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 (HICPAC)

Meeting
October 11 and 12, 2012
Washington, D.C.

Meeting Summary Report

Available from: https://www.cdc.gov/hicpac/minutes.html

Table of Contents

Attachment 1: Meeting Agenda 2
Attachment 2: List of Participants 3
Attachment 3: Acronyms Used in this Document 2
Executive Summary 4
Meeting Summary Report 6
Opening Session: October 11, 2012 Member introductions and conflict of interest disclosures 6
Review of June HICPAC Meeting Activities 7
Overview of the Fungal Meningitis Outbreak 7
HHS HAI Activity Updates 8
CDC's Role in Quality Measure Development and Use 11
Draft Guideline for Prevention of Infection Among Patients in NICU 14
Policy Update from CDC's Washington Office 23
Update on Planned Changes to NHSN 24
Update on the APIC/SHEA Compendium of Strategies to Prevent HAIs in Acute Care Hospitals 28
Public Comment Period 29
Liaison and Ex Officio Reports 30
Closing Remarks 33
Opening Session: October 12, 2012 33
Draft Guidelines for the Prevention of Surgical Site Infection 33
HICPAC Guidance on the Use of Surveillance Data in a New Environment: Healthcare-Associated Infection Surveillance for Public Reporting of Quality Outcomes 42
Public Comment Period 46
Summary and Wrap-Up 46
Certification 46

Attachment 1: Meeting Agenda

Healthcare Infection Control Practices Advisory Committee

October 11 and 12, 2012
Centers for Disease Control and Prevention
Renaissance Washington, DC Dupont Circle Hotel (Capital CD Room)
1143 New Hampshire Avenue Northwest
Washington, DC 20037

Thursday October 11, 2012

Time	Topic	Presider/Presenter
9:00	**Welcome and Introductions** Administrative issues: Meeting logistics Introductions Conflicts of interest declarations Review June Meeting Activities	Neil Fishman (HICPAC Chair) Jeff Hageman (CDC)
9:30	HHS HAI Activity Updates	Don Wright (HHS)
10:00	**Break**	
10:20	CDC's role in quality measure development and use	Dan Pollock (CDC)
10:55	Draft Guideline for Prevention of Infections Among Patients in NICU	Alexis Elward (HICPAC)
12:00	**Lunch**	
1:30	Policy Update from CDC's Washington Office	Michael Craig (CDC)
2:00	HICPAC Surveillance Working Group- NHSN definitions for Bloodstream infections and surgical site infections	Dawn Sievert (CDC)
3:00	Update on SHEA-IDSA Compendium	Deborah Yokoe (HICPAC)
3:30	Break	
3:45	Public Comment	
4:30	**Liaison/ Ex-officio Reports**	
5:00	**Adjourn**	

Friday October 12, 2012

Time	Topic	Presider/Presenter
9:00	Draft Guideline for the Prevention of Surgical Site Infections	Sandra Berrios-Torres (CDC)
10:45	**Break**	
11:00	HICPAC Guidance on the Adjudication in an Era of Public Reporting	Neil Fishman (HICPAC)
11:40	Public Comment	
11:45	Summary and Wrap Up	
12:00	**Adjourn**	

Attachment 2: List of Participants

(Note: the Designated Federal Official opened the floor for introductions on October 11 and 12, 2012, and confirmed the presence of a quorum.)

DAY 1: OCTOBER 11, 2012

HICPAC MEMBERS PRESENT:

Dr. Neil Fishman, Chair
Dr. Dale Bratzler
Dr. Ruth Carrico
Dr. Daniel Diekema
Dr. Alexis Elward
Dr. Ralph Gonzales
Dr. Tammy Lundstrom
Dr. Stephen Ostroff
Dr. Deborah Yokoe

DESIGNATED FEDERAL OFFICIAL:

Mr. Jeffrey Hageman, Deputy Chief, Prevention and Response Branch, DHQP

EX OFFICIO MEMBERS PRESENT:

Dr. William Baine, Agency for Healthcare Research and Quality
Dr. David Henderson, National Institutes of Health
Dr. Paul Moore, Health Resources and Services Administration
Dr. Sheila Murphey, Food and Drug Administration
Dr. Gary Roselle, Veterans Administration
Dr. Daniel Schwartz, Centers for Medicare and Medicaid Services

LIAISON MEMBERS PRESENT:

Ms. Barbara DeBaun, Association of Professionals of Infection Control and Epidemiology, Inc.
Ms. Kathleen Dunn, Public Health Agency of Canada
Dr. Michael Howell, Society of Critical Care Medicine
Dr. Charles Huskins, Infectious Diseases Society of America
Ms. Lisa McGiffert, Consumers Union
Dr. Mark Rupp, Society for Healthcare Epidemiology of America
Dr. Mark Russi, American College of Occupational and Environmental Medicine
Dr. Sanjay Saint, Society of Hospital Medicine
Ms. Lisa Spruce, Association of periOperative Registered Nurses
Ms. Rachel Stricof, MPH (alternate), Council of State and Territorial Epidemiologists
Ms. Margaret VanAmringe, The Joint Commission

CDC REPRESENTATIVES PRESENT:

Dr. Don Wright, Deputy Assistant Secretary for Health
Dr. Denise Cardo, DHQP Director
Dr. Michael Bell, DHQP Deputy Director
Mr. Michael Craig
Dr. Daniel Pollock
Dr. Dawn Sievert
Ms. Erin Stone

MEMBERS OF THE PUBLIC PRESENT:

Dr. Craig Umscheid, Director, Center for Evidence-Based Practice, University of Pennsylvania Health System

DAY 2: OCTOBER 12, 2012

HICPAC MEMBERS PRESENT:

Dr. Neil Fishman, Chair
Dr. Dale Bratzler
Dr. Ruth Carrico
Dr. Daniel Diekema
Dr. Alexis Elward
Dr. Ralph Gonzales
Dr. Tammy Lundstrom
Dr. Deborah Yokoe

DESIGNATED FEDERAL OFFICIAL:

Mr. Jeffrey Hageman, Deputy Chief, Prevention and Response Branch, DHQP

EX OFFICIO MEMBERS PRESENT:

Dr. William Baine, Agency for Healthcare Research and Quality
Dr. David Henderson, National Institutes of Health
Dr. Paul Moore, Health Resources and Services Administration
Dr. Sheila Murphey, Food and Drug Administration
Dr. Gary Roselle, Veterans Administration

LIAISON MEMBERS PRESENT:

Ms. Barbara DeBaun, Association of Professionals of Infection Control and Epidemiology, Inc.
Ms. Kathleen Dunn, Public Health Agency of Canada
Dr. Michael Howell, Society of Critical Care Medicine
Dr. Charles Huskins, Infectious Diseases Society of America
Ms. Lisa McGiffert, Consumers Union
Dr. Mark Rupp, Society for Healthcare Epidemiology of America
Dr. Mark Russi, American College of Occupational and Environmental Medicine
Ms. Lisa Spruce, Association of periOperative Registered Nurses
Ms. Rachel Stricof, MPH (alternate), Council of State and Territorial Epidemiologists
Ms. Margaret VanAmringe, The Joint Commission

CDC REPRESENTATIVES PRESENT:

Dr. Denise Cardo, DHQP Director
Dr. Michael Bell, DHQP Deputy Director
Dr. Sandra Berrios-Torres
Dr. Daniel Pollock
Dr. Dawn Sievert
Ms. Erin Stone

MEMBERS OF THE PUBLIC PRESENT:

Dr. Craig Umscheid, Director, Center for Evidence-Based Practice, University of Pennsylvania Health System

Attachment 3: Acronyms Used in this Document

Acronym	Expansion
AAP	American Academy of Pediatrics
ACA	(Patient Protection and) Affordable Care Act
ACIP	Advisory Committee on Immunization Practices
ACOEM	American College of Occupational and Environmental Medicine
ADE	adverse drug event
AHA	American Hospital Association
AHCA	American Health Care Association
AHRQ	Agency for Healthcare Research and Quality
AORN	Association of periOperative Registered Nurses
APIC	Association of Professionals of Infection Control and Epidemiology, Inc.
AR	antibiotic resistance
BARDA	Biomedical Advanced Research and Development Authority
BMI	Body Mass Index
BSI	bloodstream infection
C. diff	*Clostridium difficile*
CAUTI	catheter-associated urinary tract infection
CBER	Center for Biologics Evaluation and Research
CDC	Centers for Disease Control and Prevention
CDI	*Clostridium difficile* infection
CIC	certification in infection prevention and control
CLABSI	central-line-associated bloodstream infections
CMS	Centers for Medicare and Medicaid Services
CSTE	Council of State and Territorial Epidemiologists
DHQP	Division of Healthcare Quality Promotion
EIN	Emerging Infection Network
FDA	U.S. Food and Drug Administration
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HAI	healthcare-associated infection
HCW	healthcare worker
HEN	healthcare engagement network
HHS	U.S. Department of Health and Human Services
HICPAC	Healthcare Infection Control Practices Advisory Committee
HIVMA	HIV Medicine Association
HRSA	Health Resources and Services Administration
ICU	Intensive care unit
IDSA	Infectious Disease Society of America
IHI	Institute for Healthcare Improvement
IRB	Institutional Review Board
ITFAR	Interagency Task Force for Antibiotic Resistance
LPAD	Limited Population Antibacterial Drug Approval Mechanism
LTCF	long-term care facility
MBI-LCBI	mucosal barrier injury laboratory-confirmed bloodstream infection
MDRO	multi-drug resistant organism
MRSA	methicillin-resistant *Staphylococcus aureus*
NHSN	National Healthcare Safety Network

Acronym	Expansion
NICU	neonatal intensive care unit
NIH	National Institutes of Health
NQF	National Quality Forum
OMB	Office of Management and Budget
PAMPTA	Preservation of Antibiotics for Medical Treatment
PCR	polymerase chain reaction
PIDS	Pediatric Infectious Disease Society
RCT	randomized controlled trial
SHEA	Society for Healthcare Epidemiology of America
SICU	surgical intensive care unit
SIR	Standardized Infection Ratio
SSI	surgical site infections
UDI	unique device identifier
USP	United States Pharmacopeia
UTI	urinary tract infection
VAC	ventilator-associated complication
VAE	ventilator-associated event
VAP	ventilator-associated pneumonia
VTE	venous thromboembolism

Executive Summary

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) on October 11-12, 2012, in Washington, D.C.

The Designated Federal Official and Chair confirmed the presence of a quorum with voting members and ex officio members for HICPAC to conduct its business on both days of the meeting. The HICPAC voting members disclosed their conflicts of interest for the public record.

CDC presented a brief overview of the recent fungal meningitis outbreak. An intensive effort is underway to contact every individual who may have been exposed to the contaminated medication and get each symptomatic person into evaluation and care. Almost all potentially exposed individuals have now been contacted.

CDC presented an update on HHS activity in the area of HAI elimination efforts. Phase III of HHS's HAI Action Plan will cover long-term care facilities and is scheduled to be released in November 2012. An ADE Action Plan modeled after the HAI Action Plan is also being planned. The Affordable Care Act contains several provisions which are expected to improve financial incentives to reduce HAI rates. APIC, SHEA and CDC have jointly created the Partnership in Prevention Award, which will recognize leading institutions in U.S. acute care who have achieved wide-scaled HAI reductions.

The next presentation was on CDC's role in quality measure development and use. NHSN, the national quality measure system, was created by CDC and continues to evolve to meet user needs. In particular, CDC will move away from individual measures to Standardized Infection Ratios (SIRs) which provide a single summary metric at the facility level. Eventually, reliability-adjusted SIRs will enable more meaningful comparisons between healthcare facilities. HICPAC discussed the benefits and limitations of SIRs, which will not replace but rather add to individual measures.

An update on the draft guideline for infection prevention in the NICU was next presented. Revisions to the respiratory pathogen, *C. difficile* and MRSA sections have been made, some in response to previous HICPAC comments. HICPAC made extensive comments and suggestions for the writing group to consider.

CDC next presented a briefing on legislative issues relevant to HICPAC. The GAIN Act will provide incentives for the manufacture of new antibiotic and antifungal drugs, and the Senate appropriations bill, although it has not passed into law, includes language from the STAAR Act calling on CDC to address the problem of antibiotic resistance. HICPAC also heard on update on the current federal budget situation and the impact a potential sequestration would have.

CDC also presented changes to NHSN surveillance definitions. A new mucosal barrier injury-laboratory-confirmed bloodstream infection (MCI-LCBI) has been created and will include some events that would formerly have been categorized as CLABSIs. Future changes to the core HAI definition, SSI definition and VAE definition were also presented.

Dr. Deborah Yokoe of HICPAC gave a presentation on the APIC/SHEA Compendium of Strategies to Prevent HAIs in Acute Care Hospitals. The Compendium is currently being updated to account for research done since the first version of the Compendium was published in 2008. When the draft updates are available, HICPAC will be invited to provide input.

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

CDC presented portions of its draft guidelines for the prevention of SSI. The topics of glycemic control, normothermia, oxygenation, and exhaust suit use were covered at this meeting. HICPAC made numerous comments which will be considered in the final recommendations. In March 2013, HICPAC will hear draft recommendations on a number of other SSI guideline topics.

