies, and food handling practices and policies.
2. What practices decrease the risk of norovirus outbreaks? The workgroup is focusing on several issues for this question, including hand hygiene, isolation precautions and policies, visitor policies, sentinel clinical surveillance,

management of group activities, environmental management, and rapid detection and infection control response to point sources or clusters.

3. What are the best methods to identify norovirus outbreaks in healthcare settings? The workgroup is taking several actions to address this question, such as developing clinical case definitions; creating a definition to identify viral gastroenteritis outbreaks or clusters; and determining the best laboratory practices in terms of the number of clinical specimens that should be selected, sent and analyzed.
4. What patient management strategies decrease the spread of norovirus? The workgroup is focusing on several issues for this question, including hand hygiene, isolation precautions, patient movement and transfer, personal protective equipment (PPE), education, visitor and patient activity restrictions, staff cohorting, and occupational health policies.
5. What environmental management strategies decrease the spread of norovirus? The workgroup is focusing on several issues for this question, including environmental cleaning agents, surface cleaning and disinfection, policies for clinical area enclosures and duration, persistence of norovirus in the environment, food handling policies, and patient admission restrictions.

Dr. Stevenson pointed out that the workgroup has completed the guideline search and developed its five key questions. The next steps will be for the workgroup to perform a literature search to identify the evidence base for each of the five questions, conduct an abstract and screening process, extract and synthesize data, develop evidence tables, and formulate recommendations. The workgroup hopes to complete all of these activities and finalize the literature search by the February 2008 HICPAC meeting.

HICPAC commended the workgroup on its outstanding efforts to date. Several members made suggestions for the workgroup to consider in further refining the norovirus guideline.

- The workgroup should take into account the change in terminology and the lack of sensitivity for detecting a true norovirus outbreak. The literature search should be designed to capture these issues.
- The workgroup should rigorously assess the quality of the guidelines that were retrieved to verify the presence of a strong evidence base.
- The workgroup should consider the difficult aspects of laboratory practices and develop metrics for these outcomes, such as high absenteeism of personnel, geographical differences among hospitals, and the capacity of surveillance systems to trigger early assessments. These issues should be captured in key questions related to the best methods to identify an outbreak, case definitions and laboratory issues.

- The workgroup should explore the possibility of adding another key question to determine the risk of nosocomial transmission of norovirus to HCWs.
- The workgroup should extract valuable public health messages from the norovirus guideline and distribute this valuable information to various web sites that consumers frequently access.
- The workgroup should revise question 4 to include occupational management strategies. This guidance could assist in ensuring that public health departments are notified of norovirus outbreaks.
- The workgroup should obtain information on actual, available and realistic assistance that public health laboratories can provide to healthcare facilities during a norovirus outbreak.
- The workgroup should focus the norovirus guideline on infection control in healthcare-related settings only. For example, norovirus recommendations for cruise ships should not be included in the guideline.
- The workgroup should structure the norovirus guideline with the ability to be translated into practice. This approach would help to ensure that the public has knowledge of its role in this effort and also understands the norovirus guidance and expectations from healthcare facilities.

Dr. Stevenson acknowledged that time constraints did not allow HICPAC to give detailed feedback on the five key questions. He confirmed that he would distribute the questions to HICPAC after the meeting for the members to provide the workgroup with more substantive input.

Update on the Prevention EpiCenters Program

Dr. John Jernigan, of DHQP, covered the following areas in his update. CDC established the EpiCenters in 1997 to directly collaborate with academic partners in addressing important scientific questions regarding the prevention of healthcare-associated infections (HAIs), antimicrobial resistance, and other adverse events related to healthcare. CDC funds a new set of EpiCenters every five years based on peer-reviewed applications.

Funding for the current EpiCenters began in February 2006 with investigators at the University of Utah, Ohio State University, Washington University-St. Louis, Rush University Medical Center, and Harvard Pilgrim Health Care. The 2006 program announcement called for the EpiCenters to collaborate in the following areas. First, direct or surrogate markers for HAIs and processes of care linked to infections would be identified and validated. The investigators would conduct this activity through automated retrieval processing and analysis of data from electronic health records or other electronic data systems commonly used in healthcare institutions.

Second, interventions or prevention programs in various healthcare programs that result in sustained reductions in HAIs and other adverse events would be identified and validated. Third, quantitative estimates of the economic impact of interventions and prevention programs would be developed.

The EpiCenter Steering Committee of CDC staff and the investigators acknowledged the need to urgently address measurement issues. These needs have been driven by emerging legislation, upcoming requirements by the Centers for Medicare and Medicaid Services (CMS), and consumer demand. The Steering Committee also emphasized the need to focus on the future of NHSN in terms of using electronic data to enhance new reporting measures.

Dr. Jernigan summarized five major EpiCenter projects. Project 1 focuses on "automated detection of BSIs." This initiative is designed to establish reliable and accurate algorithms that use electronic hospital data systems; estimate rates of BSIs due to central venous catheters; and determine the feasibility and acceptability of using the algorithms as a surrogate marker.

Four EpiCenter sites are participating in this project and have completed the initial data collection phase. Preliminary data showed sub-optimal correlation between electronically-derived measures and more routine surveillance measures based on CDC definitions. Based on these findings, the next phase of the project will focus on measuring interrelated reliability among ICPs.

The project will be broadened to a multi-center study to compare electronic algorithms, ICP-derived rates and a reference standard. The Steering Committee will meet on November 15, 2007 to discuss expanding the project to existing NHSN hospitals to assist in validating the electronic algorithms. CDC is optimistic that the final data will facilitate the development of more useful measures to rank actual infection rates of hospitals as determined by an expert reference standard.

Project 2 focuses on "automated detection of *Clostridium difficile*-associated disease." This initiative is designed to locate performance characteristics of surveillance methods that use ICD-9 discharge codes or electronic microbiology reports. The rates will be compared to those obtained by traditional infection control surveillance methods. All five EpiCenter sites are participating in this initiative and are currently analyzing data that have been collected to date.

Project 3 focuses on "electronic measures of hospital antimicrobial utilization." This initiative is designed to determine the feasibility of collecting computerized antimicrobial utilization data across multiple centers. The measures will be validated with chart reviews, actual direct observation of antibiotic administration, and other gold standard methods. Variation in antimicrobial utilization among physicians in different patient care units will be

measured as well. Three EpiCenter sites are participating in this initiative and have completed the initial data collection phase.

Preliminary data showed that the measures can be feasibly derived from electronic information systems. However, the measures demonstrated substantial variability in antimicrobial utilization rates between and within intensive care units (ICUs) over time. Further study is needed to better understand this variation and correlate the outcomes with appropriate measures. As a potential intervention, the EpiCenters are exploring the possibility of providing these data to prescribers through an ongoing feedback mechanism.

Project 4 focuses on the "use of Medicare claims to identify hospitals with high SSI rates following cardiac surgery." The initial phase of this initiative involved a pilot assessment of the specificity and sensitivity of claim-based indicators in EpiCenters that perform surveillance for post-coronary artery bypass graft (CABG) infections.

The EpiCenters are collaborating with CMS to review the national administrative database of each hospital in the country that performs CABG surgeries to further validate rankings based on the algorithms. CMS's Clinical Data Abstraction Centers will be used to review medical records. Of 45 hospitals used in the study, 15 will represent the lowest, middle and highest death files of post-CABG SSI rates according to the algorithms.

Project 5 focuses on "alternative approaches to inpatient SSI surveillance." This initiative is designed to build on activities conducted by the initial group of EpiCenter investigators. Markers were used for antibiotic exposure procedure codes and codes for readmission with infection to identify charts of patients who might be at high risk of having post-SSIs. The markers were validated across multiple EpiCenters following CABG surgeries, Caesarian sections, breast surgeries and total hip replacement. Efforts are underway to validate the markers following hysterectomies and total knee replacement. Plans are being made to expand this effort to focus on vascular and colorectal surgeries as well.

Initial data indicated that routine surveillance failed to detect SSIs. The focused case finding methodology based on the markers appeared to be more sensitive and efficient than routine surveillance. This approach identified a smaller population of charts of patients who had Surgical Care Improvement Project (SCIP) procedures to be reviewed. The methodology also showed promise in introducing standardization to case finding for SSIs following SCIP procedures.

Dr. Jernigan informed HICPAC that the EpiCenters are expected to release a number of publications from the five major projects over the next year. He noted that the EpiCenters also are conducting several innovative studies focusing on (1) the use of information technology (IT) to support interventions; (2) electronic markers to identify opportunities to remove urinary catheters sooner; and (3) electronic markers to identify patients who might be at high risk for carriage of multidrug-resistant organisms.

In terms of prevention projects, a trial is underway at multiple EpiCenters to analyze the use of chlorhexidine bathing in reducing transmission of methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *Enterococcus* (VRE) among ICUs. The project is also designed to evaluate the impact of this intervention on BSIs. The Steering Committee will discuss approaches to utilize and incorporate newer measurement strategies into prevention activities. Resources will be allocated to expand the EpiCenter projects and partner with other large groups of facilities. For example, the EpiCenters have an opportunity to link to 20 additional Veterans Administration Medical Centers.

