



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
June 14-15, 2012
Atlanta, GA

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ATTACHMENT 1
Meeting of Healthcare Infection Control Practices Advisory Committee (HICPAC)
June 14-15, 2012

Centers for Disease Control and Prevention
Tom Harkin Global Communications Center (Building 19)
1600 Clifton Rd., NE
Atlanta, GA

Date: Thursday June 14, 2012

<u>Time</u>	<u>Topic</u>	<u>Presider/Presenter</u>
9:00	Welcome and Introductions	Neil Fishman (HICPAC Chair) Jeff Hageman (HICPAC Designated Federal Official)
9:15	Draft Guideline for Prevention of Infections Among Patients in NICUs	Martha Iwamoto (CDC) Alexis Elward (HICPAC)
10:45	Break	
11:00	CDC update on recent healthcare outbreaks	J. Todd Weber (CDC)
11:30	CDC update on injection safety including use of single-dose vials	Joe Perz (CDC)
12:00	Lunch	
1:30	Ensuring hepatitis B protection for healthcare personnel	Sarah Schillie (CDC)
2:00	Brief Update on Draft Guideline for Prevention of Surgical Infections	Sandra Berrios-Torres
2:15	Guideline Clarification-Disinfectant fogging	Jeff Hageman
2:45	Break	
3:00	Update on validation of NHSN data	Kathryn Arnold (CDC)
3:30	HICPAC Guidance on the Adjudication in an Era of Public Reporting	Tom Talbot (HICPAC)
4:30	Liaison/ Ex-officio Reports	
4:45	Public comment	
5:00	Adjourn	

Date: Friday, June 15, 2012

<u>Time</u>	<u>Topic</u>	<u>Presider/Presenter</u>
9:00	HICPAC Surveillance Workgroup <ul style="list-style-type: none">• Central-Line associated blood-stream infections• Surgical-site infections	Scott Fridkin (CDC) Nicola Thompson (CDC) Ryan Fagan (CDC)
10:30	Break	
10:45	Update of U.S. Public Health Service Guideline for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis	David Kuhar (CDC)
11:15	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 June 14 and 15, 2012 and confirmed the presence of a quorum with voting members and *ex-officio* members for HICPAC to conduct its business on both days of the meeting.)

DAY 1: JUNE 14, 2012**HICPAC Members**

Dr. Neil Fishman, Chair
 Dr. Dale Bratzler
 Dr. Ruth Carrico
 Dr. Daniel Diekema
 Dr. Alexis Elward
 Dr. Susan Huang
 Dr. Tammy Lundstrom
 Dr. Stephen Ostroff
 Dr. Thomas Talbot
 Dr. Deborah Yokoe

Designated Federal Official

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

Ex-Officio Members

Dr. David Henderson
 National Institutes of Health

Dr. Stephen Kralovic (Alternate)
 Department of Veterans Affairs

Dr. Sheila Murphey
 Food and Drug Administration

Dr. Kim Willard-Jelks (Alternate)
 Health Resources and Services
 Administration

Liaison Members

Dr. Sheri Chernetsky-Taylor (Alternate)
 Society of Hospital Medicine

Ms. Barbara DeBaun
 Association of Professionals of Infection
 Control and Epidemiology, Inc.

Ms. Sandra Fitzler

American Health Care Association
 Dr. Michael Howell
 Society of Critical Care Medicine

Dr. Charles Huskins
 Infectious Disease Society of America

Dr. Marion Kainer
 Council of State and Territorial
 Epidemiologists

Ms. Shirley Paton
 Public Health Agency of Canada

Lisa Spruce
 Association of periOperative Registered
 Nurses

Dr. Robert Wise
 The Joint Commission

CDC Representatives

Dr. Denise Cardo, DHQP Director
 Dr. Michael Bell, Deputy Director, DHQP
 Sandra Berríos-Torres
 Kathy Allen-Bridson
 Matthew Arduino
 Kathryn Arnold
 Amy Collins
 Angela Dunbar
 Ryan Fagan
 Angela Fisher
 Scott Fridkin
 Rita Helfand
 Rosa Herrera
 Teresa Horan
 Martha Iwamoto
 Kahaliah Joseph
 Rachel Kossover
 David Kuhar

Melanie Lawson
Tara MacCannell
Clifford McDonald
Anna Melville
Anne Moorman
Gloria Morrell
Trudy Murphy
Duc Nguyen
Joseph Perz
Alyssa Peterkin
Daniel Pollack
Catherine Rebmann
Ann Goding Sauer
Sarah Schillie
Erin Stone
Nicola Thompson
Abbigail Tumpsey
Todd Weber
Cindy Weinbaum
Brandy Wright

Members of the Public

Kay Argroves
American Association of Nurse Anesthetists

Brian Leas
University of Pennsylvania Health System
Center for Evidence-Based Practice

Rachel Stricof
Council of State and Territorial
Epidemiologists

DAY 2: JUNE 15, 2012

HICPAC Members

Dr. Neil Fishman, Chair
Dr. Dale Bratzler
Dr. Ruth Carrico
Dr. Daniel Diekema
Dr. Alexis Elward
Dr. Susan Huang
Dr. Tammy Lundstrom
Dr. Stephen Ostroff
Dr. Thomas Talbot
Dr. Deborah Yokoe

Designated Federal Official

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Prevention and Response Branch, DHQP

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Public Health Agency of Canada

Ms. Lisa Spruce
Association of periOperative Registered
Nurses

Dr. Robert Wise
The Joint Commission

CDC Representatives

Dr. Denise Cardo, DHQP Director
Dr. Michael Bell, Deputy Director, DHQP
Elise Beltrami

Sandra Berríos-Torres
Nicole Coffin
Amy Collins
Demetria Gardner
Teresa Horan
Martha Iwamoto
John Jernigan
Alex Kallan
David Kuhar
Clifford McDonald
Duc Nguyen
Daniel Pollack
Isaac See

Nicola Thompson
Sarah Yi

Members of the Public

Kay Argroves
American Association of Nurse Anesthetists

Michele Marill
Hospital Employee Health

Rachel Stricof
Council of State and Territorial
Epidemiologists

ATTACHMENT 3

Glossary of Acronyms

ACIP	Advisory Committee for Immunization Practices
ANC	Absolute Neutrophil Count
AORN	Association of periOperative Registered Nurses
APIC	Association for Professionals in Infection Control and Epidemiology, Inc.
ARV	Antiretroviral
ASCs	Ambulatory Surgical Centers
ASIPP	American Society of Interventional Pain Physicians
BBG	Brilliant Blue-G (Dye)
BSI	Bloodstream Infections
<i>C. difficile</i>	<i>Clostridium difficile</i>
CDC	Centers for Disease Control and Prevention
CDI	<i>Clostridium difficile</i> Infection
CLABSI	Central Line-Associated Blood Stream Infection
CMS	Centers for Medicare and Medicaid Services
CRE	Carbapenem-Resistant <i>Enterobacteriaceae</i>
CSTE	Council of State and Territorial Epidemiologists
DHQP	Division of Healthcare Quality Promotion
EDs	Emergency Departments
EPA	U.S. Environmental Protection Agency
FAQs	Frequently Asked Questions
FDA	Food and Drug Administration
FE	Fungal Endophthalmitis
FTC	Emtricitibine
GAS	Group A Streptococcal
GI	Gastrointestinal
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
GVHD	Graft-Versus-Host Disease
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
<i>K. pneumoniae</i>	<i>Klebsiella pneumoniae</i>
KPC	<i>Klebsiella pneumoniae</i> Carbapenemase
LTACHs	Long-Term Acute Care Hospitals

LTCFs	Long-Term Care Facilities
MBI-LCBI	Mucosal Barrier Injury Laboratory-Confirmed Bloodstream Infection
MRSA	Methicillin-Resistant <i>Staphylococcus aureus</i>
MSIS	Musculoskeletal Infection Society
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NHSN	National Healthcare Safety Network
NICU	Neonatal Intensive Care Unit
NIH	National Institutes of Health
NQF	National Quality Forum
NSQIP	National Surgical Quality Improvement Program
NTM	Non-Tuberculous Mycobacteria
OR	Operating Room
PAHO	Pan American Health Organization
PCR	Polymerase Chain Reaction
PEP	Postexposure Prophylaxis
PFGE	Pulsed-Field Gel Electrophoresis
PHAC	Public Health Agency of Canada
PHS	U.S. Public Health Service
PJI	Periprosthetic Joint Infection
PPE	Personal Protective Equipment
PVS	Post-Vaccination Serologic (Testing)
QALY	Quality-Adjusted Life Year
RAL	Raltegravir
RCTs	Randomized Controlled Trials
RSV	Respiratory Syncytial Virus
RTV	Ritonavir
<i>S. aureus</i>	<i>Staphylococcus aureus</i>
<i>S. marcescens</i>	<i>Serratia marcescens</i>
<i>S. pneumoniae</i>	<i>Streptococcus pneumoniae</i>
SCCM	Society of Critical Care Medicine
SCT	Stem Cell Transplant
SHEA	Society for Healthcare Epidemiology of America
SHM	Society of Hospital Medicine
SNFs	Skilled Nursing Facilities
SSI	Surgical Site Infection
SSI-JNT	Surgical site infection-joint
TDF	Tenofovir
TPN	Total Parenteral Nutrition
USP	United States Pharmacopeia
VA	Department of Veterans Affairs
VAE	Ventilator-Associated Events
VZIG	Varicella-Zoster Immunoglobulin
VZV	Varicella Zoster Virus
WBC	White Blood Count
WHO	World Health Organization
ZDV	Zidovudine

EXECUTIVE SUMMARY

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on June 14-15, 2012 in Atlanta, Georgia.

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

A plaque and certificate of appreciation were presented to Dr. Tammy Lundstrom in recognition of her tremendous contributions to the healthcare infection control profession and her valuable expertise to HICPAC. A new HICPAC member and liaison representatives were introduced: Dr. Deborah Yokoe, new HICPAC voting member; Dr. Michael Howell, new liaison for the Society of Critical Care Medicine; and Ms. Lisa Spruce, new liaison for the Association of periOperative Registered Nurses.

CDC presented a comprehensive review of the *Draft Guideline for Infection Prevention in the Neonatal Intensive Care Unit (NICU)*. For key question 1.A.1 (What are the most effective methods of prevention and control of respiratory illnesses in the NICU, including respiratory syncytial virus, pertussis and varicella?), the workgroup reviewed narrative evidence summaries and draft recommendations for the following interventions: hand hygiene, personal protective equipment, isolation and cohorting of patients, cohorting of healthcare personnel (HCP), active detection, management of visitors, education, and prophylaxis.

For key question 1.B (Should transmission-based precautions be modified for patients in isolettes?), the writing group recommended further research. The writing group also reviewed narrative evidence summaries and draft recommendations for other key questions:

- Question 1.C: What is the most effective diagnostic approach to identifying respiratory pathogen outbreaks in the NICU?
- Question 5.A: What are the most effective strategies for *Clostridium difficile* (*C. difficile*) testing in NICU patients?
- Question 5.B: When should testing for *C. difficile* be performed in NICU patients?
- Question 5.C: What is the significance of a positive *C. difficile* test in a NICU patient?

HICPAC made extensive comments and suggestions for the writing group to consider while finalizing the draft NICU Infection Prevention Guideline.

CDC presented an update on the *Prevention of Surgical Site Infection (SSI) Guideline*. Key questions regarding surgical attire, surgical techniques, anesthesia and environmental operating room issues will be removed from the guideline and placed in an appendix due to the lack of studies identified in broad and targeted searches.

CDC presented its clarification statement on the Disinfectant Fogging Guideline to account for new developments that have occurred in chemical fogging since the publication of the 2003 Environmental Guideline and the 2008 Disinfection Guideline.

None of the HICPAC voting members expressed opposition to the proposed clarification statement for the Disinfectant Fogging.

CDC presented an update on issues the Advisory Committee for Immunization Practices is considering to ensure hepatitis B virus protection for HCP. The update covered the ACIP Hepatitis workgroup's proposed post-exposure evaluation approaches, pre-exposure evaluation approaches, hybrid evaluation approach, and cost-effectiveness modeling results.

HICPAC agreed that the workgroup's proposed pre-exposure approach would be logistically easier to implement than the post-exposure approach, but this strategy would be more costly due to a larger population.

CDC presented an update on its single-dose vial activities. The American Society of Interventional Pain Physicians (ASIPP) launched a campaign in 2012 in which its members and those of other professional societies were asked to send letters to their Congressional representatives about the critical shortage of essential drugs due to the Centers for Medicare and Medicaid Services (CMS) single-dose vial policy.

ASIPP stated that the single-dose vial policy for infection control was expensive, caused numerous problems related to patient access, and has not been proven through evidence to be necessary or medically indicated. ASIPP also informed its members that CMS's modification of the rule as soon as possible would be essential to avoid further crises.

To clarify its guidelines to clinicians and dispel the dissemination of inaccurate information to healthcare providers, CDC publicly restated its position on single-dose/single-use vials in a formal statement on May 2, 2012. CDC stated that its guidelines call for medications labeled as "single dose."

DHQP presented an update on its response support to 108 outbreak investigations in diverse settings covering multiple states and international countries from January 1, 2011 to June 7, 2012. Outbreak investigations highlighted in the update included *Serratia marcescens* bloodstream infections (BSI) in patients receiving total parenteral nutrition, post-procedural fungal endophthalmitis, tattoo-related non-tuberculous Mycobacteria infections, group A streptococcal, *Streptococcus pneumoniae* serotype 15A, carbapenem-resistant *Enterobacteriaceae*, and *Klebsiella pneumoniae* carbapenemase-producing *K. pneumoniae*.

CDC presented an update on its national strategy and draft "2012 Data Validation Guidance and Toolkit" to validate National Healthcare Safety Network (NHSN) data. HICPAC was extremely pleased that CDC is developing a national strategy and toolkit with guidance in an effort to standardize reporting and validation of healthcare-associated infection (HAI) data to NHSN across states. CDC's standardized approach will play an important role in addressing the tremendous variability and uncertain quality of information among NHSN state reports and the NHSN national report.

HICPAC presented an update on its guidance on Adjudication in an Era of Public Reporting. The purpose of the guidance document is to respond to the growing use of and interest in HAI surveillance data for regulatory issues, public reporting and quality comparison metrics; address the potential for variability in application and interpretation of surveillance definitions; and address the increase in adjudication methods.

HICPAC provided extensive input on the guidance document in response to several questions.

1. What is the target audience of the guidance?
2. Should consensus and adjudication within hospital epidemiology and infection control content experts be addressed?
3. Should a discussion on “eliminating” or “targeting zero HAIs” be placed in the manuscript?
4. What language should be included to reconcile the tension between more credibility and the likely need for objective measures that might result in less clinically credible definitions, particularly in light of the unpredictable nature of clinical diagnoses?

CDC presented a comprehensive update by the HAI Surveillance Workgroup on revisions to the NHSN central line-associated BSI (CLABSI) and SSI definitions in the following areas: mucosal barrier injury-laboratory confirmed BSI definition; NHSN infection surveillance criteria; operative procedure definition; elimination of implant data collection; new 30-day/90-day rule for SSI follow-up; reporting instructions for SSI; new periprosthetic joint infection definition; and denominator for procedure form.

The HICPAC voting members **unanimously supported** the proposed revisions to the NHSN CLABSI and SSI definitions with their comments and suggestions noted for the record.

CDC presented an update on the *U.S. Public Health Service Guideline for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis*. CDC expects to finalize and submit the guideline for clearance within 3-4 months.

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

The Chair called for public comments at all times noted on the published agenda for the June 14-15, 2012 HICPAC meeting.

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

**HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE
June 14-15, 2012
Atlanta, Georgia**

Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC). The proceedings were held on June 14-15, 2012 in Building 19 of the Tom Harkin Global Communications Center at the CDC Roybal Campus in Atlanta, Georgia.

Opening Session: June 14, 2012

Mr. Jeffrey Hageman, MHS

Deputy Chief, Prevention and Response, DHQP
Centers for Disease Control and Prevention
HICPAC Designated Federal Official

Mr. Hageman opened the floor for introductions to determine the HICPAC voting members, *ex-officio* members and liaison representatives who were in attendance. He asked the voting members to publicly disclose any conflicts of interest for the record.

- Alexis Elward, MD: Recipient of research support from Sage Products, Inc. to study the efficacy of daily bathing with chlorhexidine to prevent bloodstream infections (BSI) in pediatric intensive care unit (ICU) patients.

Mr. Hageman confirmed that the voting members and *ex-officio* members in attendance constituted a quorum for HICPAC to conduct its business on June 14, 2012. He called the proceedings to order at 9:02 a.m. and welcomed the participants to the meeting.

Mr. Hageman reminded the HICPAC voting members of their individual responsibility to identify real or perceived conflicts of interest and recuse themselves from participating in these matters. The list of participants is appended to the minutes as Attachment 1.