The Chair presented a proposed HICPAC white paper entitled "Guidance on the Use of Surveillance Data in a New Environment." The document is intended to address some of the unintended consequences of HAI surveillance reporting and reduce gaming of the system. The white paper will recommend that NHSN definitions be used to measure all HAI outcomes, and clinical adjudication panels not be used. Data validation is critical. After a thorough discussion, HICPAC unanimously voted to approve the proposed guidance document, with its comments incorporated.

The Chair called for public comments at all times noted on the published agenda.

Department Of Health and Human Services

Centers for Disease Control and Prevention

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

Healthcare Infection Control Practices Advisory Committee
October 11 and 12, 2012
Washington, D.C.

Meeting Summary Report

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 October 11-12, 2012, in the City Center Ballroom of the Renaissance Washington, DC Dupont Circle Hotel, 1143 New Hampshire Avenue N.W., in Washington, D.C.

Opening Session: October 11, 2012
Member introductions and conflict of interest disclosures

Jeffrey Hageman, MHS
Deputy Chief, Prevention and Response, DHQP
HICPAC Designated Federal Official

The Designated Federal Official, Mr. Jeff Hageman, opened the floor for introductions of HICPAC voting members, ex officio members, and liaison representatives who were in attendance. He asked voting members to publicly disclose any new conflicts of interest.

- Dr. Alexis Elward received research support from Sage Products, Inc. to study the efficacy of daily bathing with chlorhexidine to prevent bloodstream infections in pediatric ICU patients.
- Dr. Ralph Gonzales serves as a scientific advisor for Phreesia, Inc., a computerized check-in company.

Mr. Hageman confirmed that the voting members and ex officio members in attendance constituted a quorum sufficient for HICPAC to conduct its business. He called the meeting to order at 9:08 a.m. and welcomed the participants.

Review of June HICPAC Meeting Activities

Jeffrey Hageman, MHS
Deputy Chief, Prevention and Response, DHQP
HICPAC Designated Federal Official

At the June meeting, HICPAC heard a presentation from Dr. Kathryn Arnold on CDC's work with CSTE to develop validation tools. That work will be going into CDC clearance soon. Also, tablet applications are being developed to help states with validation.

Dr. David Kuhar had outlined the U.S. Public Health Service guidelines for management of occupational exposures to HIV and post-exposure prophylaxis. That guidance has been submitted for CDC clearance and should be out soon.

CDC continues to work with its partners, including the Safe Injection Practices Coalition, to get out recommendations on the appropriate use of single-dose vials.

HICPAC had also discussed clarifying CDC's disinfectant fogging recommendations in the light of new technologies developed after the recommendations were made. The clarification is now posted on the HICPAC website and will be on CDC's site, embedded within the environmental and disinfectant guidelines.

Mr. Hageman outlined the agenda for the current meeting, which will follow up on several other issues discussed in June.

Overview of the Fungal Meningitis Outbreak

Michael Bell, MD
CDC/NCEZID/DHQP, Deputy Director

Dr. Michael Bell outlined the background of the recent fungal meningitis outbreak. A compounding pharmacy produced as many as 13,000 doses of methylprednisolone acetate medication potentially contaminated with at least one fungal pathogen. The contamination has resulted in 137 cases of infection so far, and there have been 12 deaths. The installation of an environmental fungus in an anti-inflammatory medication has led to an indolent infection which is masked longer than it otherwise might be.

CDC's role in the meningitis outbreak can be described as "patient salvage", while FDA is in charge of regulating medication production. An intensive effort is underway to contact every individual who may have been exposed to the contaminated medication and get each person who has any symptoms into evaluation and care. Symptomatic people will be given a lumbar puncture, and CDC has released diagnostic criteria which set a low threshold for considering the lumbar puncture abnormal.

Over 12,000 out of 13,000 potentially exposed individuals have so far been contacted. Door-to-door outreach has been conducted to contact individuals who may not be able to answer the phone. CDC is working with IDSA and other partners to put together the safest and most effective treatment for individuals with abnormal cerebrospinal fluid. CDC is also working to refine clinical treatment guidelines and tailor the suggested treatment to the fungal infections found, using a conservative approach because of the potentially serious nature of the infection. After FDA completes its evaluation of the production facility, a root cause analysis will be done.

CDC also met recently with the U.S. Pharmacopeia to discuss single-use vial guidance. The USP 797 medication management standards are designed for formal pharmacy settings. They should be retailored to make compliance more feasible in ambulatory care and other less formal settings, where problems with vial handling most often occur. Risk-based recommendations, focusing on the products which most often cause problems, are also being considered.

Questions and Comments from HICPAC:

Dr. Henderson asked whether all the meningitis cases are associated with methylprednisolone acetate and whether the compounding pharmacy's other products have been examined. Dr. Bell said that all cases so far have been associated with three lots of 80 mg/mL methylprednisolone acetate preservative-free product. All products from the pharmacy in question have been recalled and the parent company is now shut down. In response to another question from Dr. Henderson, Dr. Bell said that a listing of the 23 states and clinics that received drugs from the company is available online. No product was distributed internationally as far as is currently known. However, it is difficult to tell whether any repackaging or remarketing of pharmacy products occurred.

Dr. Baine asked whether it is true that patients all fell within an incubation period of 28 days. Dr. Bell answered that CDC is still uncertain about the incubation period. It could be 50 days or more. Presentation of symptoms might be delayed; for instance, patients who got an injection for joint pain might not recognize joint pain when it appears as a new symptom.

Dr. Bell added that the response to this outbreak is a great example of the benefit of investing in public health programs at the state as well as federal level.

HHS HAI Activity Updates

Don Wright, MD, MPH
Deputy Assistant Secretary for Health and Director of the Office of Disease Prevention and Health Promotion

National Action Plan to Prevent Healthcare-Associated Infection: Roadmap to Elimination

Dr. Wright began by outlining the evolution of the HAI Action Plan, which was born from a GAO report in March 2008 and from a House Oversight Committee hearing in April 2008. The Deputy Secretary of Health then formed a

senior-level Steering Committee for the Prevention of HAIs, which is headed by Dr. Wright. In June 2009, the Steering Committee issued the first National Action Plan to Prevent HAIs.

The Action Plan is intended to be a living document which will be revised as needed for evolving science and strategy. It is being developed in prioritized phases. The first phase, begun in 2009, involved acute care hospitals. In Phase II, outpatient settings such as ambulatory surgical centers and end-stage renal disease centers were included, as well as an effort to increase seasonal influenza immunization rates among healthcare workers.

Action Plan Phase III: Long-Term Care Facilities (LTCFs)

Phase III of the Action Plan is currently in progress and will cover long-term care facilities; an initial draft was published in the Federal Register in April 2012. This long-term care chapter was created by a work group headed by CMS with four side work groups focused on literature review, promising practices across the nation, communications, and measure data collection. The work group considered the definition of long-term care and decided to limit its scope to skilled nursing homes.

Five priority areas were identified in long-term care:

- NHSN enrollment to establish baseline data
- *C. difficile* infections
- UTI, CAUTI, and catheter care processes
- Resident influenza and pneumococcal vaccination
- Healthcare personnel influenza vaccination

The current dearth of baseline data presents a challenge, and many goals need to be developed in the future.

After the April Federal Register notice, over 214 comments were received from 50 different stakeholders. The most common comment was on staffing in nursing homes, and other comments were received on targets, financial incentives, and recommended strategies. CDC has met with stakeholder organizations to solicit additional information. Some of the priorities identified at these meetings were:

- Infrastructure
- Building a knowledge base
- Quality assurance
- Target setting
- Using lessons learned at state or local level

Some of the challenges in this area are the high level of turnover among staff and leadership in LTCFs, the need to educate staff and families and moving from a punitive culture to a proactive culture.

The new chapter will be submitted to the Steering Committee for approval in October 2012 and then to the Secretary of Health. It is scheduled to be released by the end of November 2012.

Phase IV will be started in early 2013. It has not yet been decided which healthcare facilities will be the focus of Phase IV, but ambulatory care centers, physicians' offices, and injection safety are possible topics.

ACA provisions relevant to HAIs:

Dr. Wright said that the Affordable Care Act will improve financial incentives to reduce HAIs in several ways:

- Partnership for Patients: $218 million in 26 HENs to implement strategies to reduce preventable hospital-acquired conditions, including HAIs.
- In fiscal year 2015, CMS will reduce payment for discharges from hospitals that have risk-adjusted HAC rates in the top quartile.
- In fiscal year 2015, payments will be reduced for hospitals with excessive readmission.
- The Physician Quality Reporting System will incentivize physicians to report data on quality measures.
- Physician Feedback Program: CMS will modify payment to physicians based on quality of care furnished compared to cost.
- In hospital value-based purchasing programs, performance measures must include HAI rates as identified in the HAI Action Plan.
- The ACA moves quality reporting beyond hospitals; long-term care hospitals and inpatient rehab facilities will be required to report new and worsening CAUTIs, and long-term care hospitals will be required to report CLABSIs.

Progress Towards Eliminating HAIs meeting

The 2012 Progress Towards Eliminating HAIs stakeholder meeting will be held on October 30th in Washington, D.C. Academia, professional organizations, government agencies, the private sector and consumer organizations will all be involved. At the meeting, CDC's progress towards meeting the five-year national HAI targets set at the 2008 meeting will be reviewed. Dr. Wright invited HICPAC members to attend.

HHS/APIC/SHEA Partnership in Prevention Award

In partnership with APIC and SHEA, CDC has developed the Partnership in Prevention Award, intended to recognize leaders in the U.S. acute care community who have achieved wide-scale HAI reductions by following the provisions of the HAI Action Plan and the goals of the Partnership for Patients. Over 40 applications were received. One hospital will receive the award, with three honorable mentions. The award will be presented by Dr. Howard Koh, the Assistant Secretary for Health, on October 15, 2012, as part of International Infection Prevention Week. Also on October 15th, a webinar will be held to allow the winning institution to share the secrets of its success.

Adverse Drug Events: Path Forward to a National ADE Prevention Action Plan

Adverse drug events (ADEs) are a significant cause of morbidity and mortality. They also prolong hospital stay and increase healthcare costs, with the cost of inpatient ADEs in the U.S. estimated at $4.2 billion. In fact, medications

are the most common cause of hospital adverse events and post-discharge complications. This problem has recently received Congressional attention, and the Secretary of Health has asked the CDC Office of Disease Prevention and Health Promotion to come up with an ADE Action Plan modeled after the HAI Action Plan.

Lessons learned from the Partnership for Patients show the importance of aligning public and private sectors for this effort. A gradual, targeted approach will address the most common sources of ADEs first, with an initial focus on both inpatient and outpatient ADEs resulting from anticoagulants, antidiabetics, and opioids for non-malignant pain. These particular drugs were chosen because the ADEs associated with them are clinically significant, preventable, measurable, and common; it is estimated that these drugs are responsible for 70-80% of ADEs.

The organization of this effort is analogous to that of the HAI Action Plan, with a senior-level Steering Committee and three work groups focused on the three classes of drugs, tasked with studying evidence-based prevention tools, surveillance, incentives and oversight, and research and unanswered questions.

Questions and Comments from HICPAC:

Dr. Ostroff commented that the state of Pennsylvania is also addressing HAIs in LTCFs. He noted that collecting and validating data will be an even bigger challenge in the LTCF setting, where infection prevention expertise, ability to collect useful data, and the quality of data in patient records is often very limited. Adverse events have also been seen to occur in the many facilities which perform surgery without being classified as ambulatory surgical centers. This is an area which deserves to be studied.

Dr. Rupp asked whether any thought has been given to including to anti-infectives in the ADE protocol, because of the high societal impact of antibiotic resistance. Dr. Wright replied that there are different opinions about which drugs should be included. The ADE Action Plan will be a tiered approach whose scope will be broadened in the future. Dr. Wright stated that he hopes to have an initial ADE Action Plan by midsummer 2013.

Ms. McGiffert encouraged CDC to include consumers in developing the ACE Action Plan.

Dr. Roselle commented that ADE reporting is patchy, with the worst cases reported, and lesser adverse events much less likely to be reported. This creates the risk of “iceberg metrics” which fail to accurately sample all the ADEs which occur. Dr. Wright said that the foundation for ADE reduction has yet to be built. However, the success of HAI reduction efforts in the past four years can give us hope for ADE reduction.

CDC’s Role in Quality Measure Development and Use

Daniel Pollock, MD
CDC/NCEZID/DHQP Surveillance Branch Chief

Dr. Dan Pollock described CDC's role in HAI quality measurement. CDC identifies HAI quality measures and submits them to the National Quality Forum (NQF) for vetting and endorsement. CDC also created and supports the National Healthcare Safety Network (NHSN), which is the national system for collecting, analyzing and reporting measure data. CDC also disseminates measure specifications, fosters greater use of electronic data

sources and methods for quality measure reporting, supports validation and standardization of quality measure data, and collaborates with state and federal agencies on HAI issues.

NHSN has grown from about 300 hospitals in 2005 to over 11,000 hospitals and other healthcare facilities in 2012. It has been adopted by 30 states and DC. What was once purely voluntary and confidential reporting is now almost solely mandatory public reporting. Some NHSN quality measures are also reported to CMS; for instance, acute care hospitals are currently required to report rates of CLABSIs, CAUTIs and SSIs, and this year, dialysis facilities will be required to report rates of bacteremia.