Overview of Process Measures

Dr. Dale Bratzler, of the Oklahoma Foundation for Medical Quality (OFMQ), presented information on process measures for HICPAC to consider in incorporating into guidelines and recommendations in the future. "Process measures" are performed on patients, while "outcome measures" are reported as the end-result.

On the one hand, process measures are typically based on explicit criteria and do not require risk adjustment because the process of care should be delivered to all patients with appropriate exclusions. Process measures generally require fewer resources to capture. On the other hand, outcome measures tend to be more important to patients and are challenging to compare between healthcare institutions because this approach requires appropriate risk adjustment.

The limitations of process measures include the need to link processes to desired outcomes, the need for complete control by the healthcare practitioner, resources, the provision of less meaningful information to consumers, a resource-intensive data collection process, poor performance based on solid surveillance, and an inability to be captured electronically.

Dr. Bratzler explained that organizations take different approaches in developing performance measures. For example, the American College of Cardiology and the American Heart Association have established separate committees to develop process or quality measures for the creation of guidelines. The Infectious Disease Society of America (IDSA) and the American Thoracic Society include suggested performance indicators in their respective guidelines. However, these performance measures are vague, not detailed and do not specify criteria. Hospitals typically base criteria for performance measures on impact, evidence-based recommendations and gaps in performance.

Dr. Bratzler strongly encouraged harmonization with other ongoing efforts if HICPAC decides to incorporate process measures into its guidelines or data collection processes. The lack of harmonization among measures has resulted in OFMQ receiving 2,000 questions per month from hospitals about current hospital process measures.

CMS and the Joint Commission have a standing agreement to create common performance measures. This approach allows the two groups to reduce duplicative data collection, increase standardization, modify measures at the same time when new evidence or guidelines are published, and decrease the reporting burden on healthcare providers. However, abstraction guidelines, available administrative data, hospital quality and other issues affect the development of performance measures.

The National Quality Forum (NQF) has emphasized the need for harmonization among organizations that develop performance measures. Moreover, performance measures developed by HICPAC and other groups should be submitted to NQF for a rigorous review of the criteria and scientific evidence supporting the measure as well as the importance, scientific acceptability, usability and feasibility of the measure.

Dr. Bratzler described other issues for HICPAC to consider in the decision-making process of developing process measures. Several areas should be addressed in using performance measures for pay-for-performance, such as issues that are in complete control of providers, the potential for unintended consequences, indirect harm, and the contribution of the measure.

Efforts have been recently launched to develop "bundled" measures. For example, a published paper on a central line bundle showed that five interventions could be implemented to dramatically reduce central line infections. However, bundled measures do not identify the most important intervention or articulate whether all of the interventions in the bundle must be performed.

NQF recently recommended endorsement of the ventilator-associated pneumonia bundle as a performance measure for quality improvement of healthcare organizations. However, some of the interventions in the bundle are not relevant to pneumonia. At this time, bundled measures have not been tested in randomized trials or endorsed by NQF. A randomized trial on a "head of the bed elevation" bundle was published and showed no benefit from this intervention.

Dr. Bratzler concluded that process measurements can be quite rewarding and extremely useful if solid processes are measured and sound scientific evidence is used. Measures also should be developed in a format that can be widely used in order to improve healthcare practice. However, he urged HICPAC to be mindful of the challenges and limitations associated with process measures, such as IT and programming costs for ongoing maintenance of process measures, rapidly changing science, and the timeline to modify process measures.

To guide the decision-making process, Dr. Brennan reminded HICPAC that its public disclosure document recommended linking process and outcome measures. Dr. Cardo emphasized the need for HICPAC to closely collaborate with CMS and the Joint

Commission in the initial development of process measures if HICPAC decides to undertake this effort. Dr. Bratzler offered to serve as a conduit between HICPAC and the CMS/Joint Commission group that meets weekly to discuss the development of performance measures.

The HICPAC members made two key suggestions to consider in deciding whether to incorporate process measures into future guidelines. First, cross-fertilization with IT subject matter experts should be strongly promoted to develop underlying data models. This approach would decrease the lengthy turnaround time to modify process measures. Second, CDC should incorporate its public health information models into HICPAC's efforts to develop performance measures and facilitate strong linkages with other organizations.

Update on the Multidrug-Resistant Organism (MDRO) Recommendations

Dr. Keith Ramsey, a HICPAC member, is leading the workgroup that was formed to develop recommendations for the measurement of MDROs in healthcare settings. He covered the following areas in his update. The workgroup is represented by HICPAC, CDC, APIC, IDSA and the Society for Healthcare Epidemiology of America (SHEA).

The purpose and scope of the MDRO document are summarized as follows. Reasonable and practical approaches will be defined to measure MDROs that will assist in detecting changes in occurrence and responses to interventions in healthcare settings. A guide will be provided to select appropriate, standardized and up-to-date measurements that will be most useful in specific settings.

ICPs and healthcare epidemiologists are the intended audiences of the MDRO document. The SHEA Board of Directors supported the MDRO document as a SHEA/HICPAC position paper. The MDRO document will be coordinated with NHSN and forthcoming IDSA/SHEA guidelines. The MDRO document will address MRSA, VRE, multidrug-resistant gram-negative bacilli, and vancomycin-resistant *Staphylococcus aureus*.

The workgroup considered a number of issues in developing the MDRO document, such as MDRO infection and colonization; nosocomial and community onset; patients with a history of colonization or infection; surveillance periods; duplicate MDRO isolates from the same patients; locations and patient populations; prevalence versus incidence measures; and active surveillance testing. The workgroup identified five categories of MDRO outcome measures: tracking patients; monitoring susceptibility patterns; estimating infection burden; estimating exposure burden; and quantifying healthcare acquisition, including transmission.

Dr. Ramsey outlined the workgroup's recommendations. "Basic" measures were defined as those that are routinely used as a standard of practice or are believed to be central to making a meaningful assessment of impact of a prevention effort. All facilities should

consider the use of basic measures in all circumstances. "Advanced" measures were defined as those that are of great benefit in certain settings.

In the "tracking" category, line list would be a basic measure. In the "susceptibility pattern" category, an antibiogram would be a basic measure. In the "infection burden" category, proxy nosocomial bacteremia incidence would be basic measure, while nosocomial MDRO infection incidence and MDRO device- or procedure-associated incidence would be advanced measures.

In the "exposure burden" category, overall prevalence based on clinical cultures, overall prevalence with active surveillance testing, admission prevalence, and point prevalence survey would be advanced measures. In the "healthcare acquisition" category, incidence based on clinical cultures would be a basic measure for MRSA and an advanced measure for other MDROs. Incidence based on active surveillance testing would be an advanced measure in this category.

The workgroup's recent conference calls lead to discussions of several issues. For prevalence and culture-based measures, such as proxy nosocomial BSI, isolates should be identified >3 calendar days after admission. These measures should be conservative, easy to apply and use laboratory data only, but should not rely on clinical judgment. The workgroup did not recommend adjusting denominators for incidence measures for at-risk patients, such as prior to MDRO infection. However, the workgroup acknowledged that this approach might be time-consuming and might not affect interpretation at the facility level.

The workgroup did not distinguish between "healthcare-associated" and "community onset" because this practice is burdensome and not practical for routine MRSA surveillance. The workgroup did not recommend that all facilities perform active surveillance testing. Instead, the MDRO document will offer measures with and without active surveillance testing and discuss the usefulness of this intervention. The workgroup agreed to include multiple episodes of bacteremia within a surveillance period if the episodes occur >14 days apart. The workgroup will provide an easily applied definition of separate episodes that is based on time to clearance.

Dr. Ramsey concluded that the workgroup completed a draft manuscript. At this point, the manuscript has been submitted for internal CDC clearance, external review, and to the editor of *Infection Control and Hospital Epidemiology* for initial review for possible concurrent publication with IDSA/SHEA HAI guidelines. Progress reports have been presented to the SHEA Board of Directors and HICPAC.

Dr. Scott Fridkin, of DHQP, serves on the workgroup and provided additional details about the recommendations. The MDRO document could be expanded to further define "admission prevalence" to better address community-related issues. The document emphasizes the need for hospitals to use the MDRO recommendations internally rather than for intra-hospital comparisons because experience with some of the measures is

limited. Most notably, a number of the measures are driven by studies that are specific to ICUs and might not be applicable to other settings. The MDRO document was developed to be identical to the basic recommended measures in the IDSA/SHEA MRSA guideline. However, the MDRO document might need to be modified based on outcomes of the external review.

HICPAC commended the workgroup on developing a document to assist ICPs in creating MDRO profiles for their respective facilities and identifying appropriate measurements for assessments. Several members made suggestions for the workgroup to consider in the final revisions of the MDRO document.

