

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

May 16-17, 2019

Atlanta, Georgia

Record of the Proceedings

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Meeting Agenda

Healthcare Infection Control Practices Advisory Committee (HICPAC)

May 16-17, 2019

Centers for Disease Control and Prevention

Tom Harkin Global Communications Center (Building 19, Aud. B)

1600 Clifton Rd., NE, Atlanta, GA

Thursday, May 16, 2019

<i>Time</i>	<i>Topic</i>	<i>Purpose</i>	<i>Presider/Presenter(s)</i>
9:00	Welcome and Introductions	Information	Deborah Yokoe (HICPAC Co-Chair) Lisa Maragakis (HICPAC Co-Chair) Mike Bell (DFO, HICPAC; CDC)
9:15	Division of Healthcare Quality Promotion (DHQP) Updates: National Antibiotic Resistance Planning, CARB 2.0	Information	Michael Craig (DHQP, CDC)
9:45	Healthcare Personnel Guideline Section I Workgroup Update: Public Comment	Information/ Discussion	Hilary Babcock (HICPAC)
10:45	Break		
11:00	U.S. Food and Drug Administration Update	Information	Shani Haugen (CDRH, FDA) Suzanne Schwartz (CDRH, FDA)
12:15	Lunch		
1:45	Neonatal Intensive Care Unit Guideline Update: Draft Text and Recommendations	Information/ Discussion	Kristina Bryant (HICPAC)
2:45	Break		
3:00	Bloodstream Infection Guideline Update Planning	Information	Shannon Novosad (DHQP, CDC) Erin Stone (DHQP, CDC)
3:25	Enhanced Barrier Precautions	Information	Kara Jacobs Slifka (DHQP, CDC) Nimalie Stone (DHQP, CDC)
3:50	Tuberculosis Healthcare Personnel Guideline Update	Information	Sapna Bamrah Morris (DTBE, CDC)
4:00	Public Comment		
4:30	Liaison/ Ex officio Reports		
5:00	Adjourn		

Friday, May 17, 2019

<i>Time</i>	<i>Topic</i>	<i>Purpose</i>	<i>Presenter/Presenter</i>
9:00	Welcome and Roll Call	Information	Deborah Yokoe (HICPAC Co-Chair) Lisa Maragakis (HICPAC Co-Chair) Mike Bell (DFO, HICPAC; CDC)
9:05	Healthcare Personnel Guideline Section II Workgroup Update: Draft Text and Recommendations	Information/ Discussion	Hilary Babcock (HICPAC)
10:35	Break		
10:45	Monitoring Healthcare Water Quality	Information	L. Clifford McDonald (DHQP, CDC)
11:45	Public Comment		
11:55	Summary, Vote, and Work Plan	Information	Deborah Yokoe (HICPAC Co-Chair) Lisa Maragakis (HICPAC Co-Chair)
12:00	Adjourn		

List of Attendees

Day 1: May 16, 2019

HICPAC Members

Dr. Deborah Yokoe, Co-Chair
Dr. Lisa Maragakis, Co-Chair
Dr. Deverick Anderson
Dr. Hilary Babcock
Dr. Kristina Bryant
Dr. Nicholas Daniels
Ms. Elaine Dekker
Ms. Loretta Fauerbach
Dr. Michael Howell
Dr. Charles Huskins
Dr. Jan Patterson
Ms. Michael Anne Preas

ex officio Members

Ms. Elizabeth Claverie-Williams, Food and Drug Administration (FDA)
Dr. David Henderson, National Institutes of Health (NIH)
Dr. Melissa Miller, Agency for Healthcare Research and Quality (AHRQ)
Dr. Daniel Schwartz, Centers for Medicare and Medicaid Services (CMS)
Ms. Judy Trawick, Health Resources and Service Administration (HRSA)

Liaison Representatives

Ms. Darlene Carey, Association of Professionals of Infection Control and Epidemiology (APIC)
Mr. Paul T. Conway, American Association of Kidney Patients (AAKP)
Karen deKay, Association of periOperative Registered Nurses (AORN)
Dr. Louise Demby, Society for Healthcare Epidemiology of America (SHEA)
Ms. Kathleen Dunn, Public Health Agency of Canada (PHAC)
Ms. Kristen Ehresmann, Association of State and Territorial Health Officials (ASTHO)
Dr. Marion Kainer, Council of State and Territorial Epidemiologists (CSTE)
Dr. Chris Lombardozi, America's Essential Hospitals (AEH)
Dr. Mark Russi, American College of Occupational and Environmental Medicine (ACOEM)
Dr. Christa Schorr, Society for Critical Care Medicine (SCCM)
Dr. Andrea Shane, Pediatric Infectious Disease Society (PIDS)
Ms. Linda Spaulding, DNV GL
Ms. Margaret VanAmringe, The Joint Commission
Dr. Valerie Vaughn, Society of Hospital Medicine (SHM)

CDC Representatives

Denise Albina, DHQP
Matt Arduino, DHQP
Ana Bardossy, DHQP
Michael Bell, DHQP
Andrea Benin, DHQP
Destani Bizune, DHQP

Sharon Bloom, DHQP
Richard Brooks, DHQP
Stefanie Bumpus, DHQP
Kathy Capers, DHQP
Denise Cardo, DHQP
Bryan Christensen, DHQP

Zeshan Christy, DHQP
Jessie Chung, DHQP
Koo Chung, DHQP
Samuel Clasp, DHQP
Nicole Coffin, DHQP
Kendra Cox, DHQP
Michael Craig, DHQP
Adina deCoteau, DHQP
Ryan Fagan, DHQP
Nancy Gallagher, DHQP
Julian Grass, DHQP
Nicole Gualandi, DHQP
Alison Halpin, DHQP
Jamesa Hogges, DHQP
Kelly Jackson, DHQP
Kara Jacobs-Slifka, DHQP
John Jernigan, DHQP
Sarah Jones, DHQP
Cecilia Joshi, DHQP
Alex Kallen, DHQP
Astha KC, DHQP
Amelia Keaton, DFWD
Amy Kolwaite, DHQP
David Kuhar, DHQP
Ruth Link-Gelles, DHQP
Cliff McDonald, DHQP
Muzna Mirza, DHQP
Lauren Moccia, DHQP

Members of the Public

Jody Birks, Eagle Medical
Stacy Bohl Wiehle, Boston Scientific
Jamie Byun, Advanced Sterilization Products
Laurie Cartwright, Advanced Sterilization Products
Bradley Catalone, TSO3
Charles Cogdill, Medtronic
Jonathan Cooper, Orlando Health-ABM
Valerie Deloney, SHEA
Akiko Dohi, Ken Block Consulting
Mike Ebers, STERIS Corporation
Gary Evans, Relias Media
Pam Falk, Northside Hospital
Ann Ferriter, FDA
Ben Fisher, FDA
Christopher Freedman, SAIC
Hudson Garrett Jr, Pentax Medical
Joyce Hansen, Johnson & Johnson

Shunte Moon, DHQP
Kerri Moran, DHQP
Lyn Nguyen, DHQP
Shannon Novosad, DHQP
Bola Ogundimu, DHQP
Devon Okasako Schmucker, DHQP
Belinda Ostrowsky, DHQP
Hanako Osuka, DHQP
Priti Patel, DHQP
Joe Perz, DHQP
Catherine Rebmann, DHQP
Sujan Reddy, DHQP
Hannah Rese, DHQP
Kristin Roberts, DHQP
Melissa Schaefer, DHQP
Isaac See, DHQP
Srila Sen, DHQP
Aditya Sharma, DHQP
Valan Siromany, DHQP
Rachel Slayton, DHQP
Elizabeth Soda, DHQP
Kevin Spicer, DHQP
Erin Stone, DHQP
Nimalie Stone, DHQP
Matthew Stuckey, DHQP
Sukarma Tanwar, DHQP
Amy Valderrama, DHQP
Ellen Wan, DHQP

Shani Haugen, FDA
Kaitlin Heath, Becton Dickinson
Stephanie Henry Wallace, Cambridge Communications & Training Institute
Sandra Kalter, Medtronic
Kevin Kavanagh, Health Watch USA
Timothy Kelly, BD Urology and Critical Care
Rachel Long, Becton Dickinson
Rosie Lyles, Medline Industries, Inc.
Mauricio Martinez-Ramirez, Smiths Medical
Albert May, Andersen Products
Elaine Mayhall, FDA
Betty McGinty, Northside Hospital
Mac McKeen, Boston Scientific
William Meade, 3M
Lauren Min, FDA
Clarence Murray, FDA
Ronell Myburgh, DNV GL Healthcare

George Ngatha, FDA
Silvia Quevedo, APIC
Maria Rodriguez, Xenex Disinfection Services
Michael Ruhlen, Atrium Health
Suzanne Schwartz, FDA
Lara Simmons, Medline Industries, Inc.
Keith St John, Professional Disposables
International
Connie Steed, APIC

Lisa Tomlinson, APIC
Wava Truscott, Truscott MedSci Associates, LLC.
Donald Tummineli, Highpower Validation
Testing and Lab Services
Roger Vu, Advanced Sterilization Products
Carla Warner
Kristy Weinshel, SHEA
Cindy Winfrey, Pentax Medical
Hanniebey Wiyor, FDA

Day 2: May 17, 2019

HICPAC Members

Dr. Deborah Yokoe, Co-Chair
Dr. Lisa Maragakis, Co-Chair
Dr. Deverick Anderson
Dr. Hilary Babcock
Dr. Kristina Bryant
Dr. Nicholas Daniels
Ms. Elaine Dekker
Ms. Loretta Fauerbach
Dr. Charles Huskins
Dr. Jan Patterson
Ms. Michael Anne Preas

***ex officio* Members**

Ms. Elizabeth Claverie-Williams, Food and Drug Administration (FDA)
Dr. David Henderson, National Institutes of Health (NIH)
Dr. Melissa Miller, Agency for Healthcare Research and Quality (AHRQ)
Dr. Daniel Schwartz, Centers for Medicare and Medicaid Services (CMS)
Ms. Judy Trawick, Health Resources and Service Administration (HRSA)

