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 Summary Report
February 16-17, 2012
Atlanta, GA

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ATTACHMENT 1

Meeting of Healthcare Infection Control Practices Advisory Committee (HICPAC)
February 16-17, 2012
Centers for Disease Control and Prevention
Tom Harkin Global Communications Center (Building 19)
1600 Clifton Rd., NE
Atlanta, GA

Date: Thursday February 16, 2012

Time	Topic	Presider/Presenter
9:00	Welcome and Introductions • Remembering Judene Bartley	Neil Fishman (HICPAC Chair) Jeff Hageman (HICPAC DFO)
9:30	Draft Guideline for the Prevention of Surgical Site Infection	Sandra Berríos-Torres (CDC) Dale Bratzler (HICPAC)
10:30	Update on CDC's HAI Activities in Long-term Care	Nimalie Stone (CDC)
11:00	**Break**	
11:15	Draft Guideline for Prevention of Infections Among Patients in NICUs	Alexis Elward (HICPAC) Martha Iwamoto (CDC)
11:45	Update on CDC's Dialysis Activities	Priti Patel (CDC)
12:30	**Lunch**	
1:30	CDC's National HAI Standardized Infection Ratio Reports 2012	Paul Malpiedi (CDC)
1:55	NHSN Report on Antimicrobial Resistant Pathogens Associated with HAIs	Dawn Sievert (CDC)
2:15	HICPAC Surveillance Workgroup • Central-Line Associated Blood-Stream Infections • Surgical-Site Infections	 Scott Fridkin (CDC) Ryan Fagan (CDC)
3:15	Updating Pneumonia Definitions	Shelley Magill (CDC)
3:30	Break	
3:45	Planning for Upcoming Work on New and Updated Recommendations	
4:30	Liaison/ Ex-officio Reports	
4:45	Public Comment	
5:00	**Adjourn**	

Date: Friday February 17, 2012

Time	Topic	Presider/Presenter
9:00	HICPAC Guidance for Facility Adjudication of Infection Data	Tom Talbot (HICPAC)
10:00	Update from CDC's Office of Antimicrobial Resistance	Steve Solomon (CDC)
10:30	Return on Federal Investment in HAI Prevention	John Jernigan (CDC)
11:00	Update on *Clostridium difficile*	Cliff McDonald (CDC)
11:45	Public Comment	
	Summary and Wrap Up	Neil Fishman (HICPAC Chair)
12:00	**Adjourn**	

ATTACHMENT 2

List of Participants

(*Note:* The Designated Federal Official opened the floor for introductions on February 16 and 17, 2012 and verified the presence of a quorum with voting members and *ex-officio* members for HICPAC to conduct its business on both days of the meeting.)

FEBRUARY 16, 2012

HICPAC Members

Dr. Neil Fishman, Chair
Dr. Dale Bratzler
Dr. Ruth Carrico
Dr. Daniel Diekema
Dr. Alexis Elward
Dr. Mary Hayden
Dr. Susan Huang
Dr. Stephen Ostroff
Dr. Thomas Talbot

Designated Federal Official

Mr. Jeffrey Hageman

***Ex-Officio* Members**

Dr. William Baine (Agency for Healthcare Research and Quality) [via teleconference]
Dr. David Henderson (National Institutes of Health)
Dr. Sheila Murphey (Food and Drug Administration)
Dr. Gary Roselle (Department of Veterans Affairs)
Dr. Daniel Schwartz (Centers for Medicare and Medicaid Services)
Dr. Kim Willard-Jelks (Alternate, Health Resources and Services Administration)

Liaison Members

Ms. Joan Blanchard (Association of periOperative Registered Nurses)
Dr. William Brock (Society of Critical Care Medicine)
Ms. Barbara DeBaun (Association of Professionals of Infection Control and Epidemiology, Inc.)
Ms. Lisa Grabert (Alternate, (American Hospital Association)
Dr. Charles Huskins (Infectious Disease Society of America)
Dr. Marion Kainer (Council of State and Territorial Epidemiologists)
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. Robert Wise (The Joint Commission)

CDC Representatives

Dr. Denise Cardo, DHQP Director
Dr. Michael Bell, Deputy Director, DHQP
Kathy Allen-Bridson
Sandra Berríos-Torres
Angela Bivens
Kendra Cutle
Karen Deasy
Jim Distel
Maggie Dudek
Jonathan Edwards
Ryan Fagan
Scott Fridkin
Nancy Gallagher
Jeremy Goodman
Rita Helfand
Teresa Horan
Martha Iwamoto

Melanie Lawson
Fernanda Lessa
Shelley Magill
Paul Malpiedi
Anne Melville
Priti Patel
Kristin Rainish
Alicia Shugart
Dawn Sievert
Elizabeth Skillen
Erin Stone
Nimalie Stone
Heidi Williams
Tiffany Woodard
Brandy Wright

Members of the Public

Beau Bannerman
(Lantana Consulting Group)
Anne Bickmore
(Lantana Consulting Group, Inc.)
Robert Black (Abt Associates)
Christopher Bowers (Health Plan Business Unit of Centene Corporation)
Steven Brash (Nemours Foundation/ Alfred I. duPont Hospital for Children)
Russ Castioni (3M Company)
Katrina Crist (Association of Professionals of Infection Control and Epidemiology, Inc.)
Deborah DeLisi
(McKesson Medical Surgical, Inc.)
Gary Evans (AHC Media)
Hudson Garrett, Jr. (PDI Healthcare)
Joseph Gillis (3M Company)
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Nancy Klinger (3M Company)
Patricia Kurtz (The Joint Commission)
Rachel Long (CareFusion)
Tammy Lundstrom (Providence Hospital)
Christina Melucci (Moria, Inc.)
Jonathan Otter (Bioquell (U.K.), Ltd.)
Kathy Redmond (Vitas Healthcare)
Edward Septimus
(Hospital Corporation of America)
Joseph Solomkin (University of Cincinnati College of Medicine)
Michelle Stevens (3M Company)
Rachel Stricof (New York State Department of Health)
Thomas Szymczak (Vortek Surgical, LLC)
Anna Tallman
(Optimer Pharmaceuticals, Inc.)
Lisa Thiemann (American Association of Nurse Anesthetists)
Chantay Walker
(The Medical Affairs Company)
Cindy Winfrey (PDI Healthcare)

FEBRUARY 17, 2012

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Dr. Dale Bratzler
Dr. Ruth Carrico
Dr. Daniel Diekema
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Dr. Susan Huang
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Dr. Michael Bell, Deputy Director, DHQP
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Matthew Arduino
James Baggs
Sandra Berríos-Torres
Angela Bivens
Elizabeth Bolyard
Ronda Cochran
Kendra Cutle
Karen Deasy
John Decker
Jim Distel
Maggie Dudek
Jonathan Edwards
Ryan Fagan
Scott Fridkin
Nancy Gallagher
Jeremy Goodman
Rita Helfand
Teresa Horan
Martha Iwamoto
John Jermyn
John Jernigan
Rachel Kossover
Melanie Lawson
Fernanda Lessa
Shelley Magill
Paul Malpiedi
Kelly McCormick
Clifford McDonald
Anne Melville
Kevin Myers
Duc Nguyen
Priti Patel
Kristin Rainish
Catherine Rebmann
Melissa Schaefer
Alicia Shugart
Dawn Sievert
Elizabeth Skillen
Jason Snow
Steven Solomon
Arjun Srinivasan
Erin Stone
Nimalie Stone
John Terry
Abbigail Tumpey
Todd Weber
Heidi Williams
Matthew Wise

Tiffany Woodard
Brandy Wright
Sarah Yi

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Serene Wachli
Chantay Walker
(The Medical Affairs Company)
Cindy Winfrey (PDI Healthcare)

ATTACHMENT 3

Glossary of Acronyms

ACA	Affordable Care Act
ACIP	Advisory Committee for Immunization Practices
ACOEM	American College of Occupational and Environmental Medicine
AHRQ	Agency for Healthcare Research and Quality
AMP	Antimicrobial Prophylaxis
ANC	Absolute Neutrophil Count
AORN	Association of periOperative Registered Nurses
APIC	Association for Professionals in Infection Control and Epidemiology, Inc.
AR	Antimicrobial Resistance
ARRA	American Recovery and Reinvestment Act
ASCs	Ambulatory Surgical Centers
BMT	Bone Marrow Transplant
C. difficile	*Clostridium difficile*
CAUTI	Catheter-Associated Urinary Tract Infection
CDC	Centers for Disease Control and Prevention
CDI	*Clostridium difficile* Infection
CLABSI	Central Line-Associated Blood Stream Infection
CMS	Centers for Medicare and Medicaid Services
CRE	Carbapenem-Resistant *Enterobacteriaceae*
CSTE	Council of State and Territorial Epidemiologists
CXR	Chest X-Ray
DHQP	Division of Healthcare Quality Promotion
EIAs	Enzyme Immunoassays
EIP	Emerging Infections Program
ESRD	End State Renal Disease
FDA	Food and Drug Administration
GAO	Government Accountability Office
GI	Gastrointestinal
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
GVHD	Graft-Versus-Host Disease
HACs	Hospital-Acquired Conditions
HAIs	Healthcare-Associated Infections
HBV	Hepatitis B Virus
HCP	Healthcare Personnel
HCV	Hepatitis C Virus
HHS	Department of Health and Human Services
HICPAC	Healthcare Infection Control Practices Advisory Committee
HRSA	Health Resources and Services Administration

ICU	Intensive Care Unit
IDSA	Infectious Diseases Society of America
IPC	Infection Prevention and Control
IPs	Infection Preventionists
IV	Intravenous
IVAC	Infection-related Ventilator-Associated Complications
LTACHs	Long-Term Acute Care Hospitals
LTCFs	Long-Term Care Facilities
MBI-LCBI	Mucosal Barrier Injury Laboratory-Confirmed Bloodstream Infection
MDRO	Multidrug-Resistant Organism
MedPAR	Medicare Provider Analysis and Review
MeSH®	Medical Subject Headings
MRSA	Methicillin-Resistant *Staphylococcus aureus*
NAAT	Nucleic Acid Amplification Tests
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NHSN	National Healthcare Safety Network
NICU	Neonatal Intensive Care Unit
NIH	National Institutes of Health
NNIS	National Nosocomial Infections Surveillance System
NQF	National Quality Forum
NSQIP	National Surgical Quality Improvement Program
OMB	Office of Management and Budget
OR	Operating Room
PISTol	Piloting Infection Surveillance Tools in LTC
PPHF	Prevention and Public Health Fund
PPIs	Proton Pump Inhibitors
QIP	Quality Incentive Program
RCTs	Randomized Controlled Trials
ROI	Return on Investment
S. aureus	*Staphylococcus aureus*
SCCM	Society of Critical Care Medicine
SCIP	Surgical Care Improvement Project
SHEA	Society for Healthcare Epidemiology of America
SHM	Society of Hospital Medicine
SIR	Standardized Infection Ratio
SSI	Surgical Site Infection
sVAP	Streamlined Ventilator-Associated Pneumonia
T-LCBI	Translocation Laboratory-Confirmed Bloodstream Infection
TPA	Tissue Plasminogen Activator

UTI	Urinary Tract Infection
VA	Department of Veterans Affairs
VAE	Ventilator-Associated Events
VAP	Ventilator-Associated Pneumonia
VTE	Venous Thromboembolism
WBC	White Blood Cell
WHO	World Health Organization

EXECUTIVE SUMMARY

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on February 16-17, 2012 in Atlanta, Georgia.

The Designated Federal Official (DFO) verified the presence of a quorum for HICPAC to conduct its business on both days of the meeting. The HICPAC members declared their conflicts of interest for the record. HICPAC held a special session in memory of Ms. Judene Bartley who lost her 10-year battle with breast cancer and passed away on December 26, 2011. She was still an active member of HICPAC at the time of her death. Ms. Bartley was remembered and honored for her exceptional career, outstanding leadership, strong vision and passion to advance the field of infection prevention and improve patient safety.

CDC presented an overview of the FY2013 President's budget request. Increases and decreases to core programs were described at the agency level (CDC), National Center level (National Center for Emerging and Zoonotic Infectious Diseases), and Division level (DHQP).

CDC presented comprehensive updates on two draft guidelines: the Prevention of Surgical Site Infection (SSI) Guideline and Neonatal Intensive Care Unit (NICU) Infection Prevention Guideline. Due to CDC's budget constraints, further development of the Healthcare Personnel Infection Prevention and Control Guideline is on hold at this time.

The vast majority of the meeting was devoted to CDC's detailed updates and overviews on modifications to the National Healthcare Safety Network (NHSN) surveillance definitions, changes to the NHSN information technology platform, and the use of NHSN data. An update was presented on healthcare-associated infection (HAI) prevention activities in long-term care facilities that are targeted to four major programmatic areas: develop surveillance infrastructure, promote prevention efforts, expand the evidence base through research, and provide technical expertise for response efforts.

An update was presented on HAI prevention activities in dialysis settings. Overviews were presented on the 2010 National HAI Standardized Ratio Report and the NHSN HAI Antimicrobial Resistance Report that will be published in 2012. The HICPAC HAI Surveillance Workgroup reported on their recent activities to further refine the NHSN definitions for central line-associated bloodstream infections (CLABSI), SSI and VAP.

The Chair led HICPAC in an in-depth discussion on proposed topics for future guidelines or

interim guidance documents for CDC to consider.

HICPAC proposed a new guidance document that would provide guidance to assist healthcare facilities in adjudicating HAI surveillance data. A draft outline of the 6 sections of the proposed guidance document was summarized. HICPAC fully endorsed the proposed approach and made several comments and suggestions that should be considered in developing the guidance document.

The CDC Office of Antimicrobial Resistance (OAR) described its ongoing and future activities to respond to recommendations that were made during the "Strategic Priorities for Combating Antimicrobial Resistant Infections Workshop." The expert consultants provided guidance to OAR on 3 broad program priorities and 2 targeted program priorities.

CDC presented an update to HICPAC on an emerging issue related to the use of sing-dose vials for more than one patient. Physician groups and professional organizations recently launched an effort to make these restrictions more flexible based on the perception that the recommendations are not evidence-based, are resulting in unnecessary expenses, and are reducing access to quality-of-life improving drugs and life-saving drugs. HICPAC strongly advised CDC, the Centers for Medicare and Medicaid Services, and the Food and Drug Administration (FDA) to take extreme caution in modifying the existing policy. Any exceptions to the current policy must not be misinterpreted to mean that uncontrolled use of single-dose vials in multiple patients or other breaches in infection control practices are acceptable. Any exceptions to the current policy must emphasize that patient safety is still the primary objective of infection prevention.

CDC proposed an approach to demonstrate its federal return on investment (ROI) in HAI prevention. CDC collected historical data and performed modeling to develop estimates of 4 inputs: the burden of the problem, the cost of the problem, cost of implementing prevention activities, and effectiveness of prevention activities. A preliminary model showed that the ROI of CDC's prevention activities to reduce CLABSI is relatively large. HICPAC fully supported CDC's efforts to determine its federal ROI in the prevention of HAIs and made several comments and suggestions that should be considered in further development of the proposed approach.

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

The Chair called for public comments at all times noted on the published agenda for the February 16-17, 2012 meeting.

MEETING 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). The proceedings were held on February 16-17, 2012 in Building 19 of the Tom Harkin Global Communications Center at the CDC Roybal Campus in Atlanta, Georgia.

Opening Session: February 14, 2012

Mr. Jeffrey Hageman, MHS
Deputy Chief, Prevention and Response Branch
and DFO, HICPAC
DHQP, CDC

Mr. Hageman opened the floor for introductions to determine the HICPAC members, *ex-officio* members and liaison representatives who were in attendance. He asked the members to declare any conflicts of interest for the record. He reminded the HICPAC voting members of their responsibility to identify individual conflicts of interest and recuse themselves from these matters.

- Dale Bratzler, DO, MPH: Consultant to Johnson & Johnson and Medline Industries
- Alexis Elward, MD: Recipient of research support from Sage Products, Inc. to study the efficacy of chlorhexidine bathing in pediatric intensive care unit patients
- Mary Hayden, MD: Recipient of research support from Sage Products, Inc. to conduct a decolonization project

Mr. Hageman verified that the members and *ex-officio* members in attendance constituted a quorum for HICPAC to conduct its business on February 16, 2012. He called the proceedings to order at 9:05 a.m. and welcomed the participants to the meeting. The list of participants is appended to the minutes as Attachment 1.