- The MDRO document should contain solid numerators and denominators because research is likely to emerge on MRSA and the utility of active surveillance cultures. The MDRO document should enhance the existing body of knowledge.
- More underlying data, particularly on MRSA rates, should be incorporated because ICPs will use the MDRO recommendations despite disclaimers that discourage the use of the document as guidance. A group of experts should be convened to provide the best available knowledge on potential science that could be included in the MDRO document on a trial basis.
- ICU and non-ICU patient bed days should be separated to demonstrate better risk adjustment in the MDRO document.
- The workgroup should reconsider its decision not to distinguish between "healthcare-associated" and "community onset." For example, the onset of a hospital organism could occur in the community. This definition is different than actual "community-acquired" infection in persons with no history of hospital exposure. "Community onset" or another community term should be used with the cutoff of >3 calendar days after admission to identify isolates.

Dr. Brennan acknowledged that HICPAC did not have an opportunity to review the MDRO document prior to the meeting. In addition to the input provided during the meeting, he also asked HICPAC to submit more substantive comments to Dr. Ramsey after reviewing the document. He confirmed that HICPAC's vote to approve the MDRO document would not be placed on the agenda on the following day.

Briefing on the August 2007 Partners Consultation

Dr. Chesley Richards, of DHQP, reported that CDC convened an informal brainstorming meeting with partners in August 2007. The participants included HICPAC members, preeminent healthcare epidemiologists, and representatives from CDC, CMS, state health departments, quality improvement organizations and the private sector. The purpose of the meeting was to focus on the current environment of public reporting and HAI prevention

efforts. The participants also focused on the future of the field over the next five to six years and efforts that should be undertaken by CDC and the broader infection control community to achieve HAI elimination.

Dr. Richards summarized key recommendations raised during the consultation. Specific methods and a framework for HAI elimination should be adopted. A shift should be made toward transparent public reporting of HAIs at both aggregate and hospital levels. Collaborative efforts with payers should be strengthened to align incentives to prevent and eliminate HAIs. Partnerships should be enhanced to accelerate interventions at both system and community levels.

Following the consultation, a key event was held that created a number of opportunities to address the participants' recommendations. More media attention was given to HAI elimination. Dr. Julie Gerberding, Director of CDC, provided testimony about this issue. Increased public interest in MRSA facilitated a forum for discussion of HAI elimination at high levels both within and outside of CDC.

Dr. Richards described actions CDC has taken to date to respond to recommendations raised during the consultation. The need to make a strong commitment to HAI elimination was emphasized to the highest levels of CDC. Discussions were initiated with states about using NHSN for hospital-specific public reporting at the national level in the future. NHSN is currently being used as a data entry platform in ~13 states that adopted public reporting legislation. Advancements in electronic reporting were made for several initiatives.

CDC is continuing its collaboration with CMS on healthcare-acquired conditions outlined in the Deficit Reduction Act (DRA). CDC's role in this effort is to provide expertise in selecting the best measures within CMS's existing framework. CDC is also attempting to ensure that this initiative is aligned with pay-for-performance. CDC launched a number of exploratory discussions with potential prevention implementation partners.

CDC is collaborating with the Veterans Administration (VA) on MRSA prevention and reporting efforts as well as electronic reporting for other infections through the VA system. CDC recently convened a meeting with the Leapfrog Group for Patient Safety and will hold additional consultations with business coalitions and state health departments.

CDC acknowledged the need to develop a solid research agenda on HAI elimination. Supplemental dollars from the Prevention EpiCenters Program will be allocated to advance research on electronic reporting. CDC held discussions with the VA and the Agency for Healthcare Research and Quality (AHRQ) to explore opportunities in health services research.

Dr. Richards noted several opportunities, challenges and next steps in the HAI elimination effort. HAI elimination is a controversial issue due to institutional fear or being held accountable by lawsuits, regulatory requirements, payments or other types of penalties.

CDC hopes to minimize the controversy by widely publicizing a national public health goal of eliminating HAIs one at a time. This approach will provide an initial step toward HAI elimination.

The shift toward electronic reporting will strengthen the timeliness and fluidity of data, but efforts to move data will be difficult. Increased interest in MRSA and validation activities will assist in this area. State laws on HAI and MRSA reporting are complex and national legislation is beginning to be introduced. CDC will continue to collaborate with a variety of groups to inform the legislative process.

Report cards in other fields have not been shown to be effective in changing behaviors, but actions will need to be taken in public reporting despite the lack of success. This strategy will reassure consumers and payers that healthcare facilities are making the strongest efforts possible to reduce HAIs. A public component will need to be included in NHSN to make data more relevant. Concerns related to unintended consequences of public reporting will need to be addressed.

CDC and CMS will continue to discuss performance measures for HAIs, pay-for-performance and other payment issues. CDC's prevention partners will be critical to the HAI elimination effort due to the need to make the most significant impact with limited resources. CDC and its partners that conduct or sponsor research will identify key components and resource needs for research. Efforts will be strengthened to provide consumers and payers with the best available information.

At the division level, DHQP will attempt to leverage resources from both within and outside of CDC. DHQP will continue to internally review its materials to be friendlier to consumers. DHQP will maintain its close collaboration with the CDC National Center for Public Health Informatics to advance toward an electronic reporting model.

Dr. Richards concluded his briefing by asking HICPAC to provide input on four key questions related to the HAI elimination effort.

1. What strategies should be applied to achieve 100% adherence to prevention recommendations?
2. What strategies should be applied to make NHSN and data from other systems useful at both national and local levels?
3. What payment policies should be developed at the federal level and among payers to promote prevention?
4. What actions should be taken to better inform consumers about HAIs?

HICPAC was extremely pleased that CDC shifted the focus from "zero tolerance" to "elimination" of HAIs. Several members believed that the change in language would make positive changes in daily healthcare practices. HICPAC also supported CDC's approach of extensively collaborating with partners to disseminate more information to consumers and

educate the public. Several members made suggestions for CDC to consider in the ongoing HAI elimination effort.

- CDC should be aware that the HAI elimination effort might not be feasible or practical for facilities with no knowledge or resources to achieve this goal. For example, a tremendous number of facilities believe in 100% compliance with the hand hygiene guideline only or have no knowledge of the existence of any other HICPAC guideline. A step-wise approach should be taken with these facilities in which awareness is raised to achieve 100% adherence to the prevention recommendations as the first step and actions are taken to shift toward HAI elimination as the second step. An incremental approach also could allow facilities to demonstrate progress that has been made in reducing BSIs or other HAIs on a monthly or annual basis.
- Challenges associated with a shift to electronic surveillance should be considered in the HAI elimination effort, such as increased sensitivity of data and false-positives.
- Successes and best practices of institutions in eliminating some HAIs should be compiled and widely distributed, particularly to facilities with problems in achieving lower rates of infection.
- HAI elimination projects should be piloted in small hospitals that have limited knowledge or resources to achieve this goal. Strong multi-disciplinary collaborations should be established with ICPs, professional associations, hospital leadership and other groups to provide resources to these hospitals.
- The HAI elimination effort should be conducted in a comprehensive systems approach to avoid sole reliance on ICPs in institutions.
- The HAI elimination effort should be guided by a strong scientific evidence base rather than anecdotes.
- Experiences and successes in lowering infection rates should be collected, compiled and used to present a strong case on making HAI elimination a Joint Commission standard. A requirement of 100% adherence to prevention recommendations would play a critical role in changing the culture of hospitals to achieve HAI elimination.
- HICPAC should play a leadership role and take a proactive approach in the HAI elimination effort because 100% adherence to prevention guidance refers to HICPAC's recommendations.

Ms. Louise Kuhny, HICPAC's liaison to the Joint Commission, noted that now is an optimal time for HICPAC to submit information to support HAI elimination as a Joint Commission standard. She explained that the Joint Commission completed its Standards Improvement Initiative to rewrite and clarify the current standards. The Joint Commission is now reviewing and analyzing a series of issues that potentially could be made into standards. The Joint Commission also developed several new national patient safety goals for different types of device-related infections.

Ms. Kuhny asked for the best method to communicate with HICPAC when the Joint Commission releases its proposed new standards and national patient safety goals for public comment. She strongly encouraged HICPAC to provide input on these new initiatives. Dr. Cardo also urged HICPAC collectively and the individual members as subject matter experts to submit comments on the Joint Commission's proposed new standards.

In response to Ms. Kuhny's comments, a member suggested that HICPAC take a proactive approach in commenting on the Joint Commission's proposed new standards. For example, HICPAC should closely collaborate with the Joint Commission and other groups to identify the most important new standards and key issues.

A motion was properly placed on the floor and seconded by voting members for HICPAC to compile and submit evidence to the Joint Commission on standards on processes to address three HAIs: ventilator-assisted pneumonia (VAP), SSIs and catheter-based BSIs.

