Healthcare Infection Control Practices Advisory Committee
Meeting Minutes
June 17-18, 2010
Atlanta, Georgia 30333

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

TABLE OF CONTENTS

Page

Attachment 1: List of Participants A1.1

Executive Summary ..... -i-

Meeting Minutes 1

June 17, 2010

Opening Session 1
Update on DHQP Activities 1
Status Report on HICPAC Guidelines and Documents: SESSION 1 14
Public Comment Session 29
Proposal of a New HICPAC Workgroup 30
Liaison and *Ex-Officio* Reports 32

June 18, 2010

Status Report on HICPAC Guidelines and Documents: SESSION 2 36
Update on the Use of Live Attenuated Influenza Vaccines for HCP 46
Update on Hepatitis B Vaccine for Persons with Diabetes 50
HICPAC Business Session 53
Closing Session 54

ATTACHMENT 1

List of Participants

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Ms. Barbara DeBaun (Association of Professionals of Infection Control and Epidemiology, Inc.)
Ms. Lori Harmon (Society of Critical Care Medicine)
Dr. David Henderson (National Institutes of Health) [via conference call]
Dr. Charles Huskins (Infectious Disease Society of America)
Dr. Marion Kainer (Council of State and Territorial Epidemiologists)
Dr. Lisa Maragakis (Society for (Healthcare Epidemiology of America)
Ms. Lisa McGiffert (Consumers Union)
Ms. Jeannie Miller (Centers for Medicare and Medicaid Services)
Dr. Sheila Murphey (Food and Drug Administration)
Ms. Shirley Paton (Public Health Agency of Canada)
Kelly Podgorny (The Joint Commission) [via conference call]
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Dr. Mark Russi (American College of Occupational and Environmental Medicine)
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Ms. Roslyn Schulman (American Hospital Association) [via conference call]

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Gabriela Trioch
Abbigal Tumpey
Wendy Vance
John Ward
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Members of the Public

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Russ Castioni (3M Company)
Kathy Day (Consumers Union)
Kerry Edgar (Medegen, Inc.)
Nancy Foster (American Hospital Association) [via conference call]
Hudson Garrett (PDI Healthcare)
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Danny Griffin (Sage Products)
Jane Kirk (GOJO Industries, Inc.)
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EXECUTIVE SUMMARY

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on June 17-18, 2010 in Atlanta, Georgia. None of the HICPAC voting members declared any new conflicts of interest for the record that were pertinent to the items on the published agenda for the June 17-18, 2010 HICPAC meeting.

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

- Replacement of the "*1994 U.S. Public Health Service Guidelines for HIV Prevention in Organs and Tissues*" with the expanded "*2010 U.S. Public Health Service Guidelines on Preventing Unintentional Infectious Disease Transmission Through Solid Organ Transplantation*."
- Healthcare-associated infection (HAI) activities by the Emerging Infections Program.
- Communications activities on healthcare safety issues.
- Activities to improve hand hygiene in healthcare facilities.
- Emerging resistance in Enterobactriaceae in the United States.
- Environmental Microbiology Laboratory activities.
- American Recovery and Reinvestment Act investment to the CDC Emerging Infections Program and Epidemiology and Laboratory Capacity Grants to state health departments.

HICPAC members and CDC staff presented a series of updates regarding the current status of the following HICPAC guidelines and documents:

- Neonatal Intensive Care Unit Infection Prevention Guideline.
- Guideline for the Prevention of Surgical Site Infections.
- Infection Control Guidance for Ambulatory Surgical Centers (ASCs).
- Healthcare Personnel (HCP) Infection Control Guideline.
- Guideline for the Prevention and Control of Norovirus Gastroenteritis Outbreaks in Healthcare Settings.

HICPAC provided thoughtful input to assist the workgroups in making further progress in developing and revising the guidelines. For the Norovirus Guideline, the Chair tabled HICPAC's final vote on the document because extensive commentary was offered during the meeting and the public comment period in the *Federal Register* would not close until July 16, 2010. Agreement was reached for HICPAC to convene a conference call prior to the November 2010 meeting to take a final vote on the revised Norovirus Guideline.

The Chair opened the floor for consumer advocates across the country who were attending the meeting to make public comments. During the public comment period, the Chair confirmed to CDC that HICPAC would submit formal comments on the updated "HHS National Action Plan to Prevent Healthcare-Associated Infections."

CDC made presentations on two issues that are currently being addressed by the Advisory Committee for Immunization Practices (ACIP). Efforts are underway to increase uptake of live

attenuated influenza vaccine among HCP. ACIP is proposing guiding principles and policy considerations to expand hepatitis B virus (HBV) vaccination to persons with diabetes.

HICPAC members were concerned about extremely poor infection control practices in ambulatory care settings. One study presented by CDC showed that ~21% of ASCs used single-use safety lancets on multiple patients and ~33% of ASCs failed to clean and disinfect glucometers after each use. HICPAC emphasized the critical need for CDC to immediately issue guidance about this issue.

During the business session, the HICPAC members discussed their next steps in further developing and revising the guidelines, described their future plants to continue to support the workgroups, and reviewed their action items.

The next HICPAC meeting would be held on November 4-5, 2010 in Washington, DC.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE
June 17-18, 2010
Atlanta, Georgia

Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC). The proceedings were held on June 17-18, 2010 in Building 19 of the Tom Harkin Global Communications Center at the CDC Roybal Campus in Atlanta, Georgia.

Opening Session

Dr. Patrick Brennan, Chair of HICPAC, called the meeting to order at 9:09 a.m. on June 17, 2010. He welcomed the attendees to the meeting and opened the floor for introductions. None of the HICPAC voting members declared any new conflicts of interest for the record that were pertinent to the items on the published agenda for the June 17-18, 2010 HICPAC meeting. The list of participants is appended to the minutes as Attachment 1.

Update on DHQP Activities

A panel of DHQP leadership and senior staff presented a series of updates on DHQP's recent healthcare quality and promotion activities. The updates are summarized below.

Guidelines on Preventing Unintentional Infectious Disease Transmission Through Solid Organ Transplantation. Dr. Matthew Kuehnert is the Director of the Office of Blood, Organ and Other Tissue Safety in DHQP. He reported that the Health Resources and Services Administration (HRSA) oversees organ transplantation through a contract with the United Network for Organ Sharing (UNOS) to administer the Organ Procurement and Transplantation Network (OPTN).

Organ donors are screened with a history questionnaire and limited laboratory screening, primarily serology, for a list of pathogens. With the exception of HIV-positive results, all organs

must be offered to transplant centers regardless of donor testing. UNOS/OPTN has mandated this requirement regardless of risk. Organ Procurement Organizations (OPOs) use the 1994 *U.S. Public Health Service Guidelines for HIV Prevention in Organs and Tissues* to decide whether organ donors are "CDC high risk" or "not CDC high risk."

CDC is currently developing guidelines on the prevention of unintentional infectious disease transmission through solid organ transplantation for a number of reasons. The 1994 U.S. Public Health Service (PHS) guidelines are outdated for HIV and were not initially intended to be applied to other pathogens. The Food and Drug Administration (FDA) regulations currently address tissue donor screening. The organ community has still not reached consensus on striking an appropriate balance between safety of transplantation and the availability organs.

The next-of-kin is given screening questionnaires because most organs are from deceased or brain-dead donors. Unlike blood and tissue donors, organ donors are screened with serology rather than nucleic acid testing. Even if organs are from "high-risk" donors, recipients are not routinely tested for transmitted infectious diseases post-transplantation.

The 1994 PHS guidelines outlined behavior and history exclusionary criteria for HIV risk for seven groups:

1. Men who had sex with other men in the preceding five years.
2. Persons who reported non-medical intravenous (IV), intramuscular or subcutaneous injection of drugs in the preceding five years.
3. Persons with hemophilia or related clotting disorders who received human-derived clotting factor concentrates.
4. Men and women who engaged in sex in exchange for money or drugs in the preceding five years.
5. Persons who had sex in the preceding 12 months with any individuals described in groups 1-4 above or with an individual known or suspected to have HIV infection.
6. Persons who were exposed in the preceding 12 months to known or suspected HIV-infected blood through percutaneous inoculation or contact with an open wound, non-intact skin or mucous membrane.
7. Inmates of correctional systems.

The 1994 PHS guidelines described HIV risks, but public health authorities have investigated a number of other notable organ transplant-transmitted infections since that time, including hepatitis C virus (HCV), Chagas disease, West Nile virus, lymphocytic choriomeningitis virus, rabies, TB, babesiosis, zygomycosis and coccidiodomycosis. Due to the increased demand for organ transplantation from 1988-2006, less than suitable donors have been accepted over this period of time.

Dr. Kuehnert described CDC's methodology to make objective decisions on revising and updating the 1994 PHS guidelines. The 2010 guidelines are more focused and have a broader scope than the 1994 guidelines to meet current needs. The 1994 guidelines solely focused on transmission of HIV through organs, tissues, banked breast milk and semen. However, the

2010 guidelines focus on transmission of HIV, hepatitis B virus (HBV) and HCV through solid organs in an evidence-based process.

The 2010 guidelines are designed to prevent "unintended" transmission because organ donors frequently will be positive for HBV, HCV or other pathogens screened with the exception of HIV. If a recipient is in dire need of an organ, a seropositive organ will be transplanted with the assumption that the benefit of a life-saving transplant outweighs the risk of transmitting infection.

CDC's evidence-based process to revise the 1994 guidelines was based on a targeted systematic review of the best available evidence and links between the recommendations and supporting data. CDC served as the lead PHS agency in updating the 1994 guidelines and awarded contracts to the Center for Evidence-Based Practice at the University of Pennsylvania Health System (UPHS) and the ECRI Institutes/Evidence-Based Practice Center to obtain external expertise in this effort.

CDC organized a number of advisors for the guideline development process. The Expert Panel included persons with expertise in consent issues and laboratory medicine, hepatitis and HIV content experts, an OPO representative, a transplant surgeon, transplant physicians and transplant identification physicians. The Review Committee included CDC's federal partners in PHS and various external organizations representing the broader transplant community.

After the advisors were organized, CDC and its partners conducted a preliminary literature search, developed key research questions along with inclusion and exclusion criteria, produced an evidence report, and summarized the evidence for the key research questions. CDC and its partners are currently in the process of developing the 2010 guidelines. CDC is aiming to submit the 2010 guidelines for clearance and publication over the next few months.

Dr. Kuehnert informed HICPAC of CDC's other activities related to organ transplantation. In December 2009, *The New York Times* reported a high-profile case of two kidney transplant patients who contracted brain infections from the same organ donor. This case prompted officials to reexamine organ transplant rules. In December 2009, the *Wall Street Journal* published an article, "The Informed Patient," that described the downside of organ donation. The article further noted that some experts are calling for improved testing and tracking of organ donors and recipients and raised the possibility of conducting surveillance.

A new organ and tissue transplant module has been proposed for inclusion in the CDC National Healthcare Safety Network (NHSN). CDC is currently discussing this proposal with the organ transplant community. The new module ideally would track transplantation outcomes in real time to more rapidly recognize transmission events and follow-up other organs and tissues from the same donor.

The Council of State and Territorial Epidemiologists (CSTE) recently approved a position statement on improving the detection and response to transplant-transmitted infections (TTIs), but the role of health departments in these investigations and the involvement of healthcare epidemiology in hospitals are often unclear. The role of the federal government is uncertain as well due to weak oversight of TTIs. Overall, public health concerns are being left behind as

technology advances and the definition of “organs” expands to include human faces, limbs and nerves. However, the 2010 guidelines will be a strong starting point in addressing these issues.

HAI Activities by the Emerging Infections Program (EIP). Dr. Shelley Magill is the Medical Director of the Healthcare-Associated Infections/Community Interface (HAIC) Activity in DHQP. She reported that EIP was established in 1995 as a specialized public health network of multiple CDC programs and ten state health departments. Other EIP collaborators include local health departments, academic institutions, ICPs and federal agencies. The ten EIP sites and their academic partners represent a total catchment area of 44 million persons.

EIP’s primary activities focus on active surveillance, applied epidemiology and laboratory research, implementation and evaluation of pilot prevention and intervention projects, and flexible response. Since its establishment in 1995, EIP has had a significant impact on public health practice in the United States, including activities on foodborne pathogens and other organisms. EIP’s research has been published in the *Journal of the American Medical Association* (*JAMA*), *New England Journal of Medicine* and other peer-reviewed journals.

EIP’s major projects include Active Bacterial Core Surveillance, influenza, human papillomavirus surveillance, Foodborne Disease Active Surveillance Network, hepatitis surveillance and HAIC. CDC incorporated HAIC into EIP as a result of increased federal support through American Recovery and Reinvestment Act (ARRA) dollars; the expanded role of state health departments in HAI detection and prevention; and the growing need for infrastructure to conduct a large number of HAI-related surveillance and applied research activities.

The HAIC Steering Group was formed with CDC staff and EIP site investigators in the summer of 2009 with the following charge: (1) provide an overarching vision and scientific direction for HAI-related EIP activities; (2) ensure effective communication between CDC programs and EIP sites involved in HAI-related activities; and (3) update and advise the EIP Steering Group on HAI-related activities and issues.

EIP sites recruit facilities to join NHSN and also encourage existing NHSN participants to join the EIP group and share data for the purpose of performing surveillance innovation and other EIP HAIC projects. Under HAI surveillance innovation projects in HAIC, EIP NHSN network facilities are conducting activities to reduce the burden of data collection and reporting. The first HAI surveillance innovation project is focusing on simplifying the collection of denominator data for central line-associated bloodstream infections (CLABSI).

Other HAIC projects include surveillance of *Clostridium difficile* infection (CDI) and Candidemia, administration of an HAI/antimicrobial use prevalence survey, surveillance of bloodstream infections, HCV and HBV in outpatient dialysis facilities, and surveillance of infections due to multidrug-resistant gram-negative bacilli. These projects are in various stages of development at this time.

Dr. Magill provided additional details on two of the HAIC projects. The CDI surveillance project was established with three primary objectives. First, the population-based incidence of community- and healthcare-associated CDI will be determined. To achieve this objective,

reports of all *C. difficile* toxin-positive stool specimens will be collected from clinical, reference and commercial laboratories to identify cases.

Second, *C. difficile* strains that are responsible for CDI will be characterized with a focus on strains from community-associated cases. To achieve this objective, CDC and EIP reference laboratories will collect and process *C. difficile*-positive specimens.