Mr. Hageman announced that Dr. Tammy Lundstrom's term as a HICPAC voting member would end after the current meeting. A plaque and certificate of recognition and appreciation were presented to Dr. Lundstrom with signatures by Dr. Thomas Frieden, Director of CDC, and Dr. Beth Bell, Director of NCEZID.

The participants joined Mr. Hageman in applauding Dr. Lundstrom's tremendous contributions to the healthcare infection control profession and her valuable expertise to HICPAC. She was particularly recognized for her outstanding leadership on the CDC writing group that is updating the *Healthcare Personnel Infection Prevention and Control Guideline*.

Neil Fishman, MD, HICPAC Chair

Associate Chief Medical Officer
University of Pennsylvania Health System

Dr. Fishman joined Mr. Hageman in welcoming the participants to the HICPAC meeting. He announced changes to the HICPAC membership since the February 2012 meeting:

- Deborah Yokoe, MD, MPH; Associate Professor of Medicine, Division of Infectious Diseases, Brigham & Women's Hospital: Dr. Yokoe is a new HICPAC voting member.
- Michael Howell, MD, MPH; Executive Director, Center for Healthcare Delivery Science, Beth Israel Deaconess Medical Center: Dr. Howell is the new liaison representative for the Society of Critical Care Medicine.
- Lisa Spruce, RN, DNP, ACNS, ACNP, ANP, CNOR; Director of Evidence-Based Perioperative Practice, Association of periOperative Registered Nurses (AORN). Ms. Spruce is the new liaison representative for AORN.

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

Alexis Elward, MD, MPH

Assistant Professor, Pediatrics Infectious Diseases
Washington University School of Medicine
HICPAC Member

Dr. Elward covered the following topics in her update to HICPAC on the NICU Infection Prevention Guideline. The writing group's activities in the guideline development process included performing literature searches to identify existing guidelines, references and other relevant data; formulating key questions with input from stakeholders; conducting abstract and full-text screening; extracting and synthesizing data; and drafting evidence-based recommendations.

The writing group has completed 2 major tasks since the February 2012 HICPAC meeting: (1) revised the evidence and "Grading of Recommendations, Assessment, Development and Evaluation" (GRADE) tables by extracting data from updated literature services and (2) drafted

narrative summaries and recommendations for *Clostridium difficile* (*C. difficile*), respiratory pathogens, and methicillin-resistant *Staphylococcus aureus* (MRSA).

The writing group formulated key questions in 5 categories to inform the development of the NICU guideline: respiratory infections, central line-associated BSI (CLABSI), MRSA, fungal infections, and *C. difficile*. The writing group included 218 full-text papers in GRADE tables as a result of its review and application of inclusion/exclusion criteria for 3,842 abstracts and 1,821 full-text papers.

The writing group's next steps will be to complete narrative summaries and recommendations for fungal infections and CLABSI for HICPAC's review and comment during the next meeting in 2012. Dr. Elward thanked the core writing group members and expert reviewers for their valuable time, efforts, commitment and dedication to developing, reviewing and revising the NICU guideline since January 2010.

Martha Iwamoto, MD, MPH

Medical Epidemiologist, Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

Dr. Iwamoto described the writing group's stepwise process to draft recommendations in the NICU guideline for respiratory pathogens and *C. difficile*. For respiratory pathogens, the writing group organized GRADE tables by key question and individual pathogen: respiratory virus (e.g., respiratory syncytial virus (RSV), influenza/parainfluenza and adenovirus), pertussis and varicella zoster virus (VZV).

The writing group developed GRADE tables for each intervention and assigned initial grades according to the evidence base: a "high" grade for randomized controlled trials (RCTs); a "low" grade for observational studies only; or a "very low" grade for uncontrolled or descriptive studies. To determine overall quality grades, the writing group modified the initial grades if certain criteria were met.

The writing group used the GRADE tables to draft narrative evidence summaries that include a brief introduction and evidence review organized by key questions. The narrative evidence summaries led to the development of draft recommendations for the NICU guideline based on 3 key inputs: values and preferences used to determine critical outcomes; overall GRADE of the evidence for critical outcomes; and net benefits, harms and tradeoffs resulting from weighing the critical outcomes.

The writing group members discussed the direction of each recommendation in terms of their support of or opposition to the guidance and strengths and weaknesses of the recommendation. The writing group ranked the quality of the evidence on respiratory pathogens and *C. difficile* for

recommendations in the NICU guideline based on the updated CDC/HICPAC categorization scheme:

- Category IA: a strong recommendation supported by high to moderate quality evidence suggesting net clinical benefits or harms.
- Category IB: a strong recommendation supported by low-quality evidence suggesting net clinical benefits, harms or an accepted practice (e.g., aseptic technique) supported by low- to very low-quality evidence.
- Category IC: a strong recommendation required by federal or state regulations.
- Category II: a weak recommendation supported by any quality of evidence suggesting a tradeoff between clinical benefits and harms.
- Recommendation for further research: an unresolved issue with low- to very low-quality evidence with uncertain tradeoffs between benefits and harms.

Dr. Iwamoto reviewed the narrative evidence summaries and draft recommendations for key questions in the NICU guideline on respiratory pathogens and *C. difficile*. She asked HICPAC to provide input on these issues.

Question 1.A.1: What are the most effective methods of prevention and control of respiratory illnesses in the NICU, including RSV, pertussis and varicella?

Narrative evidence summary: Hand hygiene

- Very low-quality evidence in the GRADE table suggests a benefit of the practice of hand hygiene in reducing transmission of respiratory viruses within NICUs. Several observational studies emphasize hand hygiene along with other interventions and consider this practice to be an effective measure in reducing incident infections during periods of respiratory viral activity.

Draft recommendation: Hand hygiene

- Adhere to hand hygiene recommendations as specified in the 2002 CDC/HICPAC *Guideline for Hand Hygiene in Healthcare Settings* that include recommendations for indications for hand washing and hand antisepsis, technique and agents, educational and motivational programs, and measurement of adherence. (Category IB)

Narrative evidence summary: Personal protective equipment (PPE)

- Very low-quality evidence suggested a benefit of using gown and gloves as a prevention measures against RSV transmission in the NICU. This was based on evidence from seven studies which demonstrated reductions in incidence rates with the use of gown and gloves by healthcare personnel during contact with patients with known or suspected RSV infection. The use of masks to prevent healthcare-associated RSV has not been clearly shown to be beneficial. Very low-quality evidence from five studies showed mixed results. In three observational studies, the use of masks as part of a multi-component bundle lead to decreased transmission of RSV. However, in two other studies the use of masks added no additional benefit. The use of goggles providing eye and nose protection to healthcare personnel may be of additional benefit to prevent

inadvertent self-inoculation. Very low-quality evidence from one observational study found that the use of eye-nose goggles, in addition to handwashing, isolation, and cohorting of patients, was associated with a significant decrease in healthcare-associated RSV infections. However, several subsequent studies have demonstrated that strict adherence to handwashing, in conjunction with gown and glove use and other infection prevention measures without the use of goggles, are effective and suggest that routine use of goggles may not be necessary. Very low-quality evidence supported the benefit of gowns, gloves, and masks for preventing transmission of influenza virus and adenovirus in the NICU. This was based on the control of outbreaks of adenovirus and influenza after the implementation of prevention measures including strict adherence to droplet precautions.

Draft recommendations: PPE

- Recommendations for personal protective equipment that are applicable to all healthcare settings (e.g., ICU, SICU) are specified in the *2007 CDC/HICPAC Guideline for Isolation Precautions*. The following recommendations are based on our evidence review and are consistent with the 2007 recommendations.
 - Gown and gloves: Wear gloves before direct contact with patients or surfaces and articles in close proximity to a NICU patient with any respiratory infection, including RSV, influenza, parainfluenza, adenovirus infection, pertussis, and varicella. (Category IB)
 - Wear a gown whenever anticipating that clothing will have direct contact with the infected patient or potentially contaminated environmental surfaces or equipment. (Category IB)
 - Remove gown and gloves and observe hand hygiene before leaving the patient-care environment. (Category IB)
 - Facemasks and eye protection: Wear a facemask upon entry in to the room or cubicle of patients known or suspected to be infected with pathogens transmitted by respiratory droplets (influenza, parainfluenza, adenovirus, and pertussis) that are generated by a patient who is coughing or sneezing. (Category IB)
 - Wear a facemask with eye protection during aerosol-generating procedures for NICU patients with respiratory infection. (Category IB)
 - Further research is needed on the benefit of routinely wearing eye protection, in addition to facemask, for close contact with patients with respiratory infection. (No recommendation/unresolved issue)

Narrative evidence summary: Isolation and cohorting of patients

- Isolation and cohorting of patients with respiratory viruses: Low-quality evidence suggested a benefit of promptly isolating or cohorting infants with RSV infection. In seven observational studies, cohorting of infants with RSV infection in conjunction with other infection control measures led to significant reduction in healthcare-associated RSV infections. Very low-quality evidence suggested a benefit of isolating or cohorting infants with influenza, parainfluenza, or adenovirus infection. This was based on descriptive reports of outbreaks controlled when these strategies were implemented. Very low-quality evidence suggested a benefit of ward closure for the prevention of

influenza transmission. In one outbreak report, ward closures to out-born admissions and to high-risk obstetric admissions were implemented as control measure.

- Isolation of patients infected with pertussis: Very low-quality evidence supported isolation of infected patients to prevent transmission of pertussis. This was based on evidence from one outbreak report where droplet precautions were initiated after pertussis was identified in a NICU patient, which resulted in the prevention of infection in other NICU patients.
- Cohorting of patients after varicella exposure: Very low-quality evidence suggested a benefit of isolation and cohorting of susceptible patients who have been exposed to varicella. This was based on low rates of healthcare-associated transmission where infants were cohorted on the basis of exposure and immune status after exposure to the index patient. In two of these studies, the period of isolation or cohorting was specified: the exposed, susceptible patients were placed in isolation for 7 or 8 days through 28 days after exposure.

Draft recommendations: Isolation and cohorting of patients

- Recommendations for isolation and cohorting of patients that are applicable to all healthcare settings (e.g., ICU, SICU) are specified in the *2007 CDC/HICPAC Guideline for Isolation Precautions*. The following recommendations are based on our evidence review and are consistent with the 2007 recommendations.
 - Place patients with respiratory infection in a single-patient room when available. (Category IB)
 - Place together (cohort) in the same room or patient-care area patients who are infected with the same respiratory pathogen, if a single-patient room is not available. (Category IB)
 - Place patients who require Airborne Precautions (varicella) in an airborne infection isolation room that has been constructed in accordance with current AIA/FGI guidelines. (Category IB)

Narrative evidence summary: Cohorting of healthcare personnel (HCP)

- Very low-quality evidence suggested a benefit of cohorting of healthcare personnel (HCP) to care only for patients infected with RSV. This was based on decreases in healthcare-associated RSV infections during periods when cohorting of healthcare personnel was implemented compared to periods when this was not implemented. Very low-quality evidence suggested a benefit of cohorting of healthcare personnel for patients with influenza, parainfluenza, or adenovirus infection. This was based on control of outbreaks of influenza, parainfluenza, or adenovirus infections when cohorting of HCP was implemented.

Draft recommendation: Cohorting of HCP

- Consider the assignment of dedicated healthcare personnel to care for one patient cohort and not move between patient cohorts (e.g., restrict personnel who give care to infected or exposed patients from giving care to uninfected or unexposed patients). (Category II)

Narrative evidence summary: Active detection

- Active detection: Low-quality evidence suggested a benefit with active detection of RSV by rapid laboratory diagnostic tests, such as tests for RSV antigen, to prevent healthcare-associated RSV. In several observational studies, rapid detection or screening of symptomatic children either on admission or during their hospital stay resulted in decreases in healthcare-associated transmission. In one observational study, screening of all pediatric admissions for RSV and subsequent cohorting of infected patients on admission led to substantial reductions in healthcare-associated RSV cases. Very low-quality evidence suggested a benefit for active detection of influenza and parainfluenza virus infection to prevent healthcare-associated transmission. This was based on outbreak reports where active detection of illness was among prevention measures implemented to control the outbreak. Very low-quality evidence supported active detection of pertussis by prompt clinical recognition and rapid diagnostic testing, for example by polymerase chain reaction assay (PCR), to prevent healthcare-associated transmission of pertussis. This was based on evidence from outbreak reports where active detection was used to promptly implement infection control measures, determine the extent of outbreak, and identify candidates for post-exposure prophylaxis. In each report, the outbreak occurred as a result of delayed recognition and isolation of infected persons.
- Assessment of VZV antibody status: Very low-quality evidence suggested no benefit of promptly identifying exposed NICU patients who lack evidence of immunity to varicella, either by maternal history of varicella or measurement of varicella IgG antibody. There were low rates of healthcare-associated transmission of varicella when the immune status of patients was actively assessed by presence of varicella IgG antibody. The determination of immune status was used in these studies for the purposes of identifying candidates for immunoprophylaxis. However, no correlation between immunity and varicella antibody titers or maternal history or varicella with immune status was demonstrated in studies.

Draft recommendation: Active detection

- Perform rapid diagnostic laboratory tests for RSV, influenza, parainfluenza, and pertussis on NICU patients who have symptoms of illness or who have been exposed to the particular respiratory pathogen. Promptly cohort the patients and implement appropriate isolation precautions, pending results. (Category IB)

Narrative evidence summary: Management of visitors

- Very low-quality evidence suggested a benefit of restricting visitors or screening for symptoms of respiratory infection during community outbreaks of respiratory viral infections to prevent healthcare-associated transmission of RSV and influenza. This was based on observational studies where visitor restriction policies in the NICU and pediatric wards led to decreased healthcare-associated transmission of RSV and descriptive studies where restrictions were included in sets of interventions to control outbreaks of influenza. Family members, particularly young siblings, and other visitors may be infected and may transmit the virus to uninfected patients or healthcare personnel. Specified policies varied within studies: some policies prohibited all young

children from visiting during periods of heightened community activity, while others restricted visitors with acute respiratory symptoms. The reviewed literature did not identify the impact of different levels of visitor restrictions on outbreak containment.

Draft recommendations: Management of visitors

- Do not allow persons who have symptoms of respiratory infection to visit NICU patients. (Category IB)
- Further research is needed on the risks and benefits of restricting of asymptomatic young siblings from visiting NICU patients during periods of heightened respiratory illness activity in the community. (No recommendation/unresolved issue)

Narrative evidence summary: Education

- Very low-quality evidence suggested that education of healthcare personnel was beneficial, likely by improving compliance with infection control procedures. Education as an adjunct to visitor screening policies is beneficial, as suggested by very low-quality evidence among two observational studies where education of parents about the modes of transmission and ways of preventing spread was an effective prevention measure against RSV transmission in the NICU. Very low-quality evidence supported education of parents about pertussis prophylaxis as beneficial. This was based on evidence two descriptive studies where education of parents on the benefits and risks, including infantile hypertrophic pyloric stenosis, of macrolide therapy for the prevention of pertussis was among the interventions used to control an outbreak of pertussis among infants after exposure to infected healthcare personnel.

Draft recommendations: Education

- Educate healthcare personnel about the epidemiology, modes of transmission, and means of preventing the transmission of respiratory pathogens within the NICU. (Category IB)
- Educate parents and other visitors about the epidemiology, modes of transmission, and means of preventing the transmission of respiratory pathogens within the NICU. (Category IB)

Narrative evidence summary: Prophylaxis

- Prophylaxis after RSV exposure: Very low-quality evidence suggested a benefit of administering palivizumab to exposed infants for the control of outbreaks of RSV in the NICU. This is based on descriptive reports of outbreaks of RSV, during which palivizumab administration to exposed infants was used as part of a multi-modal infection control strategy. Palivizumab is a humanized murine monoclonal immunoglobulin, which is licensed for prevention of RSV disease in certain high-risk infants. It is important to note that the use of palivizumab is not recommended for the prevention of healthcare-associated transmission among hospitalized infants, because of lacking information on the individual contribution of palivizumab in controlling outbreaks of RSV and limited data on the effectiveness in groups outside of those for which it is licensed.
- Prophylaxis after influenza exposure: Very low-quality evidence suggests benefit to providing antiviral treatment (e.g., amantadine) to symptomatic NICU patients during outbreaks of influenza in the NICU. Very low-quality evidence supported treatment and chemoprophylaxis with ostelamivir NICU patients.