CDC measures on CLABSIs, CAUTIs, SSIs, healthcare worker influenza vaccination coverage, and dialysis event (bacteremia) have been endorsed by NQF. These measures were developed with the help of the American College of Surgeons. Measures on *C. difficile*, MRSA, VAEs and antimicrobial use have been or will be proposed for endorsement.

Changes to NHSN definitions: In response to rising expectations and new public scrutiny on data collected through NHSN, CDC plans changes in HAI definitions and data validation.

- CDC will move away from metrics which show HAI rates for individual measures to Standardized Infection Ratios (SIRs) which provide a single summary metric at the facility level. Eventually, reliability-adjusted SIRs will enable more meaningful comparisons between healthcare facilities, which take into account differences in risk factors and reliability of data between facilities.

- Composite measures which combine two or more HAI measures into a single score to provide a more complete quality indicator are being considered.

- The core definition of HAI other than SSI will be modified; the phrase "infection not present or incubating on admission" will be replaced in January with "evidence of infection more than two days after admission", which can be more objectively judged.

- For SSIs, the current criteria define an operative procedure as one that ends with a primary closure; the new criteria will include all operative procedures regardless of closure technique. This is part of harmonizing work with American College of Surgeons.

- For CLABSIs, the exclusionary criterion of a mucosal barrier injury (MCI) will be added.

- CDC supports a greater emphasis on establishing national standard protocols and on-site validation of HAI quality measure data. If states can comply with this, CMS could exempt hospitals in those states from federal-level validation.

Possible concerns: Quality measures can be catalysts for change, but can also raise concerns. Data should be actionable, reliable, robust to criticism, and understood in broad terms by the public and policymakers. Public concerns can be allayed by safeguards against unreasonably burdensome requirements, gaming, or an inappropriate focus on what is measured at the expense of other aspects of care.

Summary: CDC is steward of HAI quality measures, challenged by rising expectations and increased scrutiny of NHSN and changes in HAI measures. CDC is exploring opportunities to partner with medical groups such as the

American College of Surgeons and the Society of Thoracic Surgeons, who may be more interested in collaboration now than they were in the past.

Questions and Comments from HICPAC:

Dr. Bratzler commented he was glad to see CDC is moving towards a reliability-adjusted SIR. Unadjusted HAI rates may have led to unrealistically high goals. In particular, larger facilities may not be able to achieve the zero infections which some smaller facilities have, or an oncology center with lots of immunosuppressed patients may have a higher rate of CLABSIs. The public needs to understand that NHSN measures are based on surveillance definitions, not clinical definitions.

Dr. Pollock replied that perhaps CLABSI surveillance needs to be done differently in a cancer center environment.

Dr. Cardo commented that data can be used to focus prevention efforts in diverse facilities.

Dr. Bell noted that operationalizing changes in surveillance definitions is a lot of work; each subtle change in a definition or metric means reprogramming a huge system and training people to implement it in new settings.

Dr. Diekema warned that an increased focus on unusual HAI events may lead to more effort being spent on false positives.

Dr. Yokoe said that it makes sense to have validation work done by state health departments, since data is already reported to them. Are there plans to increase the support provided to state health departments to do this important work? Dr. Pollock replied that it is to be hoped that the increased awareness of the importance of validation will lead to increased funding. CDC has committed substantial amounts from its discretionary funds to validation.

Dr. Ostroff noted that the ways state health departments deal with the challenge of small hospital infection rates may be different from the CDC methodology. This creates the risk that state hospital-level metrics may differ from CMS metrics. Dr. Pollock said that CDC understands this concern. CDC will work closely with states and provide statistical support to produce the right kind of metrics. The emphasis is on proceeding with consistent due diligence, not moving too fast.

Dr. Saint asked whether consideration has been given to changing the term CAUTI or catheter–associated urinary tract infection to “catheter-associated event”, in order to capture the non-infectious complications of catheter use, such as deep venous thrombosis or inadvertent removal. Dr. Pollock thanked him for the suggestion.

Ms. McGiffert was concerned that baseline data is based on an average from years ago. This might create the impression that hospitals are overly complacent. Dr. Pollock replied that, with a reliability-adjusted SIR, baseline data becomes a moot point because only the current year’s data is used. Updating the baseline is planned, but will be a major project. Maybe in the future, Jonathan Edwards, the Surveillance Branch’s lead statistician, could present a description of the statistical analysis involved to HICPAC. CDC is interested in moving towards annual HAI rate reporting based on the SIR, since the diminishing frequency of HAIs makes quarterly data less useful and reliable.

Dr. Carrico suggested the possibility of a partnership with the Association of Schools of Public Health. One advantage would be that students have less of the bias which comes from working in the field.

Dr. Howell asked whether inherent measure imprecision related to interobserver reliability is incorporated in the reliability-adjusted statistics. Dr. Pollock suggested this might be a question for Mr. Edwards, the statistician.

Ms. VanAmringe offered the Joint Commission's help on the important work of data validation.

Dr. Baine asked whether NHSN collects morbidity and mortality data. Dr. Pollock said that the relationship between infection and death can be reported in NHSN, but it is not a required field. Work is ongoing on whether vital statistics can be used to measure the extent of mortality from HAIs.

Ms. Stricof stated that in the 1990s, there was pressure on CDC to develop an overall infection rate number in order to compare one healthcare facility with another. She warned that this sort of summary number might be less actionable and less useful for prevention, since it masks some of the granular detail of what is happening in a hospital, such as the raw number of patients affected. More detailed information is useful to help hospitals target their prevention efforts, for instance, focusing on a specific unit.

Dr. Pollock said CDC is aware of the possibility of unintended adverse consequences from using composite measures. The composite measure will not replace other, more specific metrics, but will add to them. A single measure cannot encompass all that needs to be known about healthcare quality, but there are benefits to having a summary measure.

Dr. Cardo added that members of the public and policymakers are already trying to put together their own composites, which shows that non-experts in particular feel a need for this sort of summary measure. Dr. Lundstrom agreed that the composite measure could help when working with commercial payors and consumers. Composite and individual measures can both be used; there is no need for an either/or choice between them. And from a consumer perspective, patients simply don't want to get infections of any kind. The overall infection rate may therefore be more important to them than an individual rate.

Ms. Stricof stated she was also concerned about making even individual measures reliability-adjusted. For instance, a small hospital with a raw number of zero infections might see its reliability-adjusted measure go up to 0.3 or 0.5 infections. This calls into question the reliability of such a measure for use in prevention. She also raised the issue of data consistency between states and CDC.

Dr. Cardo commented that it is important to understand the needs of everyone who uses this data, whether hospitals, states, payors or consumers.

Draft Guideline for Prevention of Infection Among Patients in NICU

Alexis Elward, MD
HICPAC Member

Dr. Elward presented an update on the draft guideline for infection prevention in the NICU, which was previously discussed in the June HICPAC meeting. Since June, the writing group has revised its GRADE and evidence tables, and the narrative summaries for some sections. A new CDC lead has been identified for the CLABSI section. The evidence and GRADE tables are under review by the expert review panel.

The key issues the guideline will address are:

1) Respiratory infection

2) CLABSI

3) MRSA

4) Fungal infections

5) C. difficile

Evidence grading: Evidence is given an initial grade based on what type of evidence it is: that is, a randomized controlled trial gets an initial high grade, an observational study gets an initial low grade, and any other evidence, such as expert opinion, gets an initial very low grade. Other criteria are then used to adjust the grade. Study quality limitations, inconsistency, indirectness, imprecision, or risk of publication bias decrease the grade, while strength of association, evidence of a dose-response gradient, or inclusion of unmeasured confounders increasing the magnitude of effect increase the grade.

An overall quality grade of high, moderate, low or very low is then arrived at.

A **high** grade indicates that further research is *very unlikely to change* confidence in the estimate of effect.

A **moderate** grade indicates that further research is *likely* to impact confidence in the estimate of effect and *may change* the estimate.

A **low** grade indicates that further research is *very likely* to impact confidence in the estimate of effect and is *likely to change* the estimate.

A **very low** grade indicates *any* estimate of effect.

Three key inputs are used when CDC formulates recommendations. First, its values and preferences are used to determine the critical outcomes. Second, the overall GRADE of evidence concerning critical outcomes. Third, the net benefits, net harms or tradeoffs which result from weighing the critical outcomes.

The resulting recommendations vary in direction (for or against) and strength (strong or weak). Recommendations fall into one of the following categories:

Category IA: A strong recommendation supported by high to moderate quality evidence suggesting net clinical benefits or harms.

Category IB: A strong recommendation supported by low quality evidence suggesting net clinical benefits or harms, or an accepted practice supported by low to very low quality evidence (e.g., aseptic technique).

Category IC: A strong recommendation required by state or federal regulation.

Category II: A weak recommendation supported by any quality evidence suggesting a tradeoff between clinical benefits and harms.

Recommendation for further research: Indicates an unresolved issue for which there is low to very low quality evidence with uncertain tradeoffs between benefits and harms.

Respiratory pathogen section revisions: At the last meeting, questions were raised about how low to very low quality evidence can support a strong Category IB recommendation. The writing group decided this issue should be explicitly discussed in the methodology section of the guideline. A Category IB recommendation is justified when high quality evidence exists in a different patient population, when the recommendation concerns a widely accepted practice, or when randomized controlled trials would be infeasible or unethical.

Given the lack of evidence upon which to base a recommendation, but recognizing the need to provide guidance and expert opinion, the writing group thought some topics would be addressed more appropriately in an implementation document rather than a guideline. These topics included isolette distance for patients on isolation if no private room is available, cohorting of undifferentiated suspected viral illness, specific agents for postexposure prophylaxis, and recommendations on pertussis serology testing.

Within the personal protective equipment section, HICPAC recommended that the list of agents which can cause respiratory infections in the NICU be lengthened, and a phrase be added to address undifferentiated suspected viral illness. The recommendation now reads:

Evidence review table I.A.2. a) i: "Wear gloves before direct contact with patients or surfaces and articles in close proximity to a NICU patient with any respiratory infection, including RSV, influenza, parainfluenza, adenovirus infection, **rhinovirus, human metapneumovirus, Bocavirus, undifferentiated suspected viral illness,** pertussis, and varicella. (**Category IB**)."

Other revisions to the respiratory pathogen section were as follows, with new language in bold.

- A recommendation to maintain isolation precautions for the duration of illness (Category IB) was added (I.A.2 a) iv.).
- I.A.2. b) ii. "Wear a facemask with eye protection during aerosol-generating procedures for NICU patients with respiratory infection with pathogens other than influenza (Category IB)."
- I.A.2. b) iii."Wear an N95 mask with eye protection during aerosol-generating procedures for NICU patients with influenza infection (Category IB)." This was changed to harmonize with existing CDC influenza guidance.
- I.A.3. b) "Place together (cohort) in the same room or patient-care area patients who are infected with the same respiratory pathogen, if a single patient room is not available (Category IB)."
- I.A.3 d) "Patients with undifferentiated suspected infectious respiratory illness may be cohorted if epidemiology in the community suggests they are likely to have the same pathogen (Category II)."
- I.A.4. The cohorting of healthcare personnel recommendation was modified to reflect the nature of the evidence. Cohorting during an outbreak was given a Category IB recommendation and cohorting in a nonoutbreak setting had a Category II recommendation.

- The phrase “rapid diagnostic tests” was thought to set unrealistic expectations, so it was replaced with “early detection” in several places.
- I.A.5.“Perform ~~rapid diagnostic~~ early detection diagnostic laboratory tests for RSV, influenza, parainfluenza, and pertussis on NICU patients who have symptoms of illness or who have been exposed to the particular respiratory pathogen. Promptly implement appropriate isolation precautions prior to testing for symptomatic or exposed patients. Isolation precautions should be maintained for the duration of symptoms even if early detection testing is negative. (Category IB).“
- I.A.6. a) “Do not allow persons who have symptoms of respiratory illness to visit NICU patients. Establish a mechanism for screening visitors for symptoms of respiratory illness (Category IB).”
- I.A.6. b) The phrase “asymptomatic young visitors” was changed to “asymptomatic young children.”
- I.A.8. c) and d) Recommendation to administer postexposure prophylaxis to “healthcare personnel and family who have had close contact with persons with pertussis” was added. Reference to CDC, ACIP and AAP guidelines on postexposure prophylaxis after pertussis or varicella exposure was added.
- I.C.3. “Promptly perform PCR assay if available on patients suspected to be infected with or who have been exposed to persons with pertussis infection. Do not use serology (Category IB).”

Questions and Comments from HICPAC:

Dr. Huskins suggested it might be helpful to list the category of isolation precaution rather than individual elements of isolation.

Ms. Stricof asked about the source of the recommendation to wear a face mask. Does it simply come from past concerns over H1N1? Mr. Hageman said that the recommendation comes from the CDC/HHS guideline for influenza and is limited to aerosol-generating procedures, whereas the H1N1 recommendation was to wear a mask during all patient care procedures.

Dr. Bell pointed out that the definition of “aerosol-generating procedure” is unclear, which makes it hard to tell which procedures truly present a high risk of respiratory pathogen transmission.