Establishment of HICPAC Workgroups

Dr. Bell explained that HICPAC is now developing shorter guidelines to be easier to read, adopt and update. Despite this streamlined process, a new vehicle for HICPAC guidance is needed because shorter guidelines are still not the best method to reach intended audiences. Public policy documents might increase the effectiveness and reach of HICPAC guidance, such as one- to two-page memoranda from HICPAC to the CDC Director. The condensed and thoughtful memoranda could be written to address important issues that have an impact on health policy.

Dr. Bell acknowledged that HICPAC's public policy memoranda might not completely penetrate an issue or change the course of events, but the documents would serve as an initial step to place key issues in the public record. HICPAC could establish workgroups to develop the memoranda because the Federal Advisory Committee Act (FACA) requires only one member from the parent company to serve on workgroups. However, Dr. Bell stated that his preference would be for two HICPAC members to serve on each workgroup. Other workgroup members could include former and future HICPAC members, external subject matter experts, DHQP staff and CDC legal staff as needed.

Dr. Bell pointed out that according to FACA, any workgroup is charged with operating until its specific task is completed. FACA does not specify a particular cutoff date for workgroups to disband. However, workgroup recommendations must be vetted by the entire parent committee in a formal public meeting. The workgroup's guidance would then become the product of the parent committee.

Dr. Bell noted that the development of HICPAC's public policy memoranda would assist in expanding personnel and expertise. The workgroups could draft the one- to two-page

documents in between meetings to capture important public policy issues related to infection control practices in healthcare settings. He suggested drafting the memoranda with both outcome-driven topics that require adherence to processes and process-driven categories.

Drs. Bell and Cardo proposed several issues that potentially could be addressed by HICPAC workgroups: (1) strategies to incorporate process measures into surrogate measures delivered electronically; (2) a stronger focus on process measures with SSIs; (3) data collection to support the request to make HAI elimination a Joint Commission standard; (4) preparations to improve NHSN for the future, such as refinement and revision of the definitions and approaches to generalize data; and (5) guidance and model legislation to states on the prevention of MRSA or another HAI. HICPAC could select one or two of these issues as a pilot of the public policy memoranda.

Dr. Brennan emphasized that public reporting and other changes in the infection control field over the past few years have required HICPAC to take a stronger public policy position and serve as advocates. He supported the establishment of workgroups for HICPAC to fulfill its new role.

Several members made suggestions for HICPAC to consider in establishing workgroups to develop public policy and advocacy documents.

- HICPAC should closely collaborate with other organizations in developing and distributing the public policy memoranda. For example, SHEA could play an instrumental role in the implementation of successful intervention activities. APIC could provide ICPs in the field with its toolkit, modules and other resources. SHEA and its partners could provide their model legislation that is widely used by ICPs in several states.
- A HICPAC workgroup should be designated as the lead in performing an environmental scan to identify ongoing efforts by professional associations. A partnership approach would decrease duplicative efforts in the field.
- A HICPAC workgroup should draft a public policy memorandum to embrace the HAI elimination goal, but caveats of this effort should be explicitly outlined as well. The document also should address vague language in the DRA related to infections that "could reasonably have been prevented." The memorandum should be provided to CDC at the February 2008 meeting.
- A HICPAC workgroup should address strong public interest in MRSA at this time because a number of states are expected to file MRSA screening bills beginning in 2008. Evidence-based guidance from HICPAC as a leading subject matter expert in this area would greatly inform the legislative process.
- A HICPAC workgroup should take a leadership role in addressing reporting and surveillance testing of MRSA. The workgroup should identify the minimum amount of data that can be collected to satisfy the general public and still allow for sufficient resources to conduct prevention activities.

- HICPAC's public policy memoranda should clearly state the case of an issue, but subsequent documents should still be developed to specify resource needs, identify locations of available resources, and recommend specific actions that need to be taken for actual implementation.
- HICPAC's public policy memoranda should be developed based on data in the guidelines that lead to a difference in attributable risk.

Dr. Brennan summarized key points from the discussion. HICPAC generally agreed to establish "Workgroup 1" to develop a public policy memorandum advocating for the HAI elimination effort. Resource needs, process measures and other issues might be an extension of the document, but should be tabled at this time to complete and provide CDC with the memorandum by the February 2008 meeting. HICPAC generally agreed to establish "Workgroup 2" to develop MRSA model legislation.

Dr. Brennan also reviewed a motion that was properly placed on the floor and seconded by Drs. Schecter and Ramsey, respectively, for HICPAC to compile and submit evidence to the Joint Commission on standards on processes to address three HAIs: VAP, SSIs and catheter-based BSIs. The motion was **tabled** until the following day after the presentation on the IDSA/SHEA guidelines.

Liaison and *Ex-Officio* Reports

Ms. Rachel Stricof reported on key topics that were covered during the meeting of the Advisory Council for the Elimination of Tuberculosis (ACET) in July 2007. Extensively drug-resistant tuberculosis (XDR-TB) was a major focus of the meeting. Dr. Gerberding testified before a Congressional committee on this issue. The Coordinating Center for Infectious Diseases (CCID) Board of Scientific Counselors (BSC) made several high and intermediate recommendations to CDC on XDR-TB.

CDC is currently developing applied epidemiology competencies. A presentation was made on public health laws that are important to TB control. An overview was provided on CDC's onsite evaluation of TB program services for Burmese refugees in Thailand. A detailed timeline was given on the case investigation of a patient who extensively traveled with multidrug-resistant TB (MDR-TB)/XDR-TB. ACET established a new BCG Workgroup to formulate guidance on the use of BCG for persons with extensive travel or those who work in areas with a high incidence of MDR/XDR-TB.

Dr. William Baine reported that AHRQ's Evidence-Based Practice Centers (EPCs) review all relevant scientific literature on clinical, behavioral, organizational and financing issues to produce evidence reports and technology assessments. Other key activities conducted by the EPCs include conducting research on methodologies of systematic reviews and

providing technical assistance to a variety of groups. All EPCs collaborate with other medical and research organizations.

AHRQ awarded five task orders to 72 hospitals under its HAI initiative. The hospitals will report on infection rates for BSIs, VAP, SSIs, MRSA and UTIs. To assess changes in healthcare provider behavior, each hospital will evaluate its individual culture using the AHRQ-supported "Hospital Survey on Patient Safety Culture."

AHRQ is continuing to fund the "Developing Evidence to Inform Decisions About Effectiveness Network." AHRQ developed this initiative to generate new knowledge by conducting accelerated practical studies on the outcomes, safety, comparative clinical effectiveness and appropriateness of healthcare items and services. Future projects conducted under the network might focus on electronic registries, methods for analyzing health databases, and prospective observational or interventional studies. Principal investigators of the network are located at institutions throughout the country.

AHRQ awarded two-year contracts totaling \$1 million to four statewide data organizations to pilot projects. The goal of this initiative is for hospitals to more easily link administrative data and electronic clinical data. AHRQ supported a study to analyze women who developed wound infections following breast cancer surgery.

Dr. Mark Russi reported that the American College of Occupational and Environmental Medicine (ACOEM) and the International Commission on Occupational Health jointly convened the "7th International Conference on Occupational Health of Healthcare Workers." The conference was well attended by >300 persons and presentations of ~160 abstracts. MRSA in HCWs was raised as a major concern in one session of the conference. ACOEM would greatly appreciate HICPAC providing a paragraph on rational practices to screen HCWs for MRSA.

Ms. Roslyn Schulman reported that the American Hospital Association (AHA) issued quality advisories for hospitals following CDC's report on MRSA. The advisories focused on infection prevention in hospitals and communities. The guidance also encouraged hospitals to use CDC's MRSA report to reassess infection control practices and outreach to community partners in this effort. The advisories can be reviewed on AHA's web site.

AHA launched a new infection control web site with up-to-date information, best practices and other resources on infection control practices. The web site also describes strategies for hospitals to partner with communities. AHA recently convened a conference call with its membership and CDC experts to ensure that hospitals have knowledge of current data and best practices on MRSA and other infection control issues. The conference call was extremely well received with ~1,000 hospitals participating. Additional conference calls will be held in the future due to the high demand for CDC's expertise and the great deal of interest in infection control issues.

Ms. Joan Blanchard reported that the Association of periOperative Registered Nurses (AORN) will hold the "12th Conference on Infectious Disease" in December 2007. The planning committee includes AORN, APIC and SHEA representatives. The conference will be targeted to physicians, nurses, ICPs and other healthcare professionals. Continuing medical education credits and nursing contact hours will be awarded. AORN will post seven of its recommended practices online in 2008.

AORN is aware of a number of concerns regarding impregnated cloth. Studies conducted by the manufacturer do not mention replacing two showers with chlorhexidine solution with 2% chlorhexidine impregnated cloth. The package directions do not take into account that "sterile scissors" would no longer be sterile when used to cut the seal of the package. Compliance with the package directions would require 27.3 cloths for a person weighing 200 pounds. The impregnated cloth might not be as effective as two showers in terms of enhanced residual effects.