- Prophylaxis after pertussis exposure: Very low-quality evidence suggested a benefit of post-exposure macrolide prophylaxis for infants exposed to pertussis. This was based on the prevention of secondary cases in NICUs where macrolide prophylaxis was administered to exposed infants who received care from infected healthcare personnel or were hospitalized in the same unit as healthcare personnel or patients with pertussis. Monitoring for adverse effects, including infantile hypertrophic pyloric stenosis and gastrointestinal symptoms (nausea, emesis, abdominal cramping, and diarrhea) were reported in three studies. In one report, gastrointestinal symptoms were the most common side effect, occurring in 12% of infants who received azithromycin and 50% of infants who received erythromycin. No adverse events associated with either erythromycin and azithromycin were reported in the other studies, and there were no reports of infantile hypertrophic pyloric stenosis.
- Prophylaxis after varicella exposure: Very low-quality evidence suggested a benefit of passive immunoprophylaxis with immune globulin to the NICU patient after varicella exposure. This was based on lower attack rates and severity of illness among patients who had received varicella-zoster immunoglobulin (VZIG) after varicella exposure in the NICU. The use of VZIG varied among the outbreak reports: VZIG was given to infants without evidence of immunity by low levels of varicella-zoster antibody to infants with a combination of factors including gestational age and varicella antibody status and to all exposed preterm infants. Acyclovir prophylaxis, in addition to VZIG, was administered to exposed infants born before 28-weeks' gestation in one report. In one outbreak where VZIG was unavailable, prophylaxis with oral acyclovir was given and no further infections occurred. The quality of this evidence base was very low as well.

Draft recommendations: Prophylaxis

- Further research is needed on the use of palivizumab to control outbreaks of RSV infection in the NICU. (No recommendation/unresolved issue)
- Further research is needed on the risks and benefits of antiviral chemoprophylaxis (e.g., oseltamivir) to control outbreaks of influenza in the NICU. (No recommendation/unresolved issue)
- Administer postexposure prophylaxis with azithromycin to NICU patients who have had close contact with persons with pertussis and who do not have hypersensitivity or intolerance to macrolides, as recommended by CDC and AAP. (Category IB)
- Administer postexposure prophylaxis with varicella-zoster immunoglobulin to the NICU patient after varicella exposure, as recommended by CDC, ACIP, and AAP. (Category IB)

Question 1.B: Should transmission-based precautions be modified for patients in isolettes?

- No studies were identified that address this question.

Narrative evidence summary

- No studies were found describing or comparing clinical outcomes associated with the modification of transmission-based precautions for NICU patients in isolettes.

Draft recommendation

- Further research is needed to clarify the role of isolettes in the prevention of transmission of respiratory pathogens. (No recommendation/unresolved issue)

Question 1.C: What is the most effective diagnostic approach to identifying respiratory pathogen outbreaks in the NICU?

Narrative evidence summary

- Rapid diagnostic assays to detect RSV are generally effective in infants and young children; test characteristics are summarized in the following table (Table III.C). There was moderate-quality evidence from two diagnostic studies evaluating the test characteristics of the immunofluorescent techniques for detection of RSV antigen in nasopharyngeal swabs; these studies demonstrated 85.7-95.9% sensitivity and 90% specificity in comparison to viral culture. Low-quality evidence from one diagnostic study evaluating enzyme immunoassay techniques compared with viral culture demonstrated 98% sensitivity. Low-quality evidence from a diagnostic study evaluating an immunochromatography test for RSV confirmed by polymerase chain reaction showed a 100% positive predictive value. Diagnostic methods for the diagnosis of adenoviral respiratory infection included viral culture, antigen detection, and PCR assays. There was low-quality evidence from one diagnostic study that evaluated a PCR assay compared with immunofluorescence and viral culture. In this study, PCR assay had 100% sensitivity and 91.3% specificity. We found no evidence describing or comparing the predictive values, test characteristics, or clinical outcomes associated with different tests or testing strategies for detecting influenza, parainfluenza, pertussis, or varicella zoster infection specifically in hospitalized infants.

Draft recommendations

- Promptly perform immunofluorescent or rapid enzyme immunoassay or other rapid diagnostic laboratory test on patients who are suspected to be infected or who have been exposed to persons with RSV infection. (Category IB)
- Promptly perform PCR assay or other rapid diagnostic laboratory test on patients who are suspected to be infected or who have been exposed to persons with adenovirus infection. (Category IB)
- Further research is needed to determine the most appropriate diagnostic methods for the diagnosis of respiratory infections in the NICU patient. (No recommendation/unresolved issue)

Question 5.A: What are the most effective strategies for *C. difficile* testing in NICU patients?

Narrative evidence summary

- There was no evidence describing clinical outcomes associated with different testing strategies or pathways. One diagnostic study among pediatric patients evaluated the characteristics of real-time PCR targeting *C. difficile* toxin genes compared with detection of toxin production by enzyme immunoassay. This study demonstrated the following performance characteristics of real-time PCR: 95% sensitivity, 100% specificity, 100% positive predictive value, 98% negative predictive value. However,

false-positive rates would likely be very high among neonates, most often representing colonization. Additionally, *C. difficile* may be shed for long periods after symptomatic *C. difficile* infection.

Draft recommendation

- Further research is needed to describe or compare the predictive values, test characteristics, and clinical outcomes associated with different testing strategies or pathways for *C. difficile* infection. (No recommendation/unresolved issue)

Question 5.B: When should testing for *C. difficile* be performed in NICU patients?

Narrative evidence summary

- The search strategy employed did not identify studies demonstrating direct support of clinical situations in which testing for *C. difficile* should be performed in NICU patients. However, to address this question, we reviewed the quality of evidence among studies that correlated the presence of *C. difficile* toxin with clinical factors, including the presence or absence of gastrointestinal symptoms, description of stool frequency and quality, and antimicrobial administration, in order to attempt to understand better candidates or clinical situations for *C. difficile* testing. The evidence for this question consisted of four observational studies with the outcome of presence of *C. difficile*-toxin in the stool and two descriptive studies with *C. difficile* infection as the outcome. The quality of evidence was evaluated among these six studies. Very low-quality evidence was available to support gestational age, birth weight, vaginal delivery, and length of hospitalization as risk factors for disease. Very low-quality evidence from two descriptive studies did not establish a clear association between underlying gastrointestinal pathology and *C. difficile* infection. Four studies examined prior antibiotic exposure as a risk factor for the presence of *C. difficile* toxin among NICU patients. Very low quality of evidence from these studies had inconsistent results. Very low-quality evidence was available to examine the association between clinical manifestations, including diarrhea, bloody stool, and colitis, and the presence of *C. difficile* toxin or *C. difficile* infection. These studies found mixed results for clinical syndromes associated with *C. difficile*.

Draft recommendations

- Testing for *C. difficile* in the NICU patient with diarrhea should be performed only after the exclusion of other causes of diarrhea. (Category IB)
- The diagnosis of *C. difficile* infection in the NICU patient should be made based on clinical presentation of the disease, laboratory detection of *C. difficile* or its toxins, and the exclusion of other causes of diarrhea. (Category IB)

Question 5.C: What is the significance of a positive *C. difficile* test in a NICU patient?

Narrative evidence summary

- The search strategy found no studies that addressed the predictive value of a positive *C. difficile* test in a NICU patient. Additionally, there were no studies that described the most appropriate diagnostic tools to confirm *C. difficile* infection in NICU patients. Very

low-quality evidence was available to compare outcomes related to the management and treatment of infants with a positive *C. difficile* test. In one study, treatment of *C. difficile*-positive infants with metronidazole did not result in higher rates of clinical improvement compared with *C. difficile*-positive infants who received no treatment. However, most (76%) of the infants with *C. difficile* toxin-positive findings for whom the clinical outcome could be determined received treatment with metronidazole, the patients were not randomly assigned to the treatment and non-treatment groups, and the comparison was not prospectively planned.

Draft recommendations

- Further research is needed to determine the most appropriate diagnostic tools to confirm *C. difficile* infection in NICU patients. (No recommendation/unresolved issue)
- Further research is needed to compare outcomes related to the management and treatment of infants with a positive *C. difficile* test. (No recommendation/unresolved issue)
- Further research is needed to examine changes in the intestinal microbiota of infants over time; when (at what age and under what conditions) does *C. difficile* become pathogenic. (No recommendation/unresolved issue)

HICPAC made extensive comments and suggestions for the writing group to consider.

Hand hygiene

- The recommendation should be expanded to include other settings, populations and scenarios beyond the target audience of interest. New language should be added to acknowledge the existence of solid hand hygiene data in other domains. For example, “While there is no evidence of low-quality research in this particular arena for this population or for these respiratory viruses, there is a wealth of hand hygiene data that exist in other scenarios, outbreaks and contexts with a bearing on the Category IB recommendation.”
- Instead of attempting to address hand hygiene in the narrative evidence summary for the specific NICU population, other guidelines that explicitly and strongly recommend routine practice of hand hygiene in this setting should be referenced.
- The recommendation should be used to inform the development of a toolkit for front-line infection preventionists (IPs) who implement infection prevention and control (IPC) guidance in the field.
- A new paragraph should be added to the beginning of the narrative evidence summary to clarify the “very low-quality evidence” for hand hygiene. For example, “Hand hygiene is seen as a core practice. The recommendation was ranked as a Category IB based on a review of the evidence specifically for the NICU population.”

PPE

- The recommendations focus on contact and droplet precautions for all of the viruses and pathogens in NICU settings. This guidance contradicts the 2007 Isolation Precautions Guideline, particularly for influenza and pertussis. Data that are referenced in the NICU guideline to support the recommendations primarily relate to RSV.

- The recommendations do not mention the use of N95 respirators for varicella.
- The PPE recommendations in the NICU guideline should be consistent with those in other guidelines. For example, PPE for aerosol-generating procedures is recommended as a facemask with eye protection in the NICU guideline and a respirator in CDC's current influenza guidance. References should be made to the Standard Precautions Guidelines to ensure consistency.
- The recommendations should provide more guidance to clearly distinguish between "empiric" and "confirmed" precautions for patients until a definitive diagnosis is made. This language would be important because the respiratory illnesses of interest are virtually indistinguishable from a clinical perspective. The Bronchiolitis Guideline by the American Academy of Pediatrics discourages making a specific virologic diagnosis.
- The NICU guideline does not address viruses that increasingly are being detected by laboratories (e.g., rhinovirus, human metapneumovirus and bocavirus).

Isolation and cohorting and patients

- Recommendation 1 should be clarified because many NICUs still do not have single-patient rooms. To help NICUs without single-patient rooms comply with the guidance, the recommendation should be revised with clearer and more specific wording on an appropriate distance between patients or a separate area in the NICU for isolation and cohorting. For example, "Place patients with respiratory infection in a single-patient room or a separate patient care area when available."
- Recommendation 2 should be revised to avoid the risk of co-infection. Most notably, patients with an identified infection should not be cohorted with patients who have an empiric respiratory viral infection that has no definitive diagnosis. For example, recommendation 2 could begin with new language: "For patients for whom a diagnosis has been established...".
- Recommendation 2 should emphasize the necessity of precautions between patients who are cohorted with a single diagnosis.

Cohorting of HCP

- "Consider the assignment of dedicated HCP" should be replaced with "Weigh the risks and benefits of the assignment of HCP" to make the recommendation stronger.
- New language should be included in the recommendation to address cohorting of HCP in an outbreak. This setting has much more evidence and would allow the guidance to be upgraded from Category II to Category IB. However, the new language must be carefully worded for the NICU setting because cohorting of HCP potentially could compromise care in certain situations. Most notably, well-established and accepted IPC guidance advises the same HCP not to provide care to both "infected" and "uninfected" patients.

Active detection

- The recommendation should be revised to clarify and clearly distinguish between "active detection" (e.g., testing symptomatic patients) and "active surveillance" (e.g., screening all pediatric admissions for viruses). These 2 practices have extremely different impacts

on laboratory resources and other consequences. Moreover, the language on active detection of symptomatic patients should be stronger in terms of making a definitive diagnosis that may lead to different pathways for PPE. The language also should be used as an opportunity to reinforce the practice of first using PPE in the NICU setting for symptomatic patients without a definitive diagnosis.

- Reference 28 in the recommendation cites data from a non-NICU setting. As a result, the recommendation should be revised to clarify “screening” and “early detection of mild symptoms” to account for children who are admitted to hospitals from the community.
- Clearer guidance should be provided on next steps HCP should take with negative test results of NICU patients. Most notably, rapid diagnostic testing should be performed and empiric precautions should be implemented because some diagnostic tests have poor sensitivity in neonates.
- Laboratories will be challenged by implementing the recommendation because a rapid test for pertussis (e.g., PCR) is not commercially available at this time. “Rapid tests” should be clearly defined in the recommendation in terms of the period of time laboratories would have to detect respiratory viruses in the NICU.
- The temporal scope of the recommendation should be modified (e.g., perform rapid diagnostic laboratory tests first and promptly cohort patients second). The revised guidance should advise HCP to rapidly cohort patients to avoid delays of 2-6 hours.
- “Early detection” or “early testing” should be added to the recommendation to address the need to identify etiologic agents in symptomatic NICU patients. “Active detection” is well established in the literature and prompts action to test asymptomatic patients. “Active detection” should remain in the recommendation to ensure that exposed, asymptomatic NICU patients are tested.

Management of visitors

- The recommendations should be revised to refer to existing guidelines that address working HCP who are ill and the importance of influenza and pertussis immunization for HCP.
- Recommendation 1 should be revised with new language: “Establish a screening mechanism for visitors of NICU patients who have symptoms of respiratory infection.” The implementation guide to the NICU guideline should describe various models for hospitals to implement the screening mechanism (e.g., a web-based tool, printed form, or brief survey administered by admissions staff).
- “Asymptomatic young siblings” should be replaced with “asymptomatic children” to account for visitors who are not brothers or sisters of the NICU patient (e.g., relatives or friends).
- The recommendations should be revised to emphasize the importance of screening visitors of NICU patients at all times regardless of the season. For example, some hospitals might perform screening only during RSV and influenza seasons and neglect to conduct screening for parainfluenza in the summer.

Prophylaxis

- The recommendations should be revised to address the use of prophylaxis for HCP and visitors of NICU patients. For example, recommendation 2 should be modified to clarify that the guidance is directed to administration of anti-influenza medications to NICU patients. The guidance is not intended to recommend administration of anti-influenza medications to unvaccinated HCP in the event of an outbreak.
- A new recommendation should be added to address antiviral prophylaxis for varicella. Due to the availability of and challenges associated with varicella immune globulin, more hospitals might be using antiretrovirals (ARVs) as postexposure prophylaxis (PEP).
- The NICU guideline addresses “prophylaxis and treatment,” but all treatment guidance should be removed from the document.
- The importance of vaccination for HCP and family members of NICU patients should be reinforced in this section. Guidelines by the CDC Advisory Committee for Immunization Practices (ACIP) should be referenced in this effort (e.g., influenza vaccination and combined tetanus/diphtheria/pertussis vaccination).

Transmission-based precautions for patients in isolettes

- The draft recommendation should be revised as follows to explicitly answer the key question: “Further research is needed to determine whether transmission-based precautions can be modified for patients in isolettes.”
- New language should be added to address the practice in which some hospitals prevent transmission of infection by placing infants in isolettes who normally would not be candidates for these units.

Diagnostic approaches

- Existing guidance on diagnostic testing should be referenced that recommends against the use of serology for diagnosis due to the risk of detecting pseudo-outbreaks with certain PCR tests.

C. difficile testing

- The narrative evidence summary should reference data to address the pathogenicity of *C. difficile* in the neonatal population (e.g., pseudomembranes and histopathologic tissues and diagnoses). The recommendations should include language that clearly states the pathogenicity of *C. difficile* has not been established in infants.
- Recommendation 1 should be revised with new language to address a lower threshold to test earlier for *C. difficile* in the NICU setting during non-outbreak situations.
- Consideration should be given to changing the Category IB recommendations to “no recommendation/unresolved issue” for *C. difficile* testing in NICU patients.
- The overarching purpose of the guideline is to provide guidance on infection prevention in the NICU setting. As a result, any clinical language on “treatment” beyond NICU patients who are exposed during an outbreak should be reframed and carefully worded.

Overarching comments and suggestions

- CDC should develop a process that clearly establishes boundaries and appropriately balances its evidence-based guidelines and implementation guidance for the field. On

the one hand, recommendations in guidelines based on GRADE evidence should not be integrated with guidance that will be included in implementation guides for IPs in the field. On the other hand, explanatory comments or clarifying language should be included in guidelines to ensure that Category IB recommendations can be implemented and are practical for the field. .

- Companion implementation guides (e.g., a list of frequently asked questions (FAQs), expert opinion documents) should be developed in parallel with guidelines. These guides could be developed by professional societies and other experts in the field and .
- New language should be added to the beginning of the guideline to clarify that the recommendations also apply to patients in special care nurseries, particularly for facilities without NICUs.
- New language should be added to the beginning of the NICU guideline or each section to clearly explain and justify the difference between very low-quality evidence in a Category IB recommendation versus a Category IC or II recommendation. The clarifying language will play a critical role in avoiding the unintended consequence of HCP giving equal importance to all Category IB recommendations (e.g., aseptic techniques versus education).