Third, the epidemiology of community- and healthcare-associated CDI will be described and hypotheses will be generated for future research activities. To achieve this objective, case report forms and health interview questionnaires will be used to collect epidemiologic and clinical information from CDI patients. At this time, nine of the ten EIP sites are conducting CDI surveillance.

The HAI/antimicrobial use prevalence survey is being administered to fill gaps in NHSN. NHSN maintains data on device- and procedure-associated infection events from selected locations to determine incidence rates, but additional information is needed on all HAIs across all acute care patient populations. The point prevalence survey was designed as a resource-effective approach to obtain and utilize these data to inform decision-making about appropriate targets and prevention strategies in the future.

In phase 1, the HAI/antimicrobial use prevalence survey was piloted in nine facilities in one U.S. city in August 2009. In phase 2, the survey will be launched in July-August 2010 with limited rollout in all ten EIP sites. Phase 2 will be used to improve any logistical issues with the survey methodology and procedures. In phase 3, the survey will be launched in 2011 with full-scale rollout at hundreds of healthcare facilities in all ten EIP sites.

The overall objectives of the entire HAI/antimicrobial use prevalence survey effort are to (1) estimate HAI prevalence in a large sample of acute care inpatients in U.S. facilities within the EIP catchment area; (2) determine the distribution of HAIs by major infection sites and pathogens, including antimicrobial-resistant pathogens; and (3) estimate the prevalence and describe the rationale for antimicrobial use within the same large sample.

The HAI/antimicrobial use point prevalence survey was designed to be conducted on a single day by acute healthcare facilities that will volunteer for this effort. CDC and the EIP sites will make strong efforts to ensure broad representation by multiple and diverse types of facilities. Patients will represent a random sample of acute care inpatients who are in the hospital on the morning the survey is administered.

Local ICPs in the participating facilities and EIP personnel at each site will collect data from the survey. ICPs will serve as expert reviewers of the data. CDC expects these activities to be completed in the summer of 2010. CDC also hopes to make comparisons between its HAI/ antimicrobial use prevalence survey and the European-wide prevalence survey that is being conducted by the European Centre for Disease Prevention and Control.

Dr. Magill concluded that CDC is making efforts to demonstrate the effectiveness and success of the HAIC projects to sustain these activities after the ARRA funding cycle has ended. For

example, CDC will explore potential opportunities to administer the HAI/antimicrobial use prevalence survey in long-term care facilities (LTCFs) and ambulatory surgical centers (ASCs).

HICPAC advised CDC to engage the Association of Professionals of Infection Control and Epidemiology, Inc. (APIC) and the Society for Healthcare Epidemiology of America (SHEA) in the full-scale rollout of the HAI/antimicrobial use prevalence survey. HICPAC reminded CDC that both APIC and SHEA have a wealth of experience in administering one-day prevalence surveys.

Communications Activities on Healthcare Safety Issues. Ms. Abbigail Tumpey is the Associate Director for Communications Science in DHQP. She reminded HICPAC that during the November 2008 meeting, the members advised CDC to improve its communications on healthcare safety issues in four key areas. CDC should improve its web presence on HAIs. CDC should take a multifaceted approach to improve its communications and timely output of information. CDC should improve its outreach to consumers. CDC should communicate to a broader healthcare population.

Ms. Tumpey described actions CDC has taken since the November 2008 meeting to address HICPAC's recommendations on communications issues. To improve its web presence on HAIs, CDC launched new web pages on its website for HICPAC, ARRA resources by state, hand hygiene in healthcare settings, and injection safety and medical errors. By the end of 2010, CDC will launch three additional new web pages on its website: antibiotics/antimicrobial resistance, methicillin-resistant *Staphylococcus aureus* (MRSA), and HAIs.

In redesigning the website, CDC implemented an innovative solution to allow for content syndication. This approach automatically updates information on the websites of health departments, healthcare facilities and other partners when CDC updates a particular web page. CDC launched the "Safe Healthcare Blog" in March 2010 to interpret and disseminate scientific information in plain language to the public. The popular blog features commentaries by a number of experts in the field: APIC, SHEA, Infectious Diseases Society of America (IDSA), and Consumers Union.

To date, CDC and external experts have contributed to the blog in the areas of gram-negative bacilli, injection safety, catheter-associated urinary tract infections (CAUTI) and *C. difficile*. The blog received >8,500 visitors in May 2010 alone with ~300 visitors per day who remain on the site for ~2.5 minutes on average. The blog has received ~100 comments since its launch in March 2010. CDC also uses social media to promote and drive consumer traffic to the Safe Healthcare Blog. At this time, the blog has 45,000 friends on Facebook and 38,000 followers on Twitter.

DHQP manages several GovDelivery listservs in which individuals self-subscribe to receive e-mail updates on web pages of interest. The system drives persons to the CDC website and promotes availability of materials. CDC uses the listservs to track the volume of materials distributed, the number of persons who open files, and the number of persons who visit the web page. The antimicrobial resistance, HICPAC, HAI, injection safety and NHSN listservs have 61,406 subscribers, while the three vaccine safety listservs have 190,486 subscribers.

Of ~300 media inquiries that DHQP receives each year, 25% are by top-tier national shows or publications (e.g., *Time*, *Los Angeles Times*, *Chicago Tribune*, *Wall Street Journal* and CNN), 20% are by trade publications, and the remainder are by local or online publications

After CDC released its state-specific HAI summary report, >500 persons accessed the live tele-briefing with representation by 25 media outlets, 72 state health department employees and >350 healthcare facility staff. The archived tele-briefing has been accessed by 72 persons and has resulted in key messages or direct quotes in ~30 articles. The *JAMA* report on infection control in ASCs prompted interviews with 11 major outlets prior to its release in June 2010 and 311 articles as of June 10, 2010.

To improve risk communications, CDC conducted formative research in a series of focus groups to test the timeliness and effectiveness of patient notification letters. CDC will use findings from this effort to develop and distribute a communications toolkit to states and healthcare facilities. The toolkit will include a standardized template with key messages, guidance, resources (*i.e.*, the CDC-Info Call Center) and best practices on disseminating patient notification letters. CDC also will partner with the National Public Health Information Coalition to create a train-the-communicators model.

To improve outreach to clinicians, CDC collaborated with Medscape to broadcast a series of commentaries by experts in the field. To date, CDC has posted 26 three- to five-minute videos on Medscape that have been viewed >250,000 times by clinicians at an average of 10,000 views per commentary. Key commentaries on HAIs have been made by Dr. Arjun Srinivasan (Associate Director for Healthcare Associated Infection Prevention Programs, DHQP); Dr. William Schaffner (President of IDSA); and Dr. Sanjay Saint (HICPAC liaison for the Society of Hospital Medicine). The commentaries are available at www.medscape.com/cdc-commentary.

CDC, APIC, IDSA and SHEA collaborated with Medscape to provide a continuing education course to clinicians, "Roadmap for HAI Prevention Research: Bench to Bedside and Back." After filming was completed at SHEA's 5th Decennial International Conference on HAIs in March 2010, the course was viewed 35,250 times by 27,500 persons. To date, 6,085 persons have taken the post-test and claimed continuing education credits. CDC is partnering with Epocrates to develop an essential learning course that would be available to clinicians on their iPhones.

Ms. Tumpey concluded that CDC's next steps to advance and improve its communications activities on healthcare safety issues will be to continue to redesign and update the website and individual web pages; strengthen collaborations with APIC, IDSA and SHEA to cross-promote information among all partners; conduct formative research with clinicians and consumers; partner with HHS on the HAI media campaign; and offer additional continuing education courses.

HICPAC commended the CDC/DHQP Communications Teams and their partners on creating innovative and extraordinary communications activities to rapidly provide the public with accurate information on healthcare safety issues through multiple media and venues. HICPAC also was pleased that CDC is providing leadership to ensure HAI messages delivered to the

public are driven by experts in the field and rigorous science. HICPAC congratulated CDC on providing this valuable resource to the public.

HICPAC made two key suggestions for CDC to consider in further refining its communications activities. First, CDC should partner with the American Hospital Association and other professional societies to directly communicate with and provide materials to trustees in hospitals and other health systems. Hospital and health system trustees are responsible for steering organizations toward more appropriate infection control practices.

Second, CDC should consult with information technology experts to update its search engine. Front-line providers in the field who are members of professional societies frequently inform these organizations of difficulties in locating topics on the CDC website.

Hand Hygiene Activities. Dr. Katherine Ellingson is an epidemiologist in DHQP. She reported that HICPAC's hand hygiene guideline was published in October 2002, but an update is not expected in the near future. Since that time, however, the World Health Organization (WHO) published hand hygiene recommendations and implementation tools in 2009. The HICPAC guideline and WHO recommendations are consistent overall. The WHO implementation guide, tools, key documents and other resources are available at www.who.int/gpsc/5May/en.

Since its launch in 2009, >11,000 hospitals worldwide have registered in the WHO "SAVE LIVES: Clean Your Hands" Campaign, including >2,000 U.S. healthcare facilities. Participants in the campaign make a commitment to adapt WHO resources to local needs, exchange materials and share successes. To date, 38 countries have launched national coordinated hand hygiene campaigns based on WHO materials. HHS plans to sign the WHO global partnership in 2010.

Dr. Ellingson described CDC's ongoing activities to support its four priority areas to improve hand hygiene. First, a standardized hand hygiene measurement has not been developed in the United States to date. Without a standardized measurement, progress in hand hygiene cannot be properly benchmarked, adherence cannot be assessed at the national level, and published studies cannot be interpreted and compared. Consensus is needed on measures to assess hand hygiene, a platform to train observers, and a data aggregation and reporting format.

CDC is collaborating with the University of Iowa for providers to download the "iScrub" application on their iPhones at no charge. The application will allow providers to observe proper hand hygiene behaviors before and after room entry and exit as well as WHO's five opportune moments for hand hygiene: before contact with the patient, before the procedure, after exposure, after contact with the patient, and after environmental exposure. Providers who download the iScrub application can register their hospitals to participate in a pilot project of standardized training techniques for observers and a data feedback interface with hospitals.

Second, innovation in hand hygiene measurement (*i.e.*, alcohol sniffers, wireless sensors and hospital video auditing) has increased "oversight" technology. Although these technologies have generated a wealth of data with real-time feedback, CDC is conducting research at this

time to evaluate the sustainability, cost-effectiveness and optimal use of data. CDC plans to publish findings from this research in the near future.

Third, implementation guidance on emerging pathogens in healthcare settings is needed to determine knowledge gaps. With hand hygiene in the current environment of increased *C. difficile*, for example, sufficient data have not been collected to determine the incremental gain of alcohol-based hand gel versus soap and water if gloves are worn. Guidelines have not been harmonized between food preparation and services versus patient care in LTCFs and assisted living facilities. CDC is collaborating with FDA and other foodborne illness partners to address this issue.

CDC updated its hand hygiene web page in May 2010 with guidelines, interactive training and education materials, implementation tools, measurement tools, and a patient empowerment video. Other resources on CDC's updated hand hygiene web page include training modules, state campaigns, and promotional materials that are relevant to U.S. settings.

Fourth, CDC is supporting hand hygiene improvement through state and local collaboratives. For example, South Carolina adapted WHO materials in its "Grime Scene Investigation: South Carolina" campaign that was spearheaded by the South Carolina Hospital Association and involved all acute and non-acute care facilities in the state. South Carolina declared May 5, 2010 as "Clean Hands Day."

Maryland launched its "Hospital Hand Hygiene Collaborative" in November 2009 with >200 attendees from >40 acute care and specialty care hospitals. Maryland followed up the campaign with a series of webinars to standardize hand hygiene measurement across the state. CDC posted materials from both the Maryland and South Carolina hand hygiene campaigns on its website.

HICPAC commended CDC on its activities to improve hand hygiene in healthcare facilities, particularly the patient empowerment video. The HICPAC members made several suggestions to support ongoing efforts to increase adherence to hand hygiene guidelines.

- HICPAC should develop and release a supplement to its 2002 hand hygiene guideline to clarify the inaccurate belief that washing hands is better than using an alcohol-based hand gel for *C. difficile*. HICPAC's existing hand hygiene recommendations that reflect the actual workflow in U.S. healthcare facilities should be included in this document.
- CDC should recommend, standardize and compare one opportune moment (*i.e.*, before contact with the patient) for hand hygiene across institutions. Efforts to standardize and measure WHO's five opportune moments for hand hygiene will be extremely difficult in U.S. healthcare settings because many inpatients are in private rooms.
- CDC should partner with SHEA to develop a U.S.-specific hand hygiene implementation guide that would be similar to the compendium of strategies for the prevention of HAIs.
- CDC should develop and release guidance to assist healthcare facilities in auditing hand hygiene data due to tremendous differences in practices observed by ICPs, "secret shoppers," front-line staff, liaisons and unit councils.

- CDC should partner with multiple professional societies to increase access to the patient empowerment video beyond its broadcast on the NBC patient channel and CDC website. This tool should be included as an integral component of any hand hygiene program developed by healthcare facilities. Studies have shown that patients are still intimidated by and afraid to "challenge" hand hygiene and infection control practices of their physicians.

Emergence of the New Delhi Metallo-1 (NDM-1) Metallo-β-Lactamase (MBL) Among Enterobactriaceae in the United States. Dr. Brandi Limbago is the Team Lead for the Antimicrobial Resistance and Characterization Laboratory in DHQP. She reported that MBLs are a class of enzymes with the ability to hydrolyze all *β*-lactams (including carbapenems, penicillins and extended spectrum cephalosporins), but not aztreonam.

MBLs pose a serious threat to infection control because of their high mobility and capacity to confer resistance to a number of antibiotics. MBLs require zinc for enzymatic activity that is not diminished by serine *β*-lactamase inhibitors, but is inhibited by ethylenediaminetetraacetic acid and other chelators of divalent cations.

VIM classes 1-24 and IMP classes 1-27 are the most common MBLs found globally among *Pseudomonas* spp., *Acinetobacter* spp. and *Enterobacteriaceae*. However, SPM-1 and GIM-1 have been reported in *Pseudomonas aeruginosa* in Brazil and Germany, respectively, while SIM-1 has been reported in *Acinetobacter baumannii* in Korea. These species of MBLs are not common in the United States and have not rapidly spread in other countries.