Liaison Representatives

Ms. Darlene Carey, Association of Professionals of Infection Control and Epidemiology (APIC)
Mr. Paul T. Conway, American Association of Kidney Patients (AAKP)
Ms. Karen deKay, Association of periOperative Registered Nurses (AORN)
Dr. Louise Demby, Society for Healthcare Epidemiology of America (SHEA)
Ms. Kathleen Dunn, Public Health Agency of Canada (PHAC)
Ms. Kristen Ehresmann, Association of State and Territorial Health Officials (ASTHO)
Dr. Marion Kainer, Council of State and Territorial Epidemiologists (CSTE)
Dr. Chris Lombardozi, America's Essential Hospitals (AEH)
Dr. Mark Russi, American College of Occupational and Environmental Medicine (ACOEM)
Dr. Christa Schorr, Society for Critical Care Medicine (SCCM)
Dr. Andrea Shane, Pediatric Infectious Disease Society (PIDS)
Ms. Linda Spaulding, DNV GL
Ms. Margaret VanAmringe, The Joint Commission
Dr. Valerie Vaughn, Society of Hospital Medicine (SHM)

CDC Representatives

Matt Arduino, DHQP

Michael Bell, DHQP

Kathy Benedict, DFWED
Richard Brooks, DHQP
Denise Cardo, DHQP
Bryan Christensen, DHQP
Matthew Christ, DHQP
Zeshan Christy, DHQP
Koo Chung, DHQP
Erin Conners, DFWED
Kendra Cox, DHQP
Shani Doss, DHQP
Lauren Epstein, DHQP
Ryan Fagan, DHQP
Jamesa Hogges, DHQP
Sarah Jones, DHQP
Amelia Keaton, DFWED
David Kuhar, DHQP
Preeti Kutty, DHQP
Cliff McDonald, DHQP
Kerri Moran, DHQP

Members of the Public

Jamie Byun, Advanced Sterilization Products
Laurie Cartwright, Advanced Sterilization Products
Jonathan Cooper, Orlando Health-ABM
Valerie Deloney, SHEA
Akiko Dohi, Ken Block Consulting
Gary Evans, Relias Media
Kaitlin Heath, Becton Dickinson
Stephanie Henry Wallace, Cambridge Communications & Training Institute
Shani Haugen, FDA
Kevin Kavanagh, Health Watch USA
Timothy Kelly, BD Urology and Critical Care
Rachel Long, Becton Dickinson
Karla G Martinez, Avanos Medical

Duc Nguyen, DHQP
Judith Noble-Wang, DHQP
Shannon Novosad, DHQP
Devon Okasako Schmucker, DHQP
Hanako Osuka, DHQP
Priti Patel, DHQP
Molly Patrick, DHQP
Kiran Perkins, DHQP
Joe Perz, DHQP
Kristin Roberts, DHQP
SriIa Sen, DHQP
Elizabeth Soda, DHQP
Erin Stone, DHQP
Kevin Spicer, DHQP
Johnathan Stryko, DFWED
Matthew Stuckey, DHQP
Sukarma Tanwar, DHQP
Amy Valderrama, DHQP
Wendy Vance, DHQP

Mauricio Martinez-Ramirez, Smiths Medical
Albert May, Andersen Products
Mac McKeen, Boston Scientific
William Meade, 3M
Lauren Min, FDA
Clarence Murray, FDA
Ronell Myburgh, DNV GL Healthcare
George Ngatha, FDA
Silvia Quevedo, APIC
Maria Rodriguez, Xenex Disinfection Services
Connie Steed, APIC
Lisa Tomlinson, APIC
Roger Vu, Advanced Sterilization Products
Kristy Weinschel, SHEA

Executive Summary

The United States (US) Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on May 16-17, 2019, in Atlanta, Georgia. Dr. Michael Bell, Designated Federal Officer (DFO), confirmed the presence of a quorum of HICPAC voting members and *ex officio* members, which was maintained throughout each day of the meeting.

The meeting was called to order at 9:05 am on May 16, 2019. Mr. Michael Craig, DHQP, provided an update on CDC's antibiotic resistance (AR) work, including domestic and global antimicrobial resistance (AMR) efforts; the next iteration of the Combating Antibiotic-Resistant Bacteria (CARB) Action Plan; the Presidential Advisory Council on Combating Antibiotic Resistant Bacteria (PACCARB); CDC's 2019 AR Threats Report; and the AMR Challenge.

Dr. Hilary Babcock, HICPAC Member, presented public comments received on the draft *Infection Control in Healthcare Personnel: Infrastructure and Routine Practices for Occupational Infection Prevention and Control Services*, "Part 1" of the update to the *Guideline for infection control in health care personnel, 1998*, and proposed revisions to the document. HICPAC voted unanimously to approve the draft as presented, with no opposition and no abstentions.

Drs. Shani Haugen and Suzanne Schwartz, US Food and Drug Administration (FDA), provided updates on infections associated with reprocessed duodenoscopes, ethylene oxide (EtO) sterilization of medical devices, and closure of US facilities that perform EtO sterilization.

Dr. Kristina Bryant, HICPAC Member, presented draft recommendations for the central line-associated bloodstream infection (CLABSI) section of the *Guideline for Infection Prevention in Neonatal Intensive Care Unit (NICU) Patients* and updates on other sections of the Guideline. The Central Line Antimicrobial Locks recommendation was approved unanimously with no opposition or abstentions, with minor edits to the narrative accompanying the recommendation.

Dr. Shannon Novosad shared an overview of planned updates to the *2011 Guidelines for the Prevention of Intravascular Catheter-Related Infections*.

Dr. Kara Slifka, DHQP, described guidance for nursing homes on the implementation of personal protective equipment (PPE) to help prevent the spread of multidrug-resistant organisms (MDROs), including a new approach called "Enhanced Barrier Precautions."

Dr. Sapna Bamrah Morris, Division of Tuberculosis Elimination (DTBE), reported on the release of the *2019 Tuberculosis Screening, Testing and Treatment of U.S. Health Care Personnel, Recommendations from the National TB Controllers Association and CDC*.

HICPAC stood in recess from 5:00 pm on Thursday, May 16 until 9:05 am on Friday, May 17.

Dr. Hilary Babcock described progress on the individual sections of *Infection Prevention in Healthcare Personnel: Recommendations for Prevention of Infections in Healthcare Personnel: "Section 2"* of the updates to the *Guideline for infection control in health care personnel, 1998*. The draft Diphtheria, Meningococcal Disease, Pertussis, and *Streptococcus*, Group A infection sections were unanimously approved with no opposition or abstentions.

Drs. Joseph Perz, Clifford McDonald, and Matthew Stuckey, DHQP, presented on monitoring healthcare water quality, including work on the draft Water Monitoring Implementation Framework for Healthcare Settings and the CDC "From Plumbing to Patients" website. HICPAC stood in recess at 11:55 am on May 17, 2019.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Emerging and Zoonotic Diseases
Division of Healthcare Quality Promotion
Healthcare Infection Control Practices Advisory Committee (HICPAC)**

May 16-17, 2019
Atlanta, Georgia

Meeting Summary

The United States (US) Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on May 16-17, 2019, at the Tom Harkin Global Communications Center at the Centers for Disease Control and Prevention, 1600 Clifton Road NE, Atlanta, Georgia.

Thursday, May 16, 2019

Welcome and Introductions

Michael Bell, MD
Deputy Director
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Deborah Yokoe, MD, MPH
HICPAC Co-Chair

Lisa Maragakis, MD, MPH
HICPAC Co-Chair

Dr. Michael Bell called the meeting to order at 9:05 am. He established that a quorum of HICPAC voting members and *ex officio* members was present, and quorum was maintained throughout the meeting. Dr. Yokoe introduced and welcomed new HICPAC members:

- Michael Anne Preas, RN, served as the Association of Professionals of Infection Control and Epidemiology (APIC) Liaison Representative to HICPAC for a number of years. She is the Senior Director of the Infection Prevention and Hospital Epidemiology Program at the University of Maryland Medical Center and focuses on strategies to improve the sustainability of implementation practices in infection prevention.
- Nicholas Daniels, MD, MPH, is a Professor of Clinical Medicine at the University of California, San Diego (UCSD). He has experience as a hospitalist and primary care physician and leads a large outpatient practice at UCSD. He is an expert in the prevention of foodborne diseases, has a fellowship at the CDC, and served as a consultant for the World Health Organization (WHO) in Southeast Asia.
- Deverick Anderson, MD, MPH, is an Associate Professor of Medicine at Duke University and is the Director of the Duke Center for Antimicrobial Stewardship and Infection Prevention (DCASIP). He leads quality improvement and patient safety efforts at Duke University Hospital and is involved with more than 50 community hospitals that are part of the Duke Infection Control Outreach Network (DICON) and the Duke Antimicrobial Stewardship Outreach Network

(DASON). He is a Principal Investigator of the Duke-UNC Prevention Epicenter and the Director of the Duke Program for Infection Prevention for the National Football League.

In addition, Dr. Yokoe welcomed and introduced new Liaison Representatives:

- Paul T. Conway: American Association of Kidney Patients (AAKP)
- Karen DeKay, MSN, RN, CNOR, CIC: Association of periOperative Registered Nurses (AORN)
- Christa Schorr, DNP, MSN: Society of Critical Care Medicine (SCCM)

HICPAC members disclosed the following conflicts of interest:

- Dr. Kristina Bryant has been an investigator on clinical vaccine trials funded by Pfizer and has received honoraria from MedStudy.
- Ms. Loretta Fauerbach serves on the Clinical Advisory Board of Professional Disposables, International and is engaged in work with the American Hospital Association for education and consultation.
- Dr. Michael Howell is employed by Google Research and owns equity in the company.
- Dr. Lisa Maragakis receives research funding from the Clorox Company.
- Dr. Jan Patterson's spouse has received funding for antifungal research from Gilead, Merck, Pfizer, Scynexis, and Toyama.

Division of Healthcare Quality Promotion Update: National Antibiotic Resistance Planning, CARB 2.0

Michael Craig, MPP

Senior Advisor for Antibiotic Resistance

Antibiotic Resistance Coordination and Strategy Unit

Division for Healthcare Quality and Promotion

National Center for Emerging and Zoonotic Infectious Diseases

Centers for Disease Control and Prevention

Mr. Craig provided an update on CDC's current and planned work in antibiotic resistance (AR).

The Antibiotic Solutions Initiative (ARSI) is CDC's initiative to support the President's Combating Antibiotic-Resistant Bacteria (CARB) Action Plan. CDC requested \$264 million in Fiscal Year 2016 to support that work. Congress ultimately provided \$160 million, which has fundamentally transformed the way CDC, the country, and the world detect and respond to AR.