Special Session: In Memory of Judene Bartley

Denise Cardo, MD
Director, Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

With much sadness, Dr. Cardo announced that Ms. Judene Bartley lost her 10-year battle with breast cancer and passed away on December 26, 2011. At the time of her death, she was an extremely active member of HICPAC, a Clinical Consultant for the Premier Safety Institute, and Vice President of Epidemiology Consulting Services. Ms. Bartley's extraordinary career in healthcare epidemiology spanned a period of 35 years.

Dr. Cardo was amazed by Ms. Bartley's expertise in healthcare epidemiology and infection control, her strong commitment to ensuring the best outcomes for both patients and healthcare personnel (HCP), and her ability to remain up-to-date on recommendations, policy statements and scientific issues related to healthcare infection control practices.

Ms. Bartley was in the final stages of her battle with breast cancer during the November 2011 HICPAC meeting, but she was still in attendance and informed Dr. Cardo of her plans to participate in the current meeting. In addition to her expertise in healthcare epidemiology, Ms. Bartley also was a visionary. At the time of her death, for example, she was still involved in efforts to apply green initiatives for HCP to use disinfectants without damaging the environment.

Dr. Cardo noted that Ms. Bartley's major passion was for leaders in the healthcare epidemiology community to achieve a true partnership (e.g., DHQP, Association for Professionals in Infection Control and Epidemiology, Inc. (APIC), Council of State and Territorial Epidemiologists (CSTE), Infectious Disease Society of America (IDSA), and Society for Healthcare Epidemiology of America (SHEA)). Ms. Bartley's position was that a true partnership among these groups would facilitate "one voice" in healthcare epidemiology and advance the field in the appropriate direction.

Tammy Lundstrom, MD, JD
Chief Medical Officer, Providence Hospital

Dr. Lundstrom informed the participants that she met Ms. Bartley early in her career when she basically had no knowledge of healthcare epidemiology. At that time, Ms. Bartley was the Director of Infection Prevention and graciously shared her time and expertise with Dr. Lundstrom and other "inexperienced" Infectious Disease Fellows in the hospital.

Dr. Lundstrom agreed with Dr. Cardo that Ms. Bartley was indeed a visionary. For example, her leadership resulted in her hospital being one of the first institutions in the country to participate in the CDC National Nosocomial Infections Surveillance system (NNIS). Ms. Bartley was extremely passionate about health care in general, healthcare epidemiology and hospital engineering to achieve "one powerful voice" in improving patient care and safety.

At the time of her breast cancer diagnosis 10 years earlier, Ms. Bartley informed Dr. Lundstrom of her strong interest in and commitment to working until her death. Ms. Bartley achieved this goal because one week prior to her death, she was still communicating with colleagues via e-mail and coordinating activities. Dr. Lundstrom concluded that Ms. Bartley was dearly loved; had served as a mentor, advocate and inspiration; and would be missed by countless individuals and organizations in the healthcare epidemiology community.

The remembrance session was closed with a video that was produced by the American Society for Healthcare Engineering in 2011 and prominently featured Ms. Bartley. The video served as an excellent tribute to remember and honor Ms. Bartley's career, outstanding leadership, and strong vision and passion to advance the healthcare epidemiology field and improve patient care safety.

Overview of the CDC FY2013 President's Budget Request

Rita Helfand, MD
Senior Advisor for Science Integration
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Denise Cardo, MD
Director, Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

Drs. Helfand and Cardo presented an overview of the CDC FY2013 President's budget request released on February 13, 2012. At the agency level, the total budget request for CDC of $11.2 billion reflects funding of $39.5 million above the FY2012 level. The proposed funding includes discretionary authority (e.g., CDC's standard budget authority); mandatory funding (e.g., the Vaccines for Children's Program and World Trade Center Health Program); Public Health Service evaluation funds; transfer funds from the Public Health and Social Services Emergency Funds; and the Affordable Care Act (ACA) Prevention and Public Health Fund (PPHF). Overall, CDC's budget authority has steadily decreased since FY2009.

After accounting for mandatory funding of some programs, CDC's FY2013 budget would be ~$6.7 billion at the program level. The FY2013 program-level budget proposes both increases and decreases to CDC's core programs. Programs that are proposed to receive increases include scientific services ($43 million), HIV/AIDS/viral hepatitis/STD/tuberculosis ($36 million), emerging infectious diseases ($27 million), and global health ($15 million).

Programs that are proposed to receive decreases include cross-cutting activities ($130 million), immunization ($58 million), preparedness ($54 million), occupational health ($43 million), chronic disease prevention ($39 million), birth defects ($12 million), and environmental health ($7 million). The budget decreases in CDC's programs at the federal level will pose significant challenges to state and local health departments.

The President's FY2013 budget request includes increases for CDC programs that directly target 3 of 10 winnable battles established by Dr. Thomas Frieden, Director of CDC: an increase of $40 million for domestic HIV/AIDS prevention; an increase of ~$17 million for food safety; and an increase of ~$12.6 million for healthcare-associated infections (HAIs) through the National Healthcare Safety Network (NHSN). The FY2013 budget also proposes other investments in two major areas: an increase of $23 million for health statistics and an increase of $15 million for polio eradication.

At the National Center level, the President's proposed FY2013 budget for NCEZID of ~$331 million reflects an increase of $27 million over the FY2012 funding level. The proposed increases for the food safety and NHSN line items account for the overall increase in the FY2013 NCEZID budget. The FY2013 President's budget request also proposes to use PPHF to allocate $40 million to the Epidemiology and Laboratory Capacity Program to support state and local health departments and ~$12 million to prevent and/or reduce HAIs. However, the PPHF funds represent level funding for these two programs. The Emerging Infections Program (EIP) is another major line item in NCEZID, but a $2.4 million decrease has been proposed for this program in the President's FY2013 budget.

At the Division level, funding for NHSN has been flat since FY2010. The proposed $12 million increase for NHSN in the President's FY2013 budget request is critically needed for DHQP to (1) modernize the NHSN information technology platform to accommodate the enormous expansion of the system and enhance electronic data collection; (2) continue expansion of HAI reporting by facility and infection type; and (3) develop innovative and evidence-based HAI prevention strategies to ensure accurate, timely and complete data reporting to NHSN.

Although NHSN received flat funding of $15.15 million in FY2010-FY2012, DHQP projected an expansion of NHSN in FY2012 with the enrollment of acute care facilities and dialysis facilities as part of the Centers for Medicare and Medicaid Services (CMS) Value Based Purchasing and

Quality Incentive Programs. DHQP projects further expansion of NHSN in FY2013 with the enrollment of ambulatory surgical centers (ASCs) and inpatient rehabilitation facilities as part of the CMS Value Based Purchasing Program.

DHQP's projections are based on the assumption that 16,500 acute care facilities, dialysis facilities, inpatient rehabilitation facilities and ASCs will report data to NHSN. However, increases in the types of infections reported by these facilities to fulfill mandates of the CMS Value Based Purchase Program are not reflected in DHQP's projections. Additional details on CDC's proposed FY2013 budget are publicly available at www.cdc.gov/fmo.

In response to HICPAC's specific questions, Drs. Helfand and Cardo provided additional details on CDC's proposed FY2013 budget. The discussion topics included:

- the likelihood that Congress may not approve funding increases to CDC proposed in the President's FY2013 budget request and CDC's ongoing efforts to decrease internal expenditures to prepare for this possibility;
- the direct correlation between the increase in the number of NHSN reporting facilities and a perceived decrease in the quality of data;
- concerns with the end of American Recovery and Reinvestment Act (ARRA) funding in 2011 for states to validate NHSN data;
- activities that DHQP may need to postpone (e.g., utilization of electronic data sources in NHSN) if Congress does not approve the proposed increases in the President's FY2013 budget;
- activities that DHQP will prioritize and maintain even if Congress does not approve the proposed increases (e.g., modernization of the NHSN infrastructure, data validation activities with health departments, and continued support to states with public reporting mandates); and
- CDC's contingency plans to maintain core capacity in state health departments if funding is further reduced.

If Congress approves increases in the CDC budget that are proposed in the President's FY2013 budget request, HICPAC advised DHQP to invest a portion of these funds in validation activities to ensure states produce and report credible data to NHSN. HICPAC further recommended that DHQP develop a standardized data validation protocol to assist states in this effort.

Update on the Prevention of Surgical Site Infection Guideline

Sandra Berríos-Torres, MD
Medical Officer, DHQP
Centers for Disease Control and Prevention

Dr. Berríos-Torres covered the following topics in her update to HICPAC on the Surgical Site Infection (SSI) Prevention Guideline. Since the November 2011 HICPAC meeting, the writing group has completed full-title and abstract screening for both the core and arthroplasty sections of the SSI guideline, completed full-text reviews, updated the inclusion/exclusion criteria for studies, shared the bibliography of the full-text review with content experts, reviewed input from the content experts on additional studies to consider, refined the methodology for targeted searches, and initiated the data extraction process.

To identify studies for the core and arthroplasty sections of the SSI guideline, the writing group searched the Ovid-MEDLINE®, PREM®, Embase® and Cochrane® databases. After applying the inclusion/exclusion criteria (e.g., studies in English language only, studies published in 1998 to the present, removal of duplicate titles, removal of 10% of random sample studies, and inclusion of relevant references in the 1999 SSI guideline), the initial search of 2,997 studies was decreased to a total of 2,674 studies for the full-title and abstract screening process.

After inclusion/exclusion criteria were applied for the 2,674 studies identified for the full-title and abstract screening process, 418 studies were selected for full-text review. 189 studies were selected for data extraction based on their kappa scores. The content experts submitted 104 additional citations for the consideration, but only 20 were selected for data extraction after the inclusion/exclusion criteria were applied. As a result, the writing group will extract data from a total of 209 studies for the SSI guideline.

The topics with the most hits in the literature search for the core section of the SSI guideline were antimicrobial prophylaxis (AMP) duration, skin preparation, antibiotic-coated sutures, *Staphylococcus aureus* (*S. aureus*) decolonization strategies, tissue oxygenation, and *S. aureus* intravenous (IV) AMP regimens. The topics with no hits in the literature search for the core section of the SSI guideline were AMP topical dressings, the lower limit of normothermia, and *S. aureus* colonization issues (e.g., screening strategies, mupirocin resistance, oral antibiotics, timing and duration of decolonization strategies, and non-vancomycin IV AMP options).

The topics with no hits in the literature search for the arthroplasty section of the SSI guideline were intra-articular steroids, double/antimicrobial gloves, anesthesia, biofilm formation and risk of SSI, and surgical technique issues (e.g., electrocautery, antibiotic-coated prosthesis, fixation techniques, the use of drains and AMP duration in the use of drains). The writing group

suggested that its methodology for the literature search in part contributed to some of the topics receiving no hits. For example, the search term of "SSI" was utilized as the major outcome, but some studies focused on non-SSI outcomes.

The search strategy was refined by reviewing randomized controlled trials (RCTs), systematic reviews and guidelines that were based on systematic reviews. The biofilm section was used as a model to test the targeted search strategy. Infection, surgery and biofilm terms were entered into the Ovid-MEDLINE®, PREM®, Embase® and Cochrane® databases and the same exclusion criteria were applied (e.g., studies in English language only, studies published in 1998 to the present, and removal of duplicate titles).

For 380 biofilm studies that were initially identified, a "filter" was applied to only identify RCTs, systematic reviews, observational studies and diagnostic studies. After the filter was applied, 105 biofilm studies were included and 275 biofilm studies were excluded. The writing group conducted a random sample of 75 studies in each group. The analysis showed that 44% of studies in the included group (or 33 of 75 studies) and 5% of studies in the excluded group (or 4 of 75 studies) met the methodology for the biofilm targeted search.

The following factors were used to refine its criteria for studies to exclude from the SSI guideline: not relevant to any key question; not an RCT, systematic review or evidence-based guideline with the systematic review included; not in English language; no full-text available; exclusion of SSI as an outcome; a focus on oral medicine or dental health; a description of "dirty" cases (e.g., open fractures); no focus on primary closure; and use of a wound protector post-incision.

The exclusion criteria were identified for special circumstances. Non-arthroplasty studies would be excluded from the general arthroplasty key questions. Placebo controlled studies or studies that compared different antibiotics would be excluded from the IV AMP questions.

The following factors were used to refine its criteria for studies to include in the SSI guideline: pediatric studies, animal studies, basic science studies (particularly for the biofilm section), timing of AMP in high-risk Cesarean sections (e.g., cord clamping), non-AMP irrigation or topical application prior to wound closure, platelet gel prior to wound closure, vaginal antisepsis with abdominal procedures, epoetin transfusions with blood transfusions, and preoperative showers that were not specific to *S. aureus*.

In updating the SSI guideline, one of its major challenges was because the surgical literature contains a paucity of experimental RCTs; a decision must be made on whether well-designed observational study designs should be identified and reviewed to answer the key questions.

To address this issue, the writing group discussed the possibility of analyzing cohorts with and without comparator arms, systematic cohorts with sequentially different interventions over a short period of time of 2-3 years, and studies with and without control groups. "SSI" or "surgical wound infection" is a medical subject heading (MeSH®) term that traditionally is not included in peer-reviewed journals.

Some of the key questions for the guideline do not specifically focus on the use of SSI as the outcome (e.g. mupirocin resistance). As a result, the targeted searches must be refined to address this issue. Some topics in the SSI guideline (e.g., the environmental section and biofilm in the arthroplasty section) will be based on primary literature that is non-medical. Because the writing group conducted its initial literature search in July 2011, a decision will need to be made on the appropriate date to repeat the search to ensure the most up-to-date studies are included in the SSI guideline.

Overall, the writing group has made several accomplishments since the November 2011 HICPAC meeting: completed full-title and abstract screening of 3,269 studies, completed full-text reviews of 452 citations, initiated the data extraction process for 209 studies, updated inclusion/ exclusion criteria, and refined the targeted search strategy. The writing group's next steps will be to prioritize topics for the targeted searches, continue the data extraction process, apply the "Grading of Recommendations, Assessment, Development and Evaluation" (GRADE) criteria, develop narrative summaries, and submit the draft SSI guideline to the *Federal Register* for public comment.

Dr. Berríos-Torres concluded her update by requesting HICPAC's input on the following questions to assist the writing group in further development of the SSI guideline.

1. How should the writing group prioritize its targeted searches of both the broader topics and individual key questions to strike an appropriate balance between producing a thorough, valuable and relevant SSI guideline and releasing the document in a timely manner?
2. What factors should the writing group utilize to decide whether to exclude a key question and move the issue to a research agenda?
3. Should the writing group explore the possibility of expanding the literature search to include non-arthroplasty citations due to the limited number of studies on this specialty topic that were identified during the initial search?
4. Should the writing group design the meta-analyses data extraction process to focus on summarized data or data from individual studies?

Dr. Berríos-Torres informed HICPAC of comments and suggestions the content experts made during their recent discussions with the writing group. The content experts advised the writing

group to conduct targeted searches of the following topics: systemic immunosuppressive therapy, exhaust suits, transfusion, anticoagulation, the duration of AMP in the use of drains, and identification and prevention of biofilm. The position of the content experts was that two of the existing key questions could be used to address the diagnosis and prevention of prosthetic joint infections.

The content experts informed the writing group that due to the lack of studies identified in the literature searches the following topics should be eliminated as key questions and moved to a research agenda: perioperative anesthesia, intra-articular steroids and SSI, and surgical attire issues (e.g., double gloving and antimicrobial gloves). The content experts further advised the writing group to begin the data extraction process for the environmental section before conducting a targeted search of this topic.

In response to HICPAC's specific questions, Dr. Berríos-Torres provided additional details on the draft SSI Prevention Guideline. The discussion topics included:

- the absence of any gloves with added antimicrobials that have been cleared for marketing in the United States to date; and
- the possibility of the American Society of Health-System Pharmacists addressing the AMP-related questions in its upcoming guidelines.

Dr. Michael Bell is the Deputy Director of DHQP. In response to question 4 posed by Dr. Berríos-Torres, he recalled that problems with CDC recommendations occurred in the past when reliance was solely placed on meta-analyses and original data were not referenced. He strongly urged the writing group to reference original data for contentious issues or topics that most likely would be subjected to close scrutiny. Meta-analyses could be referenced for routine practices in the field or issues that are generally acknowledged by infection preventionists (IPs).

HICPAC agreed with Dr. Bell's comments in general, but some members noted that well-designed, in-depth and helpful meta-analyses also should be referenced in the SSI Prevention Guideline, particularly in areas where no other data exist.