AORN nurses are frequently asked about appropriate skin preparation solutions to use for vaginal procedures if the patient is allergic to an iodophor preparation. Chlorhexidine is being used off-label by some surgeons for this application, but AORN does not recommend off-label use of a skin preparation product. A product that is available and non-toxic for mucous membranes has been approved for use in a vaginal application. AORN is interested in HICPAC providing input on the use of this product.

Ms. Bjerke reported that APIC, SHEA and Joint Commission Resources hosted the "MRSA: The Call to Action 1 Year Later" conference on November 5-6, 2007. The objective of the conference was to examine successes, learn from emerging data and develop facility plans.

The Occupational Safety and Health Administration (OSHA) intends to monitor HCWs for mandated annual fit testing of N95 respirators. This mandate is an unfunded requirement facing healthcare institutions. APIC's Practice Guidance Council and the American Society for Healthcare Environmental Services are jointly strengthening front-line infection prevention workers by partnering on related infection prevention documents for publication.

The Future Summit was held in January 2007 to discuss a future infection prevention system with a goal to eliminate HAIs. An advisory group and workgroup were established to address recommendations that were raised during the summit in terms of better defining and describing an infection prevention system of the future. APIC recently elected its 2008 President.

Dr. Nalini Singh reported that she represented HICPAC during the CCID BSC meeting in October 2007. The BSC operates with four subcommittees to address issues in CCID's four centers. The NCPDCID Subcommittee discussed investments that would be needed for a national laboratory system to assure public health laboratory system capacity.

The subcommittee made recommendations to CDC in several key areas: (1) program integration for CDC's laboratory programs, activities and services; (2) a strategic plan for CDC and state public health laboratory reference testing; (3) a quality management system approach to all of CDC's reference testing services; (4) IT systems that are compliant, integrated, interoperable and bi-directional with the Public Health Information Network (PHIN); (5) sustainable funding streams and infrastructure; and (6) the workforce crisis.

Ms. Lisa McGiffert reported that the Consumer's Union (CU) four-year "Stop Hospital Infections" campaign advocates for public reporting of hospital infection rates. CU maintains an up-to-date web site with news stories, guidelines, studies, legislation and other information for the public and media. CU recently added a page on MRSA on its web site.

CU outreaches to consumers through regular dialogue with ~500,000 persons around the country about various consumer issues. CU collaborates with local advocates to better consolidate its existing network of consumers and consumer groups. CU undertakes this effort for consumers to become more articulate about patient safety, quality and other issues. CU is also interested in ensuring that consumers are provided opportunities to make meaningful contributions to initiatives typically involving healthcare professionals only.

CU views efforts to shift to national public reporting with NHSN as a positive development. State mandates for hospitals to participate in NHSN will greatly benefit CDC by broadening the data pool and making more information available to researchers. CU recommends that HICPAC develop different levels of guidelines for professional, legislative and lay audiences. CU has learned that many HCWs who are responsible for implementation of the guidelines have difficulty in interpreting the recommendations. CU's position is that consumers also should have access to HICPAC's guidelines because the public can play a role in successful implementation.

Ms. Marion Kainer reported that the Council of State and Territorial Epidemiologists (CSTE) convened a conference in June 2007 with a session on public reporting, including HAIs. At least two sessions on HAIs also will be held during CSTE's upcoming conference. CSTE acknowledges that state health departments can play an important role in the prevention of HAIs.

CSTE recently sent a letter to Dr. Gerberding expressing its appreciation of CDC's commitment to NHSN and collaboration with states to make NHSN available as a public reporting tool. This approach will allow states to take full advantage of electronic reporting and decrease the burden on ICPs. NHSN also will provide ICPs with more time to devote to preventing rather than measuring infections. CSTE is extremely interested in HICPAC passing a formal recommendation for CDC to increase resources for NHSN.

CSTE is writing a response to Senator Richard Durbin's proposed hospital infection legislation. The bill has some merit in terms of serving as a national reference system, but

CSTE has found the timelines to be unrealistic. HICPAC should explore the possibility of playing a role in strengthening the language in the proposed legislation.

Ms. Louise Kuhny reported that the Joint Commission revised its infection control standards under the Standards Improvement Initiative. Final approval of the revised infection control standards is scheduled for April 2008 and all of the revised standards will be effective beginning in January 2009.

The Joint Commission and other organizations are partnering with IDSA and SHEA in developing guidelines for six HAIs. The HAI Allied Task Force intends to publish the IDSA/SHEA guidelines in February 2008. The Joint Commission is continuing its hand hygiene measurement project. Manuscripts that were submitted for this initiative are currently being evaluated to provide accredited organizations with models and best practices for hand hygiene measurement. A monograph of promising hand hygiene measurement methods is expected to be published in early 2008.

The Joint Commission sponsored a number of educational activities, including its annual infection prevention and control conference. The Joint Commission also provided audio conferences and a breakfast briefing on infection control related to influenza vaccination protocols for HCWs, best practices to improve HCW vaccination rates, and infection control standards for hospitals and ambulatory programs.

Dr. Lisa Maragakis reported that SHEA is continuing to collaborate with IDSA on the development of guidelines to address four device-related infections and two MDROs. A draft of the guidelines has undergone external review. SHEA is continuing to serve on HICPAC's workgroup with APIC to develop the MDRO measurement document. SHEA is continuing to collaborate with the Institute for Healthcare Improvement to eliminate MRSA and VRE.

SHEA presented its comments on an Institute of Medicine (IOM) report entitled "Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers." SHEA urged the IOM committee to further prioritize and provide timelines for its recommendations; include an analysis of current significant limitations in PPE manufacturing and supply; and address funding and resources for needed research.

SHEA and several of its partners reviewed and provided the following comments on the proposed Durbin bill that addresses community-associated infections and HAIs. SHEA endorsed further investment in research and implementation of prevention and control measures. SHEA and IDSA supported a focus on quality improvement. SHEA and IDSA urged public reporting to follow a phased-in approach as well as accepted principles for data reliability and scope. SHEA and IDSA supported stronger interventions and additional resources for federal agencies and states to better address HAIs. SHEA and IDSA supported expanded transparency and public reporting of appropriately designed HAI measures built on existing strengths and infrastructure.

For the DHQP report, Dr. Bell announced that CDC expects to be informed of a publication date for the disinfection and sterilization guideline in the next few days.

Dr. Cardo announced that CDC is investigating the transmission of HIV and STD from a high-risk organ donor to four recipients. This case represents the first occurrence of donor-transmitted HIV in the United States since 1985 and the only occurrence of donor-transmitted HIV/STD in U.S. history.

Dr. Cardo's position was that this case would promote extensive dialogue on donor testing policies prior to organ donation. She confirmed that she would provide regular updates to HICPAC on the investigation because the case could have implications for the development of infection control guidance in the future.

With no further discussion or business brought before HICPAC, Dr. Brennan adjourned the meeting at 5:35 p.m. on November 13, 2007.

Overview of Shared Responsibility for Influenza Preparedness

Dr. Brennan reconvened the HICPAC meeting at 9:08 a.m. on November 14, 2007 and yielded the floor to the first presenter.

Dr. Benjamin Schwartz, of CDC, announced that CDC has publicly released guidance on prioritization for pandemic influenza vaccine. The public can submit comments on the document at www.pandemicflu.gov through December 31, 2007. The guidance proposes to vaccinate persons in a pandemic in one of five tiers. At the conclusion of vaccinating the tier 5 group, each individual in the population would have had an opportunity to receive influenza vaccine.

Pandemic influenza vaccine would be balanced in tiers 1-3 for persons who perform critical functions and high-risk populations. For example, critical HCWs and emergency medical service providers would be included in tier 1, while other HCWs would be included in tier 2. The guidance proposes to target pandemic influenza vaccine to ~3.2 million of ~5.5 million HCWs in acute care hospitals because these HCWs have direct patient contact or are required to maintain operations. However, CDC acknowledges that difficult choices will need to be made for individual institutions to identify the targeted HCWs.

The guidance also proposes to vaccinate pregnant women, infants and children before high-risk adults and elderly persons. This recommendation reflects feedback from the public during a series of stakeholder meetings and is in contrast to CDC's guidance for annual influenza vaccination.

The prioritization scheme for pandemic influenza vaccine includes four categories: persons who protect homeland and national security; persons who provide healthcare and community support services; persons involved with the critical infrastructure, and the general population. A different prioritization scheme would be applied based on the severity of a pandemic. For example, all of the occupational groups would not be targeted in a moderate or less severe pandemic because no threat would be posed to the critical infrastructure or capacity to maintain community services.

Dr. Schwartz announced that CDC drafted recommendations on antiviral drugs, but realizes the tremendous challenges in actual implementation. The position of the HHS Secretary is that pandemic preparedness is a shared responsibility. However, the current expectation is that the healthcare sector would cover HCW prophylaxis, including the purchase of antiviral drugs and program implementation.