Dr. Michael Bell is the Deputy Director of DHQP. He announced that time was set aside on the meeting agenda for CDC and HICPAC to discuss the formation of ongoing workgroups based on subject-matter areas. This agenda item could be used to explore strategies to make the best use of HICPAC's time and expertise and address comments by the members on the guideline development process, particularly in terms of the need for a clearly defined process to separate recommendations based on GRADE evidence and implementation guidance for the field.

Update on the Prevention of Surgical Site Infection (SSI) Guideline

Sandra Berríos-Torres, MD

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Centers for Disease Control and Prevention

Dr. Berríos-Torres covered the following topics in her update to HICPAC on the draft SSI Prevention Guideline. Since the February 2012 HICPAC meeting, the writing group has completed targeted searches for the *Staphylococcus aureus* (*S. aureus*) checklist and bundles in the core section of the SSI guideline. Additional targeted searches were performed to identify RCTs, systematic reviews and controlled observational studies to address specialty issues in the arthroplasty section (e.g., transfusion, immunosuppressive therapy, use of exhaust suits, anticoagulation and antimicrobial prophylaxis duration with a drain and biofilm).

The writing group developed standardized templates to extract data from RCTs, systematic reviews, and non-RCTs identified in targeted searches. The writing group will complete several major activities in June-July 2012: evidence tables for the original 203 studies (e.g., 169 studies for the core section and 34 studies for the arthroplasty section) identified in broad literature searches; data extraction from studies identified in core targeted searches for the *S. aureus*

surgical checklist and bundles; and data extraction from studies identified in arthroplasty targeted searches.

The writing group is reevaluating the focus of the arthroplasty section. Concerns were raised that recommendations would be presented for this section based on 2 different methodologies. During targeted and broad searches, data were extracted from studies on transfusion, exhaust suits, immunosuppressive therapy, anticoagulation and biofilm. The writing group plans to extract further data, discuss and make recommendations on these 5 topics in the arthroplasty section.

The surgical attire questions (e.g., double gloving and gloves with antimicrobial coating), technique questions (e.g., pulsatile lavage, electrocautery and closure techniques), anesthesia questions, and environmental operating room (OR)-related questions produced no more than 1 study in the original broad search. However, antibiotic-impregnated cement yielded 2 RCTs and 2 systematic reviews in the broad search.

To address this data gap, the writing group will focus the arthroplasty section only on the 5 topics with studies from both targeted and broad searches. However, evidence tables with completed data extractions from RCTs and systematic reviews will be retained for the excluded questions as an appendix to the guideline. This approach will result in a more standard methodology in the arthroplasty section and also will allow other professional societies and subject-matter experts in the field to conduct targeted searches for additional analyses.

HICPAC made several comments and suggestions for the writing group to consider in its ongoing efforts to revise the draft SSI Prevention Guideline.

- Data and outcomes from large population-based registries and Northern European studies should be reviewed to obtain more data on antibiotic-impregnated cement. This practice is common, particularly in arthroplasties.
- The biofilm questions appear to address the diagnosis of SSIs rather than the intended focus of the guideline on prevention of SSIs.
- The writing group should consider giving an expert opinion statement on key question 30 regarding the number of staff in the OR.
- Data on more modern practices (e.g., iron infusion for patients with preoperative anemia) should be added to the key question on perioperative transfusion.
- Data on standard and well-accepted basic infection control strategies (e.g., hand hygiene and aseptic techniques) that will not be changed, but are not supported by RCT data should be included in the core section of the guideline.

Overview of the Disinfectant Fogging Guideline Clarification Process

Mr. Jeffrey Hageman, MHS

Acting Prevention and Response Branch Chief, DHQP
Centers for Disease Control and Prevention
HICPAC Designated Federal Official

Mr. Hageman presented an overview of CDC's process to provide clarifications to existing CDC recommendations. The guideline development process typically is completed in 18-24 months due to the rigor of multiple steps:

- form the writing group;
- conduct an initial literature search of existing guidelines;
- develop key questions;
- review the evidence through targeted literature searches and abstract/full-text reviews;
- extract and synthesize data;
- draft recommendations and receive preliminary input from HICPAC;
- publish the draft recommendations in the *Federal Register* for a 30-day public comment period;
- revise the draft recommendations based on comments received and obtain final input from HICPAC;
- complete the CDC clearance process; and
- publish and promote the final guideline through a variety of mechanisms.

In post-development activities, CDC receives and addresses questions on the guideline from multiple audiences (e.g., HCP, health departments, facility surveyors, policymakers, consumer advocates and the general public). During this process, CDC interprets the guidelines, clarifies recommendations for certain audiences, and addresses setting-/situation-specific issues. CDC also takes action when the original intent of the guideline is lost over time due to emerging practices, techniques or products. The intent of some guidelines is clarified with no modifications to the recommendations. In post-development activities to clarify guidelines, CDC solicits input from HICPAC to raise awareness of common issues in a public forum. Mr. Hageman informed HICPAC of CDC's proposed clarification statement for the Disinfectant Fogging.

Formaldehyde and paraformaldehyde were used as chemicals in room fogging for disinfection purposes. Formaldehyde gas was used for large-scale disinfection of room surfaces in healthcare settings prior to the 1980s and primarily was generated by heating paraformaldehyde flakes in frying pans on burners in hospital rooms. This practice is no longer used in healthcare settings, but is still used in certain laboratory settings. Quaternary ammonium compounds reportedly were used to fog patient bays of ambulances.

These chemicals were effective in destroying pathogens, but issues regarding their safety led to the development of guidance beginning in 1981. The guidelines emphasized that disinfectant

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chemicals typically are not registered with the U.S. Environmental Protection Agency (EPA) for application in healthcare settings. The guidelines also noted that both patients and technicians who apply chemicals face unintended hazards (e.g., adverse health effects from hazardous chemical residues remaining on surfaces and occupationally-acquired asthma).

CDC issued recommendations on the use of fogging for room and space disinfection in its pre-HICPAC *Guideline for Hospital Environmental Control* in 1981. The guideline recommended against disinfectant fogging: “Disinfectant fogging for control of microbial contamination of air or surfaces is not only ineffective for infection control; it is time-consuming and potentially toxic.” CDC’s 1985 *Guideline for Handwashing and Hospital Environmental Control* reiterated the 1981 guidance and made no changes to the text or ranking of the recommendation.

The 2003 CDC/HICPAC *Guideline for Environmental Infection Control in Healthcare Facilities* recommended against performing disinfectant fogging in patient-care areas: “Disinfectant fogging is not recommended in general patient-care areas. Further, paraformaldehyde, which was once used in this application, is no longer registered by EPA for this purpose.”

The 2008 CDC/HICPAC *Guideline for Disinfection and Sterilization in Healthcare Facilities* recommended against performing disinfectant fogging for routine purposes in patient-care areas: “The technique of spraying of disinfectants is an unsatisfactory method of decontaminating air and surfaces and is not recommended for general infection control in routine patient-care areas. Disinfectant fogging is rarely, if ever, used in U.S. healthcare facilities for air and surface disinfection in patient-care areas.”

New developments in chemical fogging have occurred since the publication of the 2008 CDC/HICPAC guideline including vaporized hydrogen peroxide, ozone, and chlorine dioxide that primarily are used for bioterrorism decontamination of buildings. In recognition of these new developments, CDC proposes to issue the following clarification statement for the existing recommendations about disinfectant fogging:

“CDC and HICPAC have recommendations in both 2003 Guidelines for Environmental Infection Control in Healthcare Facilities and the 2008 Guideline for Disinfection and Sterilization in Healthcare Facilities that state that the CDC does not support disinfectant fogging. Specifically, the 2003 and 2008 Guidelines state:

- Do not perform disinfectant fogging for routine purposes in patient-care areas (2003).
- Do not perform disinfectant fogging in patient-care areas (2008).

These recommendations refer to the spraying or fogging of chemicals (e.g., formaldehyde, phenol-based agents, or quaternary ammonium compounds) as a way to decontaminate environmental surfaces or disinfect the air in patient rooms.

The recommendation against fogging was based on studies in the 1970s that reported a lack of microbicidal efficacy (e.g., use of quaternary ammonium compounds in mist

applications) but also adverse effects on healthcare workers and others in facilities where these methods were utilized. Furthermore, some of these chemicals are not EPA-registered for use in fogging-type applications.

These recommendations do not apply to newer technologies involving fogging for room decontamination (e.g., ozone mists, vaporized hydrogen peroxide) that have become available since the 2003 and 2008 recommendations were made.

The 2003 and 2008 recommendations still apply; however, CDC does not yet make a recommendation regarding these newer technologies. This issue will be revisited as additional evidence becomes available.”

CDC's next steps will be to post the clarification statement and link to reference materials on its website, broadly distribute the statement to partners, and identify other venues to widely publicize the statement. CDC welcomes input from HICPAC on other methods to disseminate the statement to key partners.

HICPAC made 2 suggestions for CDC to consider before broadly disseminating the clarification statement. First, the last paragraph of the statement should be changed to: “The 2003 and 2008 recommendations still apply for older disinfectants...” Second, CDC should thoroughly review EPA's actual language on the registration of chemicals for disinfectant fogging applications in patient-care areas. EPA's registration of these products is limited to surface disinfection and does not include air disinfection.

None of the HICPAC voting members expressed opposition to CDC disseminating its proposed clarification statement for disinfectant fogging.

Update by the ACIP Hepatitis Workgroup

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Epidemic Intelligence Service Officer

National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

Dr. Schillie presented issues the ACIP Hepatitis Workgroup is considering to ensure hepatitis B virus (HBV) protection for HCP. The ACIP term of reference is to ensure HBV protection for HCP, including trainees, who received HBV vaccination in the past without post-vaccination serologic (PVS) testing. ACIP selected a 10-year time frame because the collection of additional data on vaccine-induced immune protection is anticipated. As a result, the recommendations under discussion are considered to be interim.

Key points in ACIP's 2011 immunization recommendations are summarized as follows. “HCP” were defined as all paid and unpaid persons working in healthcare settings, including students

and trainees, who potentially could be exposed to patients and/or infectious materials. An HBV vaccine series of ≥ 3 doses was recommended for all unvaccinated HCP whose work-/training-related activities involved risk for blood and body fluid exposure. Completion of the vaccination series was recommended before trainees came into contact with blood.

PVS testing 1-2 months after the last HBV dose was recommended for all HCP at high risk for blood and body fluid exposures to determine the need for revaccination and guide PEP. HBV PEP was not required for vaccine responders (e.g., persons with serologic evidence of protection) regardless of the HBV surface antigen status of the source patient.

The level of antibody-to-HBV surface antigen is used to assess serologic evidence of vaccine-induced protection based on a measurement 1-2 months after the HBV vaccine series. Antibody-to-HBV surface antigen ≥ 10 mIU/mL corresponds to vaccine-induced protection. Protection among immunocompetent vaccine responders has been documented in the literature for >22 years.

Antibody-to-HBV surface antigen after the HBV vaccine series wanes over time. However, breakthrough HBV infection is uncommon in immunocompetent vaccine responders even when antibody-to-HBV surface antigen decreases to <10 mIU/mL. Antibody-to-HBV surface antigen levels <10 mIU/mL at a time distant from vaccine completion have no distinction among initial vaccine responders (~93%), delayed vaccine responders (~5%), and non-vaccine responders (~2%).

A challenge dose of HBV vaccine can be administered to induce an increase in antibody-to-HBV surface antigen and provide serologic evidence of protection. An increase of antibody-to-HBV surface antigen to ≥ 10 mIU/mL following a challenge dose of HBV vaccine correlates with protection and indicates that immune memory is intact. The purpose of a booster dose to provide rapid protective immunity against a significant breakthrough infection differs from the purpose of a challenge dose.

Response to a challenge dose is lower among persons vaccinated at <1 year of age versus those vaccinated at ≥ 1 year of age. Response also declines as the time interval since vaccination increases. The meaning of "failure" to respond to a challenge dose is not currently understood.

Efforts were initiated to change the context for occupationally-acquired HBV due to several factors. In terms of recent developments, healthcare schools and institutions are seeking guidance to ensure protection for HCP who previously received the HBV vaccine series without PVS testing, including HCP who were vaccinated as infants as part of universal infant vaccination and adults with no history or record of PVS testing.

An increasing proportion of HCP who are entering training and the workforce previously have received the HBV vaccine series. The 1991 recommendation on routine infant HBV vaccination led to coverage of $\geq 91\%$, while the 1999 recommendation on catch-up vaccination for persons 0-18 years of age led to coverage of 89% in adolescents up to 17 years of age. PVS testing is

not recommended after routine infant or child HBV vaccination. Studies indicate that ~98% of infants have a primary immune response to vaccination.

More HCP will have been vaccinated at <1 year of age instead of ≥ 1 year of age over time. This trend is significant because years after vaccination, persons vaccinated at <1 year of age more often have antibody-to-HBV surface antigen <10mIU/mL compared to persons vaccinated at ≥ 1 year of age.

Studies have projected HBV vaccination of ≥ 3 doses by age at first dose and age group in the general U.S. population in 2013, 2018 and 2023. The projections show a remarkable increase in HBV vaccine coverage at <1 year of age in the 18-20, 21-25 and 26-30 age groups from 2013 to 2023. Several U.S. studies have shown that some trainees and most non-trainees still have serologic evidence of protection ranging from 50%-100% since vaccination at ≥ 1 year of age 6.5 to 30 years ago. A number of studies have shown that many trainees still have serologic evidence of protection of <50% since vaccination at <1 year of age 2 to 17.5 years ago.

In terms of policy, the 2001 Needlestick Safety and Prevention Act directed the Occupational Safety and Health Administration to revise the Occupational Exposure to Bloodborne Pathogens standard and established more detailed requirements for employers to identify and use effective and safer medical devices.

The legislation led to a reduction in percutaneous injuries (e.g., needlesticks, cuts and bites) per 100 occupied beds from 40 injuries in 1999 to 30 injuries in 2001. Mucosal exposures (e.g., blood and body fluid contact with mucous membrane or non-intact skin) per 100 occupied beds also decreased from ~10 exposures in 1997 to ~7 exposures in 2009.

In terms of epidemiologic trends, ~3,400 new acute HBV cases in the United States were reported to the CDC National Notifiable Diseases Surveillance System in 2009. However, under-diagnosis and underreporting did not account for the estimated 38,000 new HBV cases. In the 5-year period of 2005-2010, 203 acute HBV cases among HCP were reported to CDC.

Of the HCP cases, 75 had frequent blood contact, 60% were female, and 17% reported an accidental stick or puncture with a needle or other blood-contaminated object in the 6 weeks to 6 months prior to HBV illness. The median age of HCP in these cases was 41 years with a range of 18-69 years of age. The vaccination response history was sparse among the HCP cases.

“Chronic HBV” is defined as the presence of both HBV surface antigen and antibody-to-HBV core antigen. Chronic HBV cases serve as an important reservoir for transmission. The burden of chronic HBV is ~3/100,000 persons in the United States (or an estimated 800,000-1.4 million persons). The number of asymptomatic persons with chronic HBV has remained relatively stable since 1976. Prevalence likely varies by healthcare setting with renal dialysis centers and settings with large foreign-born populations accounting for greater prevalence. An additional

54,000 chronic HBV cases are imported annually from immigration. As a result, risks to HCP will continue.

The ACIP Hepatitis Workgroup discussed 5 approaches to ensure HBV protection among HCP vaccinated in the past without PVS testing. The 2 post-exposure evaluation approaches include HBV testing of all sources (e.g., HBV-negative, HBV-positive and unknown sources). The 2 pre-exposure evaluation approaches include antibody-to-HBV surface antigen testing and an HBV dose if necessary. The hybrid evaluation approach includes a pre-exposure HBV dose and post-exposure evaluation of all sources. The workgroup supported the post-exposure and pre-exposure evaluation approaches for further deliberation, but outlined actions for all 5 approaches.

The workgroup performed cost-effectiveness modeling over a 10-year time frame and sensitivity analyses for trainees. However, the workgroup preferred the same approach for both trainees and non-trainees to increase the potential for adherence to the recommendations. The models were designed with non-cost-related inputs and values, cost inputs, and loss of quality-adjusted life year (QALY) inputs.

The models assumed that HCP with antibody-to-HBV surface antigen <10 mIU/mL would not be seroprotected and immunity without serologic evidence of protection would increase the incremental cost-effectiveness for all approaches. The models used average values for blood and body fluid exposure and source patient HBV surface antigen positivity, but these values can vary substantially across occupations and settings.