HICPAC advised the writing group to move some of the key questions in the arthroplasty section to the core section due to the lack of arthroplasty-specific evidence. Moreover, the writing group should take advantage of opportunities to address broader procedural issues beyond arthroplasty (e.g., immunosuppression, transfusion, post-lavage, double-gloving and operating room (OR) traffic).

The Chair confirmed that he would solicit volunteers from HICPAC to answer the remaining questions Dr. Berríos-Torres posed regarding the writing group's next steps in drafting the SSI guideline.

Update on DHQP's HAI Prevention Activities in Long-Term Care Facilities (LTCFs)

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Dr. Stone covered the following topics in her update to HICPAC on DHQP's activities in HAI prevention in LTCFs. "Long-term care" is defined as a variety of services that includes medical and non-medical care to persons who have a chronic illness or disability (e.g., chronic ventilator care, home-based care and senior day care services). Facilities that provide LTC include long-term acute care hospitals (LTACHs), skilled nursing facilities, sub-acute rehabilitation facilities, nursing homes for custodial care and dementia care, assisted-living facilities and hospices.

The 2010 Nursing Home Compendium, the 2000 Strausbaugh, *et al.* study, and the 2011 Ouslander, *et al.* study described the changing population of LTCF residents. In 2009, ~3.3 million residents received care in the 15,884 certified nursing homes in the United States. Hospitals served as the primary source of admission to these settings. The number of residents who entered nursing homes increased by 10% from 2000 to 2009, but the total number of beds in nursing homes decreased by ~15% over this same period of time.

An increasing proportion of persons <65 years of age are receiving care in nursing homes. The cost and morbidity from infections are high with 1.6-3.8 million infections estimated annually. Hospitalizations frequently are attributed to infections from nursing homes (e.g., 30%-50%). The increasing post-acute care population is associated with growing medical complexity and care needs; increased exposure to devices, wounds and antibiotics; and a high prevalence of multidrug-resistant organisms. The dynamic movement across healthcare settings impacts areas where HAIs manifest.

A number of challenges exist in HAI prevention in LTCFs. Data are extremely limited on the national incidence of HAIs in nursing homes. Studies on HAIs are small, have short time frames and typically are conducted in a single center. Efforts to compare results are difficult because no standard methodology or definitions are used across studies.

Capacity and resources are limited in infection prevention programs. The vast majority of program coordinators lack formal training and staff turnover impedes efforts by facilities to

make improvements in the safety of residents, infection prevention and other quality indicators. Evidence is lacking on the most applicable, feasible and best strategies to implement HAI prevention activities in LTCFs.

DHQP has launched several activities in 4 major programmatic areas to improve HAI prevention in LTCFs. To "develop surveillance infrastructure," DHQP is co-leading the revision and update of surveillance definitions for infections in LTCFs. The 1991 McGeer, *et al.* LTCF infection surveillance definitions were widely utilized in research and state-mandated programs, but these definitions were never systematically validated.

DHQP and SHEA jointly initiated the process to update the definitions in March 2009. Since that time, the updated definitions have been reviewed by the SHEA LTC Interest Group and external reviewers; approved by the SHEA Board of Trustees and Guidelines Committee; and cleared by CDC. The updated definitions will be distributed to LTC stakeholders for their formal endorsement prior to being publicly released in late spring of 2012.

DHQP is expanding NHSN to include HAI event reporting modules that will be specific to LTCFs. The new LTC component will be separate from the NHSN Patient Safety component and will only allow access to facilities designated as LTCFs. Reporting will be simplified, tailored to LTCFs, and limited to only three events initially: catheter and non-catheter-related urinary tract infections (UTI); LabID events for multidrug-resistant organisms (MDRO) and *Clostridium difficile* infection (CDI); and prevention process measures (e.g., hand hygiene).

DHQP received Office of Management and Budget (OMB) approval for the new LTC component reporting forms. The development of protocols, instructions and training manuals is underway. DHQP expects to release the LTC component in NHSN in the fall of 2012. Dr. Stone presented a screen shot of the NHSN LTC component that will be used to capture resident-specific data on event reports.

CDC awarded funds to four Emerging Program sites in Colorado, Maryland, Minnesota and Tennessee to conduct the "Piloting Infection Surveillance Tools in LTC" (PISTol) Project. The sites are funded to recruit nursing homes for participation in a 3- to 6-month pilot of NHSN LTC event protocols and reporting tools. The two overarching objectives of the project are for the pilot sites to (1) provide feedback on the usability of UTI and CDI surveillance instructions and event forms and (2) assess the burden and feasibility of data collection. The pilot sites also have an option of performing data validation through onsite audits.

To "promote prevention efforts," CDC awarded funds to support activities by state health departments to expand HAI prevention efforts to include LTCFs: (1) 6 states sustained or developed LTCF-specific infection control training courses; (2) 9 states completed, recently

launched or are planning to include LTCFs in new or ongoing HAI prevention projects; and (3) 8 states implemented a tool developed by CDC to assess LTC infection control programs (www.cdc.gov/HAI/settings/ltcsettings.html).

Dr. Stone highlighted 2 models of state efforts to promote HAI prevention efforts in LTCFs. Georgia state agencies collaborated to develop an infection control training curriculum for LTCF providers and surveyors. To date, 183 nursing home staff representing 129 facilities, 12 nursing home state surveyors, and 7 local public health staff have attended 3 regional courses. The key outcomes of the training course are to (1) improve communication and resource sharing among state health divisions and the state quality improvement organization and (2) expand access and knowledge of infection control resources to state surveyors and local public health staff.

Vermont state agencies collaborated on MDRO prevention to encourage acute care hospitals and LTCFs to partner in local "healthcare clusters." All acute care hospitals and 80% of skilled nursing facilities in the state participated in the collaborative. The key outcomes of the project are to (1) foster new relationships and improve communication across care transitions; (2) develop an infrastructure to extract electronic data from acute care hospitals and LTCFs that share laboratory services; and (3) pilot the NHSN LabID surveillance methodology for the LTC component. The CDC website for state HAI prevention activities is available at: www.cdc.gov/hai/recoveryact.

To "expand the evidence base through research," DHQP is funding prevention and surveillance programs and a study with the Department of Veterans Affairs (VA) to assess CDI transmission from asymptomatic carriers in LTCFs. The major outcomes of the study are three-fold: (1) determine the rate of facility-onset CDI cases; (2) evaluate polymerase chain reaction testing and clinical prediction rules for detecting asymptomatic carriers; and (3) implement an infection control intervention aimed at reducing CDI transmission from asymptomatic carriers in VA LTCFs.

To "provide technical expertise for response efforts," DHQP is utilizing existing CDC/HICPAC guidelines to support state HAI outbreak investigations in LTCFs. DHQP also is serving as a technical advisor to both federal and non-federal projects. DHQP is participating on the HHS Writing group that was established to develop an HAI Prevention Action Plan for LTCFs. DHQP is serving as a technical advisor on projects funded by the Agency for Healthcare Research and Quality (AHRQ) to address antibiotic use in nursing homes. DHQP is collaborating with CMS on strategies to increase awareness of infection prevention and control (IPC) through nursing home oversight activities. DHQP is partnering with LTC stakeholders to promote CDC's messages in IPC.

In response to HICPAC's specific questions, Dr. Stone provided additional details on DHQP's HAI prevention activities in LTCFs. The discussion topics included:

- challenges related to poor data quality in LTCFs;
- higher exposure to infections from urinary catheters among short-term residents of LTCFs compared to long-term residents;
- DHQP's rationale for separating and differentiating between "LTCFs" and "LTACHs" and treating LTACHs as acute care hospitals rather than LTCFs;
- the critical need to monitor and report the unintended consequences of managing sicker patients in non-acute settings;
- CSTE's ongoing efforts to address issues related to data quality and data burden in LTCFs;
- the need to distinguish between providing infection control care to LTCF patients with preventable infections and not providing infection control care to patients who are receiving end-of-life care and are expected to die; and
- the need for DHQP to increase its focus and activities on infection control in assisted living facilities in the future.

HICPAC made comments and suggestions in two areas for DHQP to consider in its ongoing HAI prevention activities in LTCFs. First, DHQP should make stronger efforts to more clearly delineate the differences between LTCFs and LTACHs. For example, skilled nursing facilities in some jurisdictions in the country offer long-term custodial care, ventilator care and dialysis services. DHQP should consider the possibility of distinguishing between LTCFs and LTACHs based on the type of care provided to patients rather than the setting alone.

Second, DHQP should reconsider its approach of including the UTI reporting module as one of the first three events in the new LTC component of NHSN. UTI is a difficult and complex event that requires a substantial amount of time and effort to determine at the chart level. DHQP should replace the UTI reporting module with a simplified version of a laboratory-based reporting module (e.g., device/no device, higher colony count, and limited fields for fever and other outcomes).

Dr. Fishman confirmed that he would engage HICPAC in a discussion at a future meeting to explore strategies to advocate for ongoing support, funding and research to address specific needs in nursing homes

Update on the Neonatal Intensive Care Unit (NICU) Infection Prevention Guideline

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HICPAC Member

Dr. Elward covered the following topics in her update to HICPAC on the CDC NICU Infection Prevention Guideline. At this time, the writing group is finalizing the GRADE tables, drafting narrative summaries and drafting the recommendations. The writing group has completed several tasks since the November 2011 HICPAC meeting.

The bibliography was submitted to the expert panel for review. The literature searches were updated for methicillin-resistant *Staphylococcus aureus* (MRSA), central line-associated blood stream infection (CLABSI) and *C. difficile* based on feedback from the expert panel. The evidence tables were finalized, additional discussions were held on the GRADE criteria, and the GRADE tables were constructed. Narrative summaries were drafted for *C. difficile* and respiratory pathogens.

The writing group's most recent discussions have focused on a standard approach to classify studies, endpoints for literature searches, and multimodal interventions and the difficulty of distinguishing the influence of each individual intervention. The writing group created key questions to guide the development of recommendations in 5 major areas of the NICU guideline: respiratory infections, CLABSI, MRSA, fungal infections and *C. difficile*.

Dr. Elward summarized the key questions for each of the 5 topics.

The writing group initially reviewed 2,980 abstracts, selected 1,738 for a full-text review, and ultimately included 349 in the NICU guideline after applying the inclusion/exclusion criteria. The expert panel advised the writing group to include references on MRSA and CLABSI that were published in 2011. Based on this feedback, the writing group re-reviewed its original searches on respiratory pathogens, MRSA, CLABSI, *C. difficile*, fungal infections and chlorhexidine in August-September 2010, February 2011 and June 2011.

The writing group's updated search yielded 309 additional papers that were published in 2011. The abstract review process to select papers for full-text review is underway. The writing group expects that of the 309 additional papers, ~30 will be selected for inclusion in the NICU guideline.

The writing group has assigned each study an initial grade of "high" (e.g., RCT), "low" (e.g., observational study) or "very low" (e.g., expert opinion or any other evidence) based on the strength of the design. The initial grade will be decreased based on study quality limitations, inconsistency, indirectness, imprecision or publication bias. The initial grade will be increased based on strength of an association, dose-response gradient, or confounding factors. Based on the criteria to increase or decrease the initial grade, each study will be assigned an overall quality grade of "high," "moderate," "low" or "very low."

An overall quality grade of "high" is defined as further research is very unlikely to change confidence in the estimate of effect. An overall quality grade of "moderate" is defined as further research is likely to impact confidence in the estimate of effect and may change the estimate. An overall quality grade of "low" is defined as further research is very unlikely to impact confidence in the estimate of effect and is likely to change the estimate. An overall quality grade of "very low" is defined as any estimate of effect is very uncertain.

The writing group reached agreement on several key points over the course of its deliberations. In terms of the risk of bias, the writing group agreed that the potential for conflict of interest is low with respect to outbreak investigations. As a result, "no conflict reported" will be equivalent to "no conflict" for purposes of grading the evidence for the NICU guideline. The writing group also agreed that RCTs are the best evidence to answer the key questions for the NICU guideline. However, observational and descriptive studies will be used if no RCTs exist or available RCTs measure adverse events.

The writing group further agreed that observational and descriptive studies are not designed for randomization and blinding and are not relevant to outbreak studies in which the entire NICU population is exposed. As a result, the quality of the evidence will not be further downgraded for lack of blinding and randomization. Dr. Elward presented an example of a GRADE table that compared various interventions for pertussis.

Dr. Elward reviewed the narrative summary for the *C. difficile* key questions. Key question 5a: What are the most effective strategies for *C. difficile* testing in NICU patients? The writing group found no evidence that described or compared the predictive values, test characteristics or clinical outcomes associated with different testing strategies or pathways.

Key question 5b: When should testing for *C. difficile* be performed in NICU patients? The writing group reviewed 5 studies that correlated the presence of *C. difficile* toxin with clinical factors (e.g., the presence or absence of gastrointestinal (GI) symptoms and the frequency and quality of stool). The writing group excluded studies that measured only carriages rates without an assessment of clinical status.

Of the 5 studies, 3 defined the "presence of *C. difficile* toxin" as the critical outcome and 2 defined the "presence of *C. difficile* infection" as the critical outcome. However, "infection" was defined differently in the 2 studies. Study 1 defined "infection" as clinical symptoms (e.g., diarrhea or bloody stools) in a patient with stool that was positive for *C. difficile*. Study 2 defined "infection" as a case identified by ICD-9 and billing codes for *C. difficile* toxin assay and an initial dose of antimicrobial therapy directed against *C. difficile*.

Based on its review of these studies, the writing group found very low quality evidence to support gestational age, birth weight and length of hospitalization as risk factors for disease. The very low quality evidence of 2 studies did not establish a clear association between underlying GI pathology and *C. difficile*. Of the 3 studies that addressed prior antibiotic exposure, 1 cross-sectional study with a cohort of infants with toxin-positive results reported a higher mean number of days of antibiotic exposure and 2 case-control studies reported no association.

Key question 5c: What is the significance of a positive *C. difficile* test in a NICU patient? The writing group reviewed studies for this key question to determine clinical manifestations (e.g., diarrhea, bloody stool, colitis, or an association with the presence of *C. difficile* toxin or *C. difficile* infection).

Of 3 studies that reported a clinical manifestation of diarrhea, 2 showed an association with a higher mean number of days with frequent and abnormal stools, but 1 of the studies was not statistically significant. Of 2 studies that reported a clinical manifestation of bloody stool, one study found no association and one study showed a higher mean number of days with heme-positive stools. The writing group's next steps will be to draft narrative summaries and recommendations for HICPAC's review and comment during the June 2012 meeting.

HICPAC advised the writing group to address bundled interventions for CLABSI in the NICU guideline by maintaining these interventions as a separate group and discussing the common elements of the bundles.

Update on CDC's HAI Prevention Activities in Dialysis Settings

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Dr. Patel covered the following topics in her update to HICPAC on CDC's HAI prevention activities in dialysis settings. At this time, >370,000 patients require hemodialysis maintenance

in the United States. Of ~5,300 outpatient dialysis facilities that provide these services, <20% are hospital-based, many have limited infection control resources or training, and most belong to one of 2 large for-profit chains.

Medicare is the primary payer for all dialysis care in the United States through the End Stage Renal Disease (ESRD) Program. Economic incentives are the major driver of all practices, procedures or products in dialysis facilities. The shared treatment setting in an open room creates unique challenges to infection prevention in dialysis facilities. Moreover, dialysis patients are hospitalized 1-2 times per year on average.
CDC released a *Vitalsigns*™ Report in March 2011 that described the CLABSI burden among dialysis patients. The report estimated that ~37,000 CLABSIs occurred in outpatient hemodialysis settings in 2008 and ~41,000 CLABSIs occurred in inpatient settings in 2009. The CDC Active Bacterial Core Surveillance System reported that dialysis patients accounted for 15% of all invasive MRSA infections and had an incidence of >100 times greater than in the general population. Hemodialysis patients also accounted for ~10% of hepatitis C virus (HCV) infections and had a prevalence of >5 times greater than in the general population.

CDC's key guideline for infection prevention in this patient population is its 2001 publication, *Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients*. The guideline included recommendations for heightened precautions that extended beyond standard precautions as well as recommendations for routine hepatitis B virus (HBV) and HCV screening (e.g., isolation of HBV patients).

CMS released new Conditions for Coverage for ESRD dialysis facilities to make infection control a separate condition for the first time and incorporate CDC recommendations. This guidance includes CDC's 2001 recommendations for preventing transmission of infections among chronic hemodialysis patients and CDC and HICPAC's 2002 guidelines for the prevention of intravascular catheter-related infections. Nearly all of CDC's 2001 recommendations are now a requirement for ESRD dialysis facilities, but CMS still does not require ESRD dialysis facilities to screen patients for HCV.