An initial report of a new NDM-1 MBL was reported in *Antimicrobial Agents and Chemotherapy* in December 2009. The case involved a Swedish patient of Indian origin who traveled to New Delhi and acquired a UTI caused by NDM-1-producing *Klebsiella pneumoniae*. The bla_{NDM-1} gene is contained in a complex genetic structure on a 180-kb plasmid that is easily transferable to an *Escherichia coli* recipient. The bla_{NDM-1} plasmid contained resistance genes for all antibodies tested except for fluoroquinolones and colistin. The NDM-1 enzyme shares little identity with other MBLs.

From December 2009 to the present, 17 hospitals in the United Kingdom reported 22 cases of NDM-1-producing isolates, including two deaths. UTI and respiratory infections were the primary cause of the NDM-1-producing isolates. All of the U.K. cases were strongly associated with receipt of medical care (*i.e.*, cancer treatment, cosmetic surgery, and renal or liver transplantation) in India or Pakistan.

Moreover, ten cases of NDM-1-producing isolates were recently documented in patients in the United Kingdom who did not travel abroad for medical treatment. In 2007, >100,000 persons traveled abroad from the United Kingdom to obtain medical treatments ranging from heart operations to cosmetic surgery. The United Kingdom expects >200,000 persons to travel abroad for medical treatment in 2010.

From April 2009 to May 2010, NDM-1-producing isolates were identified in the United States in Massachusetts, California and Illinois in three different *Enterobacteriaceae* organisms: *E.*

cloacae, *K. pneumoniae* and *E. coli*. All three cases traveled to and received medical treatment in India. The susceptibility profile of the NDM-1 MBL-producing isolates in Sweden and the three U.S. states showed that all the cases had high values with greater than the upper limit.

CDC has capacity to detect MBLs in laboratories with phenotypic and molecular testing. MBLs generally are shown to be resistant to at least one carbapenems during testing, but the Modified Hodge Test is used to detect carbapenemase activity. The MBL Etest has a chelating agent to locate organisms. The Direct TE Disk Test, blocked microdilution assay, polymerase chain reaction (PCR) and DNA sequence analysis also are used to detect MBLs. CDC shares its phenotypic and molecular testing methods with state partners and clinical laboratories to aid in the detection of MBLs.

Dr. Limbago concluded that CDC would publish a notice in the *Morbidity and Mortality Weekly Report* (*MMWR*) on June 25, 2010 to alert readers to the potential for NDM-producing *Enterobacteriaceae* in patients who received medical care in India or Pakistan. CDC also would partner with CSTE and state laboratories to more broadly communicate the alert.

CDC's current testing methods will identify these isolates as carbapenemase producers. Existing infection control guidance for Carbapenem-resistant *Enterobacteriaceae* is appropriate for MBL producers as well. CDC is aware of the need for a mechanism for surveillance and epidemiologic purposes, but not for therapeutic or infection control purposes. CDC is now requesting all Carbapenem-resistant *Enterobacteriaceae* isolates from patients with recent travel to India or Pakistan within the past six months.

Environmental Microbiology Laboratory Activities. Dr. Judith Noble-Wang is the Team Lead of the Environmental and Applied Microbiology Laboratory Group in DHQP. She reported that CDC's current water biofilm research activities are focusing on the development of tools for measuring, recovering and characterizing potable water biofilms and the development of model water biofilm systems to evaluate disinfection methods.

Drinking water distribution system biofilms can serve as reservoirs for opportunistic pathogens, such as Legionella and non-tuberculosis mycobacteria, and may cause HAIs. CDC is using its biofilm reactor to develop a model system to investigate the interaction and disinfection of pathogenic bacteria in biofilms with and without amoebae. CDC inoculated four species that are commonly found in potable water: *Mycobacterium mucogenicum*, *Sphingomonas paucimobilis*, *Delftia acidovoran*, and *Bradyrhizobium japonicum* (or *Methylobacterium mesophilicum*).

CDC created a biofilm formation on polyvinyl chloride substratum. The multi-species drinking water biofilm model showed that total bacteria grew in a consistent and repeatable pattern over a period of 16 days. Biofilm containing *B. japonicum* was dominated by *S. paucimobilis*, while *M. mesophilicum* was dominant when this species replaced *B. japonicum*. Biofilm containing *B. japonicum* or *M. mesophilicum* was disinfected with 2, 16 or 32 mg/liter monochloramine. The response of biofilm to five- or 24-hour exposure was similar.

M. mucogenicum dominated exposure to the 2 mg/liter monochloramine composition and was found to be most tolerant to monochloramine disinfection in the biofilm model. *Acanthamoeba*

polyphaga was integrated into the multi-species drinking water distribution system biofilm model. *A. polyphaga* and other free-living amoebae are frequently found in biofilms and graze on bacteria. Bacteria are known to survive the action of disinfectants, such as monochloramine, by residing within encysted amoebae.

CDC integrated *A. polyphaga* into the model to answer three research questions: (1) Can *A. polyphaga* reproducibly integrate in a multi-species drinking water biofilm model? (2) How does *A. polyphaga* impact the bacterial population structure of the biofilm? (3) Does the presence of *A. polyphaga* in the biofilm model affect the efficacy of monochloramine disinfection?

The model showed that amoebae in biofilms containing *B. japonicum* did not significantly change the end composition of the four bacterial species. *M. mesophilicum* dominated bacteria-only biofilms, but its prevalence was greatly reduced in biofilms co-cultured with amoebae. The population of *D. acidovorans* was relative to other bacterial species and was enhanced by the presence of amoebae in both biofilm system models. Amoebae enhanced bacterial tolerance to disinfection by monochloramine at 4- and 24-hour exposure concentrations.

CDC plans to conduct water biofilm HAI prevention research based on the availability of funds. The purpose of this research will be to determine if infrequent water use in hospital patient rooms results in deterioration of microbial water quality. Microbial water quality in shower fixtures and sink faucet taps will be assessed in vacant patient rooms in a volunteer acute care hospital. The efficacy of a water-flushing regime in reducing patient exposure to opportunistic pathogens will be evaluated. The potential outcome of this research will be to implement a flushing schedule for showers and sink taps in rooms known to be vacant in hospital settings.

CDC will launch the HHS healthcare environmental sampling survey in the fall of 2010 through the summer of 2011. The purpose of this effort will be to establish bioburden levels of contamination of non-critical patient care surfaces with multidrug-resistant organisms (MDRO) and general bacterial flora in hospitals and nursing homes. Sample surfaces that are common to acute care facilities, frequently touched by patients and touched by healthcare professionals (HCP) will be included in the study.

A composite sampling strategy will be implemented from surfaces with the greatest contribution to contamination: bedrails, over-the-bed tables, IV pumps and poles, bathroom handrails and toilet handles, television remotes, telephones and call bells. CDC's established sponge sampling procedure will be utilized.

CDC will design the HHS healthcare environmental sampling survey to evaluate performance and improve cleaning techniques based on pre-/post-cleaning results. Infection control data will be collected to determine whether the room was used for isolation of an MDRO patient, when the room and bathroom were last cleaned, and if clinical factors were present that could impact contamination (*i.e.*, active diarrhea, open wounds or invasive device use). Identifying data on patients or hospital personnel will not be collected in the survey.

CDC is actively recruiting facilities from HAI collaboratives in Illinois, Maryland and Vermont to participate in the survey. Agreements under the Intergovernmental Personnel Act will be used

for trained environmental samplers to have access to facilities, gather data and collect samples. Samples will be sent to the CDC/DHQP laboratory for quantitative culture. Survey results will be distributed to the participating facilities. CDC hopes to use the survey data in the future to develop additional clinical effectiveness and prevention studies to better understand the role of the environment in transmission of HAIs.

HICPAC hoped funds would be available for CDC to conduct the healthcare environmental sampling survey because these data would make an important contribution to the literature and the infection control field. HICPAC advised CDC to combine its environmental microbiology investigation with other methods to assess the environment and cleanliness of hospital settings. HICPAC encouraged CDC to utilize the extensive body of environmental hygiene research developed by Dr. Philip Carling, an infection control expert.

ARRA-HAI Activities. Dr. Denise Cardo, Director of DHQP, presented the update on behalf of Dr. Arjun Srinivasan, Associate Director for Healthcare Associated Infection Prevention Programs in DHQP, who was unable to attend the meeting.

Dr. Cardo reported that the $50 million ARRA investment for HAI prevention required the allocation of all funds to states. Of this funding, $10 million was appropriated to the Centers for Medicare and Medicaid Services (CMS) to enhance state surveys in ASCs. The remaining $40 million was appropriated to CDC for its Emerging Infections Program ($4 million) and Epidemiology and Laboratory Capacity Grants to state health departments ($35 million).

Because Dr. Magill presented a comprehensive overview of CDC's ARRA-HAI activities within the Emerging Infections Program, Dr. Cardo focused her update on the epidemiology and laboratory capacity grants. CDC allocated these funds to state health departments in a competitive process. Activity A grantees are required to enhance the HAI infrastructure by implementing Congressionally-mandated state HAI plans, convening an HAI advisory group, and hiring an HAI coordinator.

All 50 of the Activity A grantees (49 states, the District of Columbia and Puerto Rico) have assigned HAI coordinator activities to a new hire or an existing staff member. The HAI coordinators vary among states in terms of their level of dedication to HAIs and range of expertise. All 50 of the Activity A grantees have convened or will soon hold a meeting with their advisory groups.

Activity B grantees are required to enhance and improve HAI surveillance. All 30 of the Activity B grantees are making efforts to expand enrollment in NHSN and validate data that are submitted to NHSN. CDC is providing technical assistance to assist the Activity B grantees in these efforts.

Activity C grantees are required to develop and expand HAI prevention collaboratives at the state level. The 27 Activity C grantees are engaged in a variety of HAI prevention projects: 13 *C. difficile* projects, 9 MRSA projects, 8 surgical site infection (SSI) projects, 13 CLABSI projects (all expanded to the Comprehensive Unit-Based Safety Program), 1 hand hygiene project, and 1 MDRO project with a focus on gram-negative bacilli.

CDC is actively collaborating with and providing strong support to state grantees through regular conference calls, individual follow-up by DHQP public health advisors, site visits, and a second grantee meeting that will be held in October 2010. Overall, ARRA has provided resources to assist states in moving HAI prevention more firmly into the realm of public health. Some states received limited ARRA dollars, but the level of engagement in HAI prevention is extensive. For example, some Activity A grantees that were funded to focus on the HAI infrastructure only also are conducting HAI prevention projects.

Dr. Cardo concluded that CDC would continue to address major challenges in ARRA-HAI activities. Most notably, states still need additional resources to conduct HAI projects. Some states are challenged by the lack of HAI expertise within health departments. Other states are facing barriers to engaging facilities in HAI surveillance and prevention efforts, particularly in states without public reporting mandates.

Status Report on HICPAC Guidelines and Documents: SESSION 1

HICPAC members and CDC staff presented a series of updates regarding the current status of HICPAC guidelines and documents. The status reports are outlined below.

***Neonatal Intensive Care Unit (NICU) Infection Prevention Guideline*.** Dr. Alexis Elward is a HICPAC member and chair of the workgroup. She reported that the workgroup's timeline presented during the February 2010 meeting has not changed. The workgroup is currently finalizing the key research questions and will initiate the literature search in July 2010.

The workgroup is represented by HICPAC, CDC, UPHS Center for Evidence-Based Practice, and American Academy of Pediatrics (AAP). The subject-matter experts (SMEs) who will conduct an independent review of the guideline represent HICPAC, AAP, APIC and various academic institutions.

Dr. Elward highlighted results of the workgroup's initial literature search to answer its key research questions in four areas. For viral infections, the 2006 AAP guidelines on the diagnosis and management of bronchiolitis focus on HAIs in the areas of Palivizumab prophylaxis and hand hygiene. However, these guidelines do not provide recommendations on outbreaks and exposure to respiratory syncytial virus (RSV) in NICUs. The 2009 Cochrane review on physical interventions to interrupt or reduce the spread of respiratory viruses focuses on hand hygiene and personal protective equipment (PPE).

The 2008 APIC guidelines and 2006 HICPAC/Advisory Committee on Immunization Practices (ACIP) guidelines on influenza vaccination of HCP focus on annual vaccination of HCP. The 2009 ISDA guidelines on seasonal influenza in adults and children focus on antiviral treatment/prophylaxis and outbreak management. However, the sole focus of these guidelines on influenza does not provide recommendations on other pathogens in NICUs.

For CLABSI, the 2008 SHEA/IDSA guidelines, 2005 and 2009 Cochrane reviews, and 2002 HICPAC guideline do not fully answer questions on CLABSI for NICU patients. However, the

Cochrane reviews provide recommendations on vancomycin prophylaxis against sepsis in preterm neonates, the use of IV in-line filters, and the optimal number of lumens for umbilical catheterization in neonates. The workgroup agreed that a more recent review of the literature on CLABSI is needed utilizing HICPAC's current guideline development process created by the Center for Evidence-Based Practice.

For MRSA, the 2008 SHEA/IDSA guidelines, 2008 U.K. Joint Working Party guidelines, 2003 SHEA guidelines, and 2006 HICPAC guidelines address active surveillance, contact precautions, hand hygiene, screening and decontamination, and environmental cleaning. However, these guidelines do not discuss optimal anatomic sites, the best decolonization regimen, and appropriate screening intervals for NICU patients.

For Candida, the 2007 and 2009 Cochrane reviews and 2009 IDSA guidelines focus on patient isolation measures for infants with Candida colonization or infection; prophylactic oral or topical non-absorbed antifungal agents to prevent invasive fungal infection in very low birth weight infants; and management of Candidiasis in clinical practice. Similar to CLABSI, the workgroup emphasized the need for a more recent literature review on Candida.

The workgroup agreed to engage the Vermont Oxford Network (VON) due to its importance in guideline implementation, quality improvement and patient safety. VON advised the workgroup to compare and contrast VON and NHSN metrics and search for published studies examining correlates due to the complimentary nature of the two networks.

Dr. Gautham Suresh is a neonatologist and agreed to represent VON on the workgroup. He made the following recommendations. The framework of the guideline should be changed from pathogen-based to infrastructure-/process-based to address the organizational culture that prevents infection control. Strategies that broadly apply to one section (*i.e.*, hand hygiene) should be combined into one section. Screening of visitors to NICUs should be addressed. Caution should be taken in bundling recommendations to assure the guideline is based on solid evidence.

Dr. Elward reminded HICPAC of the workgroup's key research questions for viral infections in NICUs: (1) What are the most effective strategies to prevent respiratory viral infections in NICU patients? (2) What are the best methods for detection of an outbreak of respiratory viral pathogens in NICUs? (3) What are the best methods for control of respiratory viral pathogens in NICUs?