The modeling results are summarized as follows. The cost per QALY saved with post-exposure approaches to evaluate protection among trainees would decrease from \$128,565 in year 1 to \$57,756 in year 10. The cost per QALY saved with pre-exposure approaches to evaluate protection among trainees would decrease from \$247,754 in year 1 to \$42,275 in year 10. The post-exposure approaches were associated with more infections than the pre-exposure approaches. The hybrid approach had intermediate values.

The cost per QALY saved with post-exposure approaches to evaluate protection among non-trainees would decrease from \$360,416 in year 1 to \$252,970 in year 10. The cost per QALY saved with pre-exposure approaches to evaluate protection among non-trainees would decrease from \$692,833 in year 1 to \$169,334 in year 10. Compared to the trainee models, the non-trainee models had higher incremental cost-effectiveness ratios and a lower incidence of infections.

The workgroup's next steps will be answer key research questions: (1) is the risk high enough to justify a pre-exposure approach? (2) Is the information about protection certain enough to exclude a pre-exposure approach? (3) Will the answers to these questions vary between trainees (e.g., vaccination at <1 year of age) and non-trainees? (4) Could the same approach for trainees and non-trainees impact the burden on occupational health staff differently?

Dr. Fishman moderated HICPAC's discussion with Dr. Schillie regarding ongoing efforts by the ACIP Hepatitis Workgroup to ensure HBV protection for HCP. The discussion topics included:

- difficulties in measuring durable immunity after persons have been vaccinated ≥ 10 years before entering the healthcare workforce;
- the need for cost-effectiveness modeling from a public health approach to determine and compare the cost of taking no action, the cost of treating HBV with newer agents, and the cost of vaccination;
- the rationale for the relatively stable incidence of chronic HBV since 1976 (e.g., the influx of chronic cases from endemic areas);
- the need for sensitivity analyses to quantify the cost-effectiveness of HCP at various levels who would be protected;
- difficulties with the timing and logistics of testing HCP after the challenge dose, particularly with respect to the need for additional visits for follow-up testing and repeated HBV vaccine doses;
- the inconsistency between the 6-dose vaccine strategy in the workgroup's pre-exposure approach and the current HBV vaccination schedule; and
- the need to link HBV testing of HCP with annual TB testing and mandated influenza vaccination.

HICPAC agreed that the workgroup's proposed pre-exposure approach would be logistically easier to implement than the post-exposure approach, but this strategy would be more costly due to a larger population. The HICPAC members made two suggestions for the workgroup to consider in its ongoing deliberations to ensure HBV protection for HCP.

First, the workgroup should investigate other promising strategies for HCP who are non-responders (e.g., double antigen for protection). Studies on higher antigen content dosing for non-responders have reported better response rates. Second, ACIP recommends antigen testing for HCP who fail to respond to 6 HBV vaccine doses. This guidance should be more explicitly and clearly stated in the recommendation as a standard protocol.

Update on CDC's Single-Dose Vial Activities

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Dr. Perz presented an update on CDC's single-dose vial activities. CDC defines a "single-dose/single-use vial" as a vial of liquid medication intended for parenteral administration that is meant for use in a single patient for a single case, procedure or injection. Single-dose/single-use vials are labeled as such by the manufacturer and typically lack an antimicrobial preservative.

The Standard Precautions section of the 2007 *CDC/HICPAC Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* addressed

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single-dose vials in 2 injection safety recommendations: Use single-dose vials for parenteral medications whenever possible (Category IA). Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use (Category IA).

Since publication of the 2007 Safe Injection Guideline, at least 19 outbreaks have been associated with single-dose vials or single-use intravenous (IV) solutions. Of these outbreaks, 7 involved transmission of HBV and/or hepatitis C (HCV) and 12 involved transmission of bacterial infections with high rates of hospitalization for BSI. All 19 outbreaks occurred in outpatient settings (e.g., 8 in pain clinics and 5 in cancer clinics).

The May 16, 2008 edition of the *Morbidity and Mortality Weekly Report* published an article that attributed acute HCV infections to unsafe infection practices at an endoscopy clinic in Las Vegas, Nevada in 2007. Staff anesthetists routinely reentered medication vials with used syringes and used single-dose vials of propofol for more than one patient. The outbreak led to a CDC/Centers for Medicare and Medicaid Services (CMS) collaboration to assess infection control practices in ambulatory surgical centers (ASCs) in a more systematic and ongoing manner and develop the "Infection Control Surveyor Worksheet." In the list of items that must be assessed during onsite surveys, surveyors must check whether the ASC used single-dose/single-use medication vials for only one patient. A response of "no" must be cited as a deficiency. In the pilot of the worksheet in 3 states, surveyors reported that ~28% of ASCs reused single-dose vials.

The American Society of Interventional Pain Physicians (ASIPP) launched a campaign in 2012 in which its members and those of other professional societies were asked to send letters to their Congressional representatives about the critical shortage of essential drugs due to the CMS single-dose vial policy. ASIPP stated that the single-dose vial policy for infection control was expensive, caused numerous problems related to patient access, and has not been proven through evidence to be necessary or medically indicated. ASIPP also informed its members that CMS's modification of the rule as soon as possible would be essential to avoid further crises.

Major differences between the 2007 CDC/HICPAC Injection Safety Guideline and the ASIPP draft "Consensus Statement of Infection Control Measures of Single-dose Vials for Multiple Patients" are set forth in the table below.

CDC/HICPAC Injection Safety Guideline	ASIPP Draft Consensus Statement
Use aseptic technique to avoid contamination of sterile injection equipment. (Category IA)	All doses must be drawn up by licensed professionals whose scope of practice includes administration of parenteral medications and knowledge of aseptic technique.
Do not administer medications from a syringe to multiple patients, even if the needle or cannula on the syringe is changed. Needles,	This issue is not mentioned.

<p>cannulae, and syringes are sterile, single-use items; they should not be reused for another patient nor to access a medication or solution that might be used for a subsequent patient. (Category IA)</p>	
<p>Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use. (Category IA)</p>	<p>All doses from a given vial should be drawn-up and administered within a 12-hour period.</p> <p>Only one vial of a given concentration of the medication should be opened and used by the administering professional at any given time. A second vial of the same medication must not be opened until the previous vial is discarded.</p> <p>Any opened vials or filled syringes (contrast medium, local anesthetic, steroids, or other drugs) must be discarded if not used within 12 hours of the vial's first puncture. Vials must be labeled to document the time of first entry and maintained at a temperature of 2-8 degrees Celsius (or 36- 46 degrees Fahrenheit) when not in use.</p> <p>Residual amounts of these medications (either in the vial or syringes) must never be pooled with medication from another vial or syringe. If a patient requires more medication than is in a single, drawn syringe, then medication from a separate vial should be drawn into a separate syringe for administration.</p>

CDC was surprised and disturbed by some of the recommendations in the ASIPP consensus statement. Most notably, no evidence has been produced to support the safety of drawing up and administering all doses from a given vial within a 12-hour period. Moreover, the guidance on maintaining vials or filled syringes at a refrigerated temperature is problematic because many drugs are labeled for room temperature. This guidance could have unintended effects on the stability or integrity of the drug.

ASIPP launched a strong marketing campaign for prominent and notable professional societies to sign its draft consensus statement. ASIPP also gave the impression that CDC's guidance had latitude and flexibility in terms of the "12-hour grace period." To clarify its guidelines to

clinicians and dispel the dissemination of inaccurate information to healthcare providers, CDC publicly restated its position on single-dose/single-use vials in a formal statement on May 2, 2012. CDC stated that its guidelines call for medications labeled as “single dose.”

CDC’s position statement to protect patients against preventable harm from improper use of single-dose/single-use vials is outlined below.

“In times of critical need, contents from unopened single-dose/single-use vials can be repackaged for multiple patients. However, this should only be performed by qualified healthcare personnel in accordance with standards in United States Pharmacopeia (USP) General Chapter 797, Pharmaceutical Compounding-Sterile Preparations. Following the USP standards is imperative, as medication contamination and patient harm can occur when repackaging (e.g. splitting doses) is not done properly.”

CDC’s ongoing activities related to single-dose vials include regular discussions with federal partners, including CMS, USP and the Food and Drug Administration (FDA). Extensive outreach is being targeted to the healthcare community to educate providers on experiences with outbreaks associated with multi-patient use of single-dose vials. CDC also is gathering feedback from providers on their challenges and other factors in dedicating single-dose vials to individual patients (e.g., reimbursement, the national drug shortage, and access to “right-sized vials” that may not be produced by the manufacturer).

Dr. Fishman moderated HICPAC’s discussion with Dr. Perz on CDC’s single-dose vial activities. The discussion topics included:

- the likelihood of multi-patient use of single-dose vials in settings other than outpatient facilities (e.g., inpatient facilities or long-term care facilities (LTCFs)); and
- provider practices and behaviors of weighing the “low risk” or “rare occurrence” of an outbreak against the “financial benefit” of using single-dose vials for multiple patients.

HICPAC made several comments and suggestions for CDC to consider in its ongoing activities related to single-dose vials.

- CDC and its federal partners should collaborate with manufacturers to repackage and make drugs available in smaller doses at a reasonable cost. Wasting or discarding drugs, particularly those that are expensive or in short supply, is not in the best interest of society. For example, access to right-sized vials is particularly challenging in pediatric settings because propofol in large vials is wasted on small doses required for infants and children.
- In its ongoing outreach and education activities, CDC should encourage the healthcare community to adopt the model by the University of Oklahoma Health Sciences Center, College of Public Health. Staff is required to watch CDC’s Safe Injection Practices Video and all 60 clinics affiliated with the center are routinely audited to ensure injection safety. This model would help to track and monitor safe injection practices in outpatient

endoscopy centers, physician's offices, plastic surgery centers, and other facilities that are not accredited, regularly surveyed or regulated.

- CDC's position statement is too polite in light of ASIPP's inflammatory statements, irresponsible guidance and "self-created" evidence. For example, the recommendation in the 2007 CDC/HICPAC Injection Safety Guideline to use single-dose vials for parenteral medications "whenever possible" should be restated with stronger wording.
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- CDC should strongly encourage healthcare facilities to develop contracts with language that requires pharmacies to adhere to the USP 797 standard. At this time, only 22 states have mandatory compliance with this standard.

Update on DHQP's Response Support to Recent Outbreak Investigations

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Dr. Weber presented an update on DHQP's response support to recent outbreak investigations. From January 1, 2011 through June 7, 2012, DHQP received 108 requests for assistance from 38 states, including 1 multi-state investigation, 1 multi-state desk investigation, and 17 field investigations.

The top 6 organism types of the investigations were gram-negative rods, viruses, gram-positive cocci, unconfirmed sources, non-tuberculous Mycobacteria (NTM) and fungi. The top 7 issues of the investigations were inpatient HAIs, outpatient HAIs, multidrug-resistant organisms, other issues, injection safety, device-related issues, and product contamination. The top 4 settings of the investigations were hospitals, other ambulatory care settings, LTCFs and dialysis centers. A small number of outbreaks were reported in long-term acute care hospitals (LTACHs), community clinics and surgery centers, but the detection bias in these facilities is recognized.

Over time, DHQP has expanded its reach of protecting patients from HAIs from acute care hospitals to include ambulatory care facilities (e.g., surgical centers, dialysis clinics and home health facilities) and LTCFs (e.g., LTACHs, skilled nursing facilities (SNFs), rehabilitation centers and nursing homes).

A 2011 investigation in Alabama involved an outbreak of *Serratia marcescens* (*S. marcescens*) BSI in patients receiving total parenteral nutrition (TPN). Compounding pharmacies commonly prepare TPN using sterile manufactured components whenever possible to reduce the risk of contamination.

The investigation identified 19 case-patients ≥ 18 years of age from 6 hospitals who received TPN from the source pharmacy. Of these patients, 9 died. Due to a manufacturer shortage, the source pharmacy began compounding and filter-sterilizing amino acids for adult TPN in October 2010. A review of this process identified breaches in mixing, filtration and sterility testing

practices. *S. marcescens* was identified from a mixing container, amino powder and a water faucet in the source pharmacy.

Isolates were indistinguishable from case-patient isolates by PFGE. The simulation of the source pharmacy's substandard filter-sterilization procedures demonstrated breakthrough of *S. marcescens* in the post-filtered amino acid solution. Higher-risk compounding of amino acids was initiated due to a national shortage. Failure to follow recommended filter-sterilization practices resulted in an outbreak of *S. marcescens* BSI. To prevent similar outbreaks, pharmacies must understand and adhere to current USP 797 compounding standards.

A 2012 investigation involved a multi-state outbreak of post-procedural fungal endophthalmitis (FE) associated with a single compounding pharmacy. In March 2012, the California Department of Public Health was notified of 9 cases of clinically diagnosed FE at a single ASC. All case-patients had undergone vitrectomy with epiretinal membrane peeling using the Brilliant Blue-G (BBG) dye from Franck's Compounding Laboratory in Ocala, Florida. The investigation was expanded to include intravitreal injection of triamcinolone-containing products from Franck's.

The investigation identified 33 cases in 7 states. Patients who received BBE were infected with *Fusarium incarnatum-equiseti* species complex, while those who received triamcinolone were infected with *Bipolaris hawaiiensis*. Due to the infection, patients suffered partial to severe vision loss or worsened vision that required repeat ophthalmic surgery. All products involving sterile human and veterinary compounded prescriptions distributed by Franck's pharmacy from November 21, 2011 to May 21, 2012 were recalled. The United States issued an International Health Regulations notification to WHO. All sterile compounding was stopped.

A 2012 investigation involved an outbreak of tattoo-related NTM infections. NTM is a family of gram-positive bacteria found in water, soil and other environmental sources. NTM is implicated in skin, soft tissue, bone, pulmonary and ophthalmic infections. Reports of NTM infections related to permanent tattoos have been published in the literature. NTM is associated with diluting products with non-sterile water.

In January 2012, a local health department received a report of a large cluster in which 14 of 19 infections had confirmed *Mycobacterium chelonae*. The cases were associated with a single tattoo parlor that used a single grey tattoo ink product with no evidence of dilution at the point of use. In February 2012, FDA and CDC jointly investigated the likelihood of more widespread NTM infections.

CDC's Epi-X platform, Emerging Infections Network, HAI networks and dermatologists were used for initial case finding. Multiple states reported NTM infections related to tattoos, but not all of the infections were related to one product line. Some clusters were associated with other NTM infections (e.g., *Mycobacterium fortuitum* and *Mycobacterium abscessus*).

The initial interpretations of the tattoo-related infections were that contamination of tattoo inks can occur throughout the manufacturing process if sterile ingredients and aseptic techniques are not implemented. The inks were intrinsically contaminated with NTM and also were diluted with non-sterile water. Distilled water was inaccurately believed to be pathogen-free. FDA currently does not exercise regulatory authority over tattoo inks or their pigments at the national level, but local jurisdictions may regulate the practice of tattooing.

A 2009-2011 investigation in Florida involved an outbreak of carbapenem-resistant *Enterobacteriaceae* (CRE) at an LTACH. The LTACH's microbiology records were reviewed from March 2009-February 2011 to identify CRE transmission cases and cases admitted with CRE. The investigation identified 99 CRE transmission cases, 29 CRE bacteremia episodes, and 16 cases admitted with CRE. Acute care hospitals accounted for 7 of these admissions.

CRE transmission cases were included in a case-control study to evaluate risk factors for acquisition. The investigation showed that the cases were more likely to have received β -lactams, have diabetes and require mechanical ventilation. All of the tested isolates were *Klebsiella pneumoniae* (*K. pneumoniae*) carbapenemase (KPC)-producing *K. pneumoniae* and were genetically related.

Infection control activities included administering biweekly CRE prevalence surveys to the LTACH from July 2010-July 2011; educating and auditing staff; and isolating and cohorting CRE patients with dedicated nursing staff and shared medical equipment. These interventions resulted in significant reductions in CRE prevalence, the percent of patients screened with newly detected CRE, and CRE bacteremia episodes. The investigation showed that reductions in CRE within and across healthcare facilities might require a regional public health approach to be sustainable and effective over time.

The 2011 investigation in Panama involved an outbreak of KPC-producing *K. pneumoniae* in a 1,000-bed tertiary care hospital. The hospital and Panamanian government requested assistance from CDC and the Pan American Health Organization (PAHO). The overarching objectives of the investigation were to determine the nature and extent of the outbreak; identify risk factors for infection and sources of transmission; and recommend control measures to prevent further transmission.

Some conclusions as a result of its response support to recent outbreak investigations. Most investigations and response support occur in hospital settings, but this trend is changing and might be an artifact of differential detection. Improvements in ancillary settings and technology can have a direct impact on patient safety and infection risk, but these areas are not where outbreaks are detected.

Antimicrobial stewardship and use both inside and outside hospital settings affect each other. Innovative and collaborative methods must be implemented to improve safety in settings that have minimal resources and oversight. Anticipation of demographic and business trends might

play a role in developing strategies to prevent outbreaks in new settings. A combined local, regional and global focus is needed to sustain interventions.