The HHS Action Plan to Prevent HAIs established "Tier 2 ESRD Prevention Priorities" to strengthen BSI prevention and improvement of general infection control practices and enhance knowledge among dialysis facility staff. CDC has led the Dialysis BSI Prevention Collaborative since 2009 and has extensively engaged multiple dialysis facilities and ESRD Networks in this collaborative effort. The original goal of this initiative was to demonstrate preventability of BSI in dialysis patients.

CDC used NHSN as the measurement tool and developed and widely distributed an intervention package based on CDC evidence-based recommendations that focused on catheter

maintenance practices. The original 17 dialysis facilities that participated in the collaborative achieved a 31% reduction in BSI. Dr. Patel presented a screen shot of an audit tool for providers to document their observations on catheter exit site care. The audit tools, intervention package, reports, protocols and other resources for the collaborative are publicly available at www.cdc.gov/dialysis/collaborative.

At the state level, 4 states received ACA funding to conduct HAI prevention activities in dialysis settings and 15 additional states currently conduct dialysis-specific HAI activities. In Colorado, 31 dialysis facilities are participating in a prevention collaborative focusing on hand hygiene improvement. In Oregon, 9 dialysis facilities are using the entire list of CDC's collaborative interventions.

CDC is aware of a number of barriers to HAI prevention in dialysis settings. For antimicrobial ointments, the 2011 CDC and HICPAC BSI guideline recommended the use of povidone iodine antiseptic ointment or bacitracin/gramicidin/polymyxin B ointment at the hemodialysis catheter exit site after catheter insertion and at the end of each dialysis session only if this ointment does not interact with the material of the hemodialysis catheter per manufacturer's recommendations (Category IB).

In addition to polysporin triple ointment being unavailable in the United States, catheter compatibility issues present additional barriers to implementing the BSI recommendation in dialysis facilities. Most hemodialysis catheters are made of polyurethane, but several chemicals are incompatible with this material.

For skin preparation, the BSI guideline recommended preparing clean skin with a >0.5% chlorhexidine preparation with alcohol before central venous catheter and peripheral arterial catheter insertion and during dressing changes. If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives (Category IA). Poor uptake is the major barrier to implementing this recommendation in dialysis centers (e.g., cost, lack of awareness and compatibility concerns).

Sodium hypochlorite solutions are commonly used in dialysis facilities as antiseptics, but these solutions are not addressed in the CDC guidelines. However, the manufacturers of some products state that their products comply with CDC guidelines and are compatible with all catheter materials on the market.

For environmental cleaning and disinfection, expectations and proper protocols for an open and shared treatment environment must be clearly articulated. For example, cleaning and disinfection should not be initiated until after the patient has left the treatment chair.

However, CMS has informed CDC that this guidance cannot be enforced in dialysis centers until CDC formalizes the language in a written guideline or recommendation.

CDC and various health departments conducted 21 investigations of healthcare-associated adverse events from 1999-2009. The 441 infectious and non-infectious events included severe adverse patient outcomes. Of these investigations, 33% involved HCV transmission and many were identified through screening of patients. Over this 10-year period, relatively few BSI outbreaks were investigated.

The major barrier to infection prevention and response in dialysis centers is CMS's decision to not reimburse for HCV screening and exclude HCV screening from Conditions for Coverage. Many dialysis providers believe that CDC no longer recommends HCV screening. To make improvements in this area, CDC/HICPAC should release a new recommendation or reissue previous guidance.

CDC incorporated a dialysis event surveillance module into NHSN to focus on BSI and access-related BSI. The module is designed for use by dialysis center personnel rather than IPs and includes simplified surveillance definitions. For example, the meaning of "BSI" is equivalent to a "positive blood culture." The National Quality Forum (NQF) endorsed the NHSN BSI measure in August 2011.

Reporting mandates and incentives recently went into effect to increase participation in NHSN among dialysis facilities. Colorado became the first state to mandate dialysis facility reporting to NHSN in the spring of 2010. In November 2011, CMS released its ESRD Quality Incentive Program (QIP) Rule to provide incentives to facilities to enroll in and report data to NHSN during 2012.

The CMS QIP Rule has resulted in several states passing legislation related to dialysis event reporting. Because nearly all dialysis centers in the country most likely will enroll in NHSN to receive full CMS reimbursement, CDC is making efforts to enable dialysis event surveillance data to be electronically imported by August 2012. At this time, ~1,100 dialysis facilities are enrolled in NHSN.

The Tennessee Emerging Infections Program site and a medium-sized dialysis chain are conducting surveillance of BSI in dialysis settings. The aims of the project are three-fold: (1) evaluate the feasibility of using electronic health record data systems for BSI surveillance in hemodialysis settings; (2) assess the validity of electronic BSI measures against a "gold standard" definition; and (3) inform efforts targeted to electronic reporting to NHSN.

CDC is aware that improvements must be made in several areas to advance HAI prevention activities in dialysis settings. CDC's 2001 dialysis recommendations should be updated with new evidence. New language should be added to specifically address CMS's requirements and request for written clarification from CDC.

Recommendations that are specific to hemodialysis patients or settings should be consolidated (e.g., issues related to catheters, tuberculosis and immunization). CDC's infection prevention recommendations for dialysis facilities should be aligned with those developed by professional societies (e.g., the National Kidney Foundation). Surveillance capacity should be strengthened to improve validation of data that are submitted in both manual and electronic formats.

Gaps in existing recommendations for dialysis facilities should be addressed and resolved with updated guidance from CDC. The major gaps in the BSI prevention recommendations fall into 3 major areas: (1) sodium hypochlorite solutions used for both skin antisepsis and catheter disinfection; (2) catheter maintenance practices (e.g., scrubbing of the hub, tissue plasminogen activator (TPA) catheter locking solution, and closed needle-less connector devices); and (3) arteriovenous fistula and graft practices for skin antisepsis and cannulation methods.

CDC recognizes the need to address other gaps in recommendations for dialysis facilities: (1) screening and isolation precautions for HCV infection prevention; (2) environmental cleaning and disinfection; (3) prevention of peritoneal dialysis catheter infections; and (4) contact precautions. CDC's 2001 dialysis guidelines stated that infection control precautions for all hemodialysis patients were adequate to prevent transmission for most patients who were infected or colonized with pathogenic bacteria, including antimicrobial-resistant strains. However, this recommendation was not fully evidence-based at the time and should be revisited.

In response to HICPAC's specific question, Dr. Patel provided details on activities that are underway to accurately attribute and report the source of infections to dialysis patients (e.g., outpatient or hospital setting).

HICPAC made several comments and suggestions for CDC to consider in refining its HAI prevention activities in dialysis settings.

- CDC should incorporate language on TPA catheter locking solutions into its guidelines for dialysis facilities. Most notably, TPA lock therapy increasingly is being used for prophylaxis.
- CDC should emphasize safe injection practices and clearly articulate the nuances and intricacies of dialysis machines to promote its guidance on environmental cleaning and disinfection in these settings.

- CDC should develop a new guideline to specifically focus on the open and shared design of dialysis facilities; describe human factors that serve as barriers to hand hygiene; and provide general recommendations on IPC measures in these settings.

Overview of the 2010 National HAI Standardized Infection Ratio (SIR) Report

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Mr. Malpiedi presented an overview of the 2010 National and State HAI Summary Reports. The overarching purpose of the summary reports is to enable CDC to evaluate its progress by using summary statistics at national and state levels. The number of states that are mandating the use of NHSN to report HAIs is continuing to increase. CDC awarded $50 million in ARRA funds to help states build capacity in conducting HAI prevention activities. The HHS Action Plan to Prevent HAIs uses NHSN measures as its targets.

The summary reports also allow states without mandatory NHSN reporting requirements to gain insight into the status of NHSN HAI reporting despite their lack of direct access to these data. CDC quickly makes the summary data publicly available to policymakers, consumers and researchers in an understandable format.

CDC published the first state-specific HAI summary report in 2010 based on NHSN data from January-June 2009. The report described NHSN participation of all states that reported CLABSI rates, provided national data for CLABSI overall, and summarized state-specific CLABSI data for the 17 states with mandatory NHSN reporting requirements.

CDC published the first national HAI SIR report in 2010 based on NHSN data from July 2009-December 2009. The report described NHSN participation of all states that reported CLABSI and SSI rates; provided national data for CLABSI overall as well as data for LTACHs and NICUs; summarized national data for SSI (e.g., deep incisional and organ/space infections detected upon admission or readmission) following NHSN procedure categories approximating Surgical Care Improvement Project (SCIP) procedures; outlined state-specific CLABSI data for the 18 states with mandatory NHSN reporting requirements; and made serial comparisons for national and state-specific data reported to measure progress from the first to second half of 2009. Both reports are available at www.cdc.gov/hai.

The SIR compares the observed number of HAIs in a facility or state with the HAI experience of a standard population (e.g., the U.S. baseline in NHSN). The SIR adjusts for several risk factors

that may affect infection rates. These risk factors include (1) the mix of patients (e.g., type of patient care location, teaching status of the facility, and size of patient care location, such as a teaching hospital or medical/surgical ICU with <15 beds); (2) device utilization at the individual unit level; and (3) NHSN surgical risk models with parameters that vary by procedure based on the 2011 Mu, *et al.* study.

The SIR can be calculated at the local level and aggregated up to a state or national level with a predicted number of infections based on exposure, device use or surgical procedures. For the 2010 summary report, the observed number of HAIs will be used as the numerator based on 2010 NHSN data that were stopped in October 2011 to allow for the lag in reporting time.

The expected or predicted number of HAIs will be used as the denominator based on baseline data from the standard population. CLABSI will be calculated using data from the 2006-2008 NHSN annual report. Catheter-associated urinary tract infections (CAUTI) will be calculated using data from the 2009 NHSN annual report with a change in the definition that was implemented in 2009. SSI will be calculated from procedure-specific risk models using procedures entered into NHSN during 2006-2008.

If the SIR does not significantly differ from 1.0, the number of events the reporting entity (e.g., a state or healthcare facility) observed is no different than if its experience had been the same as that of the standard population. If the SIR is significantly higher or lower than 1.0., the reporting entity has a higher or lower than expected number of events than predicted given the experience of the standard population. For example, an SIR of 1.2 would be interpreted as 20% more HAIs occurred than were expected. An SIR of 0.80 would be interpreted as 20% fewer HAIs occurred than were expected.

The major features of the 2010 National and State-Specific HAI SIR Report are highlighted as follows. The report will include data for a full calendar year rather than for 6 months. CLABSI, SSI and CAUTI summary statistics will be reported. State-specific infection data will be produced using the SIR. The national publication will be limited to CLABSI, but other state-specific data will be shared with state health departments.

Location-specific CLABSI SIRs will be reported for ICUs only, non-critical care areas only and NICUs only. CLABSI SIRs will be reported for all states regardless of whether the state has a mandatory NHSN reporting requirement. SSI SIRs will be reported for procedures that approximate each of the 10 SCIP procedures.

Mr. Malpiedi presented a series of tables and appendices that will be included in the 2010 SIR report. Table 1 (national data) will provide demographic information (e.g., HAI types by year,

number of facilities, percent of possible data submitted to NHSN, the number of reporting locations, and the number of procedures reported).

Table 2 (national data) will describe national SIRs and percentiles for device-associated infections by location group and SSI by group. For CLABSI/CAUTI data eligibility, all acute care locations that reported data to NHSN will be included, but LTCFs and inpatient/outpatient dialysis facilities will be excluded. The specific locations will include critical care units, NICUs, and "wards-plus" (e.g., non-critical care units, LTAC locations, specialty care areas and step-down locations). CAUTI data will not be reported for NICUs.

For SSI data eligibility, 10 procedure categories approximating the SCIP procedures will be included. Overall and category-specific SIRs will be reported. Depending on the procedure category, ~20%-40% of superficial and post-discharge SSIs reported to NHSN will be eliminated due to the use of complex admission/readmission SSIs. For analytical conventions, state-specific SIRs will only be published if at least 5 facilities reported data to the state for a given location group. Facility-specific SIRs will be utilized in percentile distributions, but robust SIRs will be required. For example, at least 1 expected infection must have occurred. State-specific SIR percentile distributions will be calculated only if the state had $\geq$20 facilities with robust SIRs.

Table 3 (state-specific data) will report CLABSI data by location group. CDC shared shells of the tables with a CSTE in October 2011 to obtain feedback. CSTE advised CDC to publish location-specific SIRs for all states rather than for the overall CLABSI SIR alone and stratify the state-specific ICU CLABSI table between states that do and do not have mandatory NHSN reporting requirements.

Table 4 (national data) and Table 5 (state-specific data) will compare changes in the 2009 and 2010 HAI SIRs for all reporting hospitals and continuous reporters only. In Table 4, "continuous reporters" will be defined as at least one location in a facility that reported CLABSI data for at least one month in both 2009 and 2010. Appendix A will describe procedure-specific risk models for both SCIP and NHSN procedures as well as validated parameters for the risk model. State-specific CAUTI and SSI data and the SIRs for these two infections will not be publicly released in the summary report, but state health departments will have access to this information for situational awareness.

CDC has been extensively communicating with states and other partners in developing the 2010 National HAI SIR Report. In addition to its discussions with CSTE in October 2011, CDC also administered a survey to all state health departments in December 2011 regarding 2010 public reporting mandates and validation of 2010 data. In January 2012, CDC disseminated both national and state-specific SIR packets to state partners for review.

The state-specific tables for CLABSI, CAUTI and SSI were randomized and de-identified, but each state received a letter code to identify their individual data during the preview period. CDC shared the data with state HAI coordinators for broader distribution to state epidemiologists and other health department staff as needed. The DHQP Communications Team convened a conference call with state health department communications groups in January 2012. CDC expects to post the 2010 National HAI SIR Report on its website in late February 2012 and plans to release future reports on an annual basis with additional SIR metrics.

HICPAC advised CDC to update the outdated SIR benchmarks to reflect recent and significant improvements in HAI, particularly advancements made in CLABSI rates. HICPAC further advised CDC to explore the possibility of publicly releasing the survey that was administered to all state health departments regarding public reporting mandates and validation of data.

Update on the NHSN HAI Antimicrobial Resistance Report

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Dr. Sievert covered the following topics in her update to HICPAC on the NHSN HAI Antimicrobial Resistance (AR) Report. NHSN includes three sources of AR data. Device- and Procedure-Associated Modules are used to report data on CLABSI, CAUTI, SSI and ventilator-associated pneumonia (VAP), associated pathogens and susceptibility results. Almost all HAIs reported to NHSN through these modules require pathogen and susceptibility information.

The MDRO/CDI Module is used for infection surveillance or LabID Event reporting, 6 NHSN-defined MDROs and *C. difficile*. The new Antimicrobial Use and Resistance Module is used to report aggregate antibiogram data by patient-care location. Electronic reporting via a CDA platform will be available by the summer of 2013.

CDC published the first NHSN HAI AR Report in *Infection Control and Hospital Epidemiology* in November 2008. CLABSI, CAUTI, SSI and VAP data were analyzed from January 2006-October 2007. Data were included from adult, pediatric and neonatal ICUs, specialty care areas and inpatient wards.

The report described the percent resistance among the most common pathogens reported. HAI rates were reported for select antimicrobial-resistant pathogens. Special analytical considerations in the report included an evaluation of the influence of specific resistance reporting from certain regions and a review of data entry errors of unlikely phenotypes.

CDC will publish the second NHSN HAI AR Report in the summer of 2012. CLABSI, CAUTI, SSI and VAP data will be analyzed from 2009-2010 and compared to the 2007-2008 data. Data will be included from adult, pediatric and neonatal ICUs, specialty care areas and inpatient wards. The report will describe the percent resistance for select antimicrobial-resistant pathogens reported in 2009-2010, including multidrug-resistant definitions.

Significant changes in resistance between 2007-2008 and 2009-2010 will be identified. The proportion of facilities with resistant pathogens by pathogen-antimicrobial combination and HAI type will be presented in the report. Special analytical considerations in the report will include an evaluation of the impact of changes in the data by facility bed size, all reporters versus continuous reporters, and ICU versus non-ICU settings.

For the second AR report, CDC pooled data across all NHSN hospitals and calculated the total number of pathogen types reported, the total number of those tested, and the total of those that were resistant to specific drugs or classes. A log-binomial regression model was used to test whether changes in resistance percent point estimates were statistically significant between the two time periods at $p < 0.05$.