Dr. Schwartz informed HICPAC that over the next month, CDC would hold meetings with state and local governments, healthcare organizations, public health agencies, emergency services, and the business and labor sectors. CDC will report key outcomes of these meetings to the HHS Secretary to inform policy decisions on effectively implementing the antiviral drug guidance.

CDC's current antiviral drug use strategy for pandemic preparedness is to target resources for containment and early treatment of persons who are ill. Based on this approach, CDC established a stockpile target of 81 million regimens from both federal and state purchases. The federal government has nearly completed its purchase of 50 million regimens for the stockpile target, but states have not fully complied with purchasing the remaining 31 million regimens. As a result, some states would need to prioritize persons who do or do not receive treatment during a pandemic.

A potential impact of antiviral treatment includes reducing the duration of illness with the greatest decrease occurring if treatment is initiated very early after onset of symptoms. Pooled data from randomized controlled trials suggested that lower respiratory infection and hospitalization could be reduced by ~50%. Studies of interventions in nursing homes in Canada that experienced outbreaks indicated reductions in mortality. Modeling and clinical studies suggested a reduction in viral shedding and a potential decrease in illness transmission associated with treatment.

CDC has reconsidered its antiviral drug use strategies due to increased manufacturing capacity. One manufacturer has developed global capacity to produce up to 400 million regimens of antiviral drugs each year and is exploring the possibility of scaling-back production due to an overabundance of non-purchased drugs. CDC is also evaluating the potential value of prophylaxis in maintaining the healthcare sector and other critical services and reducing rates of illness as part of community mitigation strategies.

In reconsidering its antiviral drug use strategies, CDC formed an interagency workgroup with representation by public health agencies at federal, state, local and tribal levels. The interagency workgroup focused on several issues during its meetings, including drug effectiveness and resistance, mathematical modeling results, the potential for absenteeism, continuity of operations, ethics, values and stakeholder preference.

The interagency workgroup based its considerations on the following assumptions. The pandemic would be severe with an index of 5. Community mitigation strategies would reduce the pandemic attack rate from 30% to 15%. An accurate point-of-care diagnostic test would not be available. Community outbreaks might last as long as 12 weeks. "Regimens needed" would be defined based on a single pandemic wave.

For treatment and prophylaxis of household members, only one out of every three courses would be given to an individual with actual influenza disease. Remaining treatment would be administered to persons with other febrile respiratory infection. Of all influenza cases, 60% would be treated and household members would be prophylaxed. No vaccine effect would be seen for the first pandemic wave. The interagency workgroup recognized that some of its assumptions were fairly optimistic, while others were relatively pessimistic.

Antiviral drug use strategies proposed by the interagency workgroup would include treatment with a single drug regimen twice daily for five days beginning within 48 hours of onset of illness. Outbreak prophylaxis would be administered throughout the duration of a community outbreak and could include up to eight regimens of antiviral drugs. Post-exposure prophylaxis (PEP) would include a single regimen given daily for ten days.

Approval by the Food and Drug Administration (FDA) for oseltamivir prophylaxis is currently up to six weeks, but the manufacturer is conducting studies to apply for FDA approval of a 12-week course. However, a longer prophylactic regimen could be used under the Emergency Use Authorization if a pandemic occurred prior to FDA approval.

CDC's current strategy of containment and early treatment requires 81 million regimens, but the interagency workgroup also recommended providing prophylaxis for the duration of a community outbreak for front-line HCWs and emergency service workers. An additional 86 million regimens of antiviral drugs would be needed to meet the interagency workgroup's recommendation.

CDC proposed a regimen of one treatment per day for ten days for the following groups: (1) other HCWs who had no patient exposure and no increased occupational risk; (2) household contacts under community mitigation strategies; (3) air traffic controllers, nuclear power plant engineers, workers who maintain electrical power grids, professionals who sustain the liquidity and operation of the U.S. financial system, and other unique and specialized critical infrastructure workers; and (4) immunocompromised persons. CDC also proposed a 12-week regimen of prophylaxis for 80 days to control outbreaks in nursing homes and prisons.

Dr. Schwartz described the scientific basis and rationale for the HCW guidance. HCWs are frequently involved in outbreaks reported in the medical literature, but data are extremely limited to determine whether the risk of influenza among HCWs is higher compared to the general population. A study in four hospitals in Glasgow, United Kingdom documented a 23% rate of influenza infection among 518 HCWs in a single influenza season. The study indicated that many infected HCWs would still report for work during a pandemic due to minimal or no symptoms. The infected HCWs would pose a risk for transmitting infections to other HCWs and patients.

Studies in several tertiary care hospitals in the United States over three influenza seasons showed a 14% rate of infection among HCWs. A study conducted in a Tokyo hospital over three influenza seasons suggested an increased risk of influenza infection among physicians and nurses. The study showed that HCWs represented a larger proportion of infected persons during influenza seasons compared to other respiratory disease seasons. The study indicated that influenza might be an occupational risk.

The Tokyo study also analyzed the risk of respiratory infection by occupation, including physicians, nurses, administrators and technicians. Administrators had less relative risk of influenza illness compared to the other three occupational groups. The 2.5-fold increased risk of physicians and nurses combined was found to be statistically significant. These data indicated an increased risk among healthcare personnel.

A 2002 published study showed that ≥ 1 HCWs became ill in eight of nine hospital outbreaks. Rates of illness were 11% and 59%, respectively, in two outbreaks among HCWs who had direct patient exposure. Another published study reported that an outbreak probably began with and spread to HCWs and was eventually transmitted to hospital patients. Most HCWs who were infected in this study had direct patient contact.

The consequences of HCW infection include health impacts on the infected HCW and the risk of transmission to coworkers, family members and patients. Influenza vaccination of HCWs plays a critical role in preventing infection and protecting patients in acute care hospitals and long-term care facilities. A randomized controlled trial found an association between influenza infection and HCW absenteeism. The study showed a 53% decrease in absenteeism among HCWs who received vaccination compared to the control group.

HCW absenteeism during a pandemic would be more significant than during annual influenza. A mathematical model of a pandemic in Singapore predicted peak HCW absenteeism of ~10% as a result of influenza illness. A survey was administered to nurses in three Maryland counties in 2005. The results suggested that nearly 50% of the nurses surveyed would not report to work. Perceptions about the importance of individual roles in the workplace and confidence in personal safety were significant factors for nurses who would report to work. Antiviral prophylaxis would increase confidence in personal safety and increase work attendance during a pandemic.

The potential impacts of antiviral prophylaxis among HCWs include a reduction in illness-related absenteeism. The Singapore model suggested an 80% reduction of illness with eight weeks of prophylaxis. The Maryland study indicated a decrease in absenteeism due to fear of infection and a reduction in nosocomial transmission of infection.

Dr. Schwartz described other topics in CDC's guidance on prioritization for pandemic influenza vaccine. The CDC Ethics Committee suggested that the ethical principle of societal benefit over individual benefit serve as the leading principle in allocating scarce resources. A reduction in HCW absenteeism and maintenance of effective healthcare services would certainly benefit communities.

The guidance proposes antiviral prophylaxis in the emergency services sector, including fire departments, law enforcement and emergency medical services. The risk of infection in these occupational groups varies, but prophylaxis might play an important role in reducing absenteeism in these workers and maintaining essential public safety and emergency response services. Similar to HCWs, the reciprocity principle also would apply in these occupational groups if PPE is less effective in the field. CDC's guidance on protecting HCWs and emergency responders is consistent with OSHA's occupational risk pyramid for pandemic preparedness.

The guidance discusses the increased risk of infection among household contacts of influenza patients due to the magnitude of exposure. Contacts might further transmit infection within the household and community. PEP has been shown to be effective in reducing the risk of illness among individuals and entire communities. Four studies analyzed neuraminidase inhibitors for PEP in households. All of the studies showed solid efficacy in reducing secondary influenza illness in households where prophylaxis was given.

One of the four studies showed that >25% of households in the control group transmitted influenza infection to ≥ 1 household members. The reduction in risk of illness was greater among household members who were negative at baseline compared to persons who had infection at the time prophylaxis was given. Mathematical modeling suggested that household PEP could further reduce the magnitude of illness in communities in addition to non-pharmaceutical interventions and antiviral treatment alone. In addition to a decrease in the attack rate from 30% to 15% through community mitigation strategies, an incremental reduction also would be achieved in the community through household PEP at a 60% implementation rate.

Based on the assumption of a severe pandemic with a 2% case fatality, household PEP could reduce the number of deaths by ~155,000 and hospitalizations by ~1 million. The intervention would be reasonably cost-effective based on current antiviral drug prices. Similar to HCWs and emergency services personnel, the reciprocity principle also would apply in households where community mitigation strategies call for voluntary household quarantine. Although decreased transmission in the community would have a societal

benefit, compliance with quarantine would increase the risk to family members who remain in the household with an influenza patient. As a result, protection to household members would benefit the community.