Ms. DeBaun commented that the cohorting recommendation needs to be appropriately explained, since the NICU recommendations are different from those involving adults. The NICU recommendation is different because patients are at high risk. Dr. Huskins noted that cohorting is easier in the NICU since multiple infants can be placed in one room.

Dr. Carrico suggested clarifying that the phrase "and family" in the postexposure prophylaxis recommendations means families of patients, not families of healthcare workers.

Dr. Lundstrom pointed out that if a facility has staff shortages, it may not be possible to follow the cohorting recommendation during an outbreak. Dr. Elward said that the recommendation applies specifically to staff who work primarily in the NICU. There’s a balance between giving guidelines based on best practices versus giving feasible recommendations. Dr. Fishman said that one option would be to list a nursing recommendation as Category IB and a recommendation for other personnel as a Category II, if supported by the data.

Dr. Rupp asked about the recommendation for use of N95 face masks. Is it appropriate to make this recommendation in order to be congruent with previous recommendations, when the previous ones may not be

based on much good data? Dr. Bell suggested not referring to the interim CDC guidance, which was published in an emergency situation without doing a literature review. The writing group for the current recommendations should go to the literature itself.

Ms. Dunn stated that the question of N95 mask versus respirator came up in Canada in the context of the occupational health issues presented by the SARS and H1N1 viruses.

C. difficile revisions

V.B.1. The recommendation to test for C. difficile in NICU patients with diarrhea only after the exclusion of other causes of diarrhea was modified to indicate that this recommendation relates to infection prevention purposes.

Draft MRSA recommendation: **QIII.A. What are the risk factors for MRSA colonization or infection in the NICU patient?**

Narrative evidence summary:

MRSA colonization: Low to very low quality evidence suggests low birthweight, young gestational age, black and multiple gestation were risk factors for MRSA colonization. Low quality evidence suggests that central line utilization and length of hospitalization were associated with MRSA colonization.

MRSA infection: Very low quality evidence suggests low birthweight and younger gestational age are risk factors for MRSA infection. Very low quality evidence suggests that length of hospitalization, mechanical ventilation, extracorporeal membrane oxygenation, gavage feeding and medical management of necrotizing enterocolitis were associated with MRSA infection.

Draft recommendation: Minimize central line duration, mechanical ventilation use and duration and antibiotic use in all NICU patients, particularly those at higher risk for MRSA infection such as low birthweight, younger gestational age, multiple gestation or those colonized with MRSA (**Category IB**).

Q.III.C.1. What are the most effective measures to prevent hospital-acquired infection or colonization with MRSA?

Narrative evidence summary:

Hand hygiene: Observational studies with multimodal interventions show hand hygiene is associated with a decrease in MRSA infections and colonizations. Very low quality evidence suggests a benefit from monitoring hand hygiene compliance. NICU studies were heterogeneous on the most effective agent for hand hygiene.

Draft recommendation: Adhere to hand hygiene recommendations as specified in the 2002 CDC and HICPAC Guideline for Hand Hygiene in Health-Care Settings which includes indications for hand washing and hand antisepsis, technique and agents, educational and motivational programs, and measuring adherence. (**Category IB**)

Personal protective equipment: Low-quality evidence from 13 studies supported the implementation of gown and glove use as part of contact precautions prior to contact with patients infected or colonized with MRSA.

Universal glove use was additionally beneficial in several prolonged outbreaks. Low quality evidence suggested a benefit of cohorting patients colonized or infected with MRSA. The duration of contact precautions varied in these studies.

Draft recommendation: III.C.2. Contact precautions

Recommendations for transmission-based precautions that are applicable to all healthcare settings are specified in the 2007 CD C and HICPAC Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings and the 2006 CDC and HICPAC Guideline for the Management of Multidrug-Resistant Organisms in Healthcare Settings. The following recommendations are based on our evidence review and are consistent with the recommendations in those guidelines.

a) Wear gloves before contact with NICU patients or surfaces and articles in close proximity to patients who are colonized or infected with MRSA (**Category IB**).

b) Wear a gown whenever anticipating that clothing will have direct contact with patients who are colonized or infected with MRSA or potentially contaminated environmental surfaces or equipment (**Category IB**).

c) Remove gown and gloves and observe hand hygiene before leaving the care environment of patients colonized or infected with MRSA (**Category IB**).

d) Wear a facemask with eye protection according to standard precautions during splash- or aerosol-generating procedures for NICU patients colonized or infected with MRSA (**Category IB**).

e) Place patients who are colonized or infected with MRSA in a single-patient room when available (**Category IB**).

f) Place together (cohort) in the same room or patient-care area NICU patients who are colonized or infected with MRSA, if a single-patient room is not available. (**Category IB**).

g) Further research is needed on when to discontinue contact precautions for NICU patients who are colonized or infected with MRSA. (**No recommendation/unresolved issue.**)

Questions and Comments from HICPAC:

Dr. Howell asked whether the recommendation calls for separating siblings with discordant MRSA status. Dr. Elward said that it does.

Dr. Huskins said that recommendation III.C.2. should be explicitly related to the category of contact precautions.

Dr. Carrico noted that the recommendation of wearing a n N95 mask is within the context of standard precautions.

Dr. Diekema suggested that the recommendation in III.A. should read "minimize central line duration, mechanical ventilation use and duration and antibiotic use in all NICU patients," without specifying only for those at high risk.

Cohorting: Very low quality evidence suggests a benefit of cohorting healthcare personnel to care only for patients infected or colonized with MRSA.

Draft recommendation: III.C.3. Cohorting of healthcare personnel

Consider the assignment of dedicated healthcare personnel to care for patient cohorts (e.g., assign dedicated healthcare personnel to care for MRSA-colonized patients only) in the outbreak setting or when there is ongoing healthcare-associated transmission of MRSA despite the implementation of and adherence to Contact Precautions. (**Category II**).

Dr. Lundstrom suggested this recommendation might fit under MDRO Tier 2.

Surveillance testing: Low quality evidence suggests a benefit of performing surveillance testing in the context of an outbreak or ongoing healthcare-associated transmission. 12 observational studies showed decreased incidence of infection and colonization with active surveillance testing. Most studies sampled the anterior nares, which was the site found to have the best sensitivity and negative predictive value. Frequency of screening and the population screened varied between studies, as did management of patients pending test results. In three studies, contact precautions were implemented pending test results.

Draft recommendation: III.C.4. Active surveillance testing

a) Perform active surveillance testing of NICU patients in an outbreak or when there is active, ongoing healthcare-associated transmission of MRSA (**Category IB**).

If active surveillance testing is performed, implement contact precautions until the active surveillance testing result on the newly admitted patient is negative (**Category IB**).

Further research is needed on the role and effectiveness of active surveillance testing on reducing transmission of MRSA in the non-outbreak setting. **(No recommendation/unresolved issue.)**

Strategies to screen for MRSA colonization in NICU patients include the following (Key Question III.B):

i. Laboratory methods

a) To detect MRSA colonization in the NICU patient, use culture-based methods or molecular diagnostic testing methods, such as PCR (**Category IB**).

b) Further research is needed on the optimal laboratory testing methods for active surveillance testing for MRSA **(No recommendation/unresolved issue.)**

ii. Anatomical sites for sampling

Collect swab samples from the anterior nares. Samples from other anatomical sites, including the periumbilical area, axilla, and groin may be added to increase yield (**Category IB**).

iii. Frequency of testing

a) Perform active surveillance testing on NICU patients at time of admission and at regular intervals (e.g., weekly) to promptly identify newly colonized patients and to guide implementation of appropriate isolation methods (**Category IB**).

b) Further research is needed on the target populations and the appropriate intervals to perform active surveillance testing to promptly identify newly colonized patients. **(No recommendation/unresolved issue.)**

c) Further research is needed on the role and effectiveness of active surveillance testing on reducing transmission of MRSA in the non-outbreak setting **(No recommendation/unresolved issue.)**

Questions and Comments from HICPAC:

Dr. Diekema commented that in many facilities, if a newborn is found to be colonized or infected MRSA, every other patient in that unit is then screened. In other words, active surveillance is needed to find out whether there is active healthcare-associated MRSA transmission. Dr. Elward said that the recommendation is focused on the outbreak setting, and the definition of active healthcare-associated transmission is fuzzy. Dr. Huskins said that the recommendation implies only newly admitted patients are screened, but in fact periodic surveillance of already admitted patients is often appropriate. This could be clarified.

Dr. Yokoe pointed out that if active surveillance is being routinely done, then the recommendation calls for all patients being put on contact precautions pending surveillance test results. She questioned whether there is enough data to support a Category IB recommendation; an "unresolved issue" would be more appropriate.

Dr. Huskins pointed out that whether to implement contact precautions depends on the situation. Maybe this should be left to the good judgment of staff, rather than being too prescriptive.

Dr. Diekema suggested the recommendation could be bifurcated to say that if there is a known outbreak or active transmission, contact precautions should be used pending a patient's test results. However, if a point prevalence sweep is being done outside an outbreak setting, then contact precautions may not be advisable. Dr. Elward agreed to reconsider the wording of the recommendation.

Dr. Huskins asked Dr. Elward to check whether recommendation iii.b) is in an outbreak or non-outbreak setting.

Decolonization therapy: Low quality evidence suggested a benefit of decolonization. Observational studies showed that eliminating the MRSA carrier state of NICU patients is associated with decreases in infections in the NICU in the context of an outbreak or ongoing healthcare-associated transmission. Five studies decolonized MRSA-colonized infants, and three studies decolonized all NICU patients. Decolonization regimens varied. Very low quality evidence suggested routine topical therapy for umbilical cord decolonization was associated with reduced likelihood of umbilical colonization with MRSA.

Draft recommendation: III.C.5. Decolonization of NICU patients colonized with MRSA

Consider decolonization therapy for MRSA-colonized NICU patients in the outbreak setting or when there is ongoing healthcare-associated transmission of MRSA despite the implementation of and adherence to contact precautions (**Category II**.)

Further research is needed on the optimal decolonization therapy regimen. (**No recommendation/unresolved issue**.)

Further research is needed on optimal techniques for care of the umbilical cord after birth and the role of umbilical cord colonization on the risk of MRSA infection (**No recommendation/unresolved issue**.)

Environmental measures: III.C.6. Low quality evidence suggested cleaning and disinfection of the environment reduces risk of MRSA transmission.

Draft recommendation: III.C.6. Environmental measures

Adhere to recommendations as specified in the CDC and HICPAC 2003 Guidelines for Environmental Infection Control in Healthcare Facilities, which are applicable to all healthcare settings including the NICU (**Category IB**).

Use EPA–registered products for cleaning and disinfection of surfaces and equipment that may be contaminated with MRSA. Products should have label claims for use in healthcare settings. Follow the manufacturer's recommendations for product application and contact times. (**Category IC**).

Education: Low quality evidence suggested educating healthcare personnel is associated with decreased incidence of MRSA infection and colonization.

Draft recommendation: III.C.8. Education of healthcare personnel

Educate all healthcare personnel on preventing transmission of MRSA, including medical, nursing, laboratory, and maintenance personnel, students, and volunteer staff (Category IB).

III.C.9. Visitor restrictions

Further research is needed on the prevention of MRSA transmission among family members and other visitors of NICU patients (No recommendation/unresolved issue.)

Next steps: The next steps for the writing group are to draft the sections on CLABSI and fungal infections and to get those sections reviewed by the HICPAC. Feedback from the expert review panel and today's comments from HICPAC will also be considered.

Questions and Comments from HICPAC:

Ms. McGiffert suggested adding a recommendation that patients' family members should also be educated. Dr. Elward agreed that that could be added to the recommendation, since it is a standard practice, although she was unsure whether the studies in question concerned education of family members. Ms. McGiffert suggested looking for studies on the health impact of giving patients information at discharge.

Dr. Saint asked whether there are specific studies on the benefit of educating maintenance personnel, students, and volunteer staff. Dr. Elward said that the studies in question were of general education efforts and did not distinguish between different groups of healthcare workers.

Dr. Huskins commented that there may be better quality data available for the next sections. He suggested that the guidelines should identify when data is not just low quality, but limited because very few studies have been done. For instance, there is very limited data on pertussis among NICU patients, since it is fortunately a rare event. Dr. Elward agreed with this point, noting that high-quality RCT or prospective cohort study data is rarely available for respiratory infections in this population.

Dr. Craig Umscheid said that the GRADE process is a standardized language used internationally to describe evidence quality and ensure clear communication across disciplines. Hence the terms "low quality" or "very low quality" evidence.

Policy Update from CDC's Washington Office

Michael Craig, Policy Analyst, CDC Washington

Mr. Michael Craig spoke to HICPAC about current pieces of legislation relevant to HAI issues.

GAIN Act: Mr. Craig first discussed the GAIN (Generating Antibiotic Incentives Now) Act, which was included in the FDA User Fee Authorization. The intent of this act was to provide an incentive for the development of antibiotic and antifungal drugs by giving the manufacturer of such a new drug an additional five years of market exclusivity. To be eligible, the drug must address a serious or life-threatening condition.

FDA and CDC are working cooperatively to produce a list of qualifying pathogens. The two agencies will report back to Congress within five years on the effectiveness of this incentives, and on the implementation and effectiveness of antibiotic stewardship programs in healthcare settings. CDC and FDA will also make recommendations on how to encourage further development of stewardship programs.