Primary prevention strategies for viral infections would include visitation policies and immunization of HCP, pregnant women and parents. Secondary prevention strategies for viral infections would include utilization of empiric isolation precautions for exposed asymptomatic NICU patients, criteria for removal of empiric isolation precautions, and Synagis® prophylaxis for NICU patients exposed to RSV.

The workgroup's feedback on its key research questions for viral infections is summarized as follows. The prevention of potential exposure from sick parents and siblings is a priority

question that should be addressed. Consideration should be given to broadening "viral infections" to include bacterial, viral and other respiratory infections in NICUs.

Consideration should be given to adding viruses that cause gastrointestinal (GI) disease. The HICPAC Norovirus Guideline will be referenced if the workgroup agrees with this suggestion. The workgroup's general observation was that GI viral pathogens are less of a problem in NICUs, but the publication bias of this finding was recognized. The workgroup agreed to conduct a literature search to confirm or refute this observation. Clusters of necrotizing enterocolitis might be a potential exception because this GI disease has been associated with viral pathogens in some cases.

Diagnostic testing of viruses should be discussed. A new section on specific pathogens should be added that includes a discussion and links to immunization recommendations for HCP, parents and pregnant women. The specific pathogens section should prioritize RSV, varicella zoster virus, influenza and pertussis. The workgroup would decide whether to make a specific recommendation on the tetanus, diphtheria and pertussis (Tdap) vaccine for parents.

Dr. Elward noted that since the February 2010 meeting, the workgroup has developed a key research question for CLABSI in NICUs: What are the best strategies to prevent CLABSI in NICU patients? The workgroup will focus on the following issues to address this question: safety and efficacy of chlorhexidine in infants <2 months of age, impact of silver-coated catheters on CLABSI rates, efficacy of closed flush medication systems, efficacy of two-person tubing changes using sterile garb, antibiotic locks, antibiotic coated catheters, UVC lumen number, and the relationship between enteral feeding and CLABSI.

The workgroup's feedback on its key research question for CLABSI is summarized as follows. Bundled interventions will be discussed, but caution will be taken to ensure the guidance is based on strong evidence. Infection prevention in other catheter types will be addressed. The strategy of limiting infusions to only hyperalimentation and lipids will be discussed. Probioticis and lactoferrin will be described as two potential prevention modalities.

The definition change for BSI will be discussed along with the impact of requiring one positive blood culture for a common skin contaminant versus two positive blood cultures. Antibiotic locks and other strategies will be included. Other body sites as a source for BSI will be added. Recommendations will be provided on the frequency of tubing changes. Disinfection of the catheter cap before line entry, including the use of new devices for this purpose, will be described. The optimal duration of umbilical line catheterization will be discussed.

Dr. Elward noted that the workgroup revised its key research questions for MRSA in NICUs: (1) What are the risk factors for MRSA colonization in NICU patients at patient, organism and environmental levels? (2) What are the most effective strategies to identify MRSA colonization in NICU patients? (3) What are the most effective measures to prevent HAIs or colonization with MRSA? Should parents follow isolation precautions? What is the best strategy to manage multiples (*i.e.*, twins or triplets) in NICUs with discordant MRSA colonization status? What are the implications for the NICU patient if the mother is colonized with an MDRO? What are high rates and when should control measures be intensified?

The workgroup's feedback on its key research questions on MRSA is summarized as follows. Molecular techniques to detect MRSA colonization versus culture will be discussed. The best anatomic sites to culture will be described. The optimal interval for active surveillance will be recommended. The strategy of co-bedding multiples in NICUs with discordant colonization status will be discussed.

Because the primary literature on MRSA in NICUs is scant, the workgroup questioned whether these recommendations would be a valuable use of resources. Despite these data gaps, the workgroup agreed that identifying areas with little or no evidence would be helpful in developing a research agenda on MRSA in NICUs.

The workgroup would offer guidance on the appropriate time to culture to address colonization and active infection in HCP. The HICPAC HCP Infection Control Guideline will be referenced. Consideration will be given to adding methicillin-sensitive Staphylococcus aureus (MSSA) due to its ability to cause virulent and severe infections in NICU patients. The best regimen to use for decolonization and the appropriate time to use the regimen will be described. The inclusion of other MDROs will be considered.

Dr. Elward pointed out that since the February 2010 meeting, the workgroup developed key research questions for Candidal infections in NICUs: (1) What are the risk factors for invasive Candidal infections at patient, organism and environmental levels? (2) What are the most effective strategies to prevent colonization or invasive infection with Candida? High versus low rates at both unit and patient levels need to be considered to determine the best approach.

The workgroup's feedback on its key research questions for Candida is summarized as follows. Randomized controlled trials of Candida have produced Category IA evidence that can make a huge impact on pre-term infants, infection, Candida-related mortality and neurodevelopmental impairment resulting from infection. Diagnostic modalities to prevent Malazessia and filamentous fungi infections will be added. The workgroup agreed that tracking the impact of the guideline would be valuable. Although this task would be beyond the scope and charge of the workgroup, liaisons, NHSN and VON could undertake this effort.

Dr. Elward explained that in addition to its key research questions in four areas, the workgroup also discussed the possibility of addressing other key questions in the guideline:

- What is the effectiveness of family education to prevent HAIs in NICU patients?
- What is the optimal strategy for enteral feeding preparation and breast milk storage?
- What is the ideal nurse-to-patient ratio?
- What are the best hand hygiene practices in NICUs (*i.e.*, cleansing up to the forearms or hands when entering the isolette, entering the unit to wash up to the elbows, or scrubbing for two minutes)?
- What modifications are necessary for traditional transmission-based precautions? Is a mask necessary if the infant is placed in an isolette? What isolation precautions should be taken in NICUs that have no single rooms and only a corner of the room is available?

What is the optimal nursing assignment (*i.e.*, cohorting nurses for MRSA colonized infants)?
- What is the ideal architectural design and construction of NICUs for infection prevention?

Based on the extensive discussions and feedback, Dr. Elward presented the workgroup's revised key research questions for viral infections in NICUs: (1) What are the best methods for control of respiratory pathogens in NICUs with respect to primary and secondary prevention? (2) What are the best diagnostic modalities for detection of an outbreak of respiratory or GI pathogens in NICUs? (3) What are the best methods for pathogen detection and outbreak control during a cluster of necrotizing enterocolitis?

The workgroup agreed to retain the existing key research question for CLABSI in NICUs: What are the best strategies to prevent CLABSI in NICU patients? The workgroup agreed that for each of the 18 strategies proposed during its discussions and feedback, the presence or absence of evidence to support or not support a particular practice would be articulated in the guideline.

The workgroup agreed to retain the three existing key research questions for MRSA in NICUs, but two sub-questions were added to question 2 based on the feedback: What are the most effective strategies to identify MRSA colonization in NICU patients? The two sub-questions are: When should molecular techniques be used versus culture? Which sites or devices should be tested for colonization?

The workgroup agreed to retain the two existing key research question for Candidal infections in NICUs, but a new question 3 was added based on the feedback: What are the best diagnostic modalities for detection of invasive fungal infection in NICU patients?

The workgroup agreed to address additional key research questions based on the feedback:

- What are the most effective strategies for prevention of necrotizing enterocolitis?
- What are the most effective strategies for *C. difficile* testing in NICU patients?
- What is the most effective approach to perform hand hygiene to prevent infections to NICU patients?
- How should transmission-based precautions be modified for NICU patients in isolettes?
- What is the optimal architectural design and construction of NICUs to prevent infection transmission?
- What are the best methods for outbreak investigation and control in the setting of a cluster of infections with unusual organisms?
- What is the best infection prevention infrastructure?

Dr. Elward emphasized that the workgroup specifically needs HICPAC's input on whether recommendations on MSSA and other MDROs should be added to the guideline. She concluded that the workgroup's next steps would be to prioritize the key research questions, conduct a more in-depth literature search, and initiate the abstract review process.

Dr. Michael Bell is the Deputy Director of DHQP. He commended the workgroup for deciding to focus on vascular catheter maintenance issues in the NICU Guideline. His position was that this guidance would bring much needed attention to the key elements of line maintenance as opposed to insertion.

Dr. Bell made three suggestions for the workgroup to consider in the next draft of the guideline. First, the diagnostic testing recommendations should be generic. Based on HICPAC's experience with the Norovirus Guideline, specifying the best diagnostic testing methods for viral diseases can be problematic due to rapidly changing technology. The NICU Guideline should be linked to other sources with more up-to-date information.

Second, the guideline should contain minimal recommendations on vaccination. Links should be provided to ACIP guidelines to address vaccine-specific issues. Third, the workgroup should immediately focus on prioritizing the seven additional key research questions because addressing all of these issues would require a multi-year process. The workgroup should discuss the possibility of deferring some of the additional key questions to a follow-up document to ensure the NICU Guideline is produced in a timely manner.

HICPAC applauded Dr. Elward and the other workgroup members for their extensive level of thought and insight in developing the NICU Guideline to date. The members made two key suggestions for the workgroup to consider. First, key research questions with no solid evidence at this time should be placed in a separate publication to drive the development of a NICU infection prevention research agenda.

Second, the workgroup should make every effort to act on Dr. Suresh's important advice. Most notably, his suggestion to change the framework of the guideline from pathogen-based to infrastructure-/process-based would be critical for front-line providers to implement the recommendations.

Dr. Brennan confirmed that HICPAC would have an offline discussion with the workgroup to determine whether recommendations on MSSA and other MDROs should be added to the guideline. The outcomes of this discussion would be reported during the HICPAC business session on the following day.

Guideline for the Prevention of Surgical Site Infection (SSI). Dr. Sandra Berrios-Torres is a Medical Officer in DHQP. She reported that CDC published three different sets of guidelines for the prevention of SSI in 1982, 1986 and 1999. HICPAC and large multidisciplinary body of SMEs developed the comprehensive 1999 guideline.

The 1999 guideline included updated SSI definitions (*i.e.*, the replacement of "surgical wound infection" with "surgical site infection"). The 1999 guideline also contained a new section on management of infected or colonized surgical personnel; significant additions to the surveillance and operating room ventilation sections; multiple detailed tables; recommendations based on federal regulations; a continuing medical education study package; and 491 references and 21 select readings.

Dr. Berrios-Torres described the current status of SSI in the United States 11 years after the publication of the 1999 guideline. The U.S. burden of ~300,000 SSIs per year accounts for 17% of all HAIs. SSI was the third most common cause of HAIs in 1982, but is now the second most common cause only after UTI. SSI occurs in 2%-5% of patients undergoing inpatient surgery. SSI mortality is 3% with SSI patients having 2-11 times higher risk of death. SSI is directly attributable to 75% of deaths among SSI patients.

In terms of morbidity, SSI accounts for long-term disabilities and additional postoperative hospital days of ~7-10 days. Depending on the procedure and pathogen, the estimated cost of SSI can range from $3,000-$29,000 for a total of up to $10 billion annually for treatment.

CDC is proposing a new approach to have a more significant impact on the prevention of SSI. The publication of guidelines would be expanded to include overarching principles as well as updated core and cross-specialty sections, particularly an expansion on the preoperative colonization with *Staphylococcus aureus* section. The updated SSI guideline also would focus on specialty-/procedure-specific components and prioritize high-volume and high-burden procedures. CDC expects to update the core sections every few years, but hopes to release a different specialty-/procedure-specific component annually.

CDC is proposing to focus on joint arthoplasties as the first specialty component of the updated SSI guideline. This procedure has the highest volume and the third highest number of SSIs reported to NHSN. SSIs in primary arthoplasties have a high treatment burden and also account for a high burden in revision arthoplasties. Significant increases in both the number of procedures and SSIs are projected.

Arthoplasty is the replacement or reconstruction of a damaged or diseased joint, most commonly with a prosthetic implant made of metal, ceramic, plastic or a combination of these materials. Total joint replacement has evolved over time from an intervention that relieves pain with an implied functional benefit to an intervention with a promise to relieve pain and restore high levels of function in an accelerated fashion while preserving soft tissue and bone in the reconstructed joint.

Of ~1.1 million arthoplasties performed in 2008 in the United States, total knee and hip replacements accounted for ~96%. Primary arthoplasty is a new procedure to a joint that has never been replaced and accounts for >90% of procedures performed. Arthritis/osteoarthritis is the most common indication for primary arthoplasty followed by avascular necrosis, dysplasia, fractures, malalignment and tumors.

Revision arthoplasty is an additional procedure to a joint that has been replaced. Infection is the most common indication for revision arthoplasty and accounts for ~26% of revision knee arthoplasties and ~15% of revision hip arthoplasties. Infected arthoplasty often requires staged surgical procedures, longer operative times to remove the implant and any residual cement, debridement, insertion of a temporary cement spacer, IV antibiotics for at least six weeks, and replacement of a larger implant.

Revision arthoplasty is much more complex than primary arthoplasty. Failure rates of revision arthoplasty following infection are much higher than those for non-infectious indications, such as mechanical loosening, dislocation, component malposition, implant failure or breakage, and periprosthetic fracture or osteolysis.

The 2004 Kurtz, *et al.* study described the infection burden of hip and knee arthoplasty in the United States. Of 496,016 primary and revision knee arthoplasties included in the study, the rate of infection was 1.21 (or 5,838 infections). The length of hospital stay was 3.9 days for non-infected knees and 7.6 days for infected knees. Hospital charges were ~$25,800 for non-infected knees and ~$56,300 for infected knees (or 1.5 times higher).

Of 265,441 primary and revision hip arthoplasties included in the study, the rate of infection was 1.23 (or 3,352 infections). The length of hospital stay was 4.3 days for non-infected hips and 9.7 days for infected hips. Hospital charges were ~$39,700 for non-infected hips and ~$70,400 for infected hips (or 1.6 times higher). The total to treat infections in knee and hip arthoplasties was $564 million in 2004.

Clear air operating rooms, adequate antimicrobial prophylaxis, body exhaust systems and other prevention strategies have improved SSI rates in arthoplasties, but these infections continue to carry a tremendously high burden. Arthoplasty SSI risk factors are related to both patients and procedures/surgeons. For patients, rheumatoid arthritis can account for SSI rates ranging from 2%-8%, while diabetes can account for SSI rates ranging from 3%-14%. For procedures/ surgeons, biofilm formation is the most significant risk factor for arthoplasty SSI.