Dr. Schwartz pointed out a number of uncertainties in CDC's guidance on prioritization for pandemic influenza vaccine. The estimated requirements are based on assumptions of the positive predictive value of influenza, clinical diagnosis, effectiveness of community mitigation strategies, and the duration of outbreaks. CDC has made an "educated guess" on the number of regimens that need to be stockpiled to implement the guidance.

CDC contracted the IOM to conduct a study, formulate recommendations and identify best practices related to capacity to implement interventions outlined in the guidance. HICPAC members are welcome to attend a meeting on December 3-4, 2007 with CDC and IOM that will be convened to discuss this issue. HICPAC is also welcome to participate in the December 6, 2007 meeting with healthcare organizations. Both meetings will be held in Washington, DC.

The guidance also discusses uncertainties related to antiviral drug resistance. Oseltamivir resistance has been seen in both children and adults in clinical settings, but is much less likely to develop with prophylaxis compared to treatment. Resistant isolates have been shown to decrease fitness, but are unlikely to spread between persons.

Technological developments are expected to change current trends in antiviral drug resistance. A sensitive point-of-care test is being developed in conjunction with CDC and might receive FDA approval by 2009. A new antiviral drug is being developed with support from HHS and is slated for FDA approval in 2010. However, several factors are uncertain about the tests, including the accuracy, speed, availability, cost, and potential impact on the positive predictive value of a diagnosis during a pandemic.

Dr. Schwartz emphasized the need to clearly define the roles of governments, healthcare organizations, other groups, the community and individuals in the shared responsibility of pandemic preparedness in terms of purchasing, stockpiling and implementing the guidance. He noted that final decisions have not been made on policy issues and implementation of the antiviral drug guidance at this time.

Dr. Schwartz welcomed the opportunity to share HICPAC's perspectives during the December 2007 meeting with the HHS Secretary. He asked HICPAC to provide input on three key questions:

1. What is the likelihood of effectively implementing the guidance on antiviral drugs for HCWs within the healthcare sector?
2. What barriers would limit the ability of healthcare organizations to comply with the guidance?
3. What actions can the federal government take to overcome these barriers?

In addition to providing input on the three key questions, Dr. Schwartz also raised the possibility of HICPAC formally endorsing the following statement: "HICPAC endorses the guidance for antiviral prophylaxis of HCWs who are at increased risk of infection during a pandemic. However, HICPAC recognizes that significant efforts are still needed to identify optimal approaches to the purchase, stockpile and implementation of the guidance."

HICPAC thanked Dr. Schwartz for presenting a comprehensive overview of the shared responsibility for influenza preparedness. Several members made suggestions in response to his request for input.

- The guidance should consider the ethical principle of equity because the average individual would be vaccinated in the last tier. For example, one state is exploring the possibility of targeting its recently purchased stockpile to poor or unemployed persons who would be unable to pay for vaccine.
- CDC should recognize that although the guidance was developed for the nation, actual implementation will widely vary among end-users. Factors that will contribute to this diversity include the availability of resources, decisions in individual healthcare institutions about the amount of prophylaxis to administer, and levels of understanding about ethical underpinnings.
- Manufacturers should be extensively engaged in the decision-making process to overcome barriers and increase the likelihood of effective implementation of the guidance.
- CDC should clearly define and resolve policy issues before finalizing and widely releasing the draft guidance.
- CDC should extensively consult with accreditation organizations to obtain their unique perspective about implementation of the guidance. For example, the lack of a clear definition of "shared responsibility" among governments, healthcare institutions and the community would serve as a barrier to the Joint Commission surveying the guidance in hospitals and holding HCWs responsible.

Dr. Brennan proposed the following language in response to Dr. Schwartz's request for HICPAC's formal endorsement: "HICPAC endorses the recommendations for antiviral prophylaxis of HCWs as outlined in the guidance. However, HICPAC recognizes the need for further study and discussion to determine if the principle of shared responsibility can effectively ensure protection for HCWs and the critical infrastructure. Any approach must compliment a strategy of vaccination, production, distribution and administration."

A motion was properly placed on the floor and seconded by Drs. Engel and Pegues, respectively, for HICPAC to adopt the language. HICPAC **unanimously approved** the motion with no further discussion.

Dr. Brennan would send a letter of HICPAC's endorsement to Dr. Schwartz for circulation to HHS. Dr. Schwartz offered to convene a conference call with HICPAC to have further discussion on implementation issues and barriers to the guidance.

Update on the Electronic Health Record (EHR) White Paper

Dr. Ashish Atreja, of the Cleveland Clinic, is an external expert to the workgroup that was formed to develop HICPAC's EHR white paper. He covered the following areas in his update. The overarching purpose of the white paper is to raise awareness about EHR functionality that can be utilized for infection surveillance, prevention and control.

The white paper is designed for ICPs, hospital epidemiologists and IT specialists to determine the feasibility of conducting EHR projects in their individual institutions. The white paper also promotes capacity building in institutions that do not currently have the ability to conduct EHR projects.

The workgroup revised the white paper based on comments submitted by HICPAC and *AJIC* reviewers. The major changes included more details on NHSN due its increasing role in HAI surveillance in the future. A framework was added to describe strategies to evaluate public or commercial surveillance systems. The need for a multi-disciplinary team in hospitals with different skill sets was emphasized to build EHR capacity.

Several references were updated, including CMS's new language stating that CA-UTIs might not be reimbursed in hospitals. APIC's "surveillance" definition was added to clarify that EHRs could assist with case finding and many other aspects of surveillance, including prevention and outcome assessment. The revised document has been submitted to *AJIC* for publication and was distributed to HICPAC for review.

Dr. Engel's position was that the white paper is a well-written and visionary document, but is not evidence-based. He conveyed that he would be unable to endorse the white paper as a voting HICPAC member due to two reasons. First, virtually no evidence is cited that EHRs can replace the fundamental functions of infection control, such as targeted active surveillance of high-risk and high-volume procedures. Second, no references are cited to demonstrate that EHRs can assist in HAI surveillance, prevention and control.

Dr. Steven Gordon, a HICPAC member, is leading the workgroup. He suggested adding "opportunities and challenges" to the title of the white paper to address Dr. Engel's concerns regarding the lack of scientific evidence. He also pointed out that the conclusions section emphasizes opportunities in a changing environment.

Dr. Engel remarked that he would support the white paper with certain revisions. For example, the "antimicrobial stewardship" section should be deleted to maintain the focus on daily infection control activities conducted by ICPs. The document should be shortened.

Dr. Brennan recalled that HICPAC has a precedent in developing and issuing a non-evidence-based advocacy document. A lack of evidence resulted in HICPAC's public reporting document receiving minimal support and numerous misinterpretations.

Other HICPAC members commended the workgroup on developing an outstanding document despite the lack of rigorous, peer-reviewed and published studies on EHRs. Some members viewed the white paper as an important cutting-edge document that would be extremely helpful to ICPs and contribute to the published literature.

DHQP leadership and several HICPAC members made suggestions to refine the document.

- The title should be changed to "Utilizing Electronic Health Records to Support Surveillance, Prevention and Control Activity."
- The conclusions section should be modified to include a minimum list of elements or capabilities that hospitals would need to utilize EHRs. Alternatively, the minimum list of EHR elements should be extracted from the white paper and placed in a brief HICPAC document.
- A table, appendix or companion document should be developed to inform and guide ICPs, hospital epidemiologists and other lay users in purchasing IT systems for healthcare facilities. These personnel could present a chart of features and characteristics of a useful IT system for infection control to administrators when the purchase of a new IT system is being considered. For example, a table of measures could be used to ask software providers whether the system has the ability to allow ICPs to generate denominators for device days.
- Guidance should be added to adhere to NHSN, APIC or PHIN standards to facilitate interoperability.
- Language should be added to emphasize the benefits of using EHRs to report conditions to state health departments and tremendously reduce the workload of ICPs.
- The background section should be updated to describe CDC's more recent activities in EHRs, such as the use of BioSense in NHSN.
- A minimum list of EHR elements should not be added to the white paper because IT systems tremendously vary among institutions and populations served. A minimum list of EHR elements would be premature at this point because virtually no communications occur between ICPs and IT specialists. However, HICPAC should develop and distribute a minimum data set in the future as more evidence is collected.
- The white paper should include broad suggestions and helpful information to ensure ICPs do not interpret the document as an evidence-based HICPAC

guideline or standard that should be followed. For example, the following language could be added as an introductory paragraph: "This document does not represent an evidence-based guideline. The science is evolving, but a shift toward considering EHRs is important at this time."

- Research questions should be added to the white paper to develop a strong evidence base for EHRs that will be helpful for infection control purposes.

Dr. Brennan noted that HICPAC was not at a point of formally endorsing the EHR white paper based on the discussion. He summarized key suggestions by DHQP and HICPAC for the workgroup to consider in revising the document. An introductory paragraph should be added before the background section to describe the nature of the document; emphasize the lack of evidence to make prescriptive recommendations; and clearly state that the document is not an evidence-based guideline. Broad recommendations should be added to the conclusions section in either narrative or tabular form.