CDC receives \$170 million annually in AR funding, which incorporates healthcare, community, foodborne, and drug-resistant tuberculosis (TB) efforts. Over the past 3 years, ARSI has invested \$241 million in US health departments to develop domestic infrastructure to address AR. This funding includes support for the Antibiotic Resistance Laboratory Network (ARLN), which supports laboratory capacity for AR pathogens in all 50 states. The ARLN also includes the regional laboratory network which provides, among other services, colonization testing for *Candida auris* (*C. auris*) and carbapenem-resistant *Enterobacteriaceae* (CRE) in the 7 regions. In addition, nearly \$110 million supports research and piloting for 96 public-private institutions in applied public health research activities. The research cross-cuts several mechanisms, including the CDC Prevention Epicenters, Broad Agency Announcements (BAA), and a variety of other mechanisms to support improving understanding of knowledge gaps related to AR and finding solutions to pressing challenges.

To date, the ARLN has tested more than 100,000 pathogens from public health laboratories across the network. CDC has shipped over 140,000 isolates to diagnostic test manufacturers, academic researchers, and pharmaceutical companies. This project includes a partnership between CDC and the US Food and

Drug Administration (FDA) to provide consistent data for consideration of new drugs and new diagnostics.

The CARB National Action Plan, under which these activities fall, has the following aims:

1. Slow the Emergence of Resistant Bacteria and Prevent the Spread of Resistant Infections
2. Strengthen National One-Health Surveillance Efforts to Combat Resistance
3. Advance Development and Use of Rapid and Innovative Diagnostic Tests for Identification and Characterization of Resistant Bacteria
4. Accelerate Basic and Applied Research and Development for New Antibiotics, Other Therapeutics, and Vaccines
5. Improve International Collaboration and Capacities for Antibiotic-Resistance Prevention, Surveillance, Control, and Antibiotic Research and Development

The CARB National Action Plan is a US government-wide approach. CDC is one of the implementing partners, along with other agencies within HHS, the US Department of Agriculture (USDA), Department of Defense (DoD), and others. Notably, goals 1, 2, and 5 are public health-focused. The first 2 goals are focused on domestic issues, while the 5th goal encompasses all 4 of the other goals with an international focus.

The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) was established to support and provide guidance to the President and the HHS Secretary. The Council has provided feedback to HHS agencies for several years. PACCARB works similarly to HICPAC, but does not produce practice recommendations; rather, it provides advisory support to the agencies and implementing partners under the CARB Action Plan.

The current CARB National Action Plan ends in 2020, so in 2019, PACCARB has requested public feedback on the next iteration of the Plan. The name “CARB 2.0” was coined. A new infrastructure has been created and established in the US for many elements of the Plan, and partners are assessing additional steps to address remaining gaps and challenges. The implementing agencies are gathering to assess the many milestones from the last Plan. For example, CDC tracked progress on 100 different milestones, the most of any participating agency. As CDC assesses progress on those milestones, the agency is identifying goals for the next 5 years, with both existing and new resources.

In addition to these internal processes as US government agencies develop their ideas and next steps, an external process led by PACCARB is gathering broad-based feedback from partners. PACCARB issued a request for information, which was widely distributed. Cross-cutting feedback from a variety of organizations was presented, bound in an approximately 180-page document, at the January 2019 PACCARB meeting. A tremendous amount of feedback was provided in those 180 pages, including strong positive feedback regarding the CDC public health actions that had been implemented. Partners called for continued support across CDC’s AR programs, including the National Hospital Safety Network (NHSN), antibiotic stewardship activities, the National Antimicrobial Resistance Monitoring System (NARMS), the Epidemiology and Laboratory Capacity (ELC) Cooperative Agreement, and data collection and surveillance through the Emerging Infections Program (EIP). The expansion of those activities over the past 5 years was highly praised, and CDC received positive feedback regarding its direction in establishing capacities, and encouragement to broaden and extend these efforts.

The January 2019 PACCARB meeting included approximately 30 presentations across 16 panels that provided direct feedback and discussion on aspects of the CARB Action Plan that may need to be “boosted” in the Plan’s next iteration, as well as areas that merit additional attention in the next 5 years. Some of the major themes were:

- Improvement of the antibiotic pipeline,

- AR and the environment, and
- The need for greater investment by the US government in addressing AR globally.

The US has a responsive domestic infrastructure that is addressing, containing, and preventing threats and can serve as a model to be extended to help other parts of the world identify, contain, and prevent AR threats as they develop.

During its next meeting, PACCARB will synthesize the public comments, other feedback, and their own opinions. A draft report will be released at the July 2019 meeting with recommendations regarding what should be included in the next iteration of the Action Plan. That document will be reviewed and considered by partner agencies. This work will come to fruition later in 2019 or early in 2020, with the release of the new CARB National Action Plan, laying out a vision for the next 5 years.

CARB got its start with CDC's *AR Threats Report*, which was released in 2013. That report represented the first-ever "snapshot" of the challenge of domestic AR that spoke with "one voice" about all of the different threats that are faced. Previously - before CARB - this information was siloed by pathogen, and a collective assessment and discussion of the overarching challenges of AR had not been conducted; the data presented were the best available at the time for a given pathogen, but they were not ideal for releasing a threat report. A great deal has changed in the 6 years since the 2013 report was released in terms of investment, capacity, and available data. CDC has used this time to determine how best to move forward with an updated "snapshot," especially in light of feedback from a variety of AR partners that the number should not be "conservative:" partners want a number that is reliable, realistic, and reflective of the challenges they see every day.

To that end, CDC works diligently to develop new methods and methodologies and is on track to release the new Threat Report in late 2019. Data from electronic health records (EHRs) will be utilized, especially for healthcare-associated pathogens. EHR data will be combined from 3 vendors to assemble a "mega dataset" with data from 2013 onward. CDC plans to compare data from the 2013 report to the "mega dataset" and will update the baseline accordingly. Given that a conservative number was released in 2013, it is anticipated that a major theme of the updated report will be that the problem is much bigger than was previously thought and characterized in 2013. In the upcoming report, trend data from 2013 to 2019 will show progress across pathogens. Progress in preventing some pathogens has been made, with the most progress in healthcare-associated infections (HAIs). The CARB 2.0 National Action Plan will be released after the 2019 *AR Threat Report*.

In collaboration with the HHS Office of Global Health Affairs (OGHA), CDC launched the Antimicrobial Resistance (AMR) Challenge in September 2018. This yearlong effort is focused on securing global commitments from stakeholders. With the growing challenge of AR, all sectors are realizing their potential contribution to the problem. The AMR Challenge turns this realization into a platform so that each stakeholder organization can identify how to address the problem. There has been a tremendous amount of interest and success in this initiative, which was launched during the United Nations General Assembly (UNGA) in September 2018. HHS Secretary Azar and a number of other high-level officials presented and launched the Challenge. At the time of the rollout, 99 commitments had already been secured. Since then, partners have continued to be engaged: there are now over 200 commitments. A capstone event during the UNGA in September 2019 will discuss achievements, recognize the commitments that have been made, and highlight the leadership that has been shown. The 5 Challenge focus areas are:

- Tracking and Data
- Infection Prevention and Control
- Antibiotic Use

- Environment and Sanitation
- Vaccines, Diagnostics, Therapeutics.

CDC feels that these areas are critical for addressing AMR globally, and the Challenge asks organizations commit to them.

Some of the AMR Challenge commitments are general, while others are specific, with reduction targets by year for either antibiotic prescribing or reducing infections. Follow-up continues to gauge progress on the commitments, which are comprehensive and crosscutting. Highlights include:

- Aetna continues to support the reduction of inappropriate antibiotic prescribing by providing clinicians with direct feedback on their performance and suggesting actions for improvement. This collaboration has been strong, and CDC seeks to expand to other health departments or insurers in similar fashion.
- Premier, a healthcare improvement company, surpassed their goal of reducing the rate of healthcare associated *Clostridioides difficile* infection per 10,000 patients by 14%, for a total reduction of 34% in March 2019.
- McDonald's committed in December 2018 to phase out the use of human antibiotics across their global cattle supply. They have a multi-phased process and plan to accomplish this goal over the next few years. McDonald's is the first large company to make such a commitment as part of the AMR Challenge.
- The Antibiotic Alliance, a consortium of companies that develop antibiotics and diagnostics, committed to resetting hard targets and scientifically-established targets related to effluent that is released from of their factories.

The AMR Challenge is soliciting, and gaining traction and commitments from, stakeholders worldwide and across various industries. Important commitments are being made to highlight the actions of state health departments and other countries to address AR.

Discussion Points

HICPAC expressed appreciation for the tremendous amount of progress and for CDC's and DHQP's leadership.

HICPAC asked about the one-year timeframe, which seems limited. Mr. Craig clarified that the yearlong timeframe, September 2018 - September 2019, is the timeframe for obtaining commitments, not the time in which the commitments will be fulfilled. CDC recognizes that a longer trajectory is needed to fulfill the commitments, especially for corporate enterprises. For example, McDonald's made committed in September 2018, but full implementation across the global supply chain will not be achieved until 2022 - 2024. Other companies have also made multi-year commitments.

Dr. Cardo pointed out the recognition of the importance of involving groups that have not previously been involved in infectious diseases. The HHS Secretary recently convened a meeting with several embassies and USDA to illustrate to other countries the importance of having an initiative like the AMR Challenge. This meeting incorporated the critical "One Health" concept of the intersection between human, animal, and environmental perspectives.

Mr. Craig added that the environment is a particularly challenging area with many gaps in knowledge. CDC, the Wellcome Trust, and the United Kingdom (UK) government hosted a meeting in Vancouver in April 2018 that assembled experts in AR and the environment. Together, that triad of hosts published a report in December 2018 on the environment that addressed major areas and identified major gaps in knowledge to provide a framework for better understanding the potential threat of AR, reservoirs of resistance in the environment, and potential impacts on human health. A great deal of work needs to be

done in this area and there are diverse aspects for developed and low- to middle-income countries to consider, such as the downstream impact of hospital effluent and variance of sanitation by country. Challenges have arisen related to the use of antibiotics as pesticides. For example, the Environmental Protection Agency (EPA) recently approved the expansion of oxytetracycline and streptomycin as pesticides for citrus greening disease. That approval means that those antibiotics can be sprayed on trees nationwide, but it is not known whether they effectively address the disease problem. There is a tremendous amount of scientific inquiry in this area, and CDC is leading the way with a variety of research projects through the BAA process and by working with other partners such as the Wellcome Trust.