Significant increases in both the number of arthoplasties and SSIs are based on projections in several areas. Future demographics show that the U.S. population 65 years of age will increase 104% by 2030 (or 72 million persons). Of this population, 60% will have more than one chronic condition, 50% will be affected by arthritis and >33% will be obese.

The prevalence of diabetes is projected to increase 165% by 2050. The current diabetes prevalence of 4% (or 11 million persons) will grow to 7.2% (or 29 million persons). The largest percent increase will be among persons ≥75 years of age. Osteoarthritis is the most common joint disorder and is projected to affect 59.4 million Americans (or 18.2%) by 2020.

Data collected in 2008 showed that >30% of adult Americans were considered to be obese based on body mass index ≥30. By 2030, >33% of adult Americans >65 years of age are projected to be obese. An increase in the older U.S. population is projected to parallel the frail population at risk for trauma. Displaced femoral neck fractures are expected to double to 500,000 per year by 2040. Post-traumatic arthritis accounts for 12% of all osteoarthritis at this time.

The 2009 Kurtz, *et al.* study projected hip and knee arthoplasties in 2030 and their associated SSIs and cost. The study estimated that these procedures would total 5.7 million by 2030 (or a 400% increase). Knee arthoplasties were estimated to increase to 4.6 million (or a 500% increase), while hip arthoplasties were estimated to increase to nearly 1 million (or a 200% increase). Persons <65 years of age were projected to account for >50% of primary hip and

knee arthoplasties and >60% of revision knee arthoplasties. Persons >65 years of age were projected to account for >60% of revision hip arthoplasties.

The study estimated ~382,000 SSIs for all hip and knee arthoplasties (or a 1,500% increase). SSIs in knee arthoplasties were estimated to increase to ~319,000 (or a 1,800% increase), while SSIs in hip arthoplasties were estimated to increase to ~64,000 (or an 800% increase). Based on the projection of ~319,000 SSIs in knee arthoplasties, the total treatment cost would be $19.1 billion at ~$60,000 per SSI.

Based on the projection of ~64,000 SSIs in hip arthoplasties, the total treatment cost would be $4.6 billion at ~$72,000 per SSI. The total estimated cost would be $23.7 billion to treat SSIs in hip and knee arthoplasties in 2030 (or 16 times higher than the projected cost in 2010 and 400 times higher than the projected cost in 2004).

Dr. Berrios-Torres concluded that CDC is proposing a new approach to update the SSI guideline. Surgical specialty societies (*i.e.*, American Academy of Orthopaedic Surgeons and American College of Surgeons) and other SMEs in the field would be engaged as collaborators at the outset of the process to ensure the surgical community endorses and takes ownership of the guideline.

An evidence-based review would be performed to update the core and cross-specialty sections, particularly the expansion of the preoperative colonization with *S. aureus* section. Joint arthoplasties would be as the first specialty component of the updated SSI guideline. The updated SSI guideline would help to identify research gaps and guide the development of a research agenda. Implementation of the updated SSI guideline and the impact of the recommendations would be evaluated in collaboration with specialty societies and partners at state and federal levels.

Based on CDC's initial contact with a number of surgical specialty societies, Dr. Berrios-Torres announced that strong support and interest have been expressed in updating the SSI guideline. CDC's next steps will be to identify SMEs in the field who will be engaged in this effort; announce the members of the SSI Guideline Workgroup during the November 2010 HICPAC meeting; and finalize the key research questions by January 2011. CDC's goal is to publish the updated SSI guideline and the joint arthoplasty specialty component in early 2012.

HICPAC advised CDC to balance its proposed procedure-specific approach with an update to the existing core recommendations to reflect more recent data since the publication of the 1999 SSI guideline. HICPAC noted that a number of surgical groups are now eager to move beyond the Surgical Care Improvement Project (SCIP) measures. Surgeons have anecdotally reported efforts to optimize their performance utilizing the SCIP measures, but have not achieved the expected level of results.

Infection Control Guidance for Ambulatory Surgical Centers (ASCs). Dr. Melissa Schaefer is a Medical Officer in DHQP. She reported that ambulatory care settings provide care to patients who do not have an overnight stay. These diverse settings include physicians' offices, health fairs, imaging and radiology centers, ASCs, urgent care centers, oncology and infusion

centers, physical therapy and rehabilitation centers, and alternative medicine clinics. Although hemodialysis centers and dental practices are ambulatory care settings, these facilities will not be included in the CDC ambulatory care guidance document.

Dr. Schaefer presented data to illustrate the need for an ambulatory care guidance document. CDC data show that ambulatory care visits dramatically increased from 1996-2006. The number of visits to ambulatory care settings is growing faster than the U.S. population with 1.1 billion visits to these settings in 2006 alone.

Ambulatory care settings provide similar services as hospitals, including surgery, injections and infusions (*i.e.*, chemotherapy, antimicrobials and contrasts). Unlike healthcare facilities, however, ambulatory care settings have minimal oversight and regulation, operate under the physician's license, and do not have the same level of rigor in terms of infection control infrastructure and resources. The only exception to this practice is ambulatory care settings that have oversight by CMS and state survey agencies.

To address these gaps, CDC is developing an ambulatory care summary guidance document that will provide a foundation for preventing infection transmission during patient care in all healthcare settings and also will describe basic infection prevention practices: hand hygiene, use of PPE, safe infection practices, handling of equipment and items in the patient care environment, and respiratory hygiene and cough etiquette.

Several cases have been publicized in the media and reported in the literature describing adverse outcomes when ambulatory care settings failed to follow standard precautions, including use of the same glucose monitoring device on multiple patients at a health fair in New Mexico and an HBV outbreak at a cardiology clinic in New Jersey. From 2001-2009, other outbreaks of viral hepatitis due to unsafe injection practices were reported in a wide variety of outpatient settings across the country, such as private physicians' offices, oncology clinics, pain remediation clinics and endoscopy clinics.

Bacterial infections associated with unsafe injection practices, particularly improper handling of medication, were reported from 1999-2009. Of 17 bacterial infection outbreaks, 15 occurred in ambulatory care settings, such as pain clinics, oncology centers, hemodialysis centers and primary care. From 2008-2009, 48 bacterial infection outbreaks were reported in pain clinics in Florida, New York City and West Virginia. These cases involved reuse of a single-dose contrast dye on multiple patients and other unsafe infection practices or infection control deficiencies.

A public health investigation was recently launched after five patients developed MSSA at a primary care clinic in Georgia and were hospitalized. Because the clinic could not produce a sound infection control plan, the health department required the clinic to contract an ICP to help in improving care provided to patients.

Dr. Schaefer announced that CDC and CMS collaborated to incorporate better infection control practices into the survey and inspection process in ASCs. A survey was designed to evaluate infection control practices in 68 ASCs in three states. CDC and CMS used the Isolation Guideline and other HICPAC guidelines to develop an infection control checklist focusing on five

basic practices: hand hygiene and glove use; injection safety and medication handling; instrument reprocessing for both high-level disinfection and sterilization; environmental cleaning; and point-of-care devices (*i.e.*, blood glucose meters).

The checklist was intended for surveyors to physically observe procedure areas and other patient care environments in ASCs instead of merely confirming the existence of written infection control policies and procedures. The infection control assessments showed that 68% of ASCs had at least one lapse in infection control and 18% had lapses in $\geq$3 of the five infection control categories assessed.

Of 68 ASCs assessed in the survey, 46% had lapses in handling of blood glucose monitoring equipment, 28% had lapses in injection safety and medication handling, 28% had lapses in equipment processing, 19% had lapses in hand hygiene and use of gloves, and 19% had lapses in environmental cleaning.

Despite the availability of clear guidance from CDC, HICPAC and professional organizations, 28% of ASCs used single-dose vials on multiple patients. Despite clear warnings on package labels and overwhelming evidence in the published literature, 21% of ASCs used the same spring-loaded lancing penlet device for multiple patients. Despite clear guidance on the FDA website, 6% of ASCs reused single-use devices on multiple patients.

CDC recently assembled a new team that is fully dedicated to infection control in outpatient settings. In close collaboration with CMS and other federal partners, CDC is ensuring safe care in ambulatory care; strengthening regulatory and accreditation standards across healthcare settings with a particular focus on infection control; and expanding the inclusion of infection control requirements in conditions for coverage and the inspection process.

CMS released new conditions for coverage in May 2009 that now require ASCs to develop a solid infection control plan with oversight and direction by a trained ICP. Under this new policy, CMS cites ASCs for any infection control problem reported by the ICP and requires any lapses to be remediated. In addition to ASCs, CMS also has institutionalized this policy in dialysis centers and LTCFs. The ASC tool is available on the CMS website at:
(www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_37.pdf.)

Dr. Schaefer described CDC's other activities to improve infection control practices in ambulatory care settings. CDC recently launched the "One and Only" (one needle, one syringe, only one time) Campaign on its website and also released an injection safety educational video to assist providers in assuring safe care in both inpatient and outpatient settings. Preliminary feedback shows that a large number of providers are using these resources to assess and improve their practices.

CDC hosted the "Safety by Design: Innovative Approaches for Safe Injections" meeting in May 2010. The purpose of the meeting was to promote the safe use of and innovation in product development to eliminate transmission of bloodborne pathogens and other infections associated with delivery of parenteral medications. The meeting participants included stakeholders from public health, professional organizations, industry and patient advocate groups.

CDC hosted the "Sticking With Safety: Eliminating Bloodborne Pathogen Risks During Blood Glucose Monitoring" meeting in May 2010. The meeting participants included stakeholders from public health, professional organizations, industry and patient advocate groups. The meeting resulted in the participants reaching consensus in three major areas. Only auto-disabling single-use lancet devices should be used for assisted monitoring of blood glucose. Insulin pens should be utilized for single patients only. Glucose meters should be assigned to individual patients whenever possible. If meters must be shared, however, infection prevention should be taken into account by cleaning and disinfecting the used device after every use.

Workgroups convened by HHS to ensure implementation of tier 2 activities in ASCs and hemodialysis centers are currently developing modules to better describe current problems in ambulatory care settings and highlight improvements that are needed in these facilities in the future.

CDC is currently extracting existing CDC HICPAC recommendations to develop a user-friendly ambulatory care guidance document. The Isolation Guideline and elements of standard precautions will serve as the foundation of the guidance document. The document will describe expectations in any setting where healthcare is provided. The objectives of the guidance document are to summarize existing CDC HICPAC recommendations that are most appropriate for all ambulatory care settings and reaffirm standard precautions as the foundation for preventing HAI transmission in all healthcare settings.

The "Background" section will describe the movement of health care out of hospitals, the risk of HAIs in ambulatory care settings, and infection control challenges in ambulatory care settings. "Ambulatory care settings" will be clearly defined as facilities that provide care to patients who do not have an overnight stay. The guidance document will not address hemodialysis centers or dental practices because separate guidelines have been developed for these facilities.

The "Administrative Measures" section will advise ambulatory care settings to develop infection control policies and procedures specific to practices in the facility; assure individuals with training in infection control are employed by or are available by contract to the facility; and provide supplies and equipment needed for standard precautions in all areas where health care is delivered.

The "Education and Training of Healthcare Personnel" section will advise ambulatory care settings to ensure that staff has job- or task-specific education and training in preventing HAI transmission; document the competency of staff; and educate staff on patient safety and HCP safety using the Occupational Safety and Health Administration (OSHA) *Bloodborne Pathogens Manual*, PPE and vaccination.

The "Surveillance and Reporting" section will acknowledge challenges in ambulatory care settings, discuss actions that are being taken in the area of process measures (*i.e.*, the ASC checklist), and advise ambulatory care settings to refer to state and federal requirements for reporting and surveillance.

The “Standard Precautions” section will address hand hygiene; injection and sharps safety to protect patients and providers; environmental and equipment cleaning and disinfection, particularly point-of-care devices; and respiratory hygiene, cough etiquette and patient placement. CDC does not expect ASCs to need additional resources to implement standard precautions.

The “Transmission-Based Precautions” section will cite the 2007 “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.” The language will state the following: “The risk of transmission in ambulatory care settings has not been defined. Consistent use of Standard Precautions may suffice in these settings, but more information is needed.” The Isolation Guideline will serve as the basis for the recommendations in the guidance document.

Links will be provided to the Disinfection and Sterilization Guideline, Environmental Cleaning Guideline or other CDC HICPAC guidelines in which ambulatory care personnel would need more information.

HICPAC commended CDC for developing a much needed guidance document to improve infection control practices in ASCs. Several HICPAC members made suggestions for CDC to consider in drafting the next iteration of the document.

- CDC should ensure that the guidance document is supported with resources and tools for ASCs, such as training programs through health departments. Evidence shows that the publication of guidelines has minimal impact on changing performance or behaviors.
- The guidance document should specify performance measures with clearly defined numerators and denominators to track implementation of the recommendations over time.
- CDC should develop a one-page checklist to better inform patients in ASCs or persons who attend health fairs.
- The guidance document should provide links to the website of the American Society of Health-System Pharmacists to provide ASCs with a resource in the event of a drug shortage.
- The guidance document should acknowledge that many pre-assembled kits for various procedures do not contain safety needles.

***Healthcare Personnel (HCP) Infection Control Guideline*.** Dr. Tammy Lundstrom is a HICPAC member and the chair of the workgroup. She reported that the workgroup members include four other HICPAC members; technical resources from CDC/DHQP and UPHS Center for Evidence-Based Practice; and external experts from APIC, SHEA, IDSA (to be named in the future), the American College of Occupational and Environmental Medicine, and National Institute for Occupational Safety and Health (NIOSH).

The workgroup agreed to organize the guideline in three sections. The “Baseline and Routine Practices” section will cover pre-employment immunizations, annual testing, booster and annual immunizations, and education. The “Special Populations” section will cover pregnant and

immunocompromised HCP and laboratory workers. The “Specific Infectious Diseases” section will cover TB, meningitis and pertussis.

The “Appendices” will cover travel issues with links to the *Yellow Book* and recommendations on post-return surveillance of U.S. HCP. The appendices also will discuss the need for PPE among vaccinees and those having natural infection. Links will be provided to several documents, such as ACIP’s updated guidelines on vaccination of HCP and HICPAC’s norovirus and bloodborne pathogens guidelines.

The workgroup identified seven key research questions that will be addressed in the guideline.