Update on the National Healthcare Safety Network (NHSN)

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Dr. Arnold presented an update on CDC's national strategy and toolkit to validate NHSN data. Validation of HAI data is important because credible data are vital for prevention at the facility level, public reporting, and provision of incentives to improve clinical performance. However, the rapid expansion and use of NHSN have increasingly led to concerns regarding uneven data quality.

This issue always has been important to CDC, but is now more critical than in the past. Most notably, data validation can improve fairness to reporting facilities. Training is needed on all levels due to the influx of new NHSN reporters. Findings from data validation efforts can identify gaps, guide training and determine areas for improvement.

In the context of NHSN, CDC defines "validation" as assuring the production of high-quality surveillance data by undertaking 5 key activities: generating correct denominator data; identifying all candidate events in real time; documenting routine assessments of candidate events; correctly applying case definitions; and minimizing data entry errors.

CDC has made strong efforts to develop a standardized, scalable approach to validation that can be effective in any state regardless of its size or resources. In 2010-2011, states used American Recovery and Reinvestment Act funds to serve as validation laboratories and create innovative approaches.

CLABSI approaches created by states included sampling frame structures, numerator sampling approaches, case classification checklists, denominator method surveys, and risk factor/location mapping investigations. SSI approaches created by states included data linkages to enrich targeted samples or procedures for SSI, practice surveys for in-house and post-discharge case-finding practices, and risk factor audits.

Major differences between state validation of NHSN data and CMS validation of HAI data are set forth in the table below.

	States	CMS
Approaches	Differs state-by-state	Nationwide probability sample
Constraints	Statute (e.g., lack of access to NHSN data) and resources	Scope of the statute, resources, existing infrastructure
Validation methods	Numerator data, denominator	Numerator data

	methods, risk adjustment variables	
Sampling schemes	Varies and often is targeted	Small sample from all Inpatient Prospective Payment System Hospitals at least every 4 years
Primary goals	Improve surveillance practices, understand weaknesses for teaching, optimize data quality at all levels	Assure compliance, validate accuracy of metric, motivate internal improvement

CDC drafted a national strategy to document, characterize the need for, and resolve differences in NHSN data validation between states and CMS. The strategy is designed to acknowledge problems and explore approaches to improve surveillance; recognize CMS's role in motivating the engagement of facilities; collect information from non-validation states; and demonstrate the unique value of states in conducting NHSN data validation. Because all data cannot be validated, states use data to assure competence, identify weaknesses in surveillance, generate higher quality data, and enable improvements by teaching lessons learned and best practices.

The major components of CDC's "2012 Data Validation Guidance and Toolkit" for CLABSI and SSI are highlighted as follows: Chapter 1 provides an overview and framework of data validation. The "intrinsic/built-in validation" section describes data checks that are embedded in the NHSN software to minimize data entry errors and inconsistencies during data input by the user.

The "internal validation" section describes the use of canned analyses for NHSN and reporters to ensure the best possible sources of information in validating data and avoiding outliers or unusual trends. The "external validation" section describes audit validation with chart reviews that CMS, state health departments or other external sources can conduct with NHSN data. The other sections in Chapter 1 describe different types of external data validation and provide examples of external validation approaches that states have implemented (e.g., external data validation approaches targeted to facilities, locations and pathogens with problematic reporting, probability samples for external data validation, and hybrid approaches).

Tennessee and other states are highlighted in Chapter 1 as optimal models of external data validation due to their outstanding performance in efficiently improving data quality and educating other groups on reporting data errors. Connecticut, Oregon, Washington State and CMS also are featured in Chapter 1 as preferred models for longitudinal assessments and probability samples that are needed for extrapolation of CLABSI surveillance performance estimates to broader populations.

Chapters 2-4 focus on CLABSI and cover the following issues: internal data validation/quality assurance for reporting facilities and group users; targeted external data validation; and external data validation using probability samples. The chapters provide links to several CLABSI validation tools that have been developed by CDC's state partners and other groups:

- Access Database (New York)

- Facility Self-Validation Tool
- Denominator Collection Methods Survey
- Algorithmic Use of NHSN Analysis to Target Facilities
- Example Letter Requesting an External Validation Site Visit
- Checklists for Validation (Tennessee)
- Template for Audit Discrepancies Report
- Example Validation Follow-up Letters With and Without Problems
- Scalable Self-weighting Sample Using Probability Proportional to Size

Chapters 5-7 focus on SSI and cover the following issues: internal validation/quality assurance for reporters and group users; targeted external validation; and external validation using probability samples. The chapters provide links to several SSI validation tools that have been developed by CDC's state partners and other groups:

- Expected and Unusual Values for Surgery Variables
- Admission Surveillance Practices Survey
- Post-Discharge Surveillance Practices Survey
- Developing an Enriched Sampling Frame for Targeted SSI Validation
- ICD-9 Procedure Codes and ICD-9 Diagnostic Codes Suggestive of SSIs
- Expected Length of Stay for NHSN Procedures

CDC's next steps in the development of the national strategy for NHSN data validation will be to finalize and disseminate the toolkit and other guidance, determine costs, identify funding sources for continued data validation, sustain and enhance data validation capacity over time, and harmonize work among stakeholders. CDC and its broad range of partners will conduct post-validation analyses to assure quality improvement of current and future iterations of the toolkit. CDC hopes to submit the draft toolkit for clearance by July 1, 2012.

Dr. Fishman moderated HICPAC's discussion with Dr. Arnold on CDC's national strategy and toolkit to validate NHSN data. The discussion topics included:

- ongoing efforts by CDC and CMS to increase the use of electronic health record systems for both numerator and denominator data to minimize human interaction with surveillance definitions of HAIs; and
- the substantial variation in the quality of surveillance data by type of infection.

HICPAC was extremely pleased that CDC is developing a national strategy and toolkit with guidance in an effort to standardize reporting and validation of HAI data to NHSN across states. CDC's standardized approach will play an important role in addressing the tremendous variability and uncertain quality of information among NHSN state reports and the NHSN national report.

The HICPAC members made several comments and suggestions for CDC to consider in finalizing the draft NHSN data validation toolkit.

- CDC should have a more influential role in the CMS data validation process, particularly for CLABSI. Most notably, healthcare facilities develop a list of all patients who have a central line at any time during their hospitalization. These data are burdensome to capture, particularly if the line is not temporally inserted at the time of a blood culture.
- CDC should offer incentives or penalize states that do or do not validate NHSN data in their state-specific reports.
- CDC should rigorously investigate the scientific foundation for validation of NHSN data, particularly methods that are used to determine sample sizes, to improve confidence in validation results and better understand the limitations of current approaches.
- CDC should conduct risk stratifications for CLABSI and SSI in pediatric populations.

Update on the HICPAC Guidance on Adjudication in an Era of Public Reporting

Thomas Talbot, MD, MPH

Associate Professor of Medicine and Preventive Medicine & Chief Hospital Epidemiologist
Vanderbilt University Medical Center
HICPAC Member

Dr. Talbot presented an update on the HICPAC guidance document on the use adjudication in an era of public reporting. The purpose of the guidance document is to respond to the growing use of and interest in HAI surveillance data for regulatory issues, public reporting and quality comparison metrics; address the potential for variability in application and interpretation of surveillance definitions; and address the increase in adjudication methods.

HICPAC's charge to Dr. Talbot was to develop a guidance document to illuminate issues with the use of surveillance data, discuss real-world challenges with HAI data, highlight and discourage adjudication panels, and emphasize the need to improve surveillance definitions.

Since the February 2012 meeting, Dr. Talbot has drafted and revised the guidance based on input from several HICPAC members. After HICPAC's discussion of key issues, Dr. Talbot will make revisions; distribute the guidance to the HICPAC members for review and formal approval during an upcoming HICPAC meeting.

The background section describes HAIs, HAI surveillance definitions and the overall process, the shift from "house-wide" to targeted surveillance of high-risk, high-volume procedures, and broadened use of HAI surveillance data. Characteristics of an ideal metric for inter-facility comparison of HAIs are highlighted as well.

The section on traditional challenges of utilizing NHSN HAI surveillance data covers subjective components and acknowledges the development of new definitions to increase clinical credibility. Variation in record systems and surveillance programs across facilities and the absence of clinical consensus on HAIs also are discussed.

The section on use of HAI surveillance data for inter-facility comparison describes several unintended consequences, such as clinical adjudication and clinician veto; conflicts of interest for facilities and assessors; and pressures placed on hospitals to exclude events, particularly those that lack clinical credibility. The section on refinement of HAI surveillance definitions emphasizes the importance of clinical credibility and external credibility with patients and payers.

Dr. Talbot cited the recommended draft standards for HAI surveillance data that are outlined in the guidance.

1. As noted in the HICPAC guidance on public reporting of HAIs, the NHSN definitions are the standard for determining HAI burden and should be used for all HAI outcome measurements.
2. The ultimate decision as to whether an event meets an HAI surveillance definition must rest with an individual with specific content expertise and training in healthcare epidemiology and infection control. Individuals responsible for such assessment should be free from any conflicts of interest related to ramifications of public reporting of HAI data.
3. Those responsible for determining whether specific events meet the NHSN definitions should systematically document which definition criteria are met or reasons for an event's exclusion to provide clear and consistent assessment of the surveillance process.
4. Facilities should not use clinical adjudication panels or clinician veto to determine whether a given event should be reported as an HAI.
5. Reported data must be systematically validated. Unless there are consequences for variations in the use and interpretation of HAI surveillance data, practices such as adjudication will continue.
 - a. Such a validation program should be conducted by an impartial, independent party, such as a state health department or CMS surveyor.
 - b. Validation should include an evaluation of whether reported HAI events meet NHSN definitions and an assessment of potentially unreported events (such as through review of positive blood culture results to assess the presence of an unreported CLABSI). It should include a review the facility's surveillance methodology.
 - c. Additional metrics to assess for potential gaming of reported data should be examined (e.g. examination of the total number of BSIs and the total number of such BSIs classified as secondary to another infection when assessing CLABSI surveillance data). If CLABSI rates are low but the rates of secondary BSI are rising, this may be an indication of gaming the data.

6. A frank review of any institutional pressure to underreport HAI events also is extremely important.

The draft guidance ends with several concluding statements. A level playing field is important in public reporting and value-based purchasing. Unbiased and transparent reporting of HAIs based on standard surveillance definitions is critical. Investments at all levels will be necessary to create a level playing field. Public reporting should not be subjected to clinical adjudication. Validation is critical.

Dr. Talbot requested HICPAC's input on several questions to guide the development of the next iteration of the draft manuscript.

1. Who is the target audience of the guidance?
2. Should consensus and adjudication within hospital epidemiology and infection control experts be addressed?
3. Should the guidance include a discussion on "eliminating" or "targeting zero HAIs?"
4. What is the appropriate level of detail for the revised NHSN definitions?
5. What language should be included to reconcile the tension between more credibility and the need for objective measures that might result in less clinically credible definitions, particularly in light of the unpredictable nature of clinical diagnoses?
6. What is the process and definition of "validation?" What is a sustainable model for validation? Who is responsible for validation?

HICPAC made several comments and suggestions in response to Dr. Talbot's request for input.

Question 1

- Target audiences for the manuscript should include infectious disease physicians, surgeons, critical care physicians, intensivists, and hospital leadership/administrators.

Question 2

- Consensus and adjudication are valuable learning tools in IPC programs. IP panels can be used to effectively reduce rates due to the lack of uniform agreement of the current definitions among experts.
- The guidance should provide guidance to smaller hospitals outside of large academic settings that do not have the infrastructure to implement an adjudication process. The successful Tennessee model of educating groups to improve data quality and report data errors should be featured as an example.
- The guidance should include "practice adjudication cases" for hospitals to identify HAIs and state the rationale for their decisions.

Question 3

- The introduction should include a discussion on "eliminating" or "targeting zero HAIs" to describe pressures placed on hospitals.

Question 4

- HICPAC agreed with the current level of detail that broadly addresses the positive changes in the NHSN definitions.

Question 5

- The introduction should include explicit language that clearly distinguishes between clinical and surveillance definitions. For example, a case that meets a surveillance definition might not require treatment.
- The guidance should support a shift to surveillance definitions with the following functions. First, the definitions would not describe a clinical syndrome that an infectious disease physician would recognize as a treatable infection. Second, the definitions would rely on purely objective criteria that ideally would be subject to electronic surveillance. These events must be preventable and associated with adverse outcomes. The predictive value of surrogate markers must be consistent across high- and low-event hospitals.

Question 6

- The guidance states that individuals who are responsible for an assessment of public reporting of HAI data should be “free from any conflicts of interest. However, this term should be replaced with “free from administrative or other pressures to adjudicate NHSN definitions” because any responsible individual will have inherent conflicts of interest.
- In addition to expertise and training in healthcare epidemiology and infection control, persons with responsibility for validation also should have training in implementation of HAI surveillance.

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 June 14-15, 2012 meeting and their additional comments are summarized below.

- Shirley Paton, RN, MN (Public Health Agency of Canada) (PHAC). Ms. Paton reported that due to her upcoming retirement, she would be replaced with a new PHAC liaison representative at the next meeting. She thanked her HICPAC colleagues for providing expertise and guidance that have been extremely valuable to PHAC over the past few years.
- Lisa Spruce, RN, DNP, ACNS, ACNP, ANP, CNOR (Association of periOperative Registered Nurses (AORN)). Ms. Spruce reported that AORN is addressing challenges with the new process of ranking evidence and rating recommendations in its guidelines. Due to very low-grade and very low-quality evidence, some of AORN’s guidance is not recommended for practice or has no established evidence. AORN published its sterilization guideline and will publish guidelines on transmissible infections, sterile techniques and safe environment of care in 2013.

- Sheri Chernetsky-Tejedor, MD (Alternate, Society of Hospital Medicine) (SHM). Dr. Chernetsky-Tejedor reported that SHM is expanding its role as a professional society to serve as a patient safety organization. SHM subcontracted United Healthcare and the Hospital Association of Pennsylvania for the Partnership for Patients initiative to develop education, content and other resources for several hospital-acquired conditions and readmissions. SHM and its partners are providing educational content and training for a number of collaboratives. SHM is collaborating with partners to provide core hospitalist faculty to educate improvement teams on best practices utilizing the catheterout.org toolkit. SHM is drafting a letter in response to the Institute of Medicine's report on health information technology and patient safety.
- Charles Huskins, MD, MSc (Infectious Diseases Society of America) (IDSA): Dr. Huskins reported that IDSA has been involved in legislative activities related to antibiotic development. IDSA submitted testimony to Congressional subcommittees to maintain funding and support to CDC, particularly for NHSN and the EpiCenters. IDSA and its partners published an antimicrobial stewardship policy statement.
- Michael Howell, MD, MPH (Society of Critical Care Medicine) (SCCM): Dr. Howell reported that SCCM has embraced the prevention of HAIs as its core mission. SCCM is extremely excited about the changes in the NSHN definitions for ventilator-associated complications. SCCM and its partners will publish new guidelines on sepsis and systemic analgesia and sedation.
- Daniel Schwartz, MD (Centers for Medicare and Medicaid Services (CMS): Dr. Schwartz was unable to attend the meeting. Mr. Hageman highlighted key points from the CMS written report. CMS is piloting its Hospital Infection Control Surveyor Tool in states. CMS will make revisions based on comments by surveyors and finalize the tool in February 2013.
- Sheila Murphey, MD (Food and Drug Administration) (FDA). Dr. Murphey reported that FDA and its federal partners issued a joint communication on May 29, 2012 encouraging the use of blunt tip surgical needles in appropriate settings. The communication was in response to the HHS Viral Hepatitis Action Plan. FDA received an official Class 1 recall from the manufacturer on contaminated Other-Sonic Ultrasound Gel. FDA is continuing its investigation of illnesses and deaths in dogs related to chicken jerky treats imported from China. FDA will convene a public meeting on June 25, 2012 on the design of glucose sensors and systems for acute care hospitals.
- Kim Willard-Jelks, MD, MPH (Alternate, Health Resources and Services Administration) (HRSA). Dr. Willard-Jelks had no activities to report from HRSA.
- Stephen Kralovic, MD, MPH (Department of Veterans Affairs) (VA). Dr. Kralovic reported that the VA is focusing on the national rollout of its *C. difficile* initiative.