HICPAC observed that more threats have emerged on the horizon since 2013, such as New Delhi beta-lactamase (NDM)-producing *Enterobacteriaceae* and *C. auris*, and asked how experience with those organisms is shaping the next “round” of AR work.

Mr. Craig replied that CDC is assessing those new threats and how to adjust the Threat Report. Previously, pathogens were classified under 3 categories: Urgent, Serious, and Concerning. There will be additions in the new report, such as *C. auris*, to reflect awareness since 2013. The challenges addressed and classified in 2013 are not the same as the current challenges. There are also evolutionary challenges. The AR work is not only involved in discussing these issues, but also in responding to them. Consideration is given to how new forms of resistance can be addressed within the containment framework; how pathogen testing and identification can be increased; and, if need be, how colonization testing can be supported to assist healthcare facilities in stopping transmission.

Dr. Bell noted the efforts underway to address not only the terminal outcome of human infections with resistant pathogens, but also the enormous issue of upstream antecedents. HICPAC focuses on the final component of this massive issue. Everything that can be done domestically and internationally in terms of the environment, animal health, food production, etc, is an investment in reducing the ultimate burden on human health.

HICPAC asked about CDC’s vision for serving as a global model. Mr. Craig replied that CDC’s [AR Investment Map app](https://wwwn.cdc.gov/arinvestments/) (https://wwwn.cdc.gov/arinvestments/) showcases the agency’s annual state-by-state activities to combat AR with state health departments, academic investigators, and private companies. This year, a Fact Sheet was published related to the agency’s global efforts. CDC supports approximately \$10 - \$11 million in global activities. CDC was initially supported at a lower funding level for AR than requested. Given the scope of the challenges, it was necessary to prioritize domestic infrastructure. Global funds are currently focused on pilot efforts to understand and illustrate what could be done with additional resources and investments. He hoped that the CARB 2.0 Action Plan will lead to greater support from the US government to address AR globally, especially the public health aspects of AR and what CDC can accomplish with additional support. The extent of the AR challenges around the globe beyond the US and Europe are unclear. If laboratory resources were available on a regional basis globally, as in the US, countries could have the resources to understand what is occurring and provide epidemiological, response, and infection control support. Work in the US will be adapted to other locations, but the US experience forms a framework and structure for considering how to acquire more information and use it to drive change around the world.

The Council of State and Territorial Epidemiologists (CSTE) commended Mr. Craig and CDC for all of the hard work in AR, which has been a “game-changer” for state health departments. For example, Tennessee has statewide reporting of CRE. Between 2016 and 2018, the state has had a 42% reduction in *Klebsiella pneumoniae carbapenemase*. The resources devoted to the ARLN and to strengthening state health departments are making a difference. The containment effort is working. CSTE asked how the Government Accountability Office’s (GAO) assessment factors into CARB 2.0.

Mr. Craig answered that the GAO has been investigating AR across the US government for the past year. GAO is Congress's advisory /investigative arm that provides advice to committees and assesses work in the Executive Branch, or other issues Congress might examine in consideration for legislation. GAO usually has a mandate from a Congressional committee. In this case, the House Energy and Commerce and the Senate Health, Education, Labor, and Pensions Committees have asked the GAO for information about AR. Over the past year, GAO has been defining the scope of the investigation, and it is ongoing. To date, the endeavor has been positive for CDC. The GAO report may be released in the summer and could potentially inform the CARB 2.0 process. There could be a hearing, or multiple hearings, on the topic. Congress's actions will depend heavily upon the recommendations. Advocacy regarding the drug pipeline and incentives to support the development of new antibiotics is strong; it is not clear if, or how, that advocacy might have influence.

The Public Health Agency of Canada (PHAC) asked about work or plans regarding the issue of medical tourism and travel-related cases. A common link between Canada and the US is that almost all of their imported cases can be tracked to medical tourism or travel.

Mr. Craig answered that medical tourism is an area of interest for CDC. There was recently coverage on *60 Minutes* of the Harvard research project [G-TEN](https://wwwnc.cdc.gov/travel/page/gten) (<https://wwwnc.cdc.gov/travel/page/gten>), which is fully supported by CDC. In that project, whole genome sequencing is performed in travel clinics: a sample is taken before a traveler departs and after their return to look for and understand specific patterns of resistance that may have been acquired overseas. This work applies to travel with or without receipt of healthcare in order to understand whether CDC's recommendations for risk should extend beyond those who receive healthcare overseas. This project began as a pilot in one travel clinic in Boston and now has been extended to multiple travel clinics across the US. They are examining a variety of pathogens, including CRE and *C. auris*, and are noting interesting findings. When positive cases are found, household contacts are tested to determine whether onward transmission to them has occurred.

Dr. Bell added that beyond activities such as improved diagnostic capability access, effort is underway to consider ministerial policies in other countries. Antimicrobial use and healthcare are longitudinal issues that are supported and driven by governmental policy. A granular approach that focuses on the activity location is not sustainable, nor is it scalable. International efforts involve relationships with ministries and governmental policies that can drive better use, reporting, containment, hygiene, etc. The opportunities with CARB 2.0 are significant.

Healthcare Personnel Guideline Workgroup Update: Section 1

Hilary M. Babcock, MD, MPH

Chair, Healthcare Personnel Guideline Workgroup

The Healthcare Personnel (HCP) Guideline Workgroup is charged with updating the *Guideline for infection control in health care personnel, 1998*. The *1998 Guideline* focused on the epidemiology and prevention of infections known to be transmitted in healthcare settings and provided recommendations for reducing transmission of infections among HCP and patients, including immunizations and management of HCP exposures to infections or illness.

The *1998 Guideline* was divided into 2 parts, with all recommendations listed in Part II. In the revision, Section 1 focuses on recommendations for the infrastructure and routine practices for occupational infection prevention and control (IPC) services. Section 2 of the revised Guideline focuses on recommendations for specific infections known to be transmitted in healthcare settings.

Section 1 of the updated *Guideline* updates 4 sections from Part I of the *1998 Guideline* and their corresponding recommendations in Part II:

- C. Infection Control Objectives for a Personnel Health Service
- D. Elements of a Personnel Health Service for Infection Control
- H. Emergency-Response Personnel
- J. The Americans With Disabilities Act

The update incorporates a broader range of elements for an Occupational Health Service (OHS) providing IPC services to HCP. It is applicable to a wider range of healthcare delivery settings, including hospitals, long-term care facilities, and outpatient settings. Guidance is expanded on policies and procedures for occupational IPC services and strategies for delivering occupational IPC services to HCP.

The lead author and Workgroup DFO is Dr. David Kuhar. With technical advice from CDC, the Workgroup developed Section 1 and presented recommendations at HICPAC meetings. After HICPAC feedback was incorporated and HICPAC voted to approve the draft *Guideline*, it was finalized and posted on regulations.gov for public comment at the end of 2018. Comments were received from:

- The Joint Commission
- International Safety Center
- AFL-CIO
- HealthWatch USA
- American Nurses Association
- American Public Health Association
- 4 individuals

Inter-agency comments were also received from the Occupational Safety and Health Administration (OSHA).

The outline of Section 1 is:

- Introduction
- Elements of Occupational Health Services for Infection Prevention
 - Leadership and Management
 - Communication and Collaboration
 - Assessment and Reduction of Risks for Infection Among HCP Populations
 - Medical Evaluations – Occupational Infection Prevention and Control: Education and Training
 - Immunization Programs
 - Management of Potentially Infectious Exposures and Illnesses
 - Management of HCP Health Records
- Appendices

Dr. Babcock reviewed the comments received and proposed revisions to the draft document.

Many of the comments addressed issues that are outside the purview of OHS. To improve clarity, a definition of OHS was added:

Occupational Health Services (OHS):

- Used synonymously with ‘Employee Health,’ ‘Employee Health Services,’ ‘Employee Health and Safety,’ ‘Occupational Health,’ etc.
- Refers to the group, department, or program that addresses many aspects of health and safety in the workplace for HCP.
- In healthcare settings, OHS address workplace hazards including communicable diseases, slips, trips and falls, patient handling injuries, chemical exposures, HCP burnout, and workplace violence.

This definition does not imply that the *Guideline* addresses non-infectious issues, but clarifies the broad role of OHS.

Some comments addressed issues that are outside the scope of the *Guideline*, such as suggestions that OHS should be involved in “Ensuring personal protective equipment (PPE) availability in the workplace, access to safety technology, the role of environmental and engineering controls in worker safety, and cleaning, decontamination, disinfection, and sterilization.” While OHS provides input and recommendations pertaining to required PPE, ensuring access to PPE is not the responsibility of OHS. The draft narrative was revised to make this distinction clear.

Other comments focused on OHS collaboration with IPC staff, industrial hygienists, and other groups, including HCP themselves. The initial draft document addressed collaboration with IPC staff, but some sections of the draft were rearranged to emphasize this point and to reinforce the importance of OHS working directly with HCP in the development of programs and policies. Industrial hygienists and other groups were not specifically named as collaborators, as they are not available in all healthcare settings. The updated draft describes collaboration broadly and suggests potential collaborators.

Many comments requested that the *Guideline* align with OSHA standards. Revisions were made to harmonize with OSHA standards terminology where possible and appropriate. Several comments requested that this *Guideline* restate recommendations from other guidelines and requirements from OSHA standards. HICPAC strives in its guidelines not to repeat or reiterate information that is stated and held elsewhere. Instead, guidelines direct readers to primary sources and refer to recommendations or requirements from other entities, such as the Advisory Committee on Immunization Practices (ACIP), OSHA, individual states, and others. In some examples, OHS responsibilities may be broader than an OSHA requirement; in others, OHS responsibilities are one element of a broader OSHA requirement. The Workgroup revised the draft accordingly.

Several comments suggested that the narrative focus on HCP safety. While HCP safety is a key component of the *Guideline*, the *Guideline's* scope incorporates preventing transmission among HCP and patients, not just protecting HCP. Some discussion about patient safety is appropriate for this guideline.

Additional suggestions were to include topics that are addressed in other CDC guidelines, such as emerging pathogens, outbreaks, and emergency plans. The text notes these important issues, but this guideline is not focused on outbreak response and management. Further, requests were made to discuss the early identification and isolation of patients as infection control measures. While OHS may provide input into this process, it is an Infection Prevention (IP) program responsibility.