1. Should purified protein derivative or QuantiFERON® be used for annual screening or post-exposure?
2. What are the best practices for immunization programs?
3. What are the most appropriate post-travel surveillance recommendations?
4. What is the best method to address MRSA in HCP?
5. Is prophylaxis warranted for Group A streptococcus?
6. What constitutes sufficient evidence to downgrade PPE recommendations with emerging pathogens?
7. Is post-exposure prophylaxis necessary for vaccinated HCP, particularly in the setting of pertussis?

Dr. Lundstrom requested HICPAC’s input to assist the workgroup in addressing three of the seven key research questions. In terms of MRSA in HCP, should asymptomatic HCP be screened for MRSA? What is the most effective methodology for MRSA screening? Should HCP who are incidentally found to be colonized with MRSA be decolonized? If so, what is the most effective decolonization regimen? What is the most effective monitoring strategy post-decolonization?

In terms of Group A streptococcus, who should receive post-exposure prophylaxis after exposure to a patient with invasive Group A streptococcus? What is the most effective post-exposure prophylaxis for Group A streptococcus-exposed HCP?

In terms of post-return surveillance, should HCP who work in the international community be screened for immunizations and infectious diseases endemic to that country upon return? Should HCP who work in other countries be screened for epidemic diseases in those countries upon return? What is the most effective system for post-global work screening of HCP? Should screening be administered by healthcare organizations or state health departments? Should HCP be prohibited from working upon return until screening test results have been returned?

Dr. Lundstrom concluded that the workgroup’s next steps are to refine the remaining four research questions over the next week, thoroughly review the guideline in its entirety to identify additional research questions over the next two weeks, and identify other existing guidelines to be linked. The workgroup will continue to hold monthly conference calls and hopes to complete the draft HCP Guideline over the next 12-18 months.

HICPAC advised the workgroup to ensure that the infection control language in the HCP Guideline could be clearly understood by the occupational health community.

Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. Dr. Bell reported that the Isolation Guideline soon be scheduled for an update. Although the guideline was published in 2007, the entire production of the document required six years. As a result, some of the evidence is outdated at this time. Dr. Bell's position was that HICPAC and CDC realistically could update the guideline in three years.

Dr. Bell requested HICPAC's input on producing the updated guideline to be meaningful and functional to ICPs in the field and the broader infection control community, including CMS and state health departments. He noted that the updated guideline would need a more precise and detailed approach to discussing transmission issues. Moreover, HICPAC's current guideline development process would have a fundamental impact on the categories of some recommendations, particularly those relating to transmission.

Dr. Bell also asked HICPAC to provide feedback on the best methods to produce the guidelines, address transmission issues, and highlight data gaps to inform and influence the development of a research agenda.

Dr. Lundstrom noted that CDC HICPAC current guideline development process might decrease the burden in updating the Isolation Guideline. Most notably, the list of new research questions since the publication of the guideline in 2007 might be narrow. HICPAC could retain sections of the guideline that are still relevant and only update specific sections guided by the new research questions.

Dr. Brennan agreed with Dr. Lundstrom's proposed approach. He pointed out that HICPAC's first steps should be to thoroughly review the Isolation Guideline, identify gaps in the evidence, and develop key research questions only for sections requiring an update. His position was that HICPAC might be able to update the guideline in less than three years by implementing this approach and limiting the scope of the document.

Dr. Brennan added that HICPAC should obtain input from professional organizations, ICPs and epidemiologists in the field early in the process of updating the guideline to ensure the guidance is clear. He emphasized the value in collecting information from Joint Commission surveys on perceived violations of standards when an institution interpreted a particular standard in good faith or in the context of the CDC HICPAC guideline.

In response to Dr. Brennan's question, Dr. Bell agreed that CDC could convene a meeting with professional organizations, ICPs and epidemiologists in the field to guide HICPAC's efforts in updating the Isolation Guideline. Ms. Soule noted that CDC should consider administering a survey in addition to convening the meeting to ensure isolation issues in small critical access hospitals, LTCFs and other settings are addressed.

Dr. Cardo clarified that obtaining approval from the Office of Management of Budget to administer a survey and collect data from more than nine persons is a two-year process for

federal agencies. However, non-governmental organizations that are not funded by a federal agency could administer the survey and share aggregated data with CDC.

Ms. Murphy clarified that the vast majority of hospitals examine HCP compliance with the Isolation Guideline and perform a root-cause analysis to determine reasons for non-adherence. She raised the possibility of gathering and analyzing these data to inform HICPAC's efforts in updating the guideline.

Public Comment Session

Mr. Steve Langan is the Executive Director of Hepatitis Outbreaks National Organization for Reform. He conveyed that due to the concentrated migration of health care to ASCs, the 2000 HICPAC guidelines are not being followed. He offered the assistance of his organization and other stakeholder groups to help CDC in widely publicizing the ambulatory care guidance document.

Ms. Lori Nerbonne, of New Hampshire Patient Voices, advised CDC to include consumers and front-line nurses on advisory committees and workgroups to ensure that its research and other activities are transparent to the public. She emphasized that patients, consumers and other end-users need healthcare infection control data to make informed decisions.

Ms. Nerbonne noted that HICPAC primarily focuses on research and the use of devices in developing HAI guidelines. However, appropriate staffing levels in hospitals and a reduction in the number of "patient touches" per day to decrease the chance for transmission also are important issues to improve safe patient care and prevent infections. Ms. Nerbonne concluded that HAIs are responsible for a great deal of suffering and dying among patients in hospitals.

CDC informed HICPAC of ongoing efforts by various federal agencies to revise, refine and update the "HHS National Action Plan to Prevent Healthcare-Associated Infections." The Agency for Healthcare Research and Quality and CDC are co-leading the workgroup that is updating the subsection on HAI prevention research. The workgroup is charged with updating the existing research agenda in the areas of CLABSI, SSI, CAUTI, MRSA, *C. difficile* and ventilator-associated pneumonia (VAP).

The updated Action Plan will be expanded to include an HAI prevention research agenda for dialysis patients and ASCs. After the working draft of the updated Action Plan is developed and distributed, CDC asked HICPAC to provide input on the document to promote research and fill existing data gaps. CDC would provide regular updates to HICPAC on the updated Action Plan to ensure the document remains up-to-date based on emerging issues.

Dr. Brennan confirmed that during his attendance at the HHS HAI Summit in September 2010, he would announce HICPAC's intention to submit comments on the updated Action Plan. In response to a suggestion by Dr. David Henderson, the *ex-officio* member for the National Institutes of Health (NIH), Dr. Brennan confirmed that HICPAC would consider issues across the spectrum of science in healthcare epidemiology while submitting comments on the updated Action Plan. Dr. Henderson pointed out the critical need for T1, T2 and T3 studies.

Proposal of a New HICPAC Workgroup

Dr. Scott Fridkin is the Deputy Chief of the DHQP Surveillance Branch. He announced that CDC launched a new activity to make its data more useful to state partners by publishing a report summarizing national and state HAI data reported to NHSN. For the first report on CLABSI, CDC engaged external partners and convened an independent peer review panel to obtain input on the presentation of data in the report and the science involved in summarizing the data.

Dr. Fridkin outlined a proposal for HICPAC to form a new workgroup with external SMEs as needed to provide advice to CDC in the development of more reports in the future to summarize HAIs other than CLABSI.

Dr. Cardo added that CDC has HAI elimination goals at the national level and also is measuring progress in HAIs at the state level. States are measuring progress in HAIs at the local level. Instead of convening a separate panels or ad hoc workgroup to provide advice and guidance to CDC each time HAI data are summarized for a new report, the new HICPAC workgroup would serve in this capacity on an ongoing basis for CDC and its federal partners.

HICPAC fully supported the establishment of the new workgroup due to the expertise and experience of the members in measurement, risk stratification and infection prevention. Several HICPAC members made suggestions to consider if the new workgroup was formally approved.

- The charge of the workgroup should be expanded to include the following tasks. Evidence-based practices should be gathered and reviewed on the most appropriate display of data to reach various types of adult learners (*i.e.*, visual versus non-visual learners). Guidance should be provided on best practices for states to show facility-specific data. Advice should be provided to states on the best methods to illustrate to consumers progress over time in decreasing HAI rates. A clinically relevant method of risk adjustment should be developed to abstract pertinent data that demonstrate actual outcomes rather than process measures.
- CDC should encourage states to validate their HAI data.
- The proliferation of report cards on various types of conditions has been problematic and confusing to the infection control field. CDC or HHS should take leadership in developing a clearly defined and streamlined process to disseminate report cards.
- CDC should use data from small patient populations that are pooled at the national level to determine best practices and identify attainable goals in HAI elimination.

A motion was properly placed on the floor and seconded by Ms. Burns and Dr. Lundstrom, respectively, for HICPAC to form the new workgroup. The overarching charge of the workgroup would be to assist CDC and its federal partners in identifying the best reporting practices for HAI data. **HICPAC unanimously approved the motion.**

Dr. Brennan confirmed that HICPAC and CDC would refine the scope and charge of the new workgroup. He would solicit volunteers for the workgroup in an offline discussion and identify the members during the business session on the following day. Dr. Fridkin would serve as the workgroup's technical resource and point of contact with CDC.

Liaison and *Ex-Officio* Reports

The following liaison and *ex-officio* members presented verbal reports or submitted written reports into the official HICPAC record for the June 17-18, 2010 meeting:

- Joan Blanchard, RN, BSN, MSS, CNOR, CIC (Association of periOperative Registered Nurses) (AORN)
- Barbara DeBaun, MSN, RN, CIC (Association of Professionals of Infection Control and Epidemiology, Inc.) (APIC)
- Shirley Paton, RN, MN (Public Health Agency of Canada) (PHAC)
- Sanjay Saint, MD, MPH (Society of Hospital Medicine) (SHM)
- Charles Huskins, MD, MSc (Infectious Diseases Society of America) (IDSA)
- Lori Harmon, RRT, MBA (Society of Critical Care Medicine) (SCCM)
- Marion Kainer, MD, MPH (Council of State and Territorial Epidemiologists) (CSTE)
- Alexis Elward, MD (Advisory Committee on Immunization Practices) (ACIP)
- William Baine, MD (Agency for Healthcare Research and Quality) (AHRQ)
- Gary Roselle, MD (Department of Veterans Affairs) (VA)
- Mark Russi, MD, MPH (American College of Occupational and Environmental Medicine) (ACOEM)
- Lisa McGiffert (Consumers Union)
- Sheila Murphey, MD (Food and Drug Administration) (FDA)
- Kelly Podgorny, RN, MS, DPHQ (on behalf of Robert Wise, MD) (The Joint Commission)
- David Henderson, MD (National Institutes of Health)
- Lisa Maragakis, MD, MPH (Society of Healthcare Epidemiology of America) (SHEA)
- Jeannie, RN, MPH (Centers for Medicare and Medicaid Services) (CMS)

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

- Ms. Harmon reported that Dr. William Brock would begin serving as the new liaison for SCCM at the next HICPAC meeting.

- Dr. Saint reported that he attached two documents to his written report. The special article, "Growth in the Care of Older Patients by Hospitalists in the United States," was

published in the *New England Journal of Medicine* in 2009 and illustrated the dramatic increase in hospitalists since 1995. *The New York Times* published an article on May 26, 2010 that featured a group of hospitalists at the Hospital of the University of Pennsylvania. SHM is continuing to improve transitions of care through Project BOOST and conduct implementation science to help hospitalists in applying evidence from ICUs to the care of their patients on medical and surgical floors.

- Dr. Russi reported that his written summary described several position statements ACOEM issued during the past year and its recent legislative activities. The American Occupational Health Conference was held in May 2010. Representatives from NIOSH and OSHA discussed new initiatives for HCP surveillance of various exposures. ACOEM will submit formal responses to requests for information regarding infectious diseases and bloodborne pathogens. ACOEM will discuss its responses with IDSA, SHEA and the American Hospital Association

- Dr. Roselle reported that the VA developed its MRSA program in 2007 with four components: active surveillance with nasal swabs, contact precautions, hand hygiene, and culture change to emphasize the responsibility for infection control among all hospital staff. The VA provided >5 million bed days of care from 2007-2009, including ~850,000 days of care in ICUs and ~450,000 days of care in non-ICUs. HAI rates in ICUs did not change in the two years prior to implementation of the VA MRSA program, but a dramatic decline of 77% was observed with full implementation of the program. MRSA, VAP and CLABSI were the most common infections observed. VAP rates decreased by 53% and CLABSI rates decreased by 44%, despite an increase in utilization rates of central lines. Non-device-related MRSA BSI rates decreased by 58%, pneumonia rates decreased by 67%, and UTI rates decreased by 79%. The VA has seen that implementation and enforcement of a hierarchal HAI program can have tremendously positive effects in reducing rates.

- Ms. Podgorny reported that The Joint Commission recently clarified its requirements pertaining to the use of multi-dose vials and their expiration dates. The Joint Commission will require a 28-day expiration date for multi-dose vials from the date of opening or puncture unless manufacturers specify otherwise. The Joint Commission's dating requirement is now harmonized with APIC recommendations and FDA guidelines. The Joint Commission's dating requirement does not apply to vaccine in the CDC stockpile and state immunization programs, but the requirement does apply to vaccine in private stockpiles.

- Dr. Murphey reported that FDA recently updated its website with two new sections. The "Safety Reporting Portal" is still being constructed, but consumers and healthcare professionals are now able to more easily report pre-/post-market safety data to FDA related to drugs and foods. The portal contains a link to the HHS website for reporting problems related to devices or biologics. The "Home Use Device Portal" is still being constructed, but healthcare professionals, consumers and industry are able to use the portal as a resource to reduce problems associated with complex medical devices in the home setting. FDA will partner with the Communication Health Accreditation Program

and The Joint Commission to provide advice and assistance on resolving issues with medical devices in the home setting. A workgroup of the American Association of Medical Instrumentation has initiated meetings with CDC, CMS, The Joint Commission and a number of professional organizations to discuss issues related to the use of flash sterilization. The overarching goals of the workgroup are to harmonize conflicting recommendations that currently exist; collect rigorous evidence to support guidance for or against immediate-use (flash) sterilization; and develop a better term than "flash sterilization" because this language is associated with several undesirable connotations.

- Ms. DeBaun reported that APIC's membership has grown with more representation by ambulatory care personnel. APIC is targeting a number of educational activities to staff in these settings. APIC is collaborating with scientific partners to develop a position paper with guidance on distinguishing between the use of administrative or coding data versus surveillance data to evaluate HAI rates. APIC distributed its Infection Prevention Program Evaluation Tool to its entire membership to help ICPs to identify gaps in their programs and build a strong business case with hospital administrators for recruiting and enhancing the infection control staff despite severe budget cuts.