Dr. Sievert presented a series of tables and appendices that will be included in the second AR report. Table 1 will describe the characteristics of hospitals that reported HAIs to NHSN from 2007-2010. The table will show that the number of reporting hospitals increased between the two time periods of 2007-2008 and 2009-2010 within all bed size categories, but the proportional increase occurred among hospitals in the <200-bed category.

Table 2 will describe the types of HAIs reported to NHSN from 2007-2010. The table will show that although the number of HAIs reported by type increased between the two time periods of 2007-2008 and 2009-2009, the proportions by HAI type remained very similar. Table 5 will rank the distribution of selected pathogens associated with HAIs reported to NHSN overall in the two time periods of 2007-2008 and 2009-2010.

Table 9 will describe the percent pathogenic isolates resistant to selected antimicrobial agents reported to NHSN by location of patients. The table will show that the proportion of HAIs reported by non-ICU location types increased between the two time periods. As a result, CDC conducted additional analyses to ensure that significant changes were consistent between both settings.

A series of 4 separate tables will describe changes in the percent resistance among pathogens associated with CLABSI, CAUTI, SSI and VAP reported to NHSN from both critical care and non-

critical care locations for the two time periods of 2007-2008 and 2009-2010. A graph will be included in the table to show the number of facilities that reported resistant pathogens.

Overall, CDC's analyses of the NHSN HAI AR data from 2009-2010 indicate (1) significant decreases in resistance for a few specific pathogens (e.g., MRSA, VAP and SSI); (2) significant increases in resistance for a few specific pathogens (e.g., *Escherichia coli*, CLABSI and CAUTI); and (3) inconsistent changes in resistance across all HAI types. All of the results and findings will be presented in detail in the published report.

In response to HICPAC's specific questions, Dr. Sievert provided additional details on the second NHSN HAI AR Report. The discussion topics included:

- the rationale for coagulase-negative *Staphylococcus* being ranked as the number 1 pathogen in 2007-2008 and the number 4 pathogen in 2009-2010; and
- potential "false impressions" of the proportion of hospitals that reported *S. aureus*, but did not report MRSA.

HICPAC advised CDC to use device-day denominator data to examine trends in infections due to certain organisms (e.g., MRSA) for some of the major AR phenotypes.

Update by the HICPAC HAI Surveillance Workgroup: NHSN CLABSI Definition

Scott Fridkin, MD
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Dr. Fridkin covered the following topics in his update on recent activities by the HICPAC HAI Surveillance Workgroup on the NHSN CLABSI definition. The CLABSI definition will be changed in NHSN in an effort to increase its credibility among the clinical community while maintaining reliability for public reporting purposes. The workgroup is charged with articulating the implications of these changes.

The workgroup developed a process with several strategies to evaluate the risks and benefits of potential changes to NHSN definitions. Monthly teleconferences are held and the NHSN technical and clinical support staff provides input. The published literature and meeting abstracts that highlight issues related to NHSN surveillance definitions and methodologies are peer reviewed. Examples of concerns expressed by NHSN users are illustrated and potential solutions to these problems are proposed. Outreach is targeted to experts on the workgroup and other partners with access to data and evaluation infrastructures for primary assessments.

The workgroup proposed approaches for HICPAC to consider in 3 major areas to modify the CLABSI definition. **For issue 1**, the workgroup suggested not to change the NHSN protocol with respect to contaminants.

For issue 2, the workgroup proposed modifying the BSI definition for a subset of patients to address translocation of bacteria or yeast across the intestinal mucosa. "Translocation laboratory-confirmed bloodstream infection" (T-LCBI) was proposed as a new HAI event. However, some workgroup members objected to the use of "translocation" because no diagnostic test currently exists for this mechanism. Moreover, the actual role of translocation as the causal mechanism for these BSIs is unknown.

The workgroup proposed to replace T-LCBI with "mucosal barrier injury LCBI" (MBI-LCBI) because this term is used in the cancer literature and is more descriptive of the scenario targeted for the definition. The previous criteria to identify eligible patient populations are outlined below.

For bone marrow transplant (BMT) recipients with graft-versus-host disease (GVHD), the patient must be a BMT recipient and have documentation of acute GVHD affecting the GI tract within 7 days of a positive blood culture or have documentation of chronic GVHD manifested by oral or GI symptoms during the 3 months prior to positive blood culture. For patients with hematologic malignancy and neutropenia, the patient must have documentation of hematologic malignancy and at least 1 value of an absolute neutrophil count (ANC) $\leq$500 cells/mm^3 or a white blood cell (WBC) count $\leq$500 cells/mm^3 documented within 7 days of a positive blood culture.

The workgroup revisited concerns that were raised regarding the GVHD criteria. The proposed requirement for documentation of GVHD affecting the GI tract most likely would be highly subjective and variable across facilities. Sole reliance on the index hospitalization record would be the ideal approach. Feedback from 2 field testing sites indicated that grading of acute GVHD is not uniformly documented in the medical chart, but criteria used to determine an acute GVHD grade were available.

The workgroup agreed that biopsy-proven GVHD could not be required due to inherent variability in the practice of obtaining biopsies. The workgroup also agreed that efforts to distinguish between acute and chronic GVHD would not be necessary. The workgroup emphasized the need to consider simplicity in implementation.

The workgroup revisited concerns that were raised regarding the neutropenia criteria. A single day of neutropenia (e.g., ANC ≤500) may not be restrictive enough, while the limitation to hematologic malignancy may be too restrictive. The workgroup's cancer partners expressed a strong desire to link the receipt of chemotherapy to neutropenia. Due to the need to consider simplicity in implementation, the workgroup's position was that the inclusion of chemotherapy-induced language in an assessment for wide use would be unrealistic. The ideal approach would be to solely rely on laboratory tests and values.

Based on these discussions, the workgroup proposed the following changes to the draft criteria to identify eligible patient populations for MBI-LCBI. For BMT recipients with GVHD, the patient must be an allogeneic BMT recipient in the past year and have documentation in the index hospitalization record of either Grade III or IV GI GVHD or at least 1 liter of diarrhea in a 24-hour period of a positive blood culture (≥30 mL/kg in a 24-hour period for pediatric patients). For patients with profound neutropenia, the patient must have a value of ANC or total WBC <500 cells/mm^3 of at least 7 days in duration or a single value of <100 cells/mm^3 as an equivalent.

CDC plans to field test the MBI-LCBI definition in March-May 2012 to evaluate the availability of discrete data elements, assess the feasibility of implementation, and make gross estimates of the impact on established CLABSI rates. To conduct the field test, CDC will collaborate with 10 cancer hospitals to estimate 50-100 episodes in a 2-month period; 20 NHSN facilities that report data from hematology/oncology locations; and 20-30 other NHSN facilities. CDC will share drafts of the MBI-LCBI definition with other partners for specialized evaluation, research and formal assessments.

At the June 2012 HICPAC meeting the proposed changes will be presented to HICPAC for their input. Following input from HICPAC, CDC will develop a summary document to prepare for changes to NHSN in 2013; finalize the definition and forms; begin implementation of the changes to NHSN by modifying the protocol, providing training and modifying applications; and hold dedicated sessions during ID Week.

For issue 3, the workgroup proposed changes to the NSHN criteria and operations to reduce subjectivity in the interpretation and application of surveillance definitions and criteria. The workgroup extensively discussed the use of a 30-day period to classify continuation of an event from a new event. Agreement was reached to use a 14-day period to classify a duplicate event from a new event that should be reported to NHSN.

The workgroup anticipates that the proposed change will not always accurately classify all events. However, the guidance will reduce subjectivity in the classification of new versus duplicate events and improve reliability of reporting to enhance inter-facility comparisons. The workgroup's rationale for proposing the change is that given the range of organisms and

infections under consideration, a 30-day rule may lump serial events into a single event more often than a 14-day rule.

The course of treatment of most HAIs typically is to sterilize the blood or culture site by day 4. The 14-day rule will be consistent with the MDRO LabID Event in NHSN. However, the workgroup is aware of the need to address inconsistencies with the CLABSI algorithm and other CDC infection surveillance systems (e.g., EIP).

Update by the HICPAC HAI Surveillance Workgroup: NHSN SSI Definition

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Dr. Fagan covered the following topics in his update on recent activities by the HICPAC HAI Surveillance Workgroup on the NHSN SSI definition. Representatives from HICPAC and several professional societies serve on the workgroup to provide expertise in surgical practice and SSI surveillance. The workgroup primarily has focused on 3 major issues since the November 2011 HICPAC meeting.

Issue 1: The NHSN definition of an "operative procedure" might be too restrictive because surgeries under surveillance are limited to those with primary closure of the surgical incision. The workgroup proposed to remove the requirement for primary closure of the surgical incision from the NHSN definition of an operative procedure. This change will broaden SSI surveillance to include surgeries that are not primarily closed, including incisions with drains, wound vacs, open wounds, and wounds closed only to the level of deep fascia. This change will not affect eligible procedure types based on ICD-9 or CPT codes.

None of the workgroup members strongly opposed the proposed changes, but anticipated consequences were noted. In terms of pros, the new definition will be more accurate for changing surgical practices based on a perceived trend toward increased use of non-primary closure techniques. Moreover, the new definition is more patient- and disease-oriented, eliminates ambiguity about specific procedures to track, and prevents "gaming" via selection of the closure technique.

In terms of cons, the new definition potentially could increase the surveillance burden depending on whether the number of surgeries to track increases. The change will require an evaluation of other changes throughout the *SSI Event Manual*, including the level of information to collect about closure techniques and the need to revise the definition of

"operative duration" because the current end time for a surgical procedure is the time of incisional closure.

Issue 2: If the primary closure restriction is removed, then the appropriate level of information to collect about incisional closure techniques will need to be defined. The workgroup proposed 4 solutions to address this issue. Solution 1 would be to not collect information about the type of closure. In terms of pros, this approach is simple and the least burdensome based on the perception that information about incision closure techniques is only available through a manual review of the operative report. In terms of cons, the perception in many scenarios is that the incisional closure technique reflects the level of a patient's SSI risk.

Solution 2 would be a 2-tiered approach of closed primarily (e.g., closure of all tissue levels without or without extrusions, such as drains and wicks, through the incision) and not closed primarily (e.g., closed to the level of deep fascia only or not closed at all). In terms of pros, this approach is relatively simple and could improve SSI risk adjustment. This assessment of primary closure is already being performed in theory through NHSN SSI surveillance. In terms of cons, this approach might be labor-intensive. No data have been produced to support the specific level of closure information that is needed. In some facilities, information regarding closure technique is not being confirmed in practice.

Solution 3 would be a 3-tiered approach of closed primarily (e.g., closure of all tissue levels with or without extrusions through the incision), closed deep (e.g., closed deep fascia, but open skin and subcutaneous tissue), and open (e.g., not closed at all). Solution 4 would be a 4-tiered approach of closed primarily (e.g., closure of all tissue levels without extrusions through the incision), near primary (e.g., closure of all tissue levels with extrusions through the incision), closed deep (e.g., closed deep fascia, but open skin and subcutaneous tissue), and open (e.g., not closed at all).

In terms of pros for solutions 3 and 4, these approaches might provide different risk or wound care SSI prevention measures based on different levels of non-primary closure, including extrusions (e.g., drains and wicks). Moreover, solution 3 would mirror the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) and allow for easier comparison of data across facilities. In terms of cons for solutions 3 and 4, these approaches would be highly burdensome. Efforts to collect data potentially would be unfeasible. Available data about SSI risk do not support these approaches.

Overall, the benefits of additional data on closure techniques are not clearly defined. The proposal to collect no information and the 2-tiered approach are both justifiable, while the 3- and 4-tiered approaches are problematic. Operational aspects to guide the workgroup's

decisions need to be considered. If the 3-tiered approach is supported by the NSQIP experience, a revision to the NHSN SSI definition should be considered for 2013.

Issue 3: The NHSN definition of an "operative procedure" might be too restrictive because surgeries under surveillance are limited to those that occur in an OR. NHSN defines an "operating room" as a patient care area that met the Facilities Guidelines Institute's or American Institute of Architects' criteria for an OR when it was constructed or renovated.

This definition may include an OR, Caesarian-section room, cardiac catheterization laboratory or interventional radiology room. Examples of other patient care areas where surgeries may occur include procedure suites, ICUs, other inpatient bed locations and clinic offices.

The workgroup's proposed solution was to not expand NHSN SSI surveillance to non-OR environments at this time. In terms of pros, non-OR records are not standardized or captured by OR record systems. These systems typically are missing data for risk adjustment and require manual chart review. The approach maintains simplicity. No data have been produced to support the importance of tracking surgeries outside of the OR. The perception is that the majority of procedures outside of the OR are minor and would not impact quality measurement indicators.

In terms of cons, the approach would be less patient- and diagnosis-oriented. SSIs in required procedure categories might be missed. This approach may not be reflective of surgical performance at the facility level and may drive surgeons to operate in non-OR environments.

Overall, the workgroup was divided on whether to limit surveillance to the OR. On the one hand, documentation in non-OR areas is incomplete or of poor quality. Data are lacking to support the importance of expanding NHSN surveillance into non-OR patient care areas. On the other hand, the restrictive nature of the current NHSN definition does not reflect the intent of quality reporting metrics to track surgeries at the facility level. A potential compromise to this dilemma could be to collect non-OR surgery data for a limited number of procedure types or facilities.

The workgroup will focus on 3 additional issues during its upcoming discussions. Issue 1 is the NHSN definition of an "implant." Implant is a required field on the SSI denominator form. When an implant is present, surveillance for SSI is required for 1 year after the index surgery. NHSN users are instructed to check yes if a nonhuman-derived object, material or tissue was permanently paced in a patient. Examples of an implant include porcine or synthetic heart valves, mechanical hearts, metal rods, sternal wires, screws, internal staples, hemoclips and other devices.

Concerns have been raised that the NHSN definition of an implant is overly-broad because not all types of implants carry the same SSI risk. Moreover, the definition has been found to be too common for some procedures because nearly all patients could have an implant based on the current definition. Documentation of implants in medical charts may be inconsistent.

Issue 2 is the NHSN definition of an "endoscope." Endoscope is a required field on the SSI denominator form and is used as a predictor of SSI risk for certain procedure types. NHSN users are instructed to check yes if the entire operative procedure was performed using an endoscope, laparoscope or robotic assistance. NHSN users are instructed to check no if the endoscope incision was extended to allow for hand assistance or was fully converted to an open approach.

The workgroup will provide input on the current NHSN guidance. Enlargement of an incision mid-surgery or at the end of the procedure currently is classified as an "open" approach. Hand assistance for endoscopic procedures currently is classified as an "open" approach. Robotic surgeries currently are classified as "endoscopic" procedures.

Issue 3 is post-discharge surveillance issues regarding the lack of standardization or validation. The current NHSN SSI protocol stipulates that any combination of the following 4 methods is acceptable: (1) direct examination of the patient's wounds during follow-up visits to either surgery clinics or physician offices; (2) review of medical records or surgery clinic patient records; (3) surgeon surveys by mail or telephone; and (4) patient surveys by mail or telephone, but patients may be challenged by self-assessing their infections.

Concerns have been raised about post-discharge surveillance overall. Better information is needed about best practices in this area. Facilities should report and validate the specific method that is in use. Application of the same standard to all facilities would be the ideal approach.

In response to HICPAC's specific questions, Drs. Fridkin and Fagan provided additional details on the modified NHSN CLABSI and SSI definitions. The discussion topics included:

- approaches to categorize delayed sternal closures in pediatric populations;
- efforts to track newborns and young children who have operations outside the traditional OR;
- the potential of using NSQIP data to determine whether closure type is an independent risk factor for SSI; and
- the possibility of harmonizing CDC SSI surveillance data (e.g., the annual SIR report) and CMS SSI surveillance data (e.g., Hospital Compare).

Several HICPAC members emphasized the need for CDC to implement high-quality surveillance over a shorter and defined period of time by SSI procedure type instead of attempting to collect data in one-year intervals.

Update by the VAP Surveillance

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Dr. Magill covered the following topics in her update on the recent activities to refine the NHSN definitions for VAP surveillance in adult patients. CDC has been conducting surveillance of VAP since the 1970s. CDC published new NNIS surveillance definitions for pneumonia in 1988 and implemented a new NNIS pneumonia definition in 2002 that required a chest x-ray (CXR). CDC published new NHSN HAI surveillance definitions in 2008 with no changes to the pneumonia definitions and initiated the process to review and modify these definitions in 2009. The number of participating facilities dramatically increased from ~320 NNIS hospitals to >5,000 NHSN healthcare facilities.