Senate appropriations bill language from the STAAR Act: The fiscal year 2013 Senate appropriations report contains provisions from the STAAR (Strategies to Address Antibiotic Resistance) Act. It requests a report from CDC in coordination with ITFAR regarding the data collected in the U.S. on antibiotic consumption and resistance trends among humans and non-human animals. The appropriations report also urges the Secretary of HHS to designate an office and director within the office of the Assistant Secretary of Health to head the federal response to antibiotic resistance. However, the Senate appropriations bill has not passed into law. The legislation does not specify a timeframe.

Other antibiotic resistance policies in Congress: The following pieces of legislation have not yet been taken up by Congress, but may be in the future.

- STAAR Act: IDSA will push for STAAR Act provisions in the Senate appropriations report and is expected to reintroduce the whole STAAR Act in the next Congress.
- The LPAD (Limited Population Antibacterial Drug Approval Mechanism) is intended to expedite FDA drug approval for antibiotics focused on very limited populations, to address the difficulty of approving such drugs using the current regulatory pathway. It is not yet clear what the definition of "limited population" would be. An example would be people with ventilator-associated complications caused by certain multi-drug-resistant organisms.

- The PAMPTA (Preservation of Antibiotics for Medical Treatment) Act would ban specific antibiotics in animal feed. However, FDA may ban them voluntarily, thus obviating the need for legislation.

Impact of potential sequestration and budget: Mr. Craig closed by stating that most of the federal government is now operating under a continuing resolution, and it is unclear what the federal budget will be after the continuing resolution expires in March 2013. Substantial differences between the House and Senate proposed funding levels have yet to be reconciled. If Congress does not act, sequestration (sometimes called a "fiscal cliff") will occur. This would reduce spending by around 8% for most domestic discretionary programs. The OMB has calculated that, if the sequester takes effect, CDC would face a cut of $490 million.

Questions and Comments from HICPAC:

Dr. Henderson emphasized the dramatic effect sequestration would have. For administrators of federally funded hospitals, the current budget uncertainty also presents huge difficulties. Sequestration would also affect NIH's R01 grants and CDC grants to state health departments.

Dr. Cardo suggested the GAIN Act could be an opportunity to improve CDC's work on proper antibiotic stewardship. Mr. Craig agreed, and said that increased Congressional attention to this problem can be expected.

Dr. Ostroff asked Mr. Craig if he had any information on a potential Congressional response to the recent fungal meningitis outbreak. Mr. Craig said that there has been intense interest in the issue. CDC and FDA will brief Congressional offices on the topic. FDA in particular aims to specify and define its authority over compounding pharmacies.

Dr. Cardo added that the importance of maintaining state public health infrastructure should also not be overlooked when discussing the outbreak. State help was crucial in discovering the outbreak in the first place and in identifying and contacting people who may have been exposed to the contaminated drug.

Dr. Fishman asked whether there is any pending legislation on HAI issues. Mr. Craig replied that there is currently more emphasis on antibiotic resistance. The ACA's provisions on HAI were the most recent relevant legislation.

Update on Planned Changes to NHSN

Dawn Sievert, Ph.D., MS
Protocol and Public Reporting Team Lead
CDC/NCEZID/DHQP Surveillance Branch

Dr. Sievert reminded HICPAC that these changes were presented at previous HICPAC meetings by Dr. Nicola Thompson of CDC and received support from the committee.

MBI-LCBI definition: In order to meet the definition of a mucosal barrier injury laboratory-confirmed bloodstream infection (MBI-LCBI), an event must first meet the existing NHSN CLABSI criteria, plus the event must involve an

eligible patient and eligible organism. If a noneligible organism is also reported in the same blood culture, that event would be categorized as a CLABSI.

If at least one blood culture grows at least one of the following pathogens:

- Bacteroides spp.
- Candida spp.
- Clostridium spp.
- Enterococcus spp.
- Fusobacterium spp.
- Peptostreptococcus spp.
- Prevotella spp.
- Veillonella spp.
- Enterobacteriaceae

Or the patient has signs/symptoms and two or more blood cultures growing Viridans group streptococci, and no other pathogens are identified, the MBI-LCBI definition would be met.

The new definition will be implemented in NHSN on February 9, 2013, but vendors have one-year backward compatibility to allow them to catch up. This means that MBI-LCBI events involving patients with a central line will continue to be reported to NHSN as part of CLABSI surveillance through 2013. CDC will be able to watch the data and see how many facilities are moving to the new definition. Uniform reporting of this definition will begin in 2014.

CDC conducted a two-month field test to evaluate the new definition. 38 hospitals, of which about 50% were oncology or bone marrow transplant facilities, took part. The test found a high degree of agreement between CDC and facility application of the MBI-LCBI definition, and found that integrating this definition into CLABSI surveillance was feasible. A need for adjustments to the neutropenia criteria was identified due to differences in lab reporting of white blood cell count and absolute neutrophil count values.

Implementation of this definitional change will involve changes to NHSN protocols, software and training materials. User trainings and a presentation at ID Week will also take place. The changes to the NHSN report form are in OMB clearance to review the burden placed on users by this addition.

Dr. Ostroff asked how this definition will impact publically reported data. Dr. Sievert said that it is not expected to have a significant impact on the outcome improvement level hospitals must meet in value-based purchasing programs. CDC will work with CMS to make sure the new definition is compatible with CMS reporting.

HAI surveillance criteria changes:

- *Implemented January 2013:* As previously mentioned, the core definition of HAI other than SSI will be modified; the phrase "infection not present or incubating on admission" will be replaced in January with "evidence of infection more than two days after admission", which can be more objectively judged.

- The definition of a device-associated HAI will specify that the device must be in place for longer than two days in order to attribute the event to the device.
- The location of attribution/transfer rule, which determines the time period during which a transfer patient's HAI is attributed to the transferring location, will be changed from 48 hours to 2 or more calendar days.
- Some facilities are already using a 48-hour rule, but this change will formalize and standardize that practice.
- *To be implemented January 2014:* If more than 14 calendar days elapses between one event and another, for instance CLABSIs, another HAI will be reported.

These changes to NHSN are expected to help generate reliable and credible data for both internal quality improvement and public reporting, while minimizing the role of subjectivity, simplifying surveillance, and leveling the playing field for different facilities.

However, these changes, like any definitional changes, make it harder to track and interpret HAI trends over time and perform comparisons. CDC and CMS will work on this issue; one possibility is to come up with hospital data from 2011 and 2012 as it would have been reported if the new definitions had existed then, in order to give hospitals a baseline which reflects the new definitions.

These changes have not eliminated the potential for gaming the system. Robust on-site validation remains critical.

SSI definition changes: These changes were presented at the June HICPAC meeting by Dr. Ryan Fagan of CDC.

2013 changes:

- The definition of "primary closure" will be closure of all tissue levels, regardless of the presence of objects extruding through the incision.
- The presence of an implant is no longer required to be reported, which means the one-year follow-up period for post-discharge surveillance is not required.
- New surveillance follow-up periods will be defined as 30 days for most, and 90 days for 14 procedures for deep and organ space SSIs.
- The phrase "appears to be related to the operative procedure" will be removed from the deep and organ space SSI criteria.
- The NHSN Principal Operative Procedure Category Selection Lists will be updated (e.g., colon will be moved above small bowel)

Questions and Comments from HICPAC:

Ms. McGiffert was concerned about removing the documentation that an implant was involved in an SSI, considering the importance of implants. She also pointed out that different implants may present different problems; that is, sutures are different from hip replacements, and surgical mesh often presents problems.

Dr. Sievert said that there will still be a box that can be checked to note than an implant is involved, but it will no longer be required reporting. The current definitions are focused on risk factors over which surgeons have control at the time of the surgery, and the 30- to 90-day follow-up period is expected to cover at least 85% of SSIs for

those procedures. Many studies show that rates of infection plateau after 90 days, and an event which happens more than 30 to 90 days after surgery is less likely to be caused by the operation.

Dr. Bratzler noted that there was some confusion about what to count as an "implant." It was deemed preferable to do surveillance based on the operation being performed, not on the devices involved.

Dr. Pollock added that the lack of a clear, usable definition is one reason behind the removal of a requirement to report implant use. Moreover, there is a lack of data on infections directly attributable to implants.

Ms. Stricof noted that NHSN data is not the sole source of information about sources of HAIs. For instance, if rates of infection for a specific procedure rise, investigators could of course examine surgical mesh as one of the risk factors. NHSN should not be expected to include every possible risk factor.

2014 changes:

- The new criteria will remove the requirements that incisions be primarily closed and identify whether the closure is primary or other.
- New fields will be added: all procedures will have fields for type of closure, height, weight and diabetes status. “Transoral” will be added as a type of approach for spinal fusion or refusion procedures.
- The Musculoskeletal Infection Society definition of periprosthetic joint infection will be adopted. This includes new fields for “sinus tract” and “positive culture from greater than 2 separate tissue or fluid samples from the affected joint.”
- The phrase “diagnosis of SSI by the surgeon or attending physician” will be dropped from deep and organ space SSI criteria.
- For superficial and deep SSI, the criteria will be changed to “deliberately opened or otherwise drained by a physician or his/her designee.”
- If the SSI involves both an incision and an organ space, the SSI will be classified as organ space.
- A spinal abscess with meningitis will be classified as SSI-SA (spinal abscess).
- The Association of Anesthesia Clinical Directors’ definition of operative duration will be adopted, due to the removal of the incisional closure requirement.

Remaining concerns:

- Developing a tool to support requirements for post-discharge surveillance
- Reporting instruction for SSI when infection is evident at time of surgery
- Surveillance definition of diabetes
- Future migration to CPT or to ICD-10

In the future, it will be necessary to migrate from ICD-9 to new codes, either ICD-10 or CPT. Dr. Fishman added that moving to CPT codes might address Ms. McGiffert's concern over surgical mesh, because the CPT codes specify the presence of absence of mesh in certain procedures. However, the CPT codes will not be required reporting.

VAE definition changes: These changes were presented at the June HICPAC meeting by Dr. Shelley Magill of CDC.

Patients 18 years of age or older who are inpatients of acute care hospitals, long-term acute care hospitals, and inpatient rehab facilities are eligible for VAE surveillance. Children, inpatients of other facilities, and patients on high frequency ventilation or extracorporeal life support are not eligible.

The VAE definition will be implemented February 9, 2013. This will take the place of in-plan VAP surveillance for mechanically ventilated adults patients. In 2013, the current VAP protocol will still be used for neonatal and pediatric patients only. The current pneumonia definitions will still be available in 2013 for off-plan surveillance of VAP in adults or non-ventilated pneumonia in children or adults. Off-plan VAP surveillance will still be available to avoid interfering with existing multi-year research projects.

The Pediatric and Neonatal VAE Surveillance Definition Working Group had its first meeting in September 2012. This group is tasked with developing VAE surveillance for use in children. It will be challenging to modify the existing VAE algorithm for use with children, because there is a lack of evidence of association with outcomes, and it is not clear whether events detected by these definitions are preventable. The group will work on adapting the VAC definition for use in neonates and pediatric patients.

The draft protocol for adult VAE surveillance is available online at http://www.cdc.gov/nhsn/psc_da-vae.html. Dr. Sievert showed a screenshot from the VAE calculator, a web-based tool to help users learn the algorithm and make determinations. Data is entered manually into the calculator. One next step might be to tap into electronic sources of VAE data.

Update on the APIC/SHEA Compendium of Strategies to Prevent HAIs in Acute Care Hospitals

Deborah Yokoe, MD, MPH
HICPAC Member

Background: Healthcare epidemiology and HAI prevention work sit at a crossroads where quality, revenue and public policy intersect. Quality improvement not only improves patient care but creates an advantage in the marketplace. As hospitals strain to accommodate an increasing number of infection prevention initiatives, regulatory obligations, and requirements for collecting and reporting performance measures, the need for a unified set of documents hospitals can use to prioritize their HAI prevention strategies has become apparent. This is the goal of the Compendium.

The Compendium is a collaborative, implementation-focused effort, involving experts in infection prevention and control, i.e., SHEA, IDSA, CDC, and APIC, as well as implementation-focused organizations such as The Joint Commission, AHA, NQF and IHI. Many other groups are included as endorsing or supporting organizations. Having buy-in from multiple organizations is seen as crucial to the success of the Compendium.

The Compendium includes sections on CLABSIs, CAUTIs, ventilator-associated pneumonia, SSIs, MRSA, and *C. difficile* infection. A new section on hand hygiene is planned for the next version of the Compendium. Each section is organized with a statement of concern, brief summary of detection and prevention strategies, graded prevention recommendations, and performance measures to be used for internal reporting.

There will be two levels of recommendations:

- Basic practices (recommended for all acute care hospitals)
- Special approaches (strategies to consider if basic practices are in place, but a problem still exists based on risk assessment or surveillance data)

The strength of recommendations will be categorized as either A, B, or C (good, moderate or poor.)The quality of evidence will be graded as follows:

- I: Evidence from at least one properly randomized controlled trial
- II: Evidence from at least one well-designed clinical trial without randomization; or from cohort or case-controlled analytic studies (preferably from more than one center); or from multiple time-series; or from dramatic results from uncontrolled experiments.
- III: Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Process: The first version of the Compendium was published in 2008, and work on the next update is now starting. The Compendium section leads will review relevant literature published after the first Compendium, focusing on new guidelines and systematic reviews. Then, appropriate updates will be made to Compendium recommendations, performance measures and implementation strategies. The updates will go through multiple tiers of review, including Section Panels to support section leads, an Expert Review Team and Advisory Panel. Subsequently, the draft Compendium will be circulated to endorsing organizations and reviewed by the SHEA and IDSA Boards.