- Ms. McGiffert reported that Consumers Union and other consumer advocates from across the country met with CDC staff on the previous day to discuss NHSN, public reporting, MDROs and communication issues to improve dissemination of information to the public. Consumers Union hopes the productive meeting would be the first of many with CDC in the future. Consumer Reports issued an article based on data from Leap Frog and states with public reporting mandates. Consumers Union posted these data on its website and will continue to expand and update the information on a quarterly basis. Consumers Union is continuing its active participation with states by attending meetings on a regular basis and maintaining strong communications with a broad network of consumer advocates. State representatives informed Consumers Union about their barriers to reporting HAI data to NHSN. CDC should invite consumer advocates to serve on the NHSN Workgroup and provide feedback from an end-user perspective. Consumers Union received a grant to initiate the Safe Patient Network in California with a group of activists. Consumers Union will submit comments to express its strong support of the proposal to use CLABSI and SSI as measures for national reporting of HAIs as part of the HHS Action Plan. However, the position of Consumers Union is that all measures outlined in the HHS Action Plan should be nationally reportable to assure accountability in meeting the targets over the next five years.

- Dr. Huskins reported that IDSA issued new clinical practice guidelines for *C. difficile* infection in collaboration with SHEA. IDSA released a joint statement with SHEA and APIC to express concerns regarding methods that were used to generate the AHRQ *National Healthcare Quality Report*. IDSA is continuing its strong focus on antimicrobial resistance activities. IDSA provided testimony to a Congressional subcommittee in March 2010 urging a $20 million increase for federal antimicrobial resistance and antibacterial drug review programs as well as an increase for the new regulatory science initiative. IDSA's "10 x '20 Initiative" that calls for a global commitment to develop ten new antibiotics by 2020 was featured in the April 15, 2010 edition of *Clinical Infectious*

Diseases. IDSA briefed Congressional members on the 10 x '20 Initiative and the "Strategies to Address Antimicrobial Resistance Act" in May 2010.

- Ms. Blanchard reported that AORN is partnering with the American Association of Eye and Ear Centers of Excellence in a worldwide patient safety initiative to address eye- and ear-related "look alike" and "sound alike" medication errors. AORN will sponsor a one-day seminar, "Instrument Processing for the Operating Room: What You Need to Know," in eight cities across the country at no charge. The third edition of the AORN Perioperative Nursing Data Set is now available. The AORN SYNTEGRITY Standardized Perioperative Framework complements the electronic healthcare record and is designed to provide a consistent and reliable documentation data model across the continuum of perioperative patient care. After the pilot project, AORN expects to complete the framework in late 2010 or early 2011. AORN anticipates releasing recommended practices for surgical attire of non-scrub personnel in July 2010.

- Dr. Kainer reported that CSTE recently convened its annual conference with a full-day workshop on NHSN and four breakout sessions on HAIs: respiratory PPE, standardized infection ratios and reporting of HAIs, injection safety, and informatics and electronic reporting. CSTE recently approved four position statements on transplant-transmitted infections, transfusion-transmitted infections, and NHSN case definitions. Key quotes from the position statements are: "CDC should work with CSTE to initiate and maintain a CSTE/CDC process for setting national standards for HAI case criteria and data requirements. A workgroup comprised of representatives from CDC and appropriate CSTE committees and subcommittees will serve as the primary forum for considering candidate criteria and requirements in making recommendations about national standards and participation by appropriate representatives of specialty organizations who add value to the process. NHSN specifications are a logical starting place for workgroup deliberations and decision-making. Recommendations developed by the workgroup will be submitted through CSTE channels for full organizational review and consideration for approval. CDC in turn will use the specifications recommended by the workgroup and approved by CSTE to maintain NHSN in accordance with the national standards set by the CSTE/CDC process." Dr. Stephen Ostroff, a HICPAC member, was recently appointed as the new CSTE President.

- Dr. Maragakis reported that SHEA recently published new clinical practice guidelines for *C. difficile* infection in collaboration with IDSA and also published a guideline for the management of HCP infected with HBV, HCV or HIV. SHEA has nearly completed a position statement that endorses mandatory influenza vaccination of HCP. SHEA will contact CDC to discuss the development of a compendium document or implementation guide for hand hygiene. SHEA formed a workgroup to develop a response to OSHA-related issues. SHEA established a new Antimicrobial Stewardship Task Force that will convene a workshop during the upcoming IDSA meeting in October 2010. IDSA launched a new Research Network during the 5th Decennial International Conference on HAIs in March 2010.

- Ms. Miller reported that CMS is partnering with CDC and other HHS agencies in updating the "HHS National Action Plan to Prevent Healthcare-Associated Infections." In close collaboration with accreditation organizations, CMS is reviewing its budget to increase the number and frequency of surveys administered to ASCs and enforce infection control standards in these settings.

- Ms. Paton reported that PHAC would release three new guidelines on nosocomial pneumonia, endoscopy and routine practices (or standard precautions). PHAC and other public health agencies worldwide have joined with WHO to establish a Global Infection Prevention and Control Network.

- Dr. Elward reported that ACIP launched a number of educational and vaccine campaigns and would hold its next meeting on June 23-24, 2010. ACIP recently published updated recommendations on five vaccines. CDC would make presentations to HICPAC on the following day regarding two of ACIP's ongoing activities: (1) the use of live attenuated influenza vaccine for HCP and (2) consideration of HBV vaccination for persons with diabetes due to outbreaks in LTCFs associated with blood glucose monitoring. ACIP reconvened its Pertussis Workgroup to consider issues related to Tdap vaccination of HCP, particularly its use as post-exposure prophylaxis and the potential need for antibiotic post-exposure prophylaxis in vaccinated HCP.

With no further discussion or business brought before HICPAC, Dr. Brennan recessed the meeting at 4:12 p.m. on June 17, 2010.

Status Report on HICPAC Guidelines and Documents: SESSION 2

Dr. Brennan reconvened the HICPAC meeting at 9:05 a.m. on June 18, 2010 and yielded the floor to the first presenter.

***Guideline for the Prevention and Control of Norovirus Gastroenteritis Outbreaks in Healthcare Settings*.** Dr. Taranisia MacCannell is an epidemiologist in DHQP. She announced that the final draft of the Norovirus Guideline was published in the *Federal Register* for public comment. Because HICPAC's formal vote is needed on the document, she reviewed all of the draft recommendations and their rankings.

The workgroup identified three key research questions to inform the development of the guideline. First, what person, virus or environmental characteristics increase or decrease the risk of norovirus infection in healthcare settings? Second, what are the best methods to identify a norovirus outbreak in healthcare settings? Third, what interventions best prevent or contain norovirus outbreaks in healthcare settings?

Dr. MacCannell announced that DHQP and the Division of Viral Diseases (DVD) are piloting the implementation of the Norovirus Guideline in North Carolina, Ohio and Utah with state-based toolkits. The objectives of the pilot project are to:

- Improve state and local reporting of healthcare-associated norovirus outbreaks among participating healthcare facilities.
- Identify the barriers among healthcare facilities to reporting outbreak data to public health authorities.
- Utilize and refine standardized outbreak definitions for norovirus gastroenteritis outbreaks.
- Assess the utility of resource toolkits and communication frameworks for outbreak management.
- Enhance the current utilization of the National Outbreak Reporting System (NORS) person-to-person transmission module.

The following activities will be conducted during the pilot project. At state and local levels, healthcare facilities, acute care facilities and LTCFs that participate in the pilot will use the toolkit to focus on detection, control measures, diagnostics, education and communication of norovirus outbreaks. Local or state health departments will receive and process outbreak reports through NORS and provide assistance or resources to healthcare facilities as needed. State public health laboratories will perform batch identification of suspect norovirus samples.

At the CDC level, DVD will receive and assist with requests for diagnostic support using the CDC Data and Specimen Handling process. DHQP and DVD will triage and provide epidemiologic and infection control assistance for norovirus outbreaks in healthcare settings. The OutbreakNet Team and DVD will collect and report on norovirus outbreak activity from healthcare settings.

CDC will include a number of resources in the stated-based toolkits: a link to the Norovirus Guideline; definitions for norovirus gastroenteritis cases and outbreaks; general process measures to follow up on the detection of a gastrointestinal outbreak; a flowchart to identify tiered options for diagnostic support and contact information; line list templates for tracking the progress of outbreaks; and communication frameworks for reporting outbreaks.

In June 2010, DHQP and DVD will complete the proposed toolkit and educational resources. In July 2010, the toolkit will be launched, the universe of participating sites will be identified, and monthly conference calls between the three pilot states and the participating healthcare facilities will be initiated. CDC anticipates an increase in norovirus activity during the period of the pilot project from September 2010 to May 2011.

Dr. MacCannell concluded her update by thanking the HICPAC members, CDC staff and external experts for their valuable time, extensive contributions and outstanding efforts in serving on the core writing group and review panel to develop, revise and thoroughly review the guideline.

HICPAC was extremely pleased that CDC would pilot the implementation of the Norovirus Guideline and provide states with a toolkit. The HICPAC members extensively discussed the guideline and made several suggestions for CDC to consider in finalizing the draft document.

- Recommendation 1.A.1: The guidance to shift from contact precautions to standard precautions to manage single sporadic cases of norovirus will be difficult to implement in the field because norovirus meets multiple criteria to place patients on contact precautions. For example, norovirus has a low infectious dose and is difficult to eradicate with standard or non-standard environmental cleaning agents. Moreover, the attack rate of norovirus can be as high as 50% and could extend beyond HCP to include environmental staff. HICPAC members, ICPs in the field and other experts in hospital epidemiology would be extremely reluctant to not place a single patient with confirmed norovirus PCR on contact precautions. Clear evidence demonstrates that contact precautions would meet patient-to-patient and patient-to-HCP environmental risks.
- Recommendation 3.C.1.a: Available evidence should be carefully reviewed to confirm that "hand wash" rather than "hand rub" is the best hand hygiene method to use prior to contact with patients with or without norovirus.
- Recommendation 3.C.11: The guidance to "expedite the discharge of symptomatic or recovering patients who are medically suitable for discharge to their place of residence" appears to advise healthcare facilities to immediately discharge these persons regardless of the receiving facility, such as a LTCF. The guidance should be revised as follows. In the first sentence, "medical suitability" for patients who would be transferred to a skilled nursing facility or other congregate setting should be addressed. In the third sentence, "expedite" should be deleted.
- Recommendation 1.C.3.b: The first sentence should be revised as follows: "Personnel who prepare or distribute food or work in the vicinity of food must be excluded from work if they develop symptoms of acute gastroenteritis." Local health department regulations should be reviewed to determine if the revised language could result in re-ranking the recommendation from Category IB to IC.
- The guidance to "implement systems to designate patients with symptomatic norovirus and notify receiving healthcare facilities or personnel prior to transfer of such patients within or between facilities" should be re-ranked from Category II to IB. The notification requirement should be a standard of practice to eliminate major outbreaks in receiving healthcare facilities.
- Recommendation 2.B: The guidance should be revised for healthcare facilities to consult with state or local public health authorities regarding the appropriate place, type and number of stool specimens to submit during a suspected norovirus gastroenteritis outbreak. The recommendation should explicitly state that suspected norovirus specimens ideally should be submitted to public health departments rather than reference laboratories.
- Recommendation 1.C.4: The guidance should match and reference the previous language on PPE and standard precautions related to exposure to or contamination by vomitus or fecal material when caring for patients with symptoms of norovirus infection.
- Recommendation 3.C.2.b: The guidance should specify outbreak conditions in which visitors would be required to don PPE. This clarification will be critical due to differences across healthcare facilities in their approaches and procedures for visitors to don PPE.
- Recommendation 3.C.12.b.1: Guidance on the frequency of cleaning and disinfecting patient care areas should be left to the discretion of individual healthcare facilities, but examples should be provided based on available evidence. For example, the two sentences could be replaced with the following language: "Increase the frequency of

cleaning and disinfection of patient care areas and frequently touched surfaces during outbreaks of norovirus gastroenteritis to maintain cleanliness."

- Recommendation 3.C.12.d.1: Another option should be given to protect the fabric with a waterproof or water-resistant material to minimize the potential for contamination.
- Recommendations 3.C.12.d.4 & 3.C.12.d.5: The second sentences in recommendations 3.C.12.d.4 and 3.C.12.d.5 should be revised, combined and ranked as the following Standard Precaution statement: "Wear appropriate PPE, such as gloves and gowns, to minimize the likelihood of personal contamination. Staff handling soiled linens should adhere to Standard Precautions (Category IB)." The remainder of recommendation 3.C.12.d.5, "No additional provisions, such as the practice of double bagging, incineration or modifications for laundering, are recommended for linen," should be separate guidance and ranked as Category II.
- Recommendation 3.C.12.e.1: The guidance restates EPA's position on hospital disinfectants and should be re-ranked from Category IB to IC. "The presence of residual organic and protein loads on surfaces reduces the overall effectiveness of disinfectants" should be deleted from the recommendation.
- The Norovirus Guideline should provide links to current environmental guidelines to provide healthcare facilities with more detailed information in this area.
- "Staff Leave and Policy" should be replaced with "Personnel Leave and Policy." The change in terminology has been adopted by the broader healthcare field to eliminate the need to specify particular disciplines or categories (*i.e.*, non-essential staff, students or volunteers).
- Recommendation 3.C.3: The third sentence should be changed as follows: "Facilities should develop and adhere to sick leave policies for healthcare personnel symptomatic with norovirus infection. Ill staff members should be excluded from work for a minimum of 48 hours after the resolution of symptoms. Once staff returns to work, the importance of hand hygiene must be reinforced."
- Recommendation 3.C.7.b: New language should be added to the recommendation as the second sentence to encourage healthcare facilities to inform essential visitors of a norovirus outbreak. The guidance should be revised to clarify that "screening visitors for symptoms consistent with norovirus infection" is for exclusion to the healthcare setting.
- Recommendation 3.C.9.a: A link should be provided to the line listing form for healthcare-associated gastroenteritis outbreaks in the state-based toolkit. The form will provide healthcare facilities with clearer guidance on collecting "epidemiological, clinical and demographic data as well as information on patient location and outcomes."
- Recommendation 3.C.9.b: The guidance should be revised as follows: "Notify appropriate local and state health departments, as required by state and local public health regulations, if an outbreak is suspected, including norovirus gastroenteritis."
- The Norovirus Guideline should contain a link to the guideline developed by the Council to Improve Foodborne Outbreak Response (CIFOR). The new CIFOR guideline is being heavily promoted by state and local health departments.