The NHSN pneumonia definitions include a combination of CXR, signs/symptoms and laboratory criteria. Chest imaging findings and signs/symptoms of pneumonia are required. Laboratory evidence is not required, but available laboratory data from an acceptable specimen type should be used to report pneumonia to NHSN. NSHN maintains data on three specific sets of pneumonia criteria: critically-defined pneumonia (PNU1), pneumonia with laboratory findings (PNU2), and pneumonia in immunocompromised patients (PNU3). All three sets of criteria can be used in patients at any age, but special PNU1 criteria also can be used in infants in children.

"VAP" is not a distinct definition in NHSN at this time. Instead, VAP is a pneumonia event in NHSN that meets the ventilator-associated criterion. The endotracheal tube/ventilator must have been in place at some time during the 48 hours preceding the onset of pneumonia. NHSN

does not require an amount of time that the endotracheal tube/ventilator must been in place for pneumonia to count as VAP.

Since CDC published the new pneumonia definition in 2002, VAP incidence rates have significantly decreased in medical, major medical/surgical, other medical/surgical and surgical units. The decline in VAP incidence rates in part can be attributed to implementation of prevention strategies, publication of several prevention guidelines, and use of the prevention bundle approach. Other considerations include the increased burden on IPs and the current use of definitions for benchmarking and public reporting that were originally developed for internal quality improvement purposes. These definitions potentially could be manipulated if compensation and the reputations of healthcare facilities are linked to VAP rates.

The recently published Klompas study highlighted 8 initiatives that misleadingly could result in lower VAP rates (e.g., strict interpretation of clinical signs, strict interpretation of chest imaging criteria, a consensus approach to VAP determinations, requirement for critical care physicians to approve cases in a facility, transfer of patients who need prolonged mechanical ventilation, and admission of uncomplicated vented postoperative patients to ICUs).

CDC acknowledges several limitations in the current NHSN pneumonia definitions. Multiple definition pathways increase the complexity and data collection burden. Signs and symptoms are subjective and may not be well documented in medical records. CXRs are required NHSN components, but are outside the scope of IP expertise. Input from radiologists, critical care or other physicians varies among facilities. Variations in diagnostic practices influence whether pneumonia events are detected and reported.

To address these issues, CDC is focusing on the development of an objective, streamlined and reliable surveillance definition that has clinical credibility and the potential to be automated. CDC's goals for modifying the current NHSN definitions are to achieve face validity and critical credibility, improve reliability and reduce the data reporting burden.

To date, CDC has developed and evaluated a draft streamlined VAP (sVAP) definition in collaboration with CDC Prevention Epicenters investigators. Feedback was obtained during HHS-sponsored meetings and an Epicenters proposal was recently funded to evaluate the feasibility and preventability of sVAP. A VAP Surveillance Definition Workgroup (non-HICPAC workgroup) was convened in partnership with the Critical Care Societies Collaborative and representatives from other professional societies and organizations.

The initial draft sVAP definition eliminated the chest imaging requirement, included required minimum time on a ventilator of $\geq$4 calendar days, and incorporated objective criteria (e.g., respiratory deterioration based on changes in positive end-expiratory pressure or FiO_2 and

general signs of infection or inflammation defined by abnormal temperature, WBC or purulent respiratory secretions).

Initial evaluations showed that sVAP surveillance appeared to take less time than the current NHSN VAP surveillance, but the sVAP and NHSN VAP definitions had poor agreement. Not all VAP events met the sVAP definition and sVAP detected more events than VAP in some analyses. The clinical relevance of sVAP was found to be comparable to NHSN VAP in terms of length of stay and mortality. However, further evaluation is needed to modify the sVAP definition for pediatric and neonatal populations.

CDC obtained feedback from several experts in the following areas. Retention of chest imaging criteria and incorporation of microbiological criteria into a modified VAP definition were considered to be important despite significant intra-facility and inter-facility variability. The experts found that sVAP departed from current practice. The need for an infection measure was emphasized rather than a severity of illness measure to achieve face validity and clinical credibility. Demonstration of the preventability of events detected by any new surveillance definition was considered to be critical. CDC expects its Prevention Epicenters sVAP Project to address these issues.

The workgroup (non-HICPAC workgroup) includes representation by federal partners and a host of professional societies. The objectives of the workgroup are three-fold: (1) critically review CDC's draft streamlined sVAP surveillance definition for use in adult patients; (2) suggest modifications to enhance the reliability and credibility of the definition within the critical care community; and (3) propose an adult definition algorithm for implementation in NHSN for the purposes of public reporting, inter-facility comparisons, and federal pay-for-reporting and performance programs.

The workgroup has convened a face-to-face meeting and held multiple teleconferences since September 2011. To date, the workgroup has revised the definition algorithm for "ventilator-associated events" (VAE) with a 2-tiered approach. Public reporting definitions will include objective, general measures of ventilator-associated complications and infection-related events. Internal use definitions will include possible and probable VAP events. The workgroup also identified important research agenda items (e.g., a mechanism for ICU-level risk adjustment or stratification to account for differences in severity of illness and the best approach to collect denominator data).

Dr. Magill described the key components of the VAE definition algorithm
The workgroup has submitted the VAC and IVAC proposed measures to NQF for review. A number of workgroup members have communicated with the executive committees of their respective professional societies to explain the background, rationale and details of the new

VAE algorithm. CDC will present the new VAE algorithm during upcoming meetings of these organizations and engage other stakeholders in dialogue as well. The process to convene new Pediatric and Neonatal Workgroups is underway.

Evaluation will be continued on the preventability, feasibility and inter-rater reliability of the VAE algorithm. The research agenda items will continue to be a key topic of discussion for the workgroup. In preparation of implementing the VAE algorithm in NHSN in January 2013, CDC will develop a protocol, training materials and operational guidance and also will modify the application.

In response to HICPAC's specific questions, Dr. Magill provided additional details on the modified NHSN VAP surveillance definitions. The discussion topics included:

- the exclusion of patients who receive ventilation therapies from VAE surveillance at the time surveillance occurs;
- the possibility of removing ventilator days that are not at risk when reporting denominator days; and
- the pros and cons of the IVAC requirements in terms of the duration of antimicrobial therapy;

HICPAC advised CDC to reference data from a recently published multi-center evaluation in the VAP surveillance definitions. The data showed a strong association between VAC and mortality and virtually no relationship between VAP and mortality.

Prioritization of CDC Guidelines and Recommendations

Neil Fishman, MD, HICPAC Chair
Associate Chief Medical Officer
University of Pennsylvania Health System

Dr. Fishman reminded HICPAC that during the November 2011 meeting, numerous suggestions were made to revise existing guidelines and/or develop new guidelines. Since that time, the initial extensive list has been shortened based on input from HICPAC. The purpose for this agenda item would be for HICPAC to rank the next series of guidelines in order of priority based.

At this time, CDC is continuing to further develop and finalize the NICU Infection Prevention Guideline and SSI Prevention Guideline (both core and arthroplasty sections). Due to CDC's

budget constraints, however, further development of the HCP Infection Prevention and Control Guideline is on hold at this time.

Dr. Fishman reviewed the list of topics that have been proposed for the next series of CDC guidelines.

1. Environmental guidelines with respect to the effectiveness and reliability of newer techniques reported in the literature (e.g., fogging, ultraviolet irradiation, and ozone mist to reduce environmental contamination of *C. difficile* and other resistant pathogens).
2. MDRO with site-specific recommendations (e.g., dialysis facilities, LTCFs and LTACHs) as well as MDRO in the context of discontinuation of precautions.
3. SSI modules other than arthroplasty (e.g., abdominal hysterectomy and colon surgery, particularly since reporting of these procedures to CMS began on January 1, 2012).
4. Disinfection/sterilization, particularly to focus on immediate-use/flash sterilization, define the circumstances and frequency of this technique, and define and clearly articulate "immediate-use sterilization."
5. Definition of the VAC or IVAC bundle and/or development of guidance on prevention of hospital-acquired pneumonia in general to expand the focus beyond ventilator-associated conditions.
6. Hand hygiene issues in the context of product selection (e.g., soap/water versus alcohol-based hand sanitizers, indications of specific products to use before and after glove use, and indications of product use when caring for patients in non-outbreak settings with specific pathogens, such as norovirus and *C. difficile*).
7. BSI in dialysis settings or other special settings.
8. Clarification on the current recommendation regarding the need to change needleless connectors after infusing blood, blood products or lipids. The current guidelines state that infusion sets should be changed after infusing blood, blood products or fat emulsions within 24 hours. However, a separate recommendation states that needleless connectors should be changed as often as administrative sets are changed.

In response to Dr. Fishman's request, the HICPAC liaison representatives described ongoing or planned activities of their respective professional societies. Dr. Mark Rupp reported that the SHEA Implementation Guidelines are in the early stages of revision and will have overlap with several topics proposed by HICPAC (e.g., hand hygiene, pneumonia and BSI).

Dr. Charles Huskins reported that IDSA is developing guidelines on some topics proposed by HICPAC, but these recommendations will be from a treatment rather than a prevention perspective. Dr. Sheila Murphey added that several professional societies will jointly develop an Association of Medical Instrumentation standard for disinfection of endoscopes.

HICPAC's comments and suggestions on topics that should be prioritized as guidelines/interim guidance or entirely eliminated from consideration at this time are outlined below.

- Efforts should not be made at this time to define the VAC or IVAC bundle due to CDC's ongoing process to modify the VAP surveillance definition in NHSN.
- SSI modules for abdominal hysterectomy and colon surgery should not be developed because the core section of the SSI guideline and the upcoming antimicrobial guideline will adequately address these issues.
- The environmental guideline should be updated, but this effort should be limited in scope. For example, guidance could be provided to IPs on specific products and services to address environmental issues. Recommendations also could be made on peroxide-generating devices and other new technologies that did not exist when the environmental guideline was developed. IPs need clarification on whether the current CDC recommendation against spraying disinfectants to sterilize the air means that new environmental devices should not be used. However, CDC is not in a position to develop a guideline on environmental robots at this time because the data are not adequate to distinguish between these technologies.
- Some issues in the environmental guideline (e.g., clarification of fogging and provision of a streamlined guidance document on changing ultraviolet sets) appear to be straightforward and would not require extensive resources. The disinfection/sterilization guideline should be updated to reflect more recent technology and changes in the field with respect to immediate-use/flash sterilization.
- The hand hygiene guideline should be updated to reflect more recent data on *C. difficile* and alcohol-based hand sanitizers.
- BSI in dialysis settings will receive a fair amount of energy and attention as a result of the new CMS incentive. A new CDC guideline on this issue would be extremely helpful to the field.
- Upcoming MDRO clinical trials should be considered in the decision-making process of selecting the next series of guidelines. The new MDRO trials will focus on universal precautions, MRSA reduction and post-discharge effects for decolonization.
- CDC should provide guidance or issue a formal statement on disinfection practices that occur in the OR while the patient is still in the room.
- CDC should collaborate with professional societies in addressing critical issues that arise before data can be gathered to develop formal evidence-based guidelines or if an upcoming RCT will be unable to answer research questions with the GRADE methodology. For example, existing expert panels could be reconvened to provide expert opinion or develop papers on the pros and cons of a certain topic. CDC could create consistent and standardized criteria that would serve as the basis for developing expert opinion-driven papers.

- CDC should consider the possibility of releasing a statement to describe issues that can and cannot be translated from acute care settings to LTCFs/nursing homes.
- CDC should determine whether the HCP guideline should address the controversial issue of appropriate handling of HCP with certain viral illnesses in terms of screening.
- CDC should explore the possibility of issuing a guidance statement on the expectations of clinical microbiology laboratories in providing information beyond simple resistance phenotypes to support routine infection prevention activities. In response to this suggestion, Mr. Hageman confirmed that DHQP would have discussions with the CDC Clinical Laboratory Improvement Advisory Committee to address the role of clinical laboratories in infection prevention.

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 (e.g., position statements, new or pending legislation, campaigns and related activities, press activities, publications, and other items of note). Written reports by the liaison and *ex-officio* members submitted into the official HICPAC record for the February 16-17, 2012 meeting and their additional comments are summarized below.

- William Baine, MD (Agency for Healthcare Research and Quality) (AHRQ). Dr. Baine was unable to attend the meeting in person, but AHRQ's written report was distributed to HICPAC for review.

- Sheila Murphey, MD (Food and Drug Administration) (FDA). Dr. Murphey's written report was distributed to HICPAC for review.

- Gary Roselle, MD (Department of Veterans Affairs) (VA). Dr. Roselle reported that the VA renamed its MRSA Program to the MDRO Program. In preparation of addressing *C. difficile*, the VA currently is gathering data on Carbapenem-resistant *Enterobacteriaceae* (CRE). The VA convened a national workgroup that will oversee the National Antibiotic Stewardship Program.

- Kim Willard-Jelks, MD, MPH (Alternate, Health Resources and Services Administration) (HRSA). Dr. Willard-Jelks reported that she hoped to attend future HICPAC meetings to share information on healthcare infection control practices with state partners and front-line primary care providers in HRSA-funded Federally Qualified Health Centers.

- William Brock, MD, FCCM, FCCP, FACP (Society of Critical Care Medicine) (SCCM). Dr. Brock reported that SCCM is addressing VAP in collaboration with partners and is focusing on existing gap measures. SCCM participated on a Quality Improvement Task Force. SCCM developed a paper to identify existing NQF measures that need to be modified and updated to focus on future priorities in critical care. SCCM is examining national priorities for comparative clinical effective research as part of its Quality and Patient Safety Committee. SCCM expects to publish its revised sepsis guidelines in June 2012.

- Lisa McGiffert (Consumers Union). Ms. McGiffert reported that Consumers Union published an article on CLABSI in pediatric ICUs. Consumers Union has identified activists to help train HCP in applying anecdotal stories from patients in an official manner. Consumers Union recently launched a major campaign on medical device safety to improve approaches by which these devices are introduced to the market and undergo post-market surveillance.

- Mark Russi, MD, MPH (American College of Occupational and Environmental Medicine) (ACOEM). Dr. Russi reported that ACOEM recently published guidance documents focusing on occupational hearing loss and workplace fatigue. ACOEM currently is gathering information from its members who are based in medical centers regarding their practices related to testing with interferon gamma release assays. ACOEM most likely will develop a guidance document on this issue. ACOEM will convene its national meeting in Los Angeles, California in April 2012.

- Marion Kainer, MD, MPH (Council of State and Territorial Epidemiologists) (CSTE). Dr. Kainer reported that CSTE convened an HAI Standards Committee. The template for submitting position statements to CSTE has been approved. CSTE is developing a road map to assist states in phasing in reportable procedures or locations (e.g., CLABSI outside of ICUs).

- Joan Blanchard, RN, BSN, MSS, CNOR, CIC (Association of periOperative Registered Nurses) (AORN). Ms. Blanchard reported that AORN will hold its 59th Congress in New Orleans on March 24-29, 2012. AORN is aware that its recommended practices for transmissible infections need to be updated to be consistent with the 2006 MDRO Guideline and the 2007 Isolation Guideline. AORN's other recommended practices that are in progress include sterile techniques and sharps safety. AORN will host webinars on the prevention of transmission of bloodborne pathogens in the OR and the increase in sharps injuries in surgical settings after national needlestick legislation was passed. The 2012 edition of *Perioperative Standards and Recommended Practices for Inpatient and*

Ambulatory Settings is available for purchase in print and electronically. The *Ambulatory Surgery Center Resources* book is in publication.

- David Henderson, MD (National Institutes of Health) (NIH). Dr. Henderson reported that NIH successfully vaccinated 95.8% of HCP in its hospital who potentially could have face-to-face interactions with patients or their families. NIH is still addressing the outbreak of Carbapenemase-producing *Klebsiella* infections and colonization that began in its hospital during the summer of 2011. NIH is extremely appreciative of the technical assistance, guidance and expertise that CDC provided for the outbreak response.

- Charles Huskins, MD, MSc (Infectious Diseases Society of America) (IDSA). Dr. Huskins reported that IDSA is continuing to advocate for strong policies for mandatory influenza vaccination.