- David Henderson, MD (National Institutes of Health) (NIH). Dr. Henderson reported that the NIH Clinical Center has been managing an ongoing outbreak of KPC infections involving 18 patients with a mortality rate of ~60%. NIH conducted whole-genome sequencing of all 18 isolates. NIH has not observed any further transmission in the Clinical Center since January 2012.
- Marion Kainer, MD, MPH (Council of State and Territorial Epidemiologists) (CSTE). Dr. Kainer reported that CSTE has participated in monthly teleconferences with CDC and the National Coordinator for Health Information Technology to include HAI reporting through NHSN as part of core requirements in Stage 2 of Meaningful Use. CSTE held its annual conference on June 3-7, 2012 and passed a position statement that provides a road map to expand CLABSI surveillance outside the ICU. CSTE made definitional changes for multiple reportable conditions. CSTE will post its final position statements on its website within the next 2 weeks.
- Barbara DeBaun, MSN, RN, CIC (Association of Professionals of Infection Control and Epidemiology, Inc.) (APIC). Ms. DeBaun reported that APIC launched its competency model to direct professional development and guide practitioners to determine their necessary skill sets while advancing from novices to experts. APIC will focus on community outreach during International Infection Prevention Week on October 14-20, 2012. APIC was pleased to honor Dr. Ruth Carrico, a HICPAC voting member, with the Carole DeMille award.
- Mark Rupp, MD (Society of Healthcare Epidemiology of America) (SHEA). Dr. Rupp was unable to attend the meeting. Dr. Diekema highlighted key points from the SHEA written report. The SHEA Board endorsed CDC's restatement of its position on single-dose vials. The SHEA 2012 Educational Offering was tremendously successful with >600 participants. The themes were antimicrobial stewardship and basic/advanced epidemiology. SHEA will convene the 2013 Educational Offering on May 1-4, 2013 in Atlanta with a focus on the role of the environment. An advanced epidemiology track on electronic surveillance also will be held. SHEA is currently planning activities for Infectious Disease Week and has completed the abstract review process for this event.
- Alexis Elward, MD (Advisory Committee for Immunization Practices) (ACIP): Dr. Elward reported that ACIP welcomes additional input from HICPAC on its proposed strategies for HBV vaccination of HCP. The ACIP Pertussis Workgroup currently is reviewing data on intervals for booster doses.
- Robert Wise, MD (The Joint Commission): Dr. Wise's written report was distributed to HICPAC for review.

Public Comment Session

Dr. Fishman opened the floor for public comments; no participants responded.

With no further discussion or business brought before HICPAC, Dr. Fishman recessed the meeting at 4:48 p.m. on June 14, 2012.

Opening Session: June 15, 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. He asked the voting members to publicly disclose any conflicts of interest for the record.

- Alexis Elward, MD: Recipient of research support from Sage Products, Inc. to study the efficacy of daily bathing with chlorhexidine to prevent bloodstream infections (BSI) in pediatric intensive care unit (ICU) patients.

Dr. Fishman confirmed that the voting members and *ex-officio* members in attendance constituted a quorum for HICPAC to conduct its business on June 15, 2012. He called the proceedings to order at 9:07 a.m. and welcomed the participants to day 2 of the meeting.

Update by the HICPAC HAI Surveillance Workgroup: NHSN CLABSI Definition

Scott Fridkin, MD

Deputy Chief, Surveillance Branch, DHQP

Centers for Disease Control and Prevention

Nicola Thompson, PhD, MSc

Surveillance Branch/DHQP

Centers for Disease Control and Prevention

Drs. Fridkin and Thompson covered the following topics in their update on recent activities by the HICPAC HAI Surveillance Workgroup on the NHSN CLABSI definition. The purpose of the workgroup is to provide a structure for exploring implications of potential changes in surveillance methodology and reporting through NHSN with a focus on issues related to federal policy developments. The overarching goal of the workgroup is to provide input to CDC and HICPAC on potential implications (e.g., anticipated consequences of actions or changes) in periodic summary documents or presentations during HICPAC meetings.

The workgroup membership includes HICPAC and external experts in the fields of infection prevention, healthcare epidemiology, surgical infection and public health who have surveillance and analytical experience focused on process improvement and public reporting.

The workgroup fulfills its charge by answering key policy questions: (1) What is the strength of the evidence for making changes to any NHSN definition? (2) What are the pros and cons of making specific changes? (3) What are the implications for public reporting (e.g., reduce subjectivity, increase reliability and credibility, or make inter-facility comparisons)? (4) What are the implications for NHSN participation and surveillance trends (e.g., increase data collection burden or track and interpret trends over time)?

CDC also considers the implications of changes due to many interdependent components of NHSN use and users, including scientific issues (e.g., accuracy of changes), practical issues (e.g., resources for facilities to implement changes), technical issues, (e.g., software changes), partnership issues (e.g., changes to clinical architecture guidance), the expectations and needs of federal partners, collaboration with the National Quality Forum (NQF), and the relationship of the changes to legacy data.

Over the past year, the workgroup has considered changes to NHSN on the CLABSI definition and reporting; operational clarifications related to CLABSI and all other HAIs; revisions to and criteria of the SSI definition; and revisions to the SSI denominator and operational issues. Outside of the workgroup, CDC is extensively collaborating with critical care society partners to transition from the ventilator-associated definition to VAE and infection-related ventilator-associated complications. CDC also is considering aspects for refinement of the catheter-associated urinary tract infection definition.

The proposed changes to the NHSN BSI definition are summarized as follows. The BSI definition would be modified for a subset of clearly defined patient populations. The revised definition would be “mucosal barrier injury-laboratory confirmed bloodstream infection” (MBI-LCBI). A series of small changes would be made to NHSN criteria and operations to reduce subjectivity in the interpretation and application of the surveillance definitions.

In the existing NHSN BSI definition, primary BSIs are LCBI that are not secondary to community-acquired infections or HAIs meeting CDC/NHSN criteria at another body site. Criteria must be met in 3 areas for infections to be defined as LCBI. Criterion 1 is patients with a recognized pathogen cultured from ≥ 1 blood cultures and organisms cultured from blood that are not related to an infection at another site.

Criterion 2 is patients with at least one of the following signs or symptoms: a fever >38 degrees Celsius, chills or hypotension; positive laboratory results that are not related to an infection at another site; and common commensal cultured from ≥ 2 blood cultures drawn on separate occasions. Criterion 3 is the same as criterion 2 except patients <1 year of age must have at least one of the following signs or symptoms: a fever >38 Celsius, hypothermia <36 Celsius,

apnea, or bradycardia. In the existing NHSN CLABSI definition, LCBI in a patient with a central line is classified as CLABSI.

The proposed modification to the LCBI definition adds MBI-LCBI. LCBI must meet existing NHSN criteria for healthcare-associated primary BSI that requires an eligible patient and an eligible organism. MBI-LCBI in a patient with a central line is classified as central line-associated MBI-LCBI. These events will continue to be reported to NHSN as part of CLABSI surveillance.

The MBI-LCBI definition includes 2 eligible patient populations. Allogeneic hematopoietic stem cell transplant (SCT) recipients must have received an allogeneic SCT within the past year and have one of the following conditions documented during the same hospitalization as a positive blood culture: (1) Grade III or IV gastrointestinal graft-versus-host disease (GI GVHD) or (2) at least 1 liter of diarrhea in a 24-hour period (or 20 mL/kg in pediatric patients) with onset on or within 7 calendar days before the positive blood culture.

Patients with neutropenia must have (1) an absolute neutrophil count (ANC) or total white blood count (WBC) <500 cells/mm³ of least 7 days duration at the time the positive blood culture was collected or (2) a single value of ANC or WBC <100 on or within 7 days before collection of the positive blood culture. The “7-day duration” is defined by at least 2 tests demonstrating neutropenia (e.g., ANC or WBC <500) on separate days on or within 7 calendar days prior to the positive blood culture collection without any value of ANC ≥ 500 during that time.

The MBI-LCBI eligible pathogens include at least one blood culture growing at least one of the following pathogens (e.g. *Bacteroides* spp., *Candida* spp., *Clostridium* spp., *Enterococcus* spp., *Fusobacterium* spp., *Peptostreptococcus* spp., *Prevotella* spp., *Veillonella* spp., and Enterobacteriaceae); or signs and symptoms and ≥ 2 blood cultures growing Viridans group streptococci; and identification of no other pathogens. For example, patients would not have additional organisms isolated that would meet the LCBI definition.

CDC field tested the MBI-LCBI definition and conducted CLABSI/MBI-LCBI surveillance for 2 months in 38 hospitals covering 165 locations. Oncology and bone marrow transplant centers accounted for 49% of the locations. Of ~600 candidate BSIs that have been evaluated to date, 72 of 190 CLABSIs met the MBI-LCBI definition. The pilot facilities were extremely supportive of and accurately used the MBI-LCBI definition in a short period of time. Most notably, the pilot facilities and the NHSN classification had 93% agreement in defining infections as MBI-LCBI.

The workgroup identified 2 areas for reevaluation based on preliminary findings of the field test. A determination is needed on whether to retain, change or remove the GI GVHD criteria because only 7% of MBI-LCBI cases met the GI GVHD patient criteria. In some facilities, issues with laboratory reporting of ANC/WBC values prevented the use of single ANC/WBC <100 criteria for neutropenia. Alternative ANC/WBC neutropenia criteria are being evaluated.

The next steps in the MBI-LCBI definition are to complete field testing and finalize the data analysis; make necessary changes to MBI patient criteria; revise NHSN protocols, software and training materials; inform NHSN users of changes; develop an implementation timetable with January 2013 as the anticipated date of earliest deployment; and engage NQF and CMS in discussions regarding the definition.

The proposed changes to the NHSN infection surveillance criteria are summarized as follows. The healthcare facility onset rule would be defined as an infection that occurs >2 calendar days (on or after day 3) after admission to the facility. The duration of device use prior to an event rule would be defined as placement of the device for >2 calendar days with infection onset on or after day 3 in order to be considered device-associated. The day of device placement would be equivalent to day 1.

The location of attribution/transfer rule would be defined as attributing the infection to the transferring location if an HAI develops ≤ 2 calendar days (on day 1 or 2) of transfer from one inpatient location to another in the same facility. If an HAI develops ≤ 2 calendar days (on day 1 or 2) of transfer from one inpatient facility to another, the infection would be attributed to the transferring facility. Facilities should share information about these HAIs with the transferring facility to enable reporting. The day of transfer would be equivalent to day 1.

The time between HAI events rule would define the HAI event period by the 14-day period that starts on the event date. HAI criteria met during the 14-day period would be attributed to the current HAI. HAI criteria met after the 14-day period would be reported as a new HAI. The event date would be equivalent to day 1.

The next steps in changes to the NHSN surveillance criteria are to develop training materials, FAQs and implementation guidance for users; share the criteria with volunteer users to assess usability, identify areas of concern or confusion, and perform case studies to identify areas of poor understanding; make modifications if necessary; incorporate the criteria into the NHSN protocol; and initiate formal training and user support in January 2013.

HICPAC made several comments and suggestions for CDC to consider in its ongoing efforts to revise the NHSN CLABSI definitions.

MBI-LCBI Definition

- The GI GVHD criteria should be retained in the definition because these cases are much more common in some hospitals than others.
- The 7-day duration for patients with neutropenia should be shortened because the risk for gut translocation can occur before this period of time.
- Consideration should be given to expanding or stratifying the BSI definition in terms of the patient population with necrotizing enterocolitis, resected bowel, short gut syndrome, TPN dependence, or growth of gram-negative rods from blood.
- CDC should conduct a small study to evaluate the number of MBI-LCBIs that would meet the definition of truly catheter-related infections by taking simultaneous blood

cultures from the line and periphery with the same amount of volume. This practice would result in minimal added cost and would increase the confidence in accurately classifying MBI-LCBI.

- Unanticipated consequences of the MBI-LCBI definition should be addressed in which non-NHSN facilities might inappropriately use the criteria to report data.

A motion was properly placed on the floor and seconded by HICPAC voting members to support the proposed MBI-LCBI definition with HICPAC's comments and suggestions noted for the record. **HICPAC unanimously approved the motion.**

A motion was properly placed on the floor and seconded by HICPAC voting members to support the proposed changes to the NHSN infection surveillance criteria as written. **HICPAC unanimously approved the motion.**

Update by the HICPAC HAI Surveillance Workgroup: NHSN SSI Definition

Ryan Fagan, MD, MPH

Surveillance Branch/DHQP

Centers for Disease Control and Prevention

Dr. Fagan covered the following topics in his update on recent activities by the HICPAC HAI Surveillance Workgroup on the NHSN SSI definition. The workgroup membership includes the same persons who serve on the CLABSI workgroup plus additional experts in surgical practice and SSI surveillance.

Proposed changes for implementation of the operative procedure definition in the NHSN SSI protocol are summarized as follows. The current definition is problematic due to the exclusion of some patients and procedures; a perceived trend toward increased use of non-primary closure techniques; and exclusion of many patients at highest risk. In the proposed definition, "and closes the incision before the patient leaves the OR" would be removed to include procedures that are not primarily closed. A new variable would be added to indicate "Primary Closure Y/N."

CDC anticipates consequences of the proposed change to include all procedures regardless of closure. The benefits include greater accuracy for current surgical practices and a stronger focus on the overall quality of surgical performance. The risks include the perception that non-primary closure reflects an inherently higher SSI risk; the potential requirement for additional risk adjustment; and increased difficulty in making historical comparisons due to a change in the denominator.

Proposed changes for implementation of the implant definition in the NHSN SSI protocol are summarized as follows. The current definition is problematic due to implementation difficulties, particularly for internal staples and hemoclips; inconsistent application among NHSN users; and

the absence of evidence that the collection of implants is meaningful for risk adjustment. In the proposed definition, data would no longer be collected on implants and a new, procedure-based approach would be developed for determining the SSI follow-up period.

CDC anticipates consequences of the proposal to eliminate data collection of implants. The benefits include a reduction in unnecessary burden and elimination of a perceived major source of variability among facilities regarding risk adjustment and patient follow-up. The risks include the need to continue to collect valuable data on certain types of implants on a procedure-by-procedure basis.

Proposed changes for implementation of the duration of follow-up period in the NHSN SSI protocol are summarized as follows. Current instructions for the SSI surveillance period need to be revised based on the proposed elimination of the implant definition. Other problems with the current instructions include the burdensome 1-year follow-up period; the absence of a rigorous evaluation; potential magnification of inter-facility differences in post-discharge surveillance efforts; and uncertainty whether later onset SSIs truly reflect operative care or are amenable to targeted prevention efforts.

The process to redefine the follow-up period would be based on procedure type rather than the presence of an implant. The time to SSI detection would be analyzed to identify cut points <1 year that would be suitable to capture the majority of SSIs. The goal of this process would be to avoid confusion with a limit of 2 different follow-up periods: a 30-day follow-up period for some procedures and a longer follow-up period that will be defined. For procedure types in which an implant was relatively uncommon (or <25%), the default follow-up period would be 30 days.

To support the redefined process, CDC analyzed data on the number of total 1-year SSIs detected at 30 and 90 days, including surgeries with an implant that occurred in calendar year 2011, procedure categories with a minimum of 20 SSIs, and <70% of SSIs detected at 30 days. The data analysis showed that 70% of 1-year SSIs were detected by 90 days. Moreover, 90 days are beyond the follow-up period that many professional societies consider being sufficient to capture the majority of SSI.

The proposed new instructions for the SSI surveillance period are 90 days for deep incisional and organ/space SSI for breast procedures, cardiac procedures, craniectomies, shunt placements, orthopedic procedures (including fixations and hip/knee arthroplasties), hernia procedures, pacemakers, peripheral vascular bypass procedures, and spinal procedures (including fusion and refusion). Although 70% of fusions SSIs are detected at 30 days, a decision was made to use the same 90-day follow-up period to avoid confusion. Proposed new instructions for the 30-day follow-up period include superficial SSI and deep incisional and organ/space SSI for all other procedure types.

CDC anticipates consequences of the proposed new 30-day/90-day follow-up period. The benefits include simplicity, a shorter follow-up time for many procedures that will reduce burden, and an opportunity to intensify post-discharge surveillance efforts for a shorter follow-up period.

The risks include the potential to overlook some SSIs, particularly knee arthroplasties, which could provide important information to some facilities.

Proposed changes for implementation of SSI criteria in the NHSN SSI protocol are summarized as follows. Criterion “d” of the current reporting instructions for SSI in terms of the physician diagnosis is problematic due to the perception of overly subjective language. Other more objective criteria are nearly always available for deep incisional and organ/space SSI.

In the proposed new reporting instructions for SSI in terms of physician diagnosis, diagnosis of deep incisional and organ/space SSI would be removed from criterion “d.” However, criterion “d” would be retained as written for diagnosis of superficial incisional SSI because many of these infections are reported from emergency departments (EDs) and outpatient locations where more objective data may not be available.

Criterion “c” of the current reporting instructions for superficial incisional SSI includes the following language: “...and the superficial incision is deliberately opened by a surgeon...” Criterion “b” of the current reporting instructions for deep incisional SSI includes the following language: “...or is deliberately opened by a surgeon...” The current instructions are problematic due to the narrow scope of the language and the exclusion of some current practices, such as percutaneous drainage or other interventions by a physician other than a surgeon. In the proposed new instruction, “deliberately opened by a surgeon” would be replaced with “deliberately opened or otherwise drained by a physician.”