HICPAC input is solicited when the recommendation outlines are available in early 2013, and again in fall 2013 when the draft manuscripts should be available. As each section is finalized, it will be made available online. The final product is expected in December 2013 and will be published in the Infection Control and Hospital Epidemiology journal. Once the updates are available, updated FAQs aimed at patients and their family members will also be published.

Questions and Comments from HICPAC:

Ms. VanAmringe commented that the compendium could be a very useful tool, in terms of making the many HAI guidelines digestible by healthcare providers.

Public Comment Period

Dr. Fishman opened the floor for public comment. There was no public comment at this time.

Liaison and Ex Officio Reports

Dr. Fishman opened the floor for the HICPAC liaison and ex officio members to provide updates of recently completed, ongoing or future activities of their organizations and agencies.

- **David Henderson, MD (NIH):** Dr. Henderson provided HICPAC with written copies of the NIH report.

- **William Baine, MD (AHRQ):** Dr. Baine provided HICPAC with written copies of the current and prior AHRQ reports.

- **Charles Huskins, MD. MSc (IDSA):** IDSA has recently published a guideline on management of group A streptococcal pharyngitis. The guideline for diagnosis and management of prosthetic joint infection will be published later in 2012. IDSA's Seasonal Pandemic Influenza Principles for U.S. Action was also published recently. IDSA also sent a joint letter to Congressional leadership urging it to stop sequestration and continue supporting public health.

- **Michael Howell, MD, MPH (Society of Critical Care Medicine):** The Society is very pleased to be involved in the Compendium revision. Its guide on Drug-Induced Complications in the Critically Ill Patient has recently been published. The guide treats antimicrobial resistance as an adverse drug event, and includes a chapter on communicating ADEs to patients and family members. The Society is also planning revision of its guidelines on severe sepsis and septic shock and on pain, agitation and delirium, which are expected in January 2013. The ICU glycemic control guideline will be published soon. Society members are involved in the large CMS effort to improve implementation of improvements related to sepsis, which is an attempt to use Toyota's lean production system techniques in the healthcare area.

- **Kathleen Dunn, BScN, MN, RN (Public Health Agency of Canada):** The Public Health Agency is about to release its routine infection control and hand hygiene guidelines. The Agency is a federal body, but needs to achieve consensus with provinces and territories and work in two languages to produce the guideline. Another challenge is dealing with tuberculosis and HIV/AIDS, particularly in First Nations communities. The Agency, in partnership with the Canadian Thoracic Society, has written chapters of the Tuberculosis Standards book which introduce a stronger emphasis on infection control. Working with this book's external editor is a creative way of bypassing slow government processes and getting infection control information into the hands of those on the frontline. The Agency's Steering Committee has modified the GRADE system and the Agency is now using its own system. Canada has a voluntary national surveillance system which many hospitals across the country participate in.

- **Barbara DeBaun, MSN, RN, CIC (APIC):** APIC recently introduced a competency model intended to guide practitioners throughout their careers, with the ultimate goal of encouraging members to get their CIC certification.

- **Margaret VanAmringe, MHS (Joint Commission):** The Joint Commission will soon publish a set of monographs on antimicrobial stewardship programs, focusing on their power to improve patient outcomes and also making the business case for these programs. Another Joint Commission publication pulls together international findings on CLABSI, along with information on comparative CLABSI rates in different countries and their economic impact**.** The next step is to develop a toolkit to help organizations across the world bring

down CLABSI rates. The Joint Commission also has a new Center for Transforming Healthcare, tasking with tackling some of the more intractable yet preventable problems in public health. One example is the area of hand hygiene. The Center's work has shown that improved hand hygiene is associated with lower HAI rates, yet no standardized way of measuring hand hygiene compliance in different facilities exists.

- **Rachel Stricof, MPH (CSTE):** Much of CSTE's work is done through position statements adopted at its annual meeting. Some of the position statements currently being drafted are on antimicrobial resistance reporting across all state health department programs, lab ID event reporting for MRSA and *C. difficile*, SSIs, CAUTI reporting, injection safety issues, and cross-institutional reporting. Cross-institutional reporting is a particular concern; when patients move back and forth between settings, lack of communication between facilities makes outbreak identification and management, infection prevention, and patient care harder.

- **Mark Rupp, MD (SHEA):** SHEA is, as previously mentioned, working on the update to the Compendium. SHEA is also forming a number of writing groups to offer practical advice on practice issues for which the evidence is not solid enough to allow formal guidance to be issued. Healthcare worker attire and pet therapy are two such issues. In the area of policy, SHEA has weighed in in favor of BARDA funding and the UDI (unique device identifier) system for devices and offered advice on HHS's Action Plan. Next week in San Diego, the first joint meeting between IDSA and SHEA, along with PIDS and HIVMA, will be held. The May 2013 SHEA meeting will stress the role of the environment in infection prevention. In response to a question from Dr. Saint. Dr. Rupp said that the writing groups will look at the role of healthcare worker attire in building patient confidence as well as in infection prevention.

- **Lisa McGiffert (Consumers Union):** Consumer representatives recently had a productive full-day meeting with CDC in Atlanta. Consumers Union also has a new food safety campaign called Not In My Food, which aims to get antibiotics out of all the meat sold at Trader Joes. Ms. McGiffert also noted the increasing number of regional patient safety groups.

- **Sanjay Saint, MD, MPH (Society of Hospital Medicine):** The increasing number of U.S. hospitalists had led to more hospitalists becoming engaged with quality improvement and HAI elimination efforts. The Society has partnered with the University Hospital Consortium on its Healthcare Engagement Network, focusing on ADEs including *C. difficile*, antibiotic resistance, CAUTI and venous thromboembolism readmissions. The Society is also involved with an AHRQ-funded project titled *On the Cusp: Stop CAUTI*. The goal is to create a national quality improvement infrastructure to facilitate such efforts.

- **Lisa Spruce, RN, DNP, ACNS, ACNP, ANP, CNOR (AORN):** AORN's recommended practices and guidelines are now evidence-rated. The guideline on sterilization was recently accepted by the National Guideline Clearinghouse. In 2013, guidelines on prevention on transmissible infections, sterile technique, and environment of care will be published. The guideline on sterile technique is expected to be particularly controversial.

- **Mark Russi, MD, MPH (ACOEM):** ACOEM has issued a position statement on issues of population health management under ACA. Many medical centers have begun using their employees and employees' families as trial populations in the attempt to integrate care under a patient-centered medical home model. This gives occupational health physicians the opportunity to coordinate primary care and conduct wellness initiatives.

- **Paul Moore, PhD (HRSA):** HRSA had no formal report, but Dr. Moore expressed his appreciation of HICPAC's work, which informs activities at HRSA and across HHS.

- **Alexis Elward, MD (ACIP):** ACIP has put out two position statements on annual influenza vaccination and on Tdap vaccination for adults aged 65 or older. The ACIP Hepatitis Work Group is considering recommending hepatitis B vaccination for healthcare workers who were previously vaccinated in infancy. The two options being considered are postexposure prophylaxis and pre-exposure management.

- **Daniel Schwartz, MD, MBA (CMS):** CMS is involved in many different activities which are not yet ready to be shared. Dr. Schwartz said he would likely have a more detailed update by next meeting.

- **Sheila Murphey, MD (FDA):** FDA's investigation of the recent meningitis outbreak is still in progress. In particular, FDA is helping CDC with specimen collection for culture. The most timely information on the outbreak can be found on CDC's website.

- **UDI rule:** This year, FDA has published its proposed UDI (unique device identifier) rule in the Federal Register. This rule will be an important step in tying device-associated-events to the source of the device, allowing investigators to identify the device, its manufacturer, make, model and lot. For some devices, labeling will be on the device itself. The rule will be implemented in a phased way over seven years, with the highest-risk devices first. Devices sold over the counter and those Class 1 devices which are already exempt from good manufacturing practice requirements will be exempted. The rule calls for the establishment of an FDA-accredited issuing agency for the UDI system, with FDA as a backup for this agency.

- FDA is also investigating several outbreaks of potential foodborne illness.

- **Product recalls:** Dukal Corporation has issued a voluntary recall for selected lots of benzalkalonium chloride swabs and antiseptic wipes, which were found to be contaminated with Burkholderia cepacia. No illness linked to these products has yet been reported.

- Advanced Sterilization Products has recalled certain lots of Sterrad Cyclesure 24 Biological Indicators, which were found not to function effectively for the entire labeled shelf life of 15 months. Users were instructed to use the affected lots for only 6 months after the date of manufacture.

- A recall of Neptune Fluid Waste Management Systems was issued due to a serious injury event which resulted in a death.

- The Center for Biologics Evaluation and Research has posted information on the impact of severe weather conditions on biological products on the FDA website. CBER also posted a brief on options to reduce the risk of bacterial contamination of platelets.

- FDA issued a safety alert to consumers warning against the use of Intestinomicina, a product marketed for the treatment of diarrhea and sold in international grocery stores in the U.S. This product has been found to contain oral chloramphenicol, which has been withdrawn from the U.S. market due to the risk of bone marrow toxicity.

Closing Remarks

With no further discussion or business brought before HICPAC, Dr. Fishman recessed the meeting at 4:19 p.m. on October 11, 2012.

Opening Session: October 12, 2012

Jeffrey Hageman, MHS
CDC/NCEZID/DHQP
Deputy Chief, Prevention and Response
HICPAC Designated Federal Official

The Designated Federal Official, Mr. Jeff Hageman, opened the floor for introductions of HICPAC voting members, ex officio members, and liaison representatives who were in attendance.

Mr. Hageman confirmed that the voting members and ex officio members in attendance constituted a quorum sufficient for HICPAC to conduct its business. He called the meeting to order at 9:07 a.m. and welcomed the participants.

Draft Guidelines for the Prevention of Surgical Site Infection

Sandra Berrios-Torres, MD
CDC/NCEZID/DHQP

Dr. Berrios-Torres began by outlining the key topics the guideline will cover. The topics in bold are the ones which will be discussed at the current meeting.

- Core section:
    - Antimicrobial prophylaxis (both IV and topical)
    - **Glycemic control**
    - **Normothermia**
    - **Oxygenation**
    - Skin prep
    - *S. aureus* colonization
    - Surgical checklist

  - Bundles
- Arthroplasty section:
  - Transfusion
  - Anticoagulation
  - Immunosuppressive therapy
  - **Exhaust suit**
  - Antimicrobial prophylaxis duration with drain use
  - Biofilm

CDC's Achievements since February

- Completed targeted literature searches
- Found 330 final total articles for extraction into evidence tables
- Created evidence table extraction template
- Evidence tables ~80% extracted (with biofilm pending)
- GRADE tables for glycemic control, normothermia, oxygenation and exhaust suit are completed
- GRADE tables for transfusion, skin prep, and topical antimicrobial prophylaxis are in progress.
- Narrative summaries and draft recommendations are completed for glycemic control, normothermia, oxygenation and exhaust suit.

Grading/quality of evidence: Dr. Berrios-Torres reviewed the GRADE tables used to grade evidence, which are the same ones which Dr. Elward discussed on the previous day of the meeting.

Review of draft narrative summaries and recommendations:

KQ26: How safe and effective is an orthopaedic exhaust suit for reducing the risk of surgical site infection (SSI) in arthroplasty patients?

Narrative evidence summary: Three observational studies were found, each addressing a different critical outcome: deep SSI, deep SSI requiring reoperation, and deep SSI requiring revision. The studies were given an overall grade of very low quality, based on the fact that they were observational studies with only one study of each critical outcome. They showed no benefit of exhaust suit use for reducing SSIs.

Pasquarella study: deep SSI: Observational study of 62 patients undergoing total hip & hip hemiarthroplasties. Suggested increase in deep SSI with exhaust suit at 24 month follow-up, but the evidence was limited in size, with only one patient in the intervention group and none in the control group. HEPA/mixed turbulent filtration was used in both groups. This study was not specifically designed to study SSI as an outcome, but it did report SSI.

Pasquarella study: superficial SSI: No difference in superficial SSI was found at three-month follow-up, with evidence again limited in size.

Miner study: deep SSI requiring reoperation: Observational study of 8,288 patients undergoing total knee arthroscopies, using administrative data. Again, the evidence was limited in size. No difference in the critical outcome was found at three-month follow-up. Laminar flow use varied between groups.

Hooper study: deep SSI requiring revision: Observational study of 88,311 patients undergoing total knee arthroscopies or total hip arthroplasty using ten years of data from the national joint registry of New Zealand. Multiple subanalyses were performed. The study found an increased number of deep SSIs requiring revision surgery within six months of surgery. Again, the evidence was limited in size. Results did not differ in presence or absence of laminar flow. Antibiotic-impregnated cement was reported in 60% of primary procedures, which is not typical of U.S. practice.