Dr. Brennan confirmed that HICPAC would address its formal vote during the business session.

Update on the Use of Live Attenuated Influenza Vaccines (LAIV) for HCP

Dr. Anthony Fiore is a Medical Epidemiologist in the Influenza Division of the National Center for Immunization and Respiratory Diseases. He reported that the 2006 HICPAC/ACIP recommendations for influenza vaccination of HCP provided the following guidance. Influenza vaccine should be offered annually to all eligible HCP to protect staff, patients and family members and decrease HCP absenteeism. The use of either available vaccine (inactivated and LAIV) is recommended for eligible persons. During periods when inactivated vaccine is in short supply, use of LAIV is especially encouraged when feasible for eligible HCP. (Category IA).

HICPAC and ACIP recommended the use of LAIV for vaccination of healthy, non-pregnant persons 50-49 years of age, including HCP. When feasible, use of LAIV for vaccination of eligible HCP was especially encouraged during periods of limited supply of inactivated influenza vaccine because use of LAIV for HCP might increase availability of inactivated influenza vaccine for persons at high risk. Use of LAIV was determined to provide an alternative vaccine strategy for HCP who avoid influenza vaccination because of an aversion to intramuscular injections.

The 2006 HICPAC/ACIP recommendations provided supporting information for HCP to receive LAIV. Inactivated influenza vaccine was recommended as the preferred vaccine for use among HCP who have close contact with severely immunosuppressed persons (e.g., patients with hematopoietic stem cell transplants) during periods in which immunosuppressed persons require care in a protective environment. The rationale for not using LAIV among HCP caring for such patients was found to be a theoretic risk that an LAIV virus could be transmitted to severely immunosuppressed persons.

Dr. Fiore described the experience with transmission of LAIV virus to unvaccinated persons. CDC viral surveillance has not identified LAIV virus transmission. Since licensure of LAIV, tens of thousands of specimens have been submitted to CDC at a rate of ~10,000 submissions per year. Internal genetic probes to identify LAIV viruses are routinely performed on persons who report “vaccinated” on the submission form. The identification of ~5 LAIV viruses per year is always in persons recently vaccinated.

CDC assumes many instances in which immunocompromised patients are exposed to recently vaccinated persons, such as vaccinated children who are household contacts of immunocompromised relatives. No published reports are in the literature of unvaccinated immunocompromised persons acquiring LAIV from vaccinated contacts. Acquisition of LAIV virus infection among HCP who administer LAIV has not been reported.

Dr. Fiore described the experience with the use of LAIV to vaccinate immunocompromised persons. A number of published studies have demonstrated that LAIV has been used without evidence of safety concerns in immunocompromised persons, including HIV-infected adults and children, children with asthma, and mild to moderate immunocompromised children as a result of cancer or cancer treatment. Many instances are likely of inadvertent use of LAIV for vaccination of persons without LAIV indications due to age, chronic medical conditions or pregnancy. CDC data show that vaccination coverage levels among HCP remain low at 40%-50%.

Dr. Fiore described the experience with the use of LAIV among HCP during the 2009 pandemic. HCP were designated as the highest priority group before vaccine was available. Many other individuals in high priority groups (*i.e.*, pregnant women, children <2 years of age and persons with chronic medical conditions) could not receive LAIV due to contraindications. LAIV was available for use in larger amounts earlier than inactivated vaccines.

CDC received a number of inquiries that cited concerns about 2009 monovalent H1N1 LAIV transmission to patients. HCP expressed concerns about use of LAIV in any healthcare setting. Some healthcare facilities refused to allow LAIV of HCP in settings where its use should not be restricted (e.g., ICUs, oncology wards and labor/delivery units). Other healthcare facilities enforced administrative rules that refused HCP who had received LAIV to enter low-risk healthcare settings. The coverage level for the 2009 monovalent pandemic influenza vaccine was only 39.3% among HCP. Recent data have shown a much higher coverage level of ~60% for seasonal influenza vaccine among HCP.

The ACIP Influenza Vaccine Workgroup continues to be concerned about poor uptake of LAIV among HCP. The persistent belief in risks posed by contact between immunocompromised patients and HCP who have received LAIV is a potential contributor to low coverage levels. However, evidence has not demonstrated that LAIV transmission occurs in healthcare settings. Published studies have documented that immunocompromised patients are not harmed by receipt of LAIV. These data suggest that even if secondary transmission occurred from HCP to patient, the risk would be extremely low or absent.

Dr. Fiore announced that CDC has taken several actions to increase LAIV coverage among HCP, but he also requested HICPAC's input on other areas to explore. The use of LAIV in certain healthcare settings (e.g., NICUs, labor/delivery units and ICUs) is clearly stated on the CDC website and will be reemphasized in the 2010 annual influenza vaccine recommendations.

Consideration is being given to removing all restrictions on LAIV use among HCP regardless of work setting, updating the 2006 HICPAC/ACIP guidelines, and reiterating the 2006 guidelines in upcoming ACIP general vaccination recommendations for HCP. Efforts are being coordinated with key stakeholders, including transplant medicine experts and hospital associations, to determine the feasibility of recommending the use of LAIV in any healthcare setting. CDC is aware of the critical need for further research to identify reasons HCP continue to refuse LAIV.

In response to Dr. Fiore's request for input, HICPAC made a number of suggestions for CDC to consider in its ongoing efforts to increase LAIV uptake among HCP.

- Data are insufficient at this time to exclude the possibility of LAIV virus transmission to bone marrow transplant or hematopoietic stem cell transplant patients at highest risk pending engraftment. However, CDC should continue its efforts to engage hospital associations and experts in the field to articulate that LAIV can be safely used in all other healthcare situations.
- CDC should partner with the Child Health Corporation of America (CHCA) and transplant societies. For example, CDC could extract surveillance data from CHCA that showed

LAIV uptake among HCP in NICUs in a number of healthcare facilities and the lack of transmission of LAIV strains to NICU patients.

- CDC should take caution in issuing a recommendation that healthcare facilities "must" offer LAIV and the injectable. Institutions should be given flexibility to respond to their individual needs, such as a waste of vaccine due to low uptake of LAIV among HCP.
- CDC should partner with FDA to clarify the LAIV product insert because some healthcare facilities have expressed concern with this language.
- CDC should collaborate with professional associations to identify knowledgeable "physician champions" who could play a critical role in increasing LAIV uptake among HCP at the local level. For example, even some infectious disease physicians do not have basic knowledge of LAIV data.
- CDC should implement its proposal to remove all restrictions on LAIV use among HCP regardless of work setting.

Ms. Miller asked HICPAC to provide its expertise to CMS to increase uptake of influenza vaccination among HCP. CMS is considering issuing an Omnibus Rule requiring influenza vaccination of HCP in all other settings beyond healthcare facilities and LTCFs.

Ms. Miller asked the HICPAC members to share outcome data with CMS related to influenza vaccination of HCP. Following the publication of the 2006 HICPAC/ACIP guideline, influenza rates, outbreaks and absenteeism among HCP have decreased. However, CMS needs solid data to support issuing the Omnibus Rule because the requirement will be very controversial.

Dr. Huang noted that the state of California has outcome data on influenza vaccination of HCP. She offered to provide Ms. Miller with contact information for Dr. John Rosenberg. Several HICPAC members also informed Ms. Miller that solid data have been published in the literature on decreased HCP absenteeism as a result of increased influenza vaccination. Outcome data in LTCFs are available as well.

Update on Hepatitis B Vaccine for Persons with Diabetes

Dr. John Ward is the Director of the Division of Viral Hepatitis in the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention. He reported that an ACIP Workgroup has been convened to focus on HBV vaccination for diabetics. An HBV elimination strategy for the United States was developed in 1992 with the following components: infant immunization beginning at birth and catch-up vaccination for older children, adolescents and high-risk adults, including HCP and persons with behavioral risks.

The current ACIP guideline recommends HBV vaccination for persons with chronic liver disease. NHANES data have demonstrated a higher incidence and prevalence of HBV in diabetics than in non-diabetics. The prevalence of HBV is comparable between diabetics and HCP or other groups that are recommended to receive HBV vaccination. HBV vaccination of diabetics could result in gains in protection comparable to those observed in HCP.

ACIP currently recommends post-vaccination testing of persons with HIV and other groups with low seroprotection following HBV vaccination. The amount of research on seroprotection of diabetics following HBV vaccination is minimal, but one study showed a fairly robust response. However, seroprotection following HBV vaccination was found to be lower in diabetics compared to non-diabetics, particularly in older age groups.

Dr. Ward outlined the guiding principles and policy considerations for HBV vaccination of diabetics that are being proposed by the ACIP Workgroup. Future recommendations must be consistent with current guidelines. Because the guidance would be designed to maximize seroprotection at all ages, HBV vaccination would be recommended as soon as possible after a diagnosis of diabetes. Re-vaccination might be necessary for older adults with diabetes or for persons who show no evidence of immune protection.

Consistent with existing guidance, booster doses of HBV vaccine would not be recommended for diabetics. Vaccination would not be recommended for contacts of diabetics unless this guidance would be consistent with recommendations for vaccinating other contacts, such as sexual partners or close household contents.

The ACIP Workgroup is in favor of HBV vaccination for all unvaccinated adults with diabetes. The three-dose vaccination series should be completed as soon as possible after a diagnosis of diabetes. Any vaccine containing hepatitis B could be used. Post-vaccination serology would be beneficial for adults with diabetes $\geq$60 years of age to document seroprotection. Post-vaccination should be completed one to two months after completion of the vaccination series.

Dr. Ward concluded that HBV outbreaks continue to occur and are associated with significant morbidity and mortality. HBV transmission related to poor blood glucose monitoring and other substandard infection control practices pose risks for diabetics in multiple medical settings. Morbidity and mortality from HBV and other causes of liver disease are substantial for adults with diabetes compared to the general population.

Dr. Ward confirmed that he would repeat his presentation during the next ACIP meeting in June 2010. CDC and ACIP would then focus on cost-effectiveness and implementation issues regarding HBV vaccination of diabetics in collaboration with the American Diabetes Association (ADA) and other external partners. CDC hopes that Medicare and health reform would defray costs of HBV vaccination in nursing homes and increase uptake. The proposed guiding principles and policy considerations would be presented to the full ACIP membership for a formal vote during the October 2010 meeting.

HICPAC was concerned about extremely poor infection control practices in ambulatory care settings. HICPAC emphasized the critical need for CDC to immediately issue guidance on this issue.

Ms. Miller confirmed that she would serve as CDC's point of contact with CMS for the agencies to immediately initiate discussions on the serious issue of HBV outbreaks among diabetics related to poor infection control practices.

HICPAC Business Session

HICPAC Guidelines. Dr. Brennan announced that HICPAC could only take a provisional vote on the Norovirus Guideline at this time because the public comment period would not close until July 16, 2010. As a result, he took the Chair's prerogative and tabled HICPAC's vote.

This approach would allow HICPAC to take a final vote after CDC revised the guideline based on revisions suggested during the meeting and additional public comments that would be submitted. Dr. Brennan confirmed that a conference call would be held prior to the November 2010 meeting for HICPAC to take a final vote on the revised Norovirus Guideline.

Dr. Brennan returned to Dr. Elward's request for HICPAC's input on whether recommendations on MSSA and other MDROs should be added to the NICU Guideline. He confirmed that HICPAC would have an in-depth discussion at the next meeting on whether to address these issues in the guideline in the context of discontinuing isolation precautions.

HICPAC Workgroups. Dr. Brennan returned to HICPAC's unanimous approval on the previous day to establish the new workgroup. Drs. Dale Bratzler, Susan Huang and Tammy Lundstrom volunteered to serve on the new workgroup and engage external experts as needed. Dr. Fridkin would serve as the workgroup's technical resource and point of contact with CDC.

Mr. Olmsted reported that HICPAC has previously discussed the possibility of developing documents other than evidence-based guidelines, such as commentaries or white papers. He noted HICPAC's past experience in this area with the development of its white paper on the use of electronic health records for HAI surveillance and prevention.

Due to the growing field of translational research or implementation science, Mr. Olmsted proposed establishing a new workgroup with HICPAC members and liaisons to develop a translational research white paper. He outlined three potential functions of the document.

- The white paper would provide guidance on applying HAI principles or illustrate the use of translational research with an HAI-focused model.
- The white paper would address initial epidemiologic research and rigorous studies that have been implemented in facilities.
- The white paper would be targeted to ICPs, healthcare epidemiologists, funding agencies of translational research, and professionals who are conducting translational and health sciences research.

HICPAC unanimously agreed to consider forming the new workgroup.

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

- Dr. Brennan would communicate with Mr. Jeffrey Hageman, Executive Secretary of HICPAC, to convene a conference call prior to the November 2010 meeting for HICPAC to take a final vote on the Norovirus Guideline.

- Dr. Brennan would communicate with Mr. Hageman to place Dr. Dale Bratzler, a HICPAC member, on the next agenda to discuss his activities with CMS metrics.

- The HICPAC members would participate in the following ongoing or new activities:
  - Continue to serve on the core writing group or the expert review panel to make progress in developing the NICU Guideline. [Drs. Elward, Huang and Pegues, Mr. Olmsted]
  - Continue to serve on the core writing group to make progress in updating the HCP Infection Control Guideline. [Drs. Lundstrom and McCarter, Ms. Murphy, Ms. Soule]
  - Collaborate with CDC, CMS and ACIP on developing an action plan to improve infection control practices with blood glucose monitoring of diabetics in ambulatory care settings. [Dr. Schecter]
  - Develop a toolkit for professional societies to implement HICPAC guidelines at the bedside (beginning with the CAUTI Guideline). [Dr. Pegues]
  - Assist DHQP in further development of the ambulatory care guidance document. [Dr. Bratzler]

Closing Session

Dr. Brennan thanked CDC for providing extremely informative presentations throughout the meeting to guide HICPAC's deliberations. He thanked the HICPAC members and liaisons for continuing to commit their valuable time and expertise to developing the guidelines. He also thanked the consumer advocates for attending the meeting and making public comments to provide HICPAC with their insights on healthcare infection control practices from an end-user perspective.

The next HICPAC meeting would be held on November 4-5, 2010 in Washington, DC. With no further discussion or business brought before HICPAC, Dr. Brennan adjourned the meeting at 11:30 a.m. on June 18, 2010.

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

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Date

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