Comments were received regarding using consistent terminology for sharps with safety engineered devices. Commenters noted that the terminology used across many guidelines is varied and confusing and offered many suggestions for possible uniform terms. “Sharps with Engineered Sharps Injury Protection (SESIP)” is used by OSHA and CDC: “SESIP refers to devices with integrated features to prevent percutaneous injuries.” The draft has been updated to harmonize with OSHA and CDC terminology.

Some comments focused on aligning discussion about postexposure management with the OSHA standards terminology for “postexposure evaluation and follow-up.” The Workgroup decided to maintain broader descriptions of postexposure management, which may include more than “evaluation and follow-up.” For example, treatment or other investigations may be required.

The new draft includes corrections of technical inaccuracies with regard to industrial hygiene practices and terms, including a revised discussion of risk and hazard assessment and the use of the hierarchy of controls. The Web links have been updated and corrected as necessary.

The changes made to draft recommendations are:

3. Leadership and Management

Federal Register	Edit
<p><i>For occupational health services leaders and staff</i></p> <p>3.2.2b. Develop occupational infection prevention and control services that are tailored to the needs of healthcare personnel.</p>	<p><i>For occupational health services leaders and staff</i></p> <p>3.2.2b. Develop occupational infection prevention and control services that are tailored to the needs of healthcare personnel and the environment in which they work.</p>

4. Communication and Collaboration

Federal Register	Edit
<p><i>For occupational health services leaders and staff</i></p> <p>4.2.2a. Engage senior leaders, administrators, and leaders of other programs that share activities related to occupational infection prevention and control to foster collaborative decision-making.</p>	<p><i>For occupational health services leaders and staff</i></p> <p>4.2.2a. Engage senior leaders, administrators, leaders of other programs that share activities related to occupational infection prevention and control, and healthcare personnel to foster collaborative decision-making.</p>

7. Occupational Infection Prevention and Control: Education and Training

Federal Register	Edit
<p><i>For healthcare organization leaders and administrators</i></p> <p>7.2.1a. Provide healthcare personnel dedicated time during work hours to complete occupational infection prevention and control education and training.</p>	<p><i>For healthcare organization leaders and administrators</i></p> <p>7.2.1a. Provide healthcare personnel dedicated time during normal work hours to complete occupational infection prevention and control education and training.</p>
<p><i>For occupational health services leaders and staff</i></p> <p>7.2.2c. Topics for initial, periodic, and as-needed education and training should include:</p> <ul style="list-style-type: none"> • Federal, state, and local education and training requirements ... • How to access occupational health services, when needed, and the need to report exposures 	<p><i>For occupational health services leaders and staff</i></p> <p>7.2.2c. Topics for initial, periodic, and as-needed education and training should include:</p> <ul style="list-style-type: none"> • Federal, state, and local education and training requirements ... • How to access occupational health services, when needed, and expectations for reporting exposures

9. Management of Potentially Infectious Exposures and Illnesses

Federal Register	Edit
<p><i>For healthcare organization leaders and administrators</i></p> <p>9.2.1a. Implement sick leave options for healthcare personnel, and whenever possible, contract staff, that encourage healthcare personnel reporting of potentially infectious exposures or illnesses, appropriate use of sick leave, and adherence to work restrictions.</p>	<p><i>For healthcare organization leaders and administrators</i></p> <p>9.2.1a. Implement sick leave options for healthcare personnel, and whenever possible, contract staff, that encourage healthcare personnel reporting of potentially infectious exposures or illnesses, appropriate use of sick leave, and adherence to work restrictions.</p>
<p><i>For leaders and staff of occupational health services</i></p> <p>9.2.2a. Develop, review, and update when necessary policies and procedures about healthcare personnel exposure and illness management services that: ...</p> <p>9.2.2.a2. Establish a timely, confidential, and non-punitive mechanism for healthcare personnel to report exposures and access exposure and illnesses management services 24 hours a day and 7 days per week;</p> <p>9.2.2.a3. Include sick leave options that encourage healthcare personnel reporting of exposures and illness and discourage presenteeism;</p>	<p><i>For leaders and staff of occupational health services</i></p> <p>9.2.2a. Develop, review, and update when necessary policies and procedures about healthcare personnel exposure and illness management services that: ...</p> <p>9.2.2.a2. Establish a timely, confidential, and non-punitive mechanism for healthcare personnel to report potentially infectious exposures and access exposure and illnesses management services 24 hours a day and 7 days per week;</p> <p>9.2.2.a3. Include sick leave options that encourage healthcare personnel reporting of potentially infectious exposures and illnesses and discourage presenteeism;</p>
<p>9.2.2b. Define criteria, methods, and individuals responsible for reporting healthcare personnel exposures and illnesses or suspected infectious outbreaks to internal departments and external authorities.</p>	<p>9.2.2b. Define criteria, methods, and individuals responsible for reporting potentially infectious exposures and illnesses or suspected infectious outbreaks to internal departments and external authorities.</p>

Dr. Babcock invited comments and feedback from the group. After HICPAC votes to approve the draft *Guideline*, it can be submitted for final CDC clearance and posted on the HICPAC website.

Discussion Points

HICPAC thanked the Workgroup for all of the hard work that has gone into this effort.

CSTE reported that Tennessee had transmission of Hepatitis A Virus from a patient to 6 HCP and one patient. As they investigated this incident, they became aware of a punitive sick leave policy at the facility that required HCP to take personal leave before they were eligible to take sick leave. Because of this policy, infected HCP worked while symptomatic. Additionally, personnel who call in sick more than 3 times in a year are no longer eligible for a bonus. This policy encourages presenteeism and is not in the best interests of either personnel or patient safety. CSTE is concerned about how widespread these policies are and whether HICPAC should more strongly recommend against such punitive policies.

Dr. Babcock said that the Workgroup had numerous discussions about that issue; they have seen similar examples. Some hospitals have “perfect attendance awards,” which may seem like a good way to

encourage personnel not to call in sick when it is not necessary, but it is not in alignment with guidance regarding work restrictions and presenteeism. Research is being conducted to understand interactions among sick leave policies, presenteeism, and disease transmission. The draft Section 1 includes recommendations for leadership and administration of healthcare organizations with specific language regarding the need for sick leave options that encourage reporting and adherence to work restrictions; non-punitive mechanisms for personnel to report exposures and access services; and sick leave options that encourage reporting and discourage presenteeism. The *Guideline* applies to a wide range of settings and is therefore not proscriptive regarding sick leave, but examples of policies could be included.

The American College of Occupational and Environmental Medicine (ACOEM) emphasized the versions of, and variability in, policies that discourage reporting. In making arguments to hospital administrations, it is powerful to cite an overarching statement from CDC that policies should discourage presenteeism and should be non-punitive.

HICPAC stressed that because human resources departments set these policies, it is important to work with them to change language from a specific number of days, to events or episodes.

There was discussion among HICPAC regarding conducting a review of sick policies in healthcare facilities. Some facility policies state that personnel who call in sick 3 times per year will be terminated. The threat of termination may be prompting increased outbreaks, particularly in long-term care facilities (LTCF). Any opportunity to provide input to senior management would be beneficial, such as by conducting surveys about policies.

Dr. Babcock described a survey of sick leave policies through the Emerging Infections Network, which asked infectious disease doctors about policies in their facilities. There is a broad range of policies, and most were not supportive of personnel being off of work when sick. This survey focused primarily on acute care settings; a similar survey for LTCF would be useful.

AAKP observed that from a public policy standpoint, CDC is not in the role of dictating certain standards to employers. However, these standards are fundamental to large patient stakeholder organizations that view patients from the public health and workforce perspectives: patients are also in the workforce and are concerned about public health. The guideline is a powerful tool for AAKP to provide to allied partners, hospitals, and others to illustrate the standards that CDC is setting for awareness. AAKP is happy to embrace this *Guideline* and to educate their patients and partners.

In light of recent news about vaccine-preventable diseases such as measles, HICPAC commented on the language referring to the pre-placement medical evaluation. For example, the draft states, “evidence of immunity to vaccine-preventable diseases,” without detail. Additional specificity regarding what constitutes “evidence of immunity” could be helpful.

Dr. Babcock replied that the language is broad to encompass vaccine-preventable diseases and the various ways that immunity might be assessed and measured for an individual. Remembering HICPAC’s goal of not repeating recommendations, the *Guideline* refers to ACIP resources for details regarding evidence of immunity for each disease. The *Guideline* recommends alignment with all ACIP recommendations for HCP protection against vaccine-preventable diseases. Each of the infection-specific sections in Section 2 will provide links and references as well.

The Joint Commission expressed appreciation for all of the work on this guideline, especially for the added emphasis on collaboration. Will information regarding competency be incorporated into the document? There is a gap between training and capability, such as in donning and wearing PPE.

Dr. Babcock noted that the narrative includes discussion regarding competencies and states that a collaborative process and team-based approach must be taken. There is concern that it would be

challenging if all responsibility for education fell on OHS. Education and training require a multimodal approach that involves infection prevention, safety officers, unit-based staff, and monitoring of compliance.

HICPAC commented that the link between infection prevention and OHS is critically important, especially in an outbreak situation or when there is transmission between patients and HCP. Collaboration between those departments is essential, but gaining permission to speak with employees about their health can be a complex matter.

HICPAC asked whether the document addresses information technology (IT) infrastructure or database capability so that OHS can nimbly access information and take action as needed.

Dr. Babcock replied that the *Guideline* section on record keeping and infrastructure includes information about how records should be kept and states that it should be possible to access and assess the immune status of employees. APIC supported the ability to make quick determinations about the immune status of employees.

HICPAC and CSTE discussed the possibility of an implementation toolkit to supplement the language about sick leave policies, record keeping for vaccine-preventable diseases, and other recommendations.

HICPAC commented that liaison organizations such as The Joint Commission or DNV-GL could consider the approved *Guideline* in their standards.

HICPAC emphasized the importance of applying the same policies to all employees and to contractors. Dr. Babcock agreed and noted the revision in the recommendations to refer to all HCP, regardless of their employment arrangement.

HICPAC observed that the draft document describes risk assessments when evaluating programs, such as revising sick leave policies to avoid punitive measures. While toolkits can take time to develop, risk assessment is already included in the draft *Guideline*.

Regarding assessing presumptive immunity in a timely manner, CSTE suggested that healthcare organizations can ensure that staffing agency contracts address these issues.