- Barbara DeBaun, MSN, RN, CIC (Association of Professionals of Infection Control and Epidemiology, Inc.) (APIC). Ms. DeBaun reported that APIC launched its 2020 Strategic Plan with a new vision ("healthcare without infection") and a new mission ("create a safer world through prevention of infection"). The APIC/SHEA position paper that was released on antimicrobial stewardship reflects a collaborative partnership between IPs and healthcare epidemiologists. APIC launched its renovated website at www.apic.org.

- Mark Rupp, MD (Society of Healthcare Epidemiology of America) (SHEA). Dr. Rupp reported that SHEA is revising and updating the *Compendium of Implementation Guidelines* in conjunction with a broad range of partners. SHEA will convene a conference on April 13-16, 2012 in Jacksonville, Florida to offer its basic and advanced epidemiology training courses. Antimicrobial stewardship will be a key discussion topic of the conference.

- Robert Wise, MD (The Joint Commission): Dr. Wise reported that The Joint Commission successfully completed the standard for influenza vaccination of staff and licensed independent practitioners in hospitals and other healthcare settings (e.g., behavioral healthcare settings and LTCFs). Institutions will be required to reach at least 90% compliance for certain benchmarks by 2020. Other settings (e.g., behavioral home care) are only required to offer influenza vaccination at this point.

- Sheri Chernetsky-Tejedor, MD (Alternate, Society of Hospital Medicine) (SHM). Dr. Chernetsky-Tejedor reported that SHM is offering mentored implementation programs in ~300 hospitals to provide guidance on avoiding HAIs, particularly CAUTI and CLABSI. SHM is subcontracting with United Healthcare and the Hospital Association of Pennsylvania on the Partnership for Patients initiative to develop education, content

and other resources for adverse drug events, CAUTI, venous thromboembolism (VTE) and readmissions. SHM is partnering with the Health Research and Educational Trust of New Jersey on implementation of the Comprehensive Unit-Based Safety Program. SHM participated in a number of Measures Application Partnership activities and collaborated with CDC on utilizing NHSN to develop VTE measures.

- Alexis Elward, MD (Advisory Committee for Immunization Practices) (ACIP): Dr. Elward reported that ACIP published its recommendations on HBV vaccination for adults with diabetes in December 2011. ACIP recommended HBV vaccination for all persons with diabetes <65 years of age. ACIP further advised providers to weigh the risks and benefits of HBV vaccination for persons >65 years of age. The ACIP Hepatitis B Vaccine Workgroup currently is considering issues related to the durability of immunization for persons who were vaccinated as infants and are now entering the workforce as HCP. ACIP published its recommendations on HCP immunization. The ACIP Pertussis Workgroup currently is considering whether a booster dose of the combined tetanus/ diphtheria/pertussis vaccine should be administered to adults and the appropriate interval of the booster dose.

Public Comment Session

Edward Septimus, MD, FACP, FIDSA
Hospital Corporation of America

Dr. Septimus commended Dr. Shelley Magill for her outstanding leadership in convening a diverse group of partners to refine the NHSN definitions for VAP surveillance in adult patients. He emphasized the critical need to address MDRO, antimicrobial stewardship and other infection prevention issues across the entire continuum of care, particularly in the current environment of limited resources.

With no further discussion or business brought before HICPAC, Dr. Fishman recessed the meeting at 5:03 p.m. on February 16, 2012.

Opening Session: February 17, 2012

Neil Fishman, MD, HICPAC Chair
Associate Chief Medical Officer
University of Pennsylvania Health System

Dr. Fishman opened the floor for introductions to determine the HICPAC voting members, *ex-officio* members and liaison representatives who were in attendance. None of the voting members declared any new conflicts of interest for the record.

Dr. Fishman verified that the voting members and *ex-officio* members in attendance constituted a quorum for HICPAC to conduct its business on February 17, 2012. He reconvened the meeting at 9:07 a.m.

Proposal for a New HICPAC Guidance Document

Thomas Talbot, MD, MPH
Associate Professor of Medicine and Preventive Medicine & Chief Hospital Epidemiologist
Vanderbilt University Medical Center
HICPAC Member

Dr. Talbot presented a proposal for a new HICPAC guidance document on the use of HAI surveillance definitions in an era of public reporting. The use of and interest in HAI surveillance data have grown for regulatory purposes, public reporting and quality comparison metrics. However, the application and interpretation of surveillance definitions vary in the field, particularly with respect to the use of adjudication methods.

Adjudication panels would be highlighted, but some forms of adjudication would be discouraged. The need to improve definitions would be emphasized, particularly by advancing to electronic surrogates. In addition to IPs and hospital epidemiologists, the guidance document also would be targeted to medical directors and hospital administrators.

Adjudication panels are used in situations where events that meet the HAI surveillance definitions are presented to facility leadership to make a "final" determination on whether the event indeed is an actual HAI. These panels often involve leaders who are held accountable for HAI performance and use a "skewed lens" to review retrospective data. However, the clinical and surveillance perspectives must be kept separate. The use of adjudication panels should be discouraged in some situations to limit subjectivity.

An Emerging Infections Network survey was administered to determine the frequency of using adjudication panels. The survey asked about approaches that institutions use to adjudicate difficult or controversial cases in order to meet reporting requirements. Of 243 respondents, 66% used a consensus method, 25% used a single individual to make the final decision, 13% did not use an adjudication method and allowed the original decision to stand, 13% allowed the clinician to make a clinical judgment with a "veto," 10% used other methods, and 7% had no knowledge of the methods used.

In response to HICPAC's specific questions, Dr. Talbot provided additional details on the proposed HICPAC guidance document. The discussion topics included:

- consistency between HICPAC's proposed guidance document and the "HHS Action Plan to Eliminate HAIs;"
- the difficulty in striking an appropriate balance between clinical credibility and objectivity and the need to determine which of the two concepts is more important for the HAI definitions;
- the need for data validation at both individual and programmatic levels;
- the lack of resources to perform data validation; and
- the potential for vendors to share some of the burden of reporting HAIs through Meaningful Use by designing new systems that would allow for more reliable data capture.

HICPAC agreed that the development and dissemination of the proposed guidance document would be extremely valuable for the IPC field. The members fully endorsed the proposed approach. HICPAC made a number of comments and suggestions that should be considered in developing the guidance document.

- The guidance document should describe best practices to offer solutions to the problem of adjudicating HAI data in facilities. Best practice 1 would be for all institutions to treat the CDC/NHSN criteria as the gold standard for identifying and reporting HAIs. Best practice 2 would be for institutions to adopt an organizational policy of allowing trained HCP with expertise in infection prevention (e.g., hospital epidemiologists or IPs) to make final decisions on HAIs. The risk of bias in using an adjudication panel to make final decisions should be highlighted, particularly if a medical director of a unit serves on the panel and has a conflict of interest in identifying the HAI.
- The guidance document should discuss risk stratification, describe efforts to track BSI in various patient populations, highlight modifications to the CDC HAI surveillance definitions, outline existing gaps in knowledge regarding the pathophysiology and origination of gram-negative infections, and cite studies in which attention to catheter care decreased both gram-positive and gram-negative BSI rates.

- The guidance document should be framed in the broader context of patient safety.
- The guidance document should clearly articulate that the modified NHSN HAI surveillance definitions will focus on adverse outcomes and preventability of these outcomes.
- The guidance document should advise institutions to review data in their validation and surveillance systems to determine if HAIs actually were prevented or whether costs merely shifted to another category of HAIs.
- The guidance document should focus on "preventable HAIs" rather than "HAI elimination" to achieve clinical credibility.
- Hospital CEOs should be an additional target audience of the guidance document because public reporting of HAIs is linked to an institution's finances and payment structures.

Update by the CDC Office of Antimicrobial Resistance (OAR)

Steven Solomon, MD
Director, Office of Antimicrobial Resistance/DHQP
Centers for Disease Control and Prevention

Dr. Solomon covered the following topics in his update to HICPAC on OAR's recent activities in AR prevention. CDC established OAR in 1998 as part of EIP. OAR manages the CDC Antimicrobial Resistance Steering Committee; the new Antimicrobial Resistance Workgroup of the CDC Office of Infectious Diseases Board of Scientific Counselors; and the WHO Coordinating Center for Antimicrobial Resistance at CDC.

OAR facilitates external interactions and relationships at the agency level rather than at the pathogen, disease or syndrome-specific level. OAR serves as CDC's principal liaison to the Interagency Task Force on Antimicrobial Resistance to coordinate the federal Antimicrobial Resistance Action Plan, the Transatlantic Task Force on Antimicrobial Resistance, and the newly-formed WHO Antimicrobial Drug Resistance Team.

OAR's primary activities focus on 3 agency-level directions. A strategic plan will be developed and implemented to represent a synergy of disease- and pathogen-specific activities on AR. A combined AR communication initiative will be developed to link disease- and pathogen-specific communication efforts. Responses to external input will be provided by shifting from a project- to a program-oriented approach and using the agency-level AR budget to promote overarching strategies and communications to OMB, Congress, Government Accountability Office (GAO), constituents and partners.

In December 2011, OAR convened the "CDC Strategic Priorities for Combating Antimicrobial Resistant Infections" Workshop with ~40 consultants and experts from the United States, Canada and Latin America. Presentations were made and breakout sessions were held on AR surveillance, prevention and control, foodborne disease, and AR use improvement.

The consultants provided guidance to OAR on 3 broad program priorities: (1) domestic and international surveillance for early warning and public health monitoring of AR problems; (2) specific interventions to improve antimicrobial use with measurable objectives; and (3) assurance of an effective public health response through the promotion of regional prevention collaboratives and partnerships between governmental public health and the clinical healthcare delivery system. The consultants also provided guidance to OAR on 2 targeted program priorities: (1) development of the science on disease burden assessments for AR infections and (2) improvement of rapid diagnostic capacity for clinical use.

AR problems cover well over 100 issues. As a result, OAR is aware of the need to create an approach to effectively communicate AR threats to various audiences (e.g., decision-makers, the media and general public). Immediate threats would include organisms with prevalence rates >50% (e.g., MRSA and fluoroquinolone-resistant *Pseudomonas aeruginosa*).

Imminent threats would include organisms that are differentially present or distributed in various geographic areas (e.g., CRE, extensively drug-resistant tuberculosis, and Macrolide-resistant *S. pneumoniae*). Emerging threats would include organisms that are unknown, but require careful attention (e.g., Cephalosporin-resistant *Neisseria gonorrhoeae*, NDM-1 resistance determinants, influenza A resistance to neuraminidase inhibitors, and resistant meningococcus).

OAR established long-term goals for CDC's domestic AR surveillance. Over the next 5-10 years, CDC should have capacity to ensure the earliest possible identification of new forms of AR in the United States. CDC should have capacity to track the spread of AR geographically within the United States in a timely and ongoing manner. CDC should use this capacity to publish annual reports that quantify the disease burden of AR in the United States as a whole, by region, and/or by state.

A number of important developments occurred that drove OAR to initiate CDC's AR strategic planning process. GAO published a report to Congress in June 2011 to emphasize that data gaps would remain despite HHS's steps to improve monitoring of AR. The GAO report targeted two key recommendations to CDC to better prevent and control the spread of AR.

CDC was advised to develop and implement a strategy to improve its monitoring of antibiotic use in humans by identifying available sources of antibiotic use information. CDC was further

advised to develop and implement a strategy to improve its monitoring of antibiotic-resistant infections in inpatient healthcare facilities to more accurately estimate the national occurrence of these infections.

The European Centre for Disease Prevention and Control develops maps of the percentage of resistance for a wide variety of microorganisms by country. GAO, constituents and partners advised CDC to produce similar maps for the United States by each state. In the summer of 2011, IDSA published "Policy Recommendations to Save Lives: Combating Antimicrobial Resistance."

OAR is aware that grouping all AR pathogens is not a viable strategy to publishing a national AR report. Instead, OAR most likely will estimate the disease burden caused by a finite number of high-impact AR pathogens. OAR also is reviewing existing models to inform its AR strategic planning process. For example, the Center for Disease Dynamics, Economics and Policy publishes maps to illustrate the prevalence of AR pathogens in the United States. Recent data show that CRE in the United States spread from 1 state in 2000 to 37 states as of January 2012.

OAR established long-term goals for CDC to improve antimicrobial use. Over the next 5-10 years, CDC should assure the implementation of proven effective programs that are designed to optimize the use of antimicrobial drugs in all prescriber settings to the greatest degree possible. At the institutional level, the Kisuule, *et al.* study focused on "Improving Antibiotic Utilization Among Hospitalists: A Pilot Academic Detailing Project with a Public Health Approach."

The Arnold, *et al.* study described interventions to improve antibiotic prescribing practices in ambulatory care. CDC is making efforts to promote these types of best practices to facilitate the development of measurable objectives to change prescriber behavior at state, local and clinical levels.

OAR established long-term goals for CDC to strengthen AR prevention. Over the next 5-10 years, CDC should develop regional prevention collaboratives that link public health agencies and healthcare provider organizations at state, regional and local levels and are designed to prevent the emergence and spread of AR pathogens and infections. OAR plans to compile lessons learned and best practices from regional collaboratives across the country that were formed in the past to address AR pathogens and infections.

Overall, FY2012 will serve as a transition year for OAR. Activities at the division level constitute the preponderance of CDC's AR's efforts, while OAR focuses on strategic planning, program development and communications at the agency level. OAR's FY2013 priorities will focus on domestic AR surveillance; development of an international surveillance network; establishment

of state, regional and local prevention collaborations; and implementation of antimicrobial use interventions.

Some HICPAC members were uncertain of OAR's ability to actually implement the AR strategic plan activities due to limited resources and CDC's history of making modest investments in this area. To leverage resources and support for the AR portfolio, HICPAC advised OAR to identify focused and targeted "winnable battles" in the AR strategic plan that have the capacity to achieve a significant impact.

CDC Update: Emerging Issue

CAPT Arjun Srinivasan, MD
Associate Director for HAI Prevention Programs, DHQP
Centers for Disease Control and Prevention

Dr. Srinivasan joined the meeting to present an update to HICPAC on an emerging issue that arose after the agenda was published. The media has extensively reported on the issue of drug shortages in the context of current regulations and recommendations on the use of medications that are packaged in single-dose vials.

Physician groups and professional organizations recently launched an effort to make these restrictions more flexible based on the perception that the recommendations are not evidence-based, are resulting in unnecessary expenses, and are reducing access to quality-of-life improving drugs (e.g., anesthetic agents) and life-saving drugs (e.g., chemotherapeutic agents).

Single-dose vials are labeled for use in a single patient due to the absence of a preservative. CMS enforces CDC's recommendations on single-dose vials because the language is driven by the manufacturer's instructions. CDC's recommendations also are driven by well-documented episodes of transmission of bacterial and viral pathogens, including hepatitis, that were caused by inappropriate reuse and sharing of single-dose vials. However, CDC is aware that some circumstances with a critical need for access to important drugs may warrant more flexibility.

A number of issues need to be addressed before the existing regulations can be modified to allow for more flexibility. More knowledge is needed about current drug shortages (e.g., a true shortage from the manufacturer or supply and distribution issues that can be resolved). A decision is needed on whether the drug shortage would justify an exception to the regulation regarding the use of single-dose vials for multiple patients.

Rigorous evidence is needed to ensure that any exception to the regulation would be safe for patients. Criteria are needed to identify specific circumstances to which the exception would apply (e.g., any drug on the FDA shortage list or provider discretion). CDC and CMS will continue to collaborate with and obtain guidance from FDA on resolving these issues in the very near future.

HICPAC made several comments and suggestions for CDC to convey to CMS and FDA during the ongoing interagency discussions to "relax" the current single-dose vial use policy for certain situations.

- The federal agencies should review and gather lessons learned from previous strategies that were implemented to resolve similar problems in the past. For example, the Emergency Use Authorization was utilized to allow for the reuse of masks in times of shortages.
- The federal agencies should only make changes to the current policy on a case-by-case basis. A blanket approach should not be implemented on the use of single-dose vials in multiple patients.
- The federal agencies must take extreme caution in modifying the existing infection control policy. Most notably, any exceptions to the current policy must not be misinterpreted to mean that uncontrolled use of single-dose vials in multiple patients or other breaches in infection control practices are acceptable. Any exceptions to the current policy must emphasize that patient safety is still the primary objective of infection prevention.

Proposed Approach for the Return on the Federal Investment in HAI Prevention

John Jernigan, MD, MS
Director, Research and Evaluation/DHQP
Centers for Disease Control and Prevention

Dr. Jernigan proposed an approach to demonstrate the federal return on investment (ROI) in HAI prevention. The demand for ROI data is increasing due to budget realities faced by the federal government and greater scrutiny of investment decisions. Federal agencies are now utilizing ROI and other financial management tools to inform their funding decisions. However, the existing ROI literature on HAI prevention is dominated by studies that focus on the perspective of healthcare facilities.