The current reporting instruction for organ/space SSI that drains through the incision is problematic because the language is counterintuitive to IPs and surgeons. The default is to the more superficial infection site. In the proposed new instruction, the language would be changed as follows: “If the SSI involves both the incision and the organ/space, then classify the SSI as “organ/space.”

The current reporting instructions for SSI where spinal abscess and meningitis are present are problematic due to confusing language. In an analogous scenario for brain abscess with meningitis, the instruction would be to report SSI as brain abscess. In the proposed new instruction, the language would be changed as follows: “Report spinal abscess with meningitis to SSI-spinal abscess following spinal surgery.”

A new “periprosthetic joint infection” (PJI) definition for implementation in the NHSN SSI protocol is summarized as follows. The orthopedic community has made efforts to develop and agree on a PJI definition. Despite the importance of this clinical and public health concern, no standard definition has been created and no gold standard has been established to date.

A workgroup of the Musculoskeletal Infection Society (MSIS) developed a new definition that is based on available research with an aim to establish a “gold standard” to guide diagnosis and prevention efforts. CDC participated in MSIS’s deliberations to evaluate whether the definition could be adopted for SSI surveillance purposes.

In the current NHSN definition for joint or bursa SSI (SSI-JNT), a patient must meet at least 1 of the following criteria: organisms cultured from joint fluid or synovial biopsy; evidence of joint or bursa infection seen during a surgical operation or histopathologic examination; or at least 2 of the following signs or symptoms with no other recognized cause: joint pain, swelling, tenderness, heat and evidence of effusion or limitation of motion.

The patient also must meet 1 of the following criteria: organisms and white blood cells seen on Gram's stain of joint fluid; positive antigen test on blood, urine or joint fluid; cellular profile and chemistries of joint fluid compatible with infection and not explained by an underlying rheumatologic disorder; or radiographic evidence of infection.

The following criteria must be met for the new PJI definition: (1) a sinus tract communicating with the prosthesis; (2) isolation of a pathogen by culture from ≥ 2 separate tissue or fluid samples obtained from the affected prosthetic joint; or (3) existence of 4 of the following 6 criteria: a) elevated serum erythrocyte sedimentation rate and C-reactive protein; elevated synovial leukocyte count; elevated synovial neutrophil percentage; presence of purulence in the affected joint; isolation of a microorganism in one culture of periprosthetic tissue or fluid; or >5 neutrophils per high-power field in 5 high-power fields observed from histologic analysis of periprosthetic tissue at x400 magnification. The new PJI definition has been published in several journals.

The adoption of the new PJI definition in NHSN will be more objective overall and most likely will be easier to apply than the current SSI-JNT definition due to its basis on objective laboratory criteria. The PJI definition will replace the current SSI-JNT definition that involves hip and knee arthroplasties after hip and knee prosthesis procedures. However, the SSI-JNT definition will remain in use for SSI involving other prosthetic joints or for bursa-only infections that do not involve a prosthetic joint.

The workgroup has proposed several changes to instructions of the denominator for procedure form. The current instruction for incisional closure requires an assessment, but no collection of closure information. The current definition of primary closure excludes scenarios when the incision is closed to the level of the skin, but wires, wicks or other objects (e.g., drains) extrude through the incision. Based on the changes to the operative procedure definition, an assessment and preparations are needed to account for a potentially higher SSI risk for non-closed surgeries. Moreover, the NHSN definition of primary closure is difficult to implement and also is inconsistent with the understanding of primary closure in the clinical community.

In the proposed new variable for type of incisional closure, "primary closure" would be defined as closure of all tissue levels regardless of the presence of extruding wires, drains, wicks or other materials through the incision. A new variable would be added to the denominator form: "primarily closed" or "not primarily closed." In the next steps, the National Surgical Quality Improvement Program (NSQIP) would collect closure information using a 3-tiered approach.

This experience would be used to guide future refinements to the proposed NHSN approach if needed.

The current instruction for the NHSN operative duration definition contains the following language: “Enter the interval in hours and minutes between the skin incision and skin closure.” The instruction is problematic and would require a new definition because of the proposed inclusion of surgeries in which the incision is not closed.

In the proposed change to the current NHSN operative duration definition, the following definition by the Association of Anesthesia Clinical Directors would be adopted: “Time when all instrument and sponge counts are completed and verified as correct; all postoperative radiological studies to be done in the OR/PR are completed; all dressings and drains are secured; and the physician/surgeons have completed all procedure-related activities on the patient.” AORN, NSQIP and other professional societies currently are implementing the definition. The definition should be readily available from electronic records.

The current instruction for endoscope is problematic due to the need to improve the accuracy of the term. In the proposed change, “endoscope” would be renamed to “scope” (e.g., endoscope, laparoscope and arthroscope) and the instruction would be clarified accordingly.

The current requirement to collect height and weight data is limited to Cesarean surgeries only. In the proposed change, height and weight data would be collected for all operative procedures that are tracked for NHSN SSI surveillance. The change is anticipated to improve risk adjustment because body mass index is a recognized risk factor for SSI for many procedure types.

The current requirement to collect diabetes mellitus data is limited to spinal fusion or refusion of spine procedures. In the proposed change, diabetes mellitus data would be collected for all operative procedures that are tracked for NHS SSI surveillance. The change is anticipated to improve risk adjustment for a large number of surgery categories.

The workgroup’s next steps will be to develop a surveillance definition for diabetes mellitus and create guidance for the use of ICD-9 versus CPT codes for identification of eligible procedures. CDC currently is soliciting feedback from the workgroup about the best guidance for facilities that have access to both ICD-9 and CPT codes.

The workgroup will discuss standard approaches to post-discharge surveillance. The current protocol provides options, but no standard recommendations on the best practices or methods for post-discharge surveillance. The playing field needs to be leveled in terms of post-discharge case ascertainment, particularly for inter-facility comparisons.

HICPAC made several comments and suggestions for CDC to consider in its ongoing efforts to revise the NHSN SSI definitions.

Operative Procedure Definition

- Language should be included related to delayed sternal closure that is commonly used in pediatric populations to more clearly elucidate the denominator electronically.

A motion was properly placed on the floor and seconded by HICPAC voting members to support the proposed changes to the operative procedure definition with HICPAC's suggestion noted for the record. **HICPAC unanimously approved the motion.**

Elimination of Implant Data Collection/New Rule for SSI Follow-Up

- The companion guidance document should clearly explain to users that the date the patient's symptom onset began can be reported when the SSI is reported.

A motion was properly placed on the floor and seconded by HICPAC voting members to support the elimination of implant data collection and the new 30-day/90-day rule for SSI follow-up with HICPAC's suggestion noted for the record. **HICPAC unanimously approved the motion.**

Reporting Instructions for SSI

- Deep incisional SSI (criterion "b"): The proposed new instruction should be changed to "deliberately opened or otherwise drained by a licensed independent practitioner who is not a physician."
- Superficial incisional SSI (criteria "c"): The restriction to remove "cellulitis" because the word is insufficient should be eliminated since the scope of the proposed new instructions was expanded to include physicians who are not surgeons.

A motion was properly placed on the floor and seconded by HICPAC voting members to support the reporting instructions for SSI with HICPAC's suggestions noted for the record. **HICPAC unanimously approved the motion.**

A motion was properly placed on the floor and seconded by HICPAC voting members to support the new PJI definition into NHSN as written. **HICPAC unanimously approved the motion.**

Denominator for Procedure Form

- The new surveillance definition for diabetes mellitus should be designed for facilities to collect relatively easy information.
- The height of patients is not typically or accurately captured and might present a new burden to facilities.

A motion was properly placed on the floor and seconded by HICPAC voting members to support the denominator for procedure form changes with HICPAC's comments noted for the record. **HICPAC unanimously approved the motion.**

HICPAC urged CDC to implement all of the revised NHSN CLABSI and SSI definitions at the same time if possible. With this approach, hospitals would only need to train their staff once.

Update on the Postexposure Prophylaxis Guideline

David Kuhar, M.D.

Medical Officer, DHQP

Centers for Disease Control and Prevention

Dr. Kuhar presented an update on the *U.S. Public Health Service (PHS) Guideline for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis*. In 1990, PHS issued its first statement on the management of occupational exposure to HIV, including considerations regarding Zidovudine (ZDV) PEP. The PHS statement concluded as follows: “Data from animal and human studies are inadequate to establish the efficacy or safety of ZDV for prophylaxis after occupational exposure to HIV. At this time, prophylaxis with ZDV cannot be considered a necessary component of postexposure management.”

In 1996, PHS issued updated provisional recommendations for chemoprophylaxis following occupational exposure to HIV. HIV PEP regimens were recommended and stratified by exposure severity (e.g., 2- versus 3-drug regimens). In 1998, PHS issued guidelines for the management of HCP exposure to HIV and recommendations for PEP. HIV PEP regimens were expanded.

In 2001, PHS issued updated guidelines for the management of occupational exposure to HBV, HCV and HIV as well as recommendations for PEP. The management of HBV, HCV and HIV was consolidated into a single document. PEP regimens for HIV were updated and expanded to include newly available medications. In 2005, PHS issued updated guidelines for the management of occupational exposure to HIV only and recommendations for PEP. PEP regimens were updated and expanded to include newly available medications.

Key guidance in the 2005 PHS recommendations for PEP after occupational exposure to HIV is summarized as follows. A basic 2-drug regimen of nucleosides was recommended for less severe exposure and low source viral load of <1,500 copies/mL. An expanded regimen of ≥ 3 drugs was recommended for higher source viral load and/or more severe exposure. PEP was recommended to be initiated “as soon as possible” for a 4-week course.

Follow-up of exposed HCP was recommended that included counseling; monitoring for drug toxicity with testing at baseline and 2 weeks; and HIV seroconversion surveillance with testing at baseline, 6 weeks, 12 weeks and 6 months postexposure. Extended HIV follow-up was recommended for HCP who became infected with HCV after exposure to a co-infected source (e.g., HIV/HCV).

Because of complexities in selecting and administering HIV PEP, expert consultation was recommended whenever possible, particularly in the following scenarios: delayed exposure reporting (e.g., later than 24-36 hours), unknown source or source infection status, known or suspected pregnancy in exposed persons, breastfeeding in exposed persons, resistance of the source virus to ARV agents, and toxicity of the initial PEP regimen

Since the updated PHS recommendations were released in 2005, no new large RCTs have been conducted to guide the use of ARVs for occupational exposure to HIV and HIV PEP. Several new medications, including 2 new drug classes, have been developed and approved for

the treatment of HIV-infected persons. Compared to the ARVs recommended in the 2005 PHS guidelines, some of the new medications are better tolerated, have less toxicity, and are considered to be “first-line” drugs in the treatment of HIV-infected persons.

In January 2011, the PHS Workgroup was reconvened with representation by CDC, FDA, NIH and HRSA. Because no new large RCTs have been conducted to guide the use of HIV PEP, the updated guidelines would be based on expert opinion. In July 2011, CDC hosted a meeting with the PHS Workgroup and external experts to explore strategies to update the 2005 PHS guidelines. The deliberations focused on new evidence, the role of newer medications in HIV PEP, the impact of pregnancy on newer medications, and a reevaluation of the 2005 guidelines and areas for improvement.

The experts reached agreement in the following areas. New medications should be included in the guidelines. Currently recommended drugs (e.g., Azidothymidine and Lopinivir/Ritonavir (RTV)) have significant side effects and toxicities. The use of risk stratification to determine the number of recommended PEP drugs is challenging. A single recommended initial PEP regimen would be clearer and more desirable than a collection of drug combinations. Drug resistance continues to be a barrier to prompt provision of appropriate HIV PEP. Access to and the importance of expert consultation must be emphasized.

Several areas will require clarification (e.g., initial management of HCP in settings of a source patient with an unknown HIV status; PEP use and recommendations in pregnancy related to safety; and optimal HIV testing platforms). Concerns have been raised regarding the accuracy of the rapid HIV test and the “window period” in making decisions to start or continue PEP.

The proposed, revised PHS recommendations are highlighted as follows. All occupational exposures to HIV should be managed with a PEP regimen consisting of ≥ 3 ARV medications. Use of the severity of exposure to determine the number of drugs prescribed in an HIV PEP regimen will no longer be recommended. ARV PEP regimens should be selected based on tolerability, a favorable toxicity profile, and a convenient dosing schedule.

Emtricitibine (FTC)/Tenofovir (TDF)/Raltegravir (RAL) is recommended as the PEP regimen for all occupational exposures to HIV. Alternative medication regimens are recommended as well. FTC plus TDF alternatives would include Lamivudine/Zidovudine. RAL alternatives would include Darunivir/RTV, Etravirine, or Atazanavir/RTV.

The previously recommended general follow-up testing schedule that called for HIV testing at baseline, 6 weeks, 3 months and 6 months for exposed HCP will be maintained. A new follow-up testing recommendation for exposed HCP should be implemented if a fourth-generation HIV antigen-antibody immunoassay or HIV nucleic acid testing is utilized. In this scenario, HIV testing should be performed at baseline, 6 weeks and 4 months.

Increased emphasis will be placed on early initiation of PEP. Even over a small period of hours, PEP loses effectiveness as initiation is delayed. Initiation of PEP should not be delayed by

provider pregnancy or breastfeeding. If the HIV status of the exposure source is unknown, but HIV infection is suspected, PEP may be given and later discontinued if the source patient's HIV testing is subsequently negative. The risk for toxicity from these medications is low. Individual facilities should develop and disseminate HIV exposure management protocols through a "PEP Starter Packet" that contains the first dose of a recommended PEP regimen.

Emphasis on expert consultation whenever possible will continue to be emphasized. Contact information will be provided for the National HIV/AIDS Clinicians' Consultation Center and PEPLine for facilities that do not have onsite experts. Updated information will be provided on the accuracy and utility of HIV testing in making PEP decisions, but emphasis will continue to be placed on not delaying PEP initiation as a result of testing.

Increased emphasis will be placed on follow-up of exposed HCP, particularly at 72 hours after exposure. This short time period will allow facilities to more quickly address side effects or toxicities experienced by HCP and determine whether the PEP regimen should be continued. The draft PHS guidelines are complete and are currently being reviewed by expert consultants. CDC expects to submit the guidelines for clearance within 3-4 months.

Dr. Fishman moderated HICPAC's discussion with Dr. Kuhar on the updated PEP guidelines. The discussion topics included compliance with the 2005 PHS recommendations and the cost of a PEP regimen.

HICPAC made two suggestions for CDC to consider in finalizing the updated PEP guidelines. First, the guidelines should strongly emphasize that PEP is still needed if the source patient is HIV-positive, but has an undetectable viral load. This language will help in risk stratification. Second, the guidelines should describe approaches to discontinue and deescalate the PEP regimen during the 72-hour visit, particularly if the HIV status of the source patient is unknown.

Public Comment Session

Kay Argroves, CRNA

American Association of Nurse Anesthetists

Ms. Argroves commented that facilities typically do not consider office-based procedures to be inpatient or outpatient surgical procedures. For example, her facility performs all back procedures for interventional pain in an outpatient procedure room rather than in an OR. She asked CDC to describe its minimum requirements to define an "OR" for the revised NHSN SSI definitions.

In response to Ms. Argroves' question, Dr. Fagan explained that some procedure rooms qualify as an OR due to air control and sterilization procedures. For its NHSN protocol, CDC adopted a standardized definition of an "OR" that was developed by a professional society of hospital architects.

CDC is aware of and concerned about operations that are performed outside of ORs, but these procedures are difficult to track. However, NSQIP plans to pilot a category of pediatric surgeries in non-OR locations. CDC will review lessons learned and experiences from the NSQIP pilot to determine the feasibility of collecting NHSN data from non-OR locations. CDC also is developing an outpatient procedure module to capture data from ASCs and hospital outpatient departments for NHSN.

Rachel Stricof, MPH, CIC

Council of State and Territorial Epidemiologists

Ms. Stricof expressed concern about the revised NHSN CLABSI definition in terms of the duration of device placement for >2 calendar days prior to an event. Most notably, patients could remain in EDs many days before being officially admitted to the hospital. The revised definition does not sufficiently address infections related to line or device placement in EDs. Many hospitals have no knowledge of the day or time patients are transferred from EDs to their rooms. Device placement for >2 calendar days also is a concern for TPN due to contamination issues.

Drs. Fridkin and Thompson had left the meeting, but Dr. Fishman confirmed that Ms. Stricof's concerns would be conveyed to the HAI Surveillance Workgroup for the NHSN CLABSI definitions.

Closing Session

With no further discussion or business brought before HICPAC, Dr. Fishman adjourned the meeting at 11:55a.m. on June 15, 2012.

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

Date

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