Vote: Healthcare Personnel Guideline “Section 1”

A motion was made to approve the draft *Infection Control in Healthcare Personnel: Infrastructure and Routine Practices for Occupational Infection Prevention and Control Services* (“Section 1”). No substantive changes were suggested for the draft recommendations or narrative. HICPAC voted unanimously to approve the draft, with no opposition and no abstentions. The disposition of the vote was as follows:

- 11 Favored: Anderson, Babcock, Bryant, Daniels, Dekker, Fauerbach, Huskins, Maragakis, Patterson, Preas, Yokoe
- 0 Opposed
- 0 Abstained

US Food & Drug Administration Update

FDA Update on Infections Associated with Reprocessed Duodenoscopes

Shani Haugen, PhD

Microbiologist & Acting Assistant Division Director

Gastroenterology & Endoscopy Devices

Center for Devices and Radiological Health

US Food & Drug Administration

Dr. Haugen provided an update on infections associated with processed duodenoscopes.

Duodenoscopes are flexible gastrointestinal (GI) endoscopes. They are inserted orally to the duodenum to access the bile or pancreatic ducts using an “elevator” feature at the distal tip of the device. CDC alerted FDA of an association between multi-drug resistant organism (MDRO) infections and duodenoscopes in September 2013. Since then, multiple healthcare facilities have reported infections associated with duodenoscope use. FDA has taken several approaches to reduce the risk of infections associated with duodenoscopes.

One of FDA’s first actions upon learning of this association was to work with duodenoscope manufacturers as they updated and validated their reprocessing instructions. The device’s elevator can actuate up or down; this angulation alters the trajectory of accessory instruments and allows access to the bile and pancreatic ducts. Some facilities that experienced outbreaks of infections associated with duodenoscopes reported viable bacteria in the area surrounding and underneath the elevator. Duodenoscope manufacturers updated the reprocessing instructions with additional cleaning and disinfection steps for the elevator recess, including additional brushing and flushing of the area. The new reprocessing instructions were released starting in 2015.

FDA encourages innovation in device designs to reduce the risk of infection and has worked with duodenoscope manufacturers as they address device design. Recently-cleared duodenoscopes have design modifications that are intended to reduce the risk of fluid ingress. Duodenoscope labeling includes recommendations for annual inspection to identify and replace worn and damaged parts of the device. FDA has cleared 2 duodenoscopes with design modifications to the elevator channel sealing mechanism. The updated designs include removable distal caps that improve access for cleaning the elevator and the elevator recess. FDA looks forward to additional advancements in duodenoscope technology.

FDA has engaged in public outreach efforts. In February 2015, an FDA Safety Communication alerted the public of the association between duodenoscopes and infections. FDA also convened an Advisory Committee meeting in May 2015, during which an expert panel evaluated available data. The expert panel and others in the field provided recommendations for reducing the risk of infections associated with duodenoscopes. FDA provided updates at the HICPAC meeting in July 2015 and welcomed feedback from HICPAC members. Additional communications focused on revised reprocessing instructions, device clearance, and device recalls for design modifications. This information is housed on a website, [Infections Associated with Reprocessed Duodenoscopes](https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/infections-associated-reprocessed-duodenoscopes) (https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/infections-associated-reprocessed-duodenoscopes).

Based on the recommendations from the May 2015 Advisory Committee meeting, FDA released a summary of optional supplemental measures to enhance duodenoscope reprocessing:

- Microbiological culturing,
- Ethylene oxide (EtO) sterilization
- Use of a liquid chemical sterilant processing system, and
- Repeat high-level disinfection (HLD).

To help facilities implement one or more of these options, FDA worked with CDC, the American Society for Microbiology, and other experts to develop a [protocol](https://www.fda.gov/media/111081/download) (https://www.fda.gov/media/111081/download) for surveillance, sampling, and culturing of duodenoscopes. The protocol was validated by the duodenoscope manufacturers and released in February 2018, serving as an update to CDC’s interim “Duodenoscope Surveillance Sampling & Culturing” protocol released in March 2015.

FDA has also conducted regulatory actions:

- In 2015, FDA conducted directed inspections and issued Warning Letters to the 3 US duodenoscope manufacturers for various violations of the Quality System Regulations.
- In October 2015, FDA ordered duodenoscope manufacturers to conduct post-market surveillance studies:
 - one “human factors” study assesses user comprehension and the ability to adhere to reprocessing instructions
 - one microbiological sampling and culturing study assesses the effectiveness of duodenoscope reprocessing in a real-world setting
- In March 2018, FDA issued Warning Letters to duodenoscope manufacturers for failing to comply with the post-market surveillance studies.
 - Since then, progress has been made on those studies.

Medical Device Reports (MDRs) are the adverse event (AE) reports submitted to FDA. The number of reports of device contamination has increased since 2015, possibly due to additional sampling and culturing conducted by facilities. The number of patient exposures - instances in which a contaminated duodenoscope was used on a patient - remains low and has decreased over time. An encouraging decrease has been observed in the numbers of infection reports, which indicates that the efforts by FDA, CDC, duodenoscope manufacturers, professional societies, and others have had an impact. However, FDA continues to receive reports of infections, and there is continued need to improve the safety of reprocessed duodenoscopes.

The results of the post-market studies are informing FDA’s next steps. The human factor study was intended to determine whether the reprocessing user materials (eg, reprocessing manual and educational materials) are sufficient to promote adherence and comprehension, and whether personnel can follow the reprocessing instructions without errors or failures that can result in harm to patients. The results indicate that the user materials can be strengthened: reprocessing instructions in current user manuals are difficult for personnel to comprehend and follow. Some reprocessing staff missed one or more steps in the process and needed additional training to complete the process properly. The descriptions of some of the processing steps in current user manuals were unclear.

The purpose of the microbiological sampling and culturing study was to assess the effectiveness of reprocessing instructions in a real-world setting. Interim results from the duodenoscope manufacturers indicate that up to 3.6% of properly collected samples tested positive with ≥ 100 colony-forming units (CFU) of low- to moderate-concern organisms, which may be associated with environmental contamination. Up to 5.4% of properly collected samples tested positive for high-concern organisms, defined as organisms that are more often associated with disease, such as *Escherichia coli* (*E. coli*) or *Pseudomonas aeruginosa* (*P. aeruginosa*). These interim data demonstrate that improvements are necessary.

The results of the post-market surveillance studies are consistent with the literature. In the past 4 years, a number of studies have evaluated various aspects of duodenoscope reprocessing. In 2018, Thaker and colleagues conducted a survey of 249 healthcare facilities that used duodenoscopes. Of these, 90% implemented one or more supplemental measures from FDA’s August 2015 Safety Communication:

- 63% (157/249) reported conducting repeat manual cleaning and HLD.
- 53% (133/249) reported conducting some type of surveillance microbiological culturing.
- 35% (86/249) reported conducting liquid chemical sterilization.
- 12% (30/249) reported utilizing EtO gas sterilization.

These results suggest that outreach efforts have been successful and that facilities are working to improve their reprocessing procedures.

With the increase in microbiological culturing of endoscopes, additional reports evaluate reprocessing procedures in a clinical setting. Several recent studies have found that a percentage of duodenoscopes remain contaminated after reprocessing.¹ Because the studies assess different methods and apply different definitions for contamination, it is not possible to compare their results directly; however, a contamination rate of approximately 2% to 5% is observed in larger studies and is consistent with the post-market surveillance study results. Reports also indicate that double HLD does not improve contamination outcomes relative to single HLD.²

FDA defines HLD as a lethal process utilizing a sterilant under less than sterilizing conditions. The process kills all forms of microbial life except for large numbers of bacterial spores. In contrast, EtO sterilization is a validated process used to render a product free from viable microorganisms. Liquid chemical sterilization falls between the two and does not convey the same sterility assurance level as sterilization using thermal or low-temperature sterilization methods such as EtO. Testing and validation processes are different for each of the methods and may require different types of test organisms, soil challenges, test cycles, and test endpoints. In general, EtO sterilization provides a higher margin of safety than either HLD or liquid chemical sterilization.

Contamination rates after EtO sterilization are variable, perhaps due to differences in test methodologies.³ It has been demonstrated that EtO sterilization of duodenoscopes led to a cessation of outbreaks in at least 3 healthcare facilities.⁴ FDA is aware that additional sterilization technologies are in development for duodenoscopes⁵; however, no terminal low-temperature sterilizers with claims to sterilize duodenoscopes have been cleared by FDA at this time.

FDA's conclusions from evaluating the available data are that current practices for reprocessing duodenoscopes are not sufficient to avoid all infections associated with duodenoscope use. FDA is concerned that HLD is not sufficient to ensure the safe use of these devices in all cases. The benefits of the procedure, however, outweigh the risks in appropriate patients.

In closing, Dr. Haugen posed issues that FDA is exploring:

- What changes could be made to ensure the safer use of duodenoscopes, and how should those changes be implemented, considering potential challenges?
- What is the level of concern regarding the safety of reprocessed duodenoscopes?
- Does high-level disinfection provide an adequate assurance of safety?
- What are the challenges to sterilizing duodenoscopes?

An additional issue is whether the level of safety concern warrants additional actions and, if so, what those actions might be. FDA is committed to reducing the risk of infection associated with duodenoscopes and will continue to discuss further steps.

¹ Bartles 2018, Rauwers 2018, Ross 2015, Rex 2018, Snyder 2017, Visrodia 2017

² Bartles 2018, Snyder 2017

³ Naryzhny 2016, Snyder 2017

⁴ Epstein 2015, Smith 2015, Humphries 2017

⁵ Molloy-Simard 2019

Discussion Points

HICPAC Members

Concern was expressed regarding the current interim contamination rate data and MDRs, as well as the effectiveness of the suggested mitigation strategies and the response from device manufacturers if processes other than those they recommend are used.

Data on the correlation between the supplemental measures described, whether facilities are performing them, and the culture results or reports would be useful.

It would be helpful to understand the impact of the new design modifications mentioned, such as removable pieces and better shielding of the elevator mechanism. Dr. Haugen said that while the modifications have the potential to reduce the risk of infection, FDA does not yet have data on their impact.

HICPAC asked about the post-market study that showed 5% contamination: what type of reprocessing was done, and were any of the additional steps used? Dr. Haugen answered that the information presented was the “worst-case” levels of contamination from one of the duodenoscope manufacturers. The contamination results from the different manufacturers and device models varied. The reprocessing steps conducted at the facilities also varied. Duodenoscope manufacturers assessed samples from devices that were processed in accordance with current reprocessing instructions. The majority of samples were collected from devices that were subjected to the full manual cleaning process, HLD, and then an automated endoscope reprocessor. Some facilities conducted double HLD; however, the initial, interim analysis indicates that this step did not have an impact on contamination rates. That finding is consistent with the literature.