Dr. Atreja confirmed that he and Dr. Gordon would revise the white paper based on the suggestions made by DHQP and HICPAC.

Update on the IDSA/SHEA Guidelines

Dr. Pegues is representing HICPAC on the workgroup to develop the IDSA/SHEA guidelines. He covered the following areas in his update. IDSA and SHEA formed a workgroup to develop useful guidelines for relevant device-associated infections and multidrug-resistant pathogens. The guidelines are linked by conceptual formats and outlines, but also could stand alone as working documents to be used by ICPs and quality professionals to affect change within their respective institutions.

The best evidence published in the medical literature, data from recent randomized clinical trials and other existing guidelines were used to inform the development of the guidelines. The regulatory framework of practicing healthcare professionals and national guidelines served as guiding principles for the guidelines.

The format of the guidelines is summarized as follows. The rationale for the guidance was described, including the clinical impact, morbidity and mortality of HAIs. Approaches to detection were outlined, such as infection control surveillance. Evidence-based or evidence-graded prevention measures were articulated to improve patient care practices. Language on performance improvement was included, such as internal and external performance and outcome measures and appropriate strategies to report and incorporate these measures. A practical guideline for implementing the guidelines was provided.

Drafts of the guidelines were vetted internally and revised based on extensive comments. IDSA, SHEA, Joint Commission and the Pediatric Infectious Disease Society have

submitted comments on the guidelines to date. The external review process is underway with three independent reviewers. The lead authors for the guidelines have been charged with formally responding to comments submitted by the external reviewers and professional societies by November 29, 2007.

HICPAC members and other infection control experts met to discuss approaches for HICPAC to review, offer constructive feedback and endorse the guidelines. However, HICPAC must comply with the rapid timeline to submit comments and endorse the guidelines because the documents are slated for publication in February 2008. The draft guidelines were distributed to HICPAC in October 2007, but these versions did not include comments by the workgroup members, external reviewers or professional societies. HICPAC was instructed not to distribute the document to any persons outside of its membership.

Dr. Bell was in favor of HICPAC supporting the guidelines so long as the traditional scientific quality associated with HICPAC was not undermined. His position was that a narrative statement of support could serve both purposes. For example, "HICPAC reviewed the content and process for the development of the IDSA/SHEA guidelines and is in agreement with and support of the recommendations." This statement would clearly explain that HICPAC did not conduct a literature search, review the IDSA/SHEA guidelines to identify inconsistencies with HICPAC guidance, or take any other actions in the development of the IDSA/SHEA guidelines.

Dr. Bell clarified that the statement would not extend beyond the purview of HICPAC's charter to advise the CDC Director and HHS Secretary. Instead, the statement would be framed for HICPAC to recommend that CDC endorse the IDSA/SHEA guidelines. Dr. Bell saw tremendous benefits in HICPAC issuing a narrative statement of support for the guidelines, such as ensuring that disparate guidelines are not released by various groups and enhancing collaborations with SHEA and IDSA.

Several HICPAC members were in favor of supporting the IDSA/SHEA guidelines, particularly since both SHEA and IDSA liaisons serve on HICPAC and a HICPAC member serves as an author of the guidelines. However, a number of members made comments to emphasize that HICPAC's support should not extend to formal endorsement.

- HICPAC should help to inform the guidelines as an advocate or expert panel instead of formally endorsing the guidelines.
- HICPAC should develop and distribute a one-page commentary to explain to users that the IDSA/SHEA guidelines compliment HICPAC's previous recommendations.
- HICPAC should not formally endorse the guidelines for the following reasons.
 - The documents are embargoed and cannot be openly discussed in a public meeting.

- The terminology, format and style are inconsistent between each of the IDSA/SHEA guidelines.
- The language on MDROs is different than CDC's recommendations.
- The "basic" category sends conflicting messages in terms of whether an institution does or does not have additional resources.
- Differences between the IDSA/SHEA guidelines and published guidelines are not clearly identified in the recommendations.
- Some of the language in the "external reporting" section is premature and references activities that have not yet been completed.
- Some of the external measures have not been vetted or scientifically validated in terms of unintended consequences.
- The vast list of recommended process and outcomes measures are not categorized as "basic" or "advanced" and will be overwhelming to ICPs and hospital epidemiologists.
- The MRSA guideline does not recommend tiering until later in the document.

Dr. Pegues placed the following motion on the floor. HICPAC should ask the IDSA/SHEA HAI Guideline Committee to (1) allow HICPAC to formally review the next iteration of the draft guidelines; (2) provide feedback within a two-week period; (3) offer a brief editorial to accompany the publication of the guidelines in *Infection Control and Hospital Epidemiology (ICHE)*; and (4) submit a one-page commentary to explain the role of the IDSA/SHEA guidelines into existing guidelines. The motion was seconded by Dr. Singh and **unanimously approved** by HICPAC.

Dr. Brennan acknowledged that HICPAC's one-page commentary to IDSA and SHEA was part of the unanimously approved motion. However, he clarified that the commentary should be directed to *ICHE* rather than IDSA and SHEA. HICPAC should appeal to *ICHE* about the importance of providing HICPAC with a platform to explain differences between the HICPAC and IDSA/SHEA guideline development processes. HICPAC should also use this opportunity to describe its role in the process and elaborate on its narrative statement of support.

HICPAC Votes

Issue 1. Dr. Brennan announced that he, Ms. Bjerke, Drs. Bell and Cardo, and other HICPAC members as needed would participate on a conference call on November 29, 2007 to further discuss and revise the clinical sepsis and BSI sections of the home healthcare definitions. The changes would be distributed to HICPAC within 24 hours of the conference call.

A motion was properly placed on the floor and seconded by Drs. Pegues and Ramsey, respectively, for HICPAC to approve the sections of the home healthcare definitions that do not require revision. HICPAC would call for a subsequent vote on the final iteration of the document after the clinical sepsis and BSI sections were revised. HICPAC **unanimously approved** the motion with no further discussion.

Issue 2. Dr. Engel suggested modifying question 3 for the norovirus guideline with the following language: "What are the best methods to identify norovirus outbreaks in healthcare settings, including community surveillance where these outbreaks often originate?" Dr. Stevenson encouraged other HICPAC members to submit additional comments on the norovirus guideline.

A motion was properly placed on the floor and seconded by Drs. Pegues and Lundstrom, respectively, for HICPAC to adopt the five key questions that were proposed to guide the development of the norovirus guideline. HICPAC also would adopt the revisions to question 3 as suggested by Dr. Engel. HICPAC **unanimously approved** the motion with no further discussion.

Issue 3. HICPAC agreed to further table Dr. Schecter's tabled motion to compile and submit evidence to the Joint Commission on standards on processes to address three HAIs: VAP, SSIs and catheter-based BSIs.

HICPAC Business

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

- Dr. Brennan will circulate an e-mail message to HICPAC to solicit volunteers to serve on the two new workgroups to develop a public policy memorandum advocating for the HAI elimination effort and also to create MRSA model legislation.
- Dr. Brennan will circulate an e-mail message to HICPAC to reinforce the need for members to participate in a formal review of evidence tables for the CA-UTI and norovirus guidelines.
- Dr. Brennan will send a letter of HICPAC's endorsement of CDC's guidance on prioritization for pandemic influenza vaccine to Dr. Schwartz for circulation to HHS.
- Dr. Brennan will provide Dr. Bell with a breakdown of the resources and costs that have been expended to date in developing the CA-UTI guideline.

- Dr. Brennan will send a letter to the IDSA/SHEA HAI Guideline Committee with the requests as outlined in HICPAC's unanimously approved motion.
- Dr. Brennan will send a letter to *ICHE* to explore the possibility of HICPAC submitting a two-page commentary related to the IDSA/SHEA guidelines.
- Dr. Brennan will participate in the next conference call of the MDRO Workgroup.
- Dr. Bell will identify mechanisms to provide risk communications training to HICPAC.
- Dr. Bell will convene a conference call on November 29, 2007 with Ms. Bjerke and Drs. Brennan and Cardo to further discuss and revise the clinical sepsis and BSI sections of the home healthcare definitions.
- Dr. Bell will convene a conference call with HICPAC and Dr. Schwartz to further discuss CDC's guidance on prioritization for pandemic influenza vaccine.
- Dr. Bell will facilitate involving Dr. Daniel Pollock, of CDC, to assist the EHR Workgroup in revising the white paper.
- The HICPAC members and liaisons will continue to participate in their respective workgroups to further develop the CA-UTI, norovirus and MDRO guidelines.
- The HICPAC members and liaisons will volunteer to serve on one of the two new workgroups.
- DHQP will provide HICPAC with copies of the presenters' slides.

Closing Session

The next HICPAC meeting will be held on February 11-12, 2008 in Atlanta, Georgia.

With no further discussion or business brought before HICPAC, Dr. Brennan adjourned the meeting at 12:10 p.m. on November 14, 2007.

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

Date

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