Dr. Jernigan explained that the proposed approach to determine the ROI for "federal" HAI prevention activities primarily would target CDC's investments and focus on CLABSI as an example. The ROI analysis for HAI prevention requires estimates of 4 inputs.

Input 1 is an estimate of the burden of the problem. CDC has estimated the annual burden of CLABSI by combining information on inpatient-days for U.S. hospitals based on CMS Hospital Cost Reports as well as central-line utilization ratios and CLABSI rates from both NNIS and NHSN. CDC published annual estimates of the U.S. CLABSI burden in a *Vitalsigns*™ report in 2011.

Input 2 is an estimate of the cost of the problem and is dependent on the perspective of the entity (e.g., a healthcare facility or federal agency). The cost is equivalent to attributable reimbursement by the government. For CLABSI, CDC links patient-specific NHSN CLABSI data to Medicare claim files through CMS Medicare Provider Analysis and Review (MedPAR) files. CDC uses these data to determine and compare hospitalization-specific reimbursement to control hospitals that did not report CLABSI events in patients.

After making adjustments for patients with non-Medicare primary coverage, patients who are not enrolled in Medicare Part A or B, or patients who are enrolled in a Medicare health maintenance organization, CDC has been successful in matching 83% of its NHSN CLABSI events to events in the CMS MedPAR files. CDC matches 5 controls to 1 case for individual facilities, patients with an ICU stay, and procedure categories based on the AHRQ Clinical Classifications Software.

The software classifies 3,900 potential procedure codes into ~250 categories and provides a control pool with the same expected length of stay as cases based on outcomes during hospitalization. CDC also performs random effects linear modeling for reimbursement and controls for demographics, central-line codes and an underlying morbidity score.

Input 3 is an estimate of the cost of implementing prevention activities and is dependent on the perspective of the entity (e.g., a healthcare facility or federal agency). The cost of prevention activities is equivalent to the federal investment in HAI prevention. CDC focused on the time period of 1990-2006 during its role as the primary federal agency that invested in CLABSI prevention.

CDC held key informant interviews with both internal and external stakeholders to determine its historical contributions in reducing CLABSI rates over time. The key informant interviews showed that CDC developed and released CLABSI surveillance definitions and systems through NNIS and NHSN; published CLABSI prevention guidelines in collaboration with HICPAC; and

responded to outbreak investigations. CDC also reviewed its annual budgets for HAI prevention to estimate the percentage of funding that was dedicated to CLABSI prevention activities.

Input 4 is an estimate of the effectiveness of prevention activities. CDC reviewed trends in the annual CLABSI burden to estimate the prevention of these infections in 1990-2008. CDC produced trend models that accounted for changes in its CLABSI definition, reviewed changes in facilities participating in NNIS/NHSN over time, and evaluated the impact of the transition from NNIS to NHSN.

CDC used these trends to estimate the number of CLABSI events that were prevented each year. Annual estimates were compared to an expected "counterfactual rate" based on the assumption that hospital type-specific CLABSI rates did not change after 1990. After estimating the effectiveness of its prevention activities, CDC conducted further analyses to determine the relationship between its investments and the observed reductions in CLABSI.

The observed reductions in CLABSI were the result of diverse efforts by multiple stakeholders (e.g., infection control staff and other HCP at the facility level, professional societies, The Joint Commission, and innovations within industry and academia). Due to these numerous efforts, the ability to quantify CDC's individual contribution to reductions in CLABSI is difficult if not impossible. However, CDC is attempting to incorporate a sensitivity analysis into these estimates to allow for varying assumptions about its CLABSI prevention efforts. A preliminary model showed that the ROI of CDC's prevention activities to reduce CLABSI is relatively large.

In response to Dr. Jernigan's request for input on whether to abandon or proceed with the proposed approach, HICPAC fully supported CDC's efforts to determine its federal ROI in the prevention of HAIs. HICPAC particularly was impressed by CDC's activities to gather historical data and perform modeling to answer complex questions related to its ROI.

The HICPAC members made several comments and suggestions for CDC to consider in further development of the proposed approach.

- CDC should include an additional component in its sensitivity analysis by reviewing the number of hospitals that originally participated in NNIS and determining the change in their HAI burden over time.
- CDC is to be commended for incorporating efforts by multiple stakeholders into its model of CLABSI reduction at the national level. However, CDC should estimate and take credit for the proportion of its federal dollars that were allocated to reducing HAIs over time.
- CDC should conduct additional analyses to determine the cost-effectiveness of its HAI prevention activities from a broader societal perspective.

- CDC should publish a paper on its proposed approach to describe methodological issues associated with estimating the attributable cost of HAIs.

Update on CDC's CDI Activities

Clifford McDonald, MD
Senior Advisor for Science and Integrity, DHQP
Centers for Disease Control and Prevention

Dr. McDonald covered the following topics in his update to HICPAC on CDC's recent CDI activities. CDI is a spore-forming anaerobe that causes toxin-mediated disease through fecal-oral and exogenous transmission. Microbiota and humoral immunity are the main host defenses of CDI, while antibiotics and advanced age are its major risk factors. CDI reoccurs in 20%-30% of patients. Hospital-onset CDI accounts for ~5% of mortality and ~$6,000 in costs.

CDI was the subject of extensive media coverage throughout 2011 and the early part of 2012. Dr. McDonald provided details on each of these media headlines. Headline 1 focused on the plateau of CDI disease and deaths at historically high levels. AHRQ data showed that trends in hospital stays associated with CDI dramatically increased from ~87,000 patients in 1993 to ~337,000 patients in 2009. Tremendous growth also was observed in the age-adjusted rate of CDI as the underlying cause of death based on death certificate data (e.g., <5 cases/1 million in 1999 to >20 cases/1 million in 2010).

Headline 2 focused on the continued role of the NAP1 strain as a major influence. The 2011 Black, *et al*. study reported the epidemiology of CDI in Chicago hospitals in 2009. However, CDC is continuing to gather data from EIP to determine the actual contribution of the NAP1 strain to all CDI cases in the United States.

Headline 3 focused on the arrival of a new antibiotic therapy option in 2011. The 2011 Louie, *et al.* study reported RCT results. FDA ultimately approved fidaxomicin with an indication for CDI treatment, but research investigators hoped that the drug would be approved with an indication for a lower recurrence rate for non-NAP1 strains.

Headline 4 focused on disease pathogenesis paradigms. The 2012 Walker, *et al.* modeling study repeated previous research questions regarding intra-hospital transmission. The study showed that only 25% of CDI cases could be linked to a ward-based source. Although this outcome suggested prolonged carriage or incubation, the cases were detected with enzyme immunoassays (EIAs) and up to 50% of symptomatic cases could have been missed. Moreover, inter-ward transmission was not accounted for in the study.

The 2010 Cohen, *et al.* study estimated that the period between exposure to *C. difficile* and the occurrence of CDI was a median of 2-3 days based on 3 prior studies. The Miyajima, *et al.* study reported that 6 of 149 elderly persons (or 4%) were colonized with CDI in community dwellings. The 2011 Loo, *et al.* study reported that both colonization and infection increased with the duration of exposure to ward settings.

Headline 5 focused on strategies to make early and accurate diagnosis a reality. The 2011 Goldenberg and French study surveyed 170 hospitals in England and reported that low sensitivity of EIAs resulted in over-testing of CDI, a low laboratory prevalence of ≤5%, and low positive predictive values. The 2011 Kufelnicka and Kirn study reported that two-step testing paradigms held early promise. However, emerging evidence suggests that assays for glutamate dehydrogenase may not be uniformly sensitive.

The 2011 Deshpande, *et al.* study emphasized the need for a rational testing strategy to realize the benefits of nucleic acid amplification tests (NAAT). Of 19 studies that included 7,392 samples, the mean sensitivity was 90% and the mean specificity was 96%. Dr. McDonald's analysis of these studies found that a 15%-20% testing prevalence with NAAT might be more achievable than prevalence of 8%-12% with an EIA.

To achieve this goal, clinicians must be educated to test only significant diarrhea of ≥3 unformed stools in a 24-hour period. Laboratories must reject all formed stools. Only one test should be allowed every 5-7 days with NAAT. No test should be performed for cure. The 2011 Fong, *et al.* study and the 2011 Goldenber, *et al.* study reported that NAAT and non-NAAT surveillance rates were not comparable. The studies showed that ~30% of NHSN hospitals are using NAAT. CDC is attempting to risk adjust and incorporate these rates into an SIR.

Headline 6 focused on risk stratification for public reporting. The 2011 Zilberberg, *et al.* study reported that 85 hospitals with ~1.4 million unique patients accounted for ~2 million admissions. Of 9,803 CDI cases that were identified, ~51% were hospital onset and 23% were community onset/no hospital contact. The prevalence of community onset/no hospital contact on admission CDI was associated with hospital-onset CDI across all facilities. This study demonstrates that as states mandate public reporting of hospital-onset CDI rates, data should be collected and reported on the prevalence of community onset/no hospital contact on admission CDI for the purpose of risk stratification.

Headline 7 focused on the FDA alert regarding proton pump inhibitors (PPIs). The FDA Drug Safety Communication stated that *C. difficile*-associated diarrhea could be associated with stomach acid drugs (e.g., PPIs). A number of observational studies have been published over several years, but conflicting results have both confirmed and denied the FDA communication.

However, potentially important interactions must be considered. The 2011 Stevens, *et al.* study reported that patients on PPIs had a much stronger odds ratio of being on fewer or less risky antibiotics.

Headline 8 focused on the brave new world of intestinal microbiota transplants. The 2011 Gough, *et al.* systematic review generated new interest in this issue. The 317 patients treated in the study accounted for 27 case series and reports. The study suggested that the use of intestinal microbiota transplants to treat the regular reoccurrence of CDI was highly effective with 92% resolution. However, efficacy of the intestinal microbiota transplants varied by the route of installation, relationship of the stool donor, treatment before transplant, and volume of the transplant.

CDC is aware that several terms need to be clearly defined in the area of human microbiome and infection control. "Flora" should be replaced with "microbiota" to clearly articulate and define resident microbial communities. "Microbiome" is defined as the collective genome of microbial communities. "Metagenomics" is defined as the entire genomic sequencing of microbiota, but this technology often is limited to sequences of DNA encoding of 16S ribosomal RNA (e.g., those limited to species identification). "Metabolomics" is defined as chemical fingerprints of cellular processes.

The 2012 Tosh and McDonald reported on infection control in a multidrug-resistant era and emphasized the need to focus on the human microbiome. The number of problem pathogens is continuing to grow and certain epidemiologic factors are common (e.g., direct and indirect contact transmission between patients, far more colonized patients than infected patients, colonization before infection by days to weeks, and colonization lasting weeks to months or even years after). Colonization occurs at pathologic biofilms and body sites that normally are inhabited by complex and diverse human microbiota.

CDC will publish a *Vitalsigns*™ Report on CDI prevention on March 6, 2012. The report will describe the overall CDI epidemiology with respect to healthcare exposures; highlight early success in CDI prevention across a cohort of U.S. hospitals; and issue a call to action to demonstrate the need for expansion and implementation of prevention efforts in additional settings. The report will be supported by data from EIP, NHSN, and 3 CDI prevention collaboratives led by 3 states.

The report will conclude that nearly all of the CDI cases cited in the studies were healthcare-related as a result of hospital onset or present on admission. The report will show that the 3 state-led collaboratives successfully reduced their hospital-onset CDI rates. The report will highlight prevention messages in 4 key areas: antibiotic stewardship, early and reliable diagnosis, isolation with an emphasis on gloves, and solid environmental cleaning.

The report will reiterate that colonized and infected patients are links in the transmission chain between neighboring healthcare settings. These settings include older persons in communities, colonized or recently infected patients, ambulatory care settings, acute care hospitals and skilled nursing facilities. A recent study showed that antibiotics predisposed patients to CDI across care settings.

CDC will use the report to convey 4 overarching messages. "CDI causes too many Americans to become sick or die." "CDI is a problem across the spectrum of healthcare delivery." "The prevention of CDI is possible." "Health departments may be uniquely positioned to address the problem of CDI across the spectrum of healthcare delivery."

Similar to CDC, IDSA also is updating its CDI guidelines to answer questions in three broad areas.

- What is the role of different treatments for CDI? (How can these treatments be best utilized to improve patient outcomes, including cost? How can these treatments be used to reduce transmission?)
- What are the most appropriate tests to diagnose CDI and how should these tests be used? (What performance measures exist for testing practices?)
- What is the role of intestinal microbiota transplant for CDI and how should this procedure be performed? (What are the infection prevention concerns with this procedure?)

CDC is funding research and taking other actions at this time to answer additional questions that are a high priority for CDI. What is the appropriate duration of isolation? What is the role of standard and enhanced environmental cleaning strategies to remove or inactivate spores? In what settings should these methods be used? What is the role and best methods for hand hygiene versus gloves? What is the role of asymptomatic carriers in overall transmission? What are the priority infection prevention strategies for non-hospital settings?

Public Comment Session

Edward Septimus, MD, FACP, FIDSA
Hospital Corporation of America

Dr. Septimus commended HICPAC on proposing an outstanding guidance document on the use of HAI surveillance definitions in an era of public reporting. However, he noted that the level of expertise and knowledge of the HAI surveillance definitions greatly varies among the proposed

target audiences of medical directors and hospital epidemiologists, particularly those in non-academic center community hospitals. Moreover, IPs are under tremendous pressure to adjudicate disparities between HAIs and hospital-acquired conditions (HACs) at the local level.

Dr. Septimus emphasized the need for CDC to use the guidance document as an opportunity to educate HCP at the community level about public reporting, adjudication, surveillance definitions, clinical variability and subjectivity.

Rachel Stricof, MPH, CIC
Director, Hospital-Acquired Infection Reporting Program
New York State Department of Health

Ms. Stricof commented that HICPAC's proposed guidance document on the use of HAI surveillance definitions in an era of public reporting would be extremely valuable to various components of the IPC community and diverse audiences. She agreed with HICPAC on the critical need to provide training on auditing and validating surveillance data. She reinforced the importance of public health being involved in this effort for the purposes of external validation. Ms. Stricof advised HICPAC to review its original guidance document on public reporting of HAIs to make recommendations.

Steven Brash, RN, CIC
Nemours Foundation/Alfred I. duPont Hospital for Children

Mr. Brash commented that public reporting, present-on-arrival HACs and CMS penalties have significantly increased pressure on IPs. He agreed with Ms. Stricof that extensive involvement by federal, state and local public health is needed to help hospital administrators understand the daily pressures placed on IPs.

Mr. Brash thanked CDC and HICPAC for presenting a wealth of valuable information over the course of the meeting. Similar to the HICPAC members, he also encouraged CDC to continue its efforts to determine the federal ROI in HAI prevention. He emphasized that advancements in HAI prevention are a direct result of the leadership and innovation by CDC and HICPAC. Mr. Brash asked CDC/HHS to consider investments that could be made at the federal level to help hospitals to support and use better surveillance systems.

Jonathan Otter, BSc
Bioquell (U.K.), Ltd.

Dr. Otter emphasized the need to address the routine practice in the United States of "blaming" hospital-acquired CDI cases on community-acquired CDI. This goal could be achieved by clearly defining the acquisition of CDI in other areas and relieving some of the pressure on hospitals to reduce CDI rates.

Thomas Szymczak
Vortek Surgical, LLC

Mr. Szymczak emphasized the need to be mindful of the fundamental basics of standard precautions, isolation and common infection control issues. Vortek Surgical focuses on containing bacteria in areas of hospitals that serve as a major source for the prevalence of HAIs and contamination. Mr. Szymczak was pleased that CDC and HICPAC are focusing on these areas through research and the development of formal guidelines/interim guidance documents.

HICPAC Business Session

Neil Fishman, MD, HICPAC Chair
Associate Chief Medical Officer
University of Pennsylvania Health System

Dr. Fishman reviewed the HICPAC business items that were raised over the course of the meeting.

1. Preliminary drafts of the NICU Infection Prevention Guideline will be presented to HICPAC during the June 2012 meeting for review and comment.

2. HICPAC will provide input on the Surveillance Workgroup's proposed NHSN changes for CLABSI and SSI.

Closing Session

With no further discussion or business brought before HICPAC, Dr. Fishman adjourned the meeting at 11:52 a.m. on February 17, 2012.

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

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Date

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