Interest in engineering solutions to allow simpler and more effective reprocessing is laudable and should be an immediate goal. Some of the solutions designed to decrease ingress may make the device more difficult to clean, however. Data about contamination rates from the newer devices would be helpful. Dr. Haugen said that typically, data from bench testing prior to clearance is used to support devices and their reprocessing instructions. Assessment of contamination rates could be conducted prior to the device being marketed in the US. HICPAC commented that new duodenoscopes may undergo relatively limited evaluation because they are based on predicate devices; additional evaluation for contamination could be helpful.

There was discussion regarding the potential role of manufacturer “exchange programs” that offer low-cost exchange of older device designs with newer device designs. Dr. Haugen said that FDA could explore this issue as next steps are determined.

HICPAC commented on the data regarding AEs related to duodenoscopes over time, noting that it is helpful to see how FDA has approached these questions over the past 5 years and asking whether the data were only from the Manufacturer and User Facility Device Experience Database (MAUDE); whether they included all events, such as from the Alternative Summary Reporting (ASR); and whether these events were all in publicly-accessible databases. Dr. Haugen replied that all of the reports should be publicly available.

Patients who need a procedure with a duodenoscope are different from patients who need a standard endoscopy or colonoscopy. With that in mind, HICPAC wondered if FDA has evaluated other types of endoscopes for similar risks. Dr. Haugen answered that FDA monitors the safety of other types of endoscopes.

In the past, the prevailing belief was that “it was not possible to get to zero” device-associated infections. It is now known, based on central line-associated bloodstream infection (CLABSI), that “zero” can be achieved. For duodenoscopes and a vulnerable patient population, human factor technology may play an important role in reaching “zero.” This technology requires work and investment.

Post-market surveillance contamination rates could be made available by device and manufacturer, and this information could be included with manufacturers’ marketing information, similar to package inserts for drug products. Reporting this type of information could allow for comparisons and for finding solutions through better technology, disinfection, or other approaches.

HICPAC commented on the intersection of various components: device, type of disinfection or sterilization recommended, type of reprocessing, how reprocessing is conducted. Each component impacts contamination rates. It would be challenging, but helpful, to better understand the interplay of the components, including the expanse of disinfection and sterilization strategies, old scopes and new scopes, technologies, etc. This understanding could lead to better ways to reprocess devices and to avoid potential human errors.

Practicing physicians encounter patients who are concerned about undergoing a scoping procedure. Based on the current state of knowledge, it can be difficult to deliver messages to patients. Dr. Haugen reiterated that FDA’s message continues to be that for appropriately selected patients, the benefits of the procedure outweigh the risks of infection.

HICPAC observed reluctance among patients who feel that any risk is too great. It is important to work toward eliminating risks associated with scopes.

HICPAC wondered whether data regarding deaths yield commonalities or “lessons learned.” Dr. Haugen replied that the numbers of reported deaths related to duodenoscopes also have decreased since 2016, the peak of death reports submitted to FDA. This decrease suggests improvement, but infections and deaths continue, illustrating that there is more work to be done.

It is problematic when a device is created and sent to facilities without establishing that it can be cleaned and disinfected by following its instructions for use. Each type of scope has a different set of complex and multi-step procedures for processing. Manufacturers’ human factor studies show that cleaning and disinfection are difficult and challenging to do correctly, but the responsibility for cleaning and disinfection lies with facilities, which are not in a position to fix these aspects of the problem. It is important for devices to be cleanable in the facilities that use them, not just in the manufacturer’s setting.

While each step toward more impactful sterilization represents a more difficult process, the notion that EtO can clean devices that cannot be cleaned by manufacturer-recommended processes is not necessarily appropriate. Many facilities are phasing out EtO, restricting its use due to safety concerns, or not using it at all. These changes pose risks and problems not only for those trying to implement this process, but also in terms of timing, voiding the manufacturer’s warranty, and shortening the device’s “lifespan.” Alternative sterilization methodologies to EtO, or different scope technologies that offer better options, could be developed.

Companies compete to make the best product, but companies could work together to design and develop a singular duodenoscope with a standardized design and reprocessing instructions.

If better solutions are not forthcoming, a fundamental shift will be required in how risk associated with these procedures is described to patients. The patient perspective is critical regarding types of risk, which may be perceived as a question of the facility not being able to clean and sterilize correctly.

Given that the level of risk associated with these devices is clear, and the inability to clean and disinfect them adequately is known, the risk-benefit ratio may not be acceptable. A paradigm shift or redesign, or a move toward disposable products, may be needed. However, the benefit that duodenoscopes with disposable parts have over existing devices should be demonstrated before healthcare facilities switch to those new devices; contamination rate data evaluated premarket and included in the labeling would be helpful for healthcare facilities that are considering switching to the newer models of duodenoscopes. There may be competing risks associated with disposable items, such as a relatively narrow field of procedures that can be conducted with them.

In response to a HICPAC question regarding the infection data, Dr. Haugen said that medical device issues risk being under-reported. More than 500,000 procedures are performed annually in the US.

HICPAC asked about the proportion of healthcare facilities with access to liquid sterilization systems. Not all of the systems are compatible with these scopes. Dr. Haugen responded that while it is not clear how many facilities have access to these systems, survey results of facilities that conduct endoscopic retrograde cholangiopancreatography (ERCP) procedures indicate that approximately 35% use a liquid chemical sterilant processing system.

There was discussion regarding incorporating contamination risks into pre-market assessment for designs and devices, and pre-market manufacturer testing of the cleanability of devices, particularly given that many of these devices will be marketed as easier to clean and disinfect. There is a need for a simpler process for cleanability and assurance of sterilization. Given the available data, the margin of safety with current reprocessing practices (including high-level disinfection) is not sufficiently high enough, however that may change if the devices were more cleanable.

Liaison Representatives and *ex officio* Members

APIC expressed concern with the preliminary post-market data showing a 3% to 5.4% contamination rate of harmful pathogens. The steps for cleaning and disinfection are so convoluted that success is difficult, even for an experienced technician.

With the emergence of methods other than HLD, APIC encouraged providing sufficient data to support practice changes so that practice is not influenced when it is not necessary. Dr. Haugen noted that microbiology culturing and safe sterilization were discussed during FDA's 2015 Expert Panel meeting. The methods have been successfully implemented by facilities to stop outbreaks.

DNV asked whether the devices causing problems have been replaced with modified devices. Dr. Haugen replied that design changes were implemented as part of the clearance and concurrent recall of devices to reduce the risk of fluid ingress in various parts of the device. The manufacturers conducted a recall to repair the devices that were in the field.

AORN commented that EtO and liquid chemical sterilization are time-consuming; additionally, there are concerns associated with exposure to EtO. Working with manufacturers to develop another sterilization process has potential benefit.

The National Institutes of Health (NIH) asked how EtO sterilization reduces the lifetime use of a scope. Dr. Haugen answered that FDA receives anecdotal reports of device damage following EtO sterilization.

From the patient stakeholder perspective, AAKP emphasized that the volume of procedures performed in the US is less relevant than understanding that patient interest starts with "Patient #1." Given the standards conveyed and the amount of time that has passed, the onus is on all stakeholders in this process to raise questions and educate patients on both the risk and the device being used. Informed patients can make informed decisions, but uninformed patients' lives are at risk.

DNV asked whether vendors that train personnel on cleaning procedures are required to report incompatible hospital conditions or lack of compliance with manufacturer instructions for use.

CDC

Dr. Bell emphasized the importance of thinking broadly about relative risks. HICPAC typically focuses on microbial contamination, disinfection, and sterilization. That focus is important, but safety is an important aspect of the conversation. The challenges include variations in scope design; the multitude of scopes; and the variety of automated reproprocessors, with different connections and formats. Improving device design includes improving platforms to make them similar. A unique item is helpful in terms of controlling market share, but that approach may not be the best strategy for the health system and the patient.

Dr. Bell commented on the topic of informed consent and due diligence. An individual patient might be willing to consider modest risk if his life was at stake; however, he needs to know what that risk is.

Dr. Bell thanked FDA for the “forward lean” that they have demonstrated. He further thanked industry colleagues for their efforts. When this conversation began, disposable tips for scopes did not exist but were a “wish list” from HICPAC: it is gratifying to see that 2 manufacturers now produce disposable tips. While it is clear that much more work remains in design improvements and human factors, FDA and industry have made significant progress.

Dr. Bell raised the issue of the environment in which reprocessing is conducted. Many of these spaces are small, cramped “afterthoughts” in a facility. Factors such as the amount of work surface area, infrastructure, quality of lighting, etc, could have impact.

FDA Update on the Sterigenics Facility Closure and Ethylene Oxide Sterilization

Suzanne Schwartz, MD, MBA

Acting Director

Office of Strategic Partnerships and Technology Innovation

Center for Devices and Radiological Health

US Food & Drug Administration

Dr. Schwartz said that duodenoscopes are an illustration of the difficulties of adequate reprocessing of reusable devices. A more expansive challenge is the need to maintain capacity for terminal sterilization of a range of new devices that serve the US healthcare system before they can be distributed for patient use as sterile package products (procedure kits, surgical packs, stints, sutures, clamps, implantables, tracheostomy tubes, etc).

FDA recognizes, and is sensitive to, the environmental concern for EtO emissions that are released into the air at unacceptable levels that can present increased risk to the health of surrounding communities. FDA is working closely with government partners and stakeholders not only to understand the magnitude of the public’s concern, but also to take a proactive stance to address these risks head-on.

Because FDA is responsible for ensuring the safety and effectiveness of all medical devices, the agency has been closely monitoring the effects of the closure of the Sterigenics facility in Willowbrook, Illinois, and working with device manufacturers affected by the closure to minimize impact to patients needing access to these medical devices. In order to reduce the risk of device-related infections, certain medical devices need to be sterilized before use. Sterilization of medical devices is well-established and scientifically proven as a method of preventing harmful microorganisms from reproducing and transmitting infections. EtO has been a common method for medical device sterilization, primarily because of material compatibility considerations: 50% of medical devices that require sterilization

before use are sterilized by EtO. Many devices are composed of multiple components, such as polymers, cellulose, and other materials, that are unable to withstand other sterilization modalities without an alteration to the device that would place its safe performance in jeopardy. Therefore, FDA considers EtO a safe and effective method for sterilization.