Adverse events: The literature search did not identify studies that quantified potential complications. The Hooper study included comments by surgeons that an exhaust suit can cause "limited spatial awareness" and lead to "ease of contamination due to apparent false sense of security." Dr. Berrios-Torres commented that she had repeatedly heard this risk of a false sense of security mentioned by surgeons.

The purpose of the current guideline is not to examine the efficacy of an exhaust suit as personal protective equipment.

Who should wear exhaust suits? None of the studies established a clear association between specific personnel wearing exhaust suits and SSI. The Hooper study included comments by surgeons that the surgeon, assistant, and scrub nurse were the team members wearing exhaust suits, and the Pasquarella study reported the same team members wearing the suit in its intervention group.

Draft recommendation: Unresolved issue. No recommendation. Further research addressing the use of orthopaedic exhaust suits and SSIs following arthroscopy procedures should evaluate the potential benefits and harms, including impact on personnel safety.

Questions and Comments from HICPAC:

Ms. Stricof asked whether the evidence is sufficient to support a finding that use of exhaust suits increases risk. Dr. Berrios-Torres replied that the limited size of evidence (only one case of deep SSI in the small Pasquarella study, and only one case in the large Hooper study) makes it difficult to support such a finding. Also, the studies in question show rates of SSI below 1%, much lower than the 1 to 4% rate which one would expect for hip and knee surgery. Moreover, the Hooper study is called into question by evidence suggesting that SSIs are less likely to be identified in national registry data than in an RCT. Overall, the data does not support a recommendation either for or against use of exhaust suits.

Dr. Rupp noted that several of the studies had laminar air flow as a confounder. There is little evidence to suggest benefit, and a recent systematic review suggests possible harm from laminar air flow in operating rooms for orthopedic surgery. CDC should consider addressing this issue in its guidelines.

KQ4: How effective is maintenance of normothermia in reducing the risk of SSI?

Narrative evidence summary:

Warming vs. no warming: Two RCTs found a reduced risk of SSI with warming using various techniques. This evidence was graded high quality.

Kurz study: An RCT of 200 patients comparing intraoperative warming during colorectal surgery with no warming. 6% of patients given warming suffered SSI compared to 19% of patients in the control group, a statistically significant result. A temperature of 36.5 degrees C was maintained for most patients. With intraoperative systemic warming, core temperature at end of surgery was increased and remained higher for more than 5 hours postoperatively.

Melling study: An RCT of 416 patients undergoing elective hernia repair, varicose vein and breast surgeries comparing preoperative warming with no warming. 5% of patients given preoperative warming suffered SSI compared to 14% of those in the control group, a statistically significant result. 30 minutes of preoperative warming were done using either local or systemic warming, which increased core temperature.

Both studies showed lower ASEPSIS wound scores with warming. Neither study reported any adverse events associated with warming.

Additional findings: moderate quality evidence because based on only Kurz study. Maintenance of normothermia was shown to result in less blood transfused and reduced length of hospital stay. Mortality at 30 days was rare and unrelated to warming.

Perioperative vs. intraoperative warming

Wong study: An RCT studying 103 patients undergoing elective major abdominal surgery. A reduced incidence of SSI was observed in patients with perioperative as opposed to intraoperative warming, but this was not a statistically significant result. This evidence was graded moderate quality, because it is based on only one RCT.

The Wong study showed core temperature increased with perioperative warming preoperatively, maintained during the first 90 minutes of an approximately three-hour surgery, and not maintained postoperatively. Less blood loss and less blood transfusion was observed, but this was not a statistically significant result. There was no difference in length of hospital stay. Mortality was rare and unrelated to warming. No adverse events were reported.

Draft recommendation: Maintenance of perioperative normothermia is recommended. (**Category IA**).

KQ5: What are the most effective strategies for achieving and maintaining normothermia?

*Narrative evidence summary***:** No studies were identified that both evaluated the most effective strategies for achieving and maintaining normothermia and included SSI as an outcome. No studies defined a lower limit for normothermia.

Draft recommendation: Unresolved issue. No recommendation. Further research is needed on the most effective strategies for achieving and maintaining normothermia, particularly with respect to determining the lower limit, optimal timing and duration, and the most effective techniques for managing normothermia. The studies should all include SSI as an outcome.

Questions and comments from HICPAC

Studies which report results which are not statistically significant should be described in the narrative summary as showing no difference between the intervention and control groups.

KQ6: In patients with normal pulmonary function, how safe and effective is the perioperative use of inspired oxygen fraction (FiO_2) in reducing the risk of SSI and when is it indicated?

Background: Numerous systematic reviews have been written on this topic. A meta-analysis of the five most commonly referenced RCTs shows no difference in SSI. However, three studies looked at individually show a 40% reduction in SSIs. Overall, oxygenation is not by itself useful without adequate tissue perfusion through maintenance of normothermia and adequate volume replacement. This highlights the fact that SSI prevention needs to be thought of in the context of a complex process of wound healing.

*Narrative evidence summary***:** Nine RCTs were identified; seven dealing with perioperative oxygenation, using either general or regional anesthesia, and two dealing with only postoperative oxygenation. The type of anesthesia used is significant because only general anesthesia allows a researcher to be sure exactly what percentage of oxygen a patient had received.

Six RCTs studied perioperative oxygenation with patients under general anesthesia undergoing colorectal, gynecologic, urologic and other surgeries.

Greif, Belda and Bickel studies: RCTs using 80% O_2 in the intervention group and 30% O_2 in the control group with no nitrous oxide (NO_2). All three studies found a 40% reduction in SSI at 14-15 day follow-up. Importantly, all three studies optimized tissue oxygen delivery with normothermia and liberal volume replacement. One study found significantly higher subcutaneous tissue oxygen tension both intra- and postoperatively with oxygenation.

Meyhoff study and Staehr subanalysis: Large RCT of 1400 patients using 80% O_2 in the intervention group and 30% O_2 in the control group both without nitrous oxide (NO_2). No difference in organ/space, deep, or superficial SSI was found. However, in this study tissue oxygen delivery was not optimized; normothermia was not consistently maintained as part of the protocol and volume replacement was markedly restricted to avoid >1kg weight gain postop. Moreover, about 28% of patients had a history of hypertension.

ASEPSIS scores greater than or equal to 20, but this was not a statistically significant result.

Respiratory failure: moderate quality evidence from Meyhoff found no increased risk of respiratory failure from oxygenation.

Atelectasis: moderate quality evidence from Meyhoff found no increased risk of atelectasis from oxygenation.

Mortality: No difference in 14-30 day mortality was observed between groups in the Belda, Greif, Meyhoff and Staehr studies. Evidence was moderate quality.

Length of stay: No difference observed in two studies; two studies suggested longer duration of hospital stay, but this was not a statistically significant result. Evidence was low quality.

Pryor study: An interim analysis RCT of 160 mixed surgical patients given 80% O_2 versus 35% O_2, with NO_2 30 minutes post-incision. This study found increased risk of SSI with oxygenation.

There were some concerns with this study. The intervention group had more patients with increased BMI, BMI greater than or equal to 30, higher blood loss, more crystalloid infused, and longer operations. 32% of patients studied overall had a history of hypertension. Five patients in the intervention group remained intubated versus one patient in the control group; this is a factor shown to be predictive of SSI on multivariate analysis. Also, target core temperature and fluid replacement were not standardized in this study.

Mortality was found to be low and unrelated to oxygenation. Evidence was low quality.

The Pryor study suggested oxygenation was associated with longer mean hospital stays, but the result was not statistically significant.

Gardella study: RCT of 143 patients studying perioperative oxygenation with patients under regional anesthesia undergoing Cesarean sections, with 80% O_2 in the intervention group and 30% O_2 in the control group. This study found a higher incidence of SSI, endometritis and cellulitis in the intervention group, but the result was not statistically significant. Normothermia and fluid replacement protocols were not reported. There was no difference in blood loss or length of stay between groups. The use of a non-rebreather mask in this study makes it hard to know what percentage of O_2 patients actually received.

Turtiainen study: RCT of 275 patients undergoing lower limb vascular surgery comparing postoperative oxygenation with 28-30% O_2 to room air of about 21% O_2. No benefit of oxygenation was found. A benefit of supplemental oxygen with incisional groin wounds was noted.

Whitney study: RCT of 24 patients undergoing cervical spine surgery comparing postoperative oxygenation with 28-30% O_2 to room air of about 21% O_2. No benefit of oxygenation was found.

Draft recommendation: Increased perioperative oxygenation alone, in the absence of strategies to optimize oxygen tissue delivery, including maintenance of perioperative normothermia and liberal fluid/volume replacement is not recommended for the prevention of surgical site infection. (**Category IA**)

KQ7: What is the optimal concentration of FiO_2 or inspired oxygen, and how and when should it be administered?

*Narrative evidence summary***:** No studies were identified that evaluated optimal concentration of inspired oxygen or its timing or duration, and included SSI as an outcome.

Draft recommendation: Unresolved issue. No recommendation. Further research addressing the optimal concentration, timing, duration, and delivery method of FiO_2 or inspired oxygen in SSI prevention should also evaluate potential benefits and harms.

Questions and Comments from HICPAC:

HICPAC discussed how best to word the recommendation. Some suggested emphasizing the benefit of optimizing oxygen tissue delivery rather than emphasizing that increased perioperative oxygenation alone is not recommended.

Dr. Berrios-Torres clarified that appropriate volume replacement varies from surgery to surgery and cannot be described by a specific number regardless of the procedure. Referring to "adequate" volume replacement rather than "liberal" might be preferable.

In response to a question from Dr. Howell, Dr. Berrios-Torres stated that increased arterial oxygenation was not one of the variables of interest in this analysis.

The phrase "increased perioperative FiO_2" might be more clear and consistent with the pulmonology literature.

In the draft recommendation, it would be more precise to say "intra- and immediate postoperative FiO_2" as opposed to "perioperative FiO_2".

Glycemic control: KQ3: In diabetics and non-diabetics, how is the risk of SSI impacted by hemoglobin A1C levels or perioperative blood glucose levels and what are the optimal targets?

KQ3A: In diabetics and non-diabetics, how is the risk of SSI impacted by hemoglobin A1C levels?

*Narrative evidence summary***:** No data was found on the association between hemoglobin A1C levels and risk of SSI.

Draft recommendation: Unresolved issue. No recommendation. Further research is needed to understand the association between hemoglobin A1C and the risk of SSI in diabetic and non-diabetic patients.

KQ3B: In diabetics and non-diabetics, how is the risk of SSI impacted by blood glucose levels and what are the optimal targets?

Narrative evidence summary: Two systematic reviews determined that the data were too heterogeneous to be able to make any recommendations. However, further examination shows that the existing studies were of two very difficult populations; cardiac surgery patients on the one hand and critically ill mixed surgical patients on the other hand. Every study reported a primary composite outcome variable including SSI.

Three RCTs looked at short protocol duration (12-36 hours) in SICU (surgical intensive care unit) patients undergoing cardiac surgery.

Strict vs. standard blood glucose levels: Ghandi and Chan studies: No benefit was found for strict over standard blood glucose target levels in reducing SSI in 70-80% non-diabetic cardiac patients with glycemic control protocols instituted intraoperatively and continued 24-36 hours postoperatively in SICU. Evidence was high quality. No increased risk for hypoglycemia was found with strict blood glucose target levels; however, the definition and reporting methodology for hypoglycemia was inconsistent between the two studies. Evidence was high quality. Mortality and length of stay were not associated with blood glucose levels (moderate quality evidence).

Standard vs. lesser blood glucose levels: Lazar study: This study dealt with 141 diabetic patients undergoing cardiac surgery, and found a benefit of standard vs. lesser blood glucose levels. A composite outcome variable composed of pneumonia and wound infections was used. Evidence was low quality. Low quality evidence suggested a lower risk of mortality and shorter length of stay with standard blood glucose levels.

Two RCTs looked at long protocol duration (~14-30 days) in SICU patients, comparing strict vs. standard blood glucose target levels. Evidence was moderate quality.

Bilotta study: No benefit of intra- and postoperative strict blood glucose target levels for reducing SSI was found in 90% non-diabetic neurosurgery patients in SICU for 10-14 days. The study dealt with 78 patients.

Grey study: Post-operative only strict blood glucose levels were found to reduce SSI in 90% non-diabetic critically ill mixed surgical patients in SICU for 25-30 days.

Both the Bilotta and Grey studies found an increased risk of hypoglycemia with strict blood glucose levels, but again, definitions and reporting of hypoglycemia differed. None of the reported hypoglycemic events were related to clinical complications (high-quality evidence.) In both studies, mortality was high but unrelated to blood glucose target levels (high-quality evidence). Moderate quality evidence showed length of stay to be unrelated to blood glucose target levels.

Draft recommendations (short ICU stays): KQ3B1a: Perioperative glycemic control using strict blood glucose target levels, solely for the prevention of SSIs, in predominantly non-diabetic cardiac surgery patients with expected short SICU stays is not recommended. (**Category IA**).

KQ3B1b: For diabetic cardiac surgery patients with short SICU stays, standard practice of blood glucose targets <200mg/dL is recommended. (Category IB).

Questions and Comments from HICPAC:

CDC's 1999 recommendation calls for avoiding hyperglycemia in diabetic patients perioperatively. However, given the predominantly non-diabetic patient populations in the above studies, properly adjusting this recommendation for non-diabetic patients presents a challenge. Dr. Berrios-Torres stated that it is unclear whether the data support recommending standard glycemic control for non-diabetic patients.

Dr. Bratzler commented that the recommendation should not be taken to say that no blood glucose control is appropriate. The control groups in the studies mentioned above were kept at the blood glucose levels currently recommended by physician societies. Observational data suggests a trend toward higher rates of SSIs with higher blood glucose levels in both diabetic and non-diabetic patients, and this result has been found in cardiac and non-cardiac surgery patients. There is no RCT data, however, comparing standard blood glucose level control with no control, and such a study would be hard to fund or to justify to an IRB.

Dr. Bratzler suggested that CDC could look at the observational data to support a recommendation of maintaining standard blood glucose level for non-diabetic patients, even if no RCT data is available. Dr. Berrios-Torres agreed that it might be appropriate to broaden the recommendation beyond diabetic patients.

Dr. Craig Umscheid said that the writing group has debated whether to use the word "standard" or a specific number or range of blood glucose levels in the recommendation. Although different professional societies use slightly different numbers, there is agreement that standard control is appropriate. The recommendation is not meant to discourage standard control, but to recommend standard over strict control because of the possible consequences of strict control.

Dr. Umscheid also encouraged the HICPAC to take on the difficult conversations about how far a recommendation based on data about a limited population can be extrapolated to other patient groups. It might be easier to have those discussions now than in the CDC clearance or public comment phases of guideline development. He invited the HICPAC to send written comments in the next two weeks.

Dr. Berrios-Torres added that all the studies referred to have a target range for blood glucose, not a target number.

Moving on to postoperative glycemic control in critically ill patients with expected long ICU stays, Dr. Berrios-Torres presented two possibilities. The small size of the relevant studies and the failure of the Bilotta study to find reduced SSI warrant either a weak Category II recommendation or perhaps no recommendation at all.

Draft recommendations (long ICU stays): **KQ3B2a:** Postoperative glycemic control using strict blood glucose target levels in diabetic, non-diabetic, and critically ill surgical patients with expected long ICU stays is recommended. (**Category II**)

KQ3B2b: Unresolved issue. No recommendation. Further research to define optimal blood glucose target levels in diabetic, non-diabetic, and critically ill surgical patients should evaluate the benefits and harms associated with glycemic control in different surgical populations and postoperative settings which may impact optimal target levels, delivery methods, timing of instituting and duration of the protocol.

Dr. Berrios-Torres commented that the procedure used for glycemic control should differ depending on the type of procedure patients undergo. This is an important area for further research.

Questions and Comments from HICPAC:

Dr. Howell stated that the small size of the Bilotta and Grey studies makes a recommendation for strict glycemic control in this population unwarranted. Moreover, preventing SSI is only one of several potential concerns. For instance, there is compelling evidence that single episodes of hypoglycemia increase the long-term risk of substantial cognitive defects. This risk was not accounted for in these studies. Dr. Berrios-Torres pointed out that the number of reported hypoglycemic events is much greater in the Bilotta and Grey studies of critically ill patients than in the cardiac surgery studies.

Next steps: CDC will finalize the recommendations based on HICPAC input. The draft narrative summaries and recommendations have been shared with external subject matter experts. The final recommendations are scheduled to be presented to the HICPAC in March.

Also in March, CDC will present draft narrative summaries and recommendations for the following topics:

- KQ1: Antimicrobial prophylaxis (intravenous)

- KQ2: Antimicrobial prophylaxis (topical)
- KQ8: Surgical skin prep
- KQ17: Transfusion
- KQ18-22: Immunosuppressive therapy
- KQ23: Anticoagulation

Dr. Berrios-Torres concluded by thanking the subject matter experts involved and the other members of the core writing group, which included Drs. Dale Bratzler and William Schecter from HICPAC, Dr. Umscheid and others from the Center for Evidence-Based Practice, and Dr. Berrios-Torres and Ms. Erin Stone from CDC.

HICPAC Guidance on the Use of Surveillance Data in a New Environment: Healthcare-Associated Infection Surveillance for Public Reporting of Quality Outcomes

Neil Fishman, MD
HICPAC Chair

Dr. Fishman presented the proposed HICPAC white paper on behalf of Dr. Tom Talbot of HICPAC and the rest of the writing group.

Background: HAI prevention has become a major focus for payors, consumers and quality improvement organizations. However, some of the incentives to achieve low HAI rates can have unintended consequences. Also, HAI surveillance definitions, originally designed as internal metrics, are now publicly reported, used for external inter-facility comparisons and in pay-for-performance schemes.

HAI surveillance data has certain limitations. There are variations in how definitions are interpreted, and some definitions are subjective (e.g. change in character of sputum.) Surveillance often relies on the existence and quality of documentation. This means that institutions with better surveillance systems can have higher HAI rates. Also, low inter-relator reliability has been observed.

Surveillance definitions and clinical diagnosis may be discordant. Clinical diagnoses are based on clinical judgment and intended to guide treatment, while surveillance definitions are ideally based upon objective data and are intended to assess the burden of HAIs and guide prevention efforts.

HAI surveillance is intended to spur investment in infection prevention and ultimately reduce the number of HAIs. However, unintended consequences, such as gaming the system by excluding or reclassifying HAI events, are possible. One example would be gaming the system by inappropriately classifying a CLABSI as secondary versus primary. As a result, infection prevention personnel are under increased scrutiny.

In many institutions, this has led to the emergence of clinical adjudication panels. Often, the members of such panels are not trained in HAI surveillance or familiar with NHSN definitions. The final determination of how to

classify an event may be subject to a clinical veto based on a clinical, not surveillance, definition. And in some cases, performance incentives introduce bias to panel members' interpretation of the data.

On an Emerging Infection Network (EIN) survey, 70% of respondents said that clinical judgment or adjudication was incorporated into a CLABSI determination. The current NHSN training includes only two sentences addressing this issue:

"[T]he definitions used in this manual are the only criteria that should be used when identifying and reporting NHSN events. While all participants may not agree with all the criteria, it is important that NHSN participants consistently use them for reporting infection, so that metrics between hospitals can be appropriately compared."

Well-intentioned pressure to "get to zero" infections also carries with it a risk of unintended consequences. All preventable HAIs should be eliminated, but elimination of all HAIs may not be realistic, particularly in certain populations. This may lead to incentives for underreporting HAIs or disincentives to care for critically ill patients or to perform high-risk procedures. Validation of reported data is essential. The importance of validation is shown by one Connecticut study which showed greater than 50% underreporting of CLABSIs, and an Oregon validation program which led to a 27% increase in reported CLABSI rates.

Recommendations: Based on this evidence, the HICPAC white paper will recommend:

- NHSN definitions should be used to measure all HAI outcomes. Discordance between surveillance and clinical definitions is acceptable and to be expected.
- Hospital leadership should assign final determination of an HAI to those trained in healthcare epidemiology. Surveillance definitions should be strictly adhered to.
- Systematic documentation of NHSN criteria should be used to include or exclude events.
- Clinical adjudication panels or clinician veto should not be used. However, ongoing discussion of challenging cases is encouraged.
- Reported data should be validated, with consequences for variation and for use of post hoc adjudication.
- Validation programs need to be performed by impartial and independent surveyors, such as state health departments or CMS.
- They should review surveillance methodology and operations and guarantee consistent application of NHSN definitions, particularly with respect to whether all reported events meet the definitions.
- Assessment of unreported events should be conducted, as well as assessment of potential manipulation of data. For instance, are decreases in reporting of primary CLABSIs paralleled by increases in secondary CLABSIs?
- Any reported institutional pressure to underreport should be reviewed.

Conclusions:

- HAI data integrity and reliability is critical
- Reporting must be unbiased and transparent, with standardized surveillance definitions, prohibition of post hoc adjudication, and validation.

Future public health investments are necessary to maintain and expand NHSN and help state health departments conduct validation and infection prevention. Healthcare facilities will also need funding for increased infection prevention and informatics personnel.

Questions and Comments from HICPAC:

Dr. Henderson commented that many are still unaware that clinical and surveillance definitions can be discordant; more education is needed on this issue.

Dr. Lundstrom commented the paper takes a somewhat negative tone when discussing elimination of HAIs and the zero goal. Some wording changes might be advisable to make it clear that HICPAC does support the concept of eliminating HAIs.

Dr. Fishman responded that the paper states that elimination of HAIs may not be possible in high-risk groups because of the existing knowledge gaps.

Ms. McGiffert stated that a clear, bright-line goal of zero HAIs helps create the right kind of mindset in the hospital. She added that the paper's suggestion that providers theoretically might be disincentivized from treating critically ill patients is not supported by evidence. Dr. Bratzler agreed. He went on to say that zero is an aspirational and motivational tool in the effort to reduce HAIs. However, the lack of a perfect measurement system which can determine preventability or the lack thereof makes it difficult to get to zero.

Dr. Howell pointed out that a multicenter study of invasive cardiac procedures found that sicker patients were less likely to receive invasive cardiac procedures depending on which state they were in, seemingly because public reporting procedures varied by state. However, he agreed that the concern about disincentivizing care for critically ill patients is overstated. Getting to zero preventable infections is impossible when surveillance measures are known to count events which are truly not infections as infections. That may be a subtle point to communicate to the public, but it is essential if the public is to understand the nature of HAI surveillance.

Dr. Huskins asked whether the paper will provide any additional guidance on distinguishing primary from secondary CLABSI. Dr. Fishman answered that the paper is solely on adjudication issues, not on interpretation of definitions. The paper will be published for a more general audience.

Dr. Baine suggested that validation should include looking at corollary events which could verify whether HAIs are really going down. He suggested reporting the upper 95% confidence bound as a way to keep aiming towards a goal of zero, while acknowledging that perfection may not be attainable.

Dr. Elward agreed that gaps in current knowledge are part of the reason HAIs still occur. For instance, host risk factors, such as the intestinal microbiome, may make prevention harder.

Ms. VanAmringe noted that resources need to be invested in making sure the quality of measures coming out of the surveillance system is sufficient to do quality improvement. Many healthcare organizations, especially smaller ones, may not have enough trained personnel to enter data into a surveillance system. It may be advisable to make such systems more user-friendly.

Dr. Henderson stated that the way the "getting to zero" message is communicated or marketed should depend on the audience being addressed.

Ms. McGiffert suggested using the validation studies to bring critical attention to the gaming which is going on and discourage it.

Dr. Pollock stated that clinical definitions exist for diagnostic and therapeutic use, and are inevitably not standardized because of variations in clinical training and practice. On the other hand, surveillance definitions are used for enumeration and measurement and must be standardized. The paper should use the phrase "medical care surveillance", not "public health surveillance", since the former more accurately describes NHSN surveillance. Dr. Pollock referred the group to a paper in the American Journal of Public Health which makes the distinction between medical care surveillance and public health surveillance clearer.

He added that not all validation studies are created equal. In the future, maybe validation of validation will be needed. Although there are few systematic studies of gaming, there is anecdotal evidence that it happens. The overall message which needs to be put out is: we need more investment in validation.

Dr. Bratzler emphasized the importance of capturing accurate data. In order to prevent HAIs, we first have to know that they are happening, and underreporting, sometimes driven by pay-for-performance schemes, makes prevention harder.

Dr. Diekema stated that an appropriately sensitive surveillance system means that some events will be misclassified as HAIs, making it unfeasible to get to zero. The language in the paper can be refined to make this clear, and to highlight the need for an expanded infection prevention knowledge base.

Ms. McGiffert stated that the goal of getting to zero is often stated more prominently than a description of the nature of the HAI problem, which may not be clear to the public. Maybe the paper could balance that out by beginning with a description of the scale and urgency of the problem. Dr. Fishman answered that the paper does begin with statistics about HAIs, and statements about the urgency of solving the problem could be added.

Dr. Carrico asked about what should happen when healthcare providers are unsure about whether an event fits the HAI definition. Should they err on the side of meeting the definition or not meeting it? Maybe that should be discussed in the paper. Dr. Fishman replied that at his institution, the default is to judge that it does fit the definition. This highlights the need to systematically document how these decisions are made, which is addressed in the paper.

Ms. Stricof stated that, in any quality improvement program, there will be pressure within institutions to reach the goal, whether that is zero or something higher. The paper is not intended to question what the goal should be, but to address the institutional practices which result in unintended consequences.

Dr. Bratzler made a motion to approve the proposed guidance on the use of surveillance data, with today's comments from HICPAC incorporated. Dr. Lundstrom seconded the motion. Dr. Fishman called for a show of hands, and the motion passed unanimously.

Public Comment Period

There was no public comment at this time.

Summary and Wrap-Up

Dr. Fishman gave a recap of the events of the meeting.

Dr. Diekema announced that there will be a section on the recent fungal meningitis outbreak at the coming ID (Infectious Disease) Week.

With no further discussion or business brought before HICPAC, Dr. Fishman adjourned the meeting at 11:38 a.m. on October 12, 2012.

Certification

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

_____ _____

Date

Neil O. Fishman, MD,
Chair, Healthcare Infection Control
Practices Advisory Committee