Prompted by recent events affecting closure of one contract sterilizer facility, FDA has taken a proactive and multi-pronged approach with 3 objectives:

- Mitigate potential product supply issues that can put patient safety and the public's health at risk due to delays and disruption in clinical care.
- Explore mitigation approaches to reduce the exposure of unacceptable levels of EtO emissions into the environment without compromising the efficacy of device sterilization.
- Address the need to identify safe and effective alternative modalities for sterilization of medical devices.

FDA appreciates the opportunity to bring this matter to CDC and HICPAC for their awareness.

On February 15, 2019, the Illinois EPA issued a Seal Order to stop the Sterigenics facility in Willowbrook, Illinois, from further sterilizing medical products and other products with EtO. There are approximately 155 contract sterilizers in the US; Sterigenics has 9 sterilization facilities. Another contract sterilizer, Viant, has announced its closure by the end of 2019. Contract sterilizers are working at, or close to, maximum capacity. They are working "24/7" and have limited ability to increase capacity. The closure of a single site can have significant consequences for the availability of medical devices that need to be delivered to healthcare.

FDA is aware of an April 2019 report from the Illinois Department of Public Health regarding cancer risk. FDA is also aware of ongoing surveillance being conducted by the state EPA, federal EPA, and CDC to gain a better understanding of risk to the communities and areas around these facilities, as well as the associations with the levels of emissions within those areas. FDA's efforts have been three-fold:

- Addressing where there could be imminent potential shortages or spot shortages of products,
- Exploring sterilization alternatives, and
- Exploring mitigating measures to enable the use of EtO with different concentrations to reduce exposure and concerns for toxic emissions within the environment.

Immediately upon notification of the closure of the Willowbrook facility, FDA initiated outreach to the Sterigenics facility, individual device manufacturers, and the industry as a whole through its trade organizations and distributors in order to assess the landscape of the effects of this closure, including which devices may be impacted and where disruptions might occur within the supply chain. FDA has identified potential concerns with regard to product availability. For example, the availability of a pediatric tracheostomy tube manufactured by Smiths Medical was impacted by the Sterigenics closure the week of April 22, 2019. FDA established a device shortages mailbox (deviceshortages@fda.hhs.gov) for the public, healthcare organizations, manufacturers, distributors, and others in the supply chain to communicate potential unavailability or inventory shortfall.

It has been critical for FDA to communicate early, frequently, and as transparently as possible regarding the potential for shortages. FDA released a letter to industry on February 28, 2019, indicating what manufacturers affected by the closure can and should do to help streamline the process of transitioning to another facility for EtO sterilization. For instance, when a sterilization site change needs to occur for a Class III device that is under a Premarket Approval (PMA) and data needs to be submitted for a review as a Supplemental Submission, the timeline is generally 180 days. FDA indicated in the letter to industry that the agency would commit to a review for site changes in under 30 days. FDA has been able to

conduct reviews in less than 30 days in order to minimize the possibility of manufacturers lacking contingency plans for sterilization.

On March 26, 2019, Commissioner Gottlieb provided a statement, and FDA launched a webpage that continues to serve as a resource for announcing new information as it becomes available. On April 12, 2019, the Center for Devices and Radiological Health (CDRH) Center Director, Dr. Shuren, released a statement about the temporary Bivona tracheostomy tube shortage. FDA has worked closely with the manufacturer to identify an alternate site for the devices to be sterilized and distributed and for FDA to be able to review those data to provide clearance.

In keeping with the importance of communication and transparency, FDA has been forward-leaning in informing Congressional delegations of its observations and its plans:

- March 15, 2019: Illinois delegation briefing - impacted directly by Sterigenics
- March 25, 2019: Minnesota delegation briefing - Minnesota is a hub for many medical device manufacturers
- April 11, 2019: Illinois Senate delegation sent a letter to the FDA Commissioner asking about FDA actions to evaluate EtO alternatives - FDA is in the process of addressing
- April 24, 2019: Illinois House delegation sent a letter to the FDA Commissioner asking about FDA actions to evaluate EtO alternatives - FDA is in the process of addressing

FDA is engaging with multiple stakeholders as part of its approach to these issues. The agency has reached out to sterilization experts to provide additional information on methodologies that could be utilized for EtO reduction, as well as potential alternatives to EtO for sterilization of medical devices. FDA is working closely with the US EPA and is engaged in discussions regarding EPA's Rule Making to ensure that facilities and methodologies are in place for performing medical device sterilization. FDA is working with CDC to understand the public health impact of EtO emissions on the communities around facilities that perform contract sterilization.

Questions FDA is exploring include:

- Can a reduction in the amount of EtO used to sterilize medical devices achieve/maintain sterility assurance?
- Are there alternative methods to EtO sterilization that can adequately sterilize medical devices?

FDA will announce the launch of an Innovation Challenge in Summer 2019. The objective of this challenge is to encourage EtO reduction and alternative sterilization methods. FDA is in the early phases of planning an Advisory Committee Meeting in Fall 2019, with the objective of obtaining stakeholder feedback to inform FDA decision-making regarding challenges and opportunities for EtO reduction and the use of alternative strategies.

FDA will continue frequent engagement with a variety of stakeholders (manufacturers, distributors, healthcare organizations, group purchasing organizations, trade organizations, etc) regarding potential device shortages. The objective is to mitigate shortages via real-time review of sterilization approaches. In parallel with these efforts, FDA has been working toward accepting submissions of informational Q-Submissions (Q-Subs) from subject matter experts (SMEs) for alternative sterilization methods. These efforts will help the agency to be better informed and to explore alternative methods as part of the decision-making process.

Discussion Points

HICPAC expressed appreciation to FDA for presenting information on this important issue. It is clear that closing even one commercial facility performing EtO sterilization of these devices has a significant impact.

HICPAC asked whether closures will expand beyond Sterigenics and Viant.

Dr. Schwartz said that other manufacturers and devices have been affected even by the single site closure. Because some of those manufacturers had contingency plans in place, the nation is not experiencing the “spot shortages” that might otherwise be seen. However, it is important to underscore that a “domino effect” would have an impact. Part of the strategy to be proactive and prepared incorporates understanding which products and manufacturers may be impacted by the closure of a sterilization facility, and identifying in advance alternative EtO sites or methodologies that can be validated.

Neonatal Intensive Care Unit Guideline Update

Kristina Bryant, MD

Chair, NICU Guideline Workgroup

Dr. Bryant presented draft recommendations for the CLABSI section of the *Guideline for Prevention and Control of Infections in Neonatal Intensive Care Unit Patients* (“NICU Guideline”) and brief updates on the Respiratory Illness section of the Guideline, the proposed NICU Core Practices document, and the *Staphylococcus aureus* (*S. aureus*) section of the Guideline.

The NICU Guideline uses the new HICPAC recommendation categorization scheme. In order for HICPAC to make a recommendation, the benefits of the intervention must clearly exceed the harms, or vice versa. The level of confidence in the supporting evidence should be high to moderate, but recommendations can be based on confidence levels that are low or very low, or on expert opinion, if high-quality evidence is impossible to obtain or if a federal regulation applies.

In the GRADE scheme, randomized controlled trials (RCTs) begin with a high level of confidence in the evidence, and non-randomized studies begin with a low level of confidence. A number of factors can lower the quality of evidence (Risk of Bias, Inconsistency, Indirectness, Imprecision, and Publication Bias), while other factors can increase the quality of evidence (Large Magnitude of Effect, Dose-Response, and Confounding). Dr. Bryant cautioned that much of the evidence to be considered for this *Guideline* is from non-randomized studies.

HICPAC’s new recommendation categorization scheme includes a Justification Table, which makes the process by which the committee arrived at the Recommendation, Conditional Recommendation, or No Recommendation more transparent. The table includes:

- *Statement* (Recommendation; Conditional Recommendation; No Recommendation)
- Supporting Evidence
- Level of Confidence in Evidence
- Benefits
- Harms
- Resource Use
- Balance of Benefits and Harms
- Value Judgments
- Intentional Vagueness
- Exceptions

CLABSI

Key Question: *What are effective strategies to prevent CLABSI in neonatal intensive care unit patients?*

The literature search retrieved 168 studies that met the inclusion criteria.

- 72 studies were included from the 2012 work on the Guideline

- 96 studies were included from 2012-2018

The Workgroup identified 4 topics of particular importance:

- Central Line Antimicrobial Locks
- Optimal Umbilical Venous Catheter (UVC) Duration
- Optimal Central Line Type
- Optimal Central Line Insertion Site.

Central Line Antimicrobial Locks

Key Question: *In NICU patients with central line catheters, does the use of central line antimicrobial locks, compared to standard of care, prevent CLABSI?*

Three RCTs address this issue in NICU patients. Each used a different agent at a different frequency, and let it dwell for different durations:

- Seliem 2010: n=83 (Amikacin-heparin saline locks 2x/ day for 20 minutes)
- Filippi 2007: n=103 (Fucidic acid-heparin locks 1x/day for 30-60 minutes)
- Garland 2006: n=84 (Vancomycin-heparin saline locks 2x/ day. 20 minutes for neonates fed by parenteral hyperalimentation, and 60 minutes when feeding exceeded 20ml/kg/day)

Central line antimicrobial locks demonstrated benefit when the outcome of interest was catheter-related bloodstream infection (CRBSI): there was a reduction in CRBSI compared to the control intervention, which was no lock or a heparin saline lock. The baseline rates or rates in the control arm in these studies were somewhat higher than seen today. It is also important to note that the years of publication of these studies were in the era before widespread and reliable implementation of central line insertion and maintenance bundles.

Regarding other outcomes, there was not a significant difference in suspected or probable bloodstream infection (BSI). Potential AEs included hypoglycemia and AMR. Locks were not associated with an increased frequency of hypoglycemia, but hypoglycemia was relatively common in both arms of the studies. Interruption of continuous infusion of intravenous fluids will result in some babies becoming hypoglycemic; the reason for the interruption does not matter. No AMR was found, but data were limited.

CLABSI: Central Line Antimicrobial Lock *Draft Recommendation*

“Consider central line antimicrobial locks for neonatal intensive care unit patients in addition to core infection prevention and control strategies when a unit is experiencing ongoing CLABSIs. **Conditional Recommendation.**”

- **Supporting Evidence:** Three randomized controlled trials. (Seliem, Garland, Filipi)
- **Level of Confidence in Evidence:** The level of confidence in this evidence is high because randomized controlled trials are considered at low risk of bias. This evidence could be rated down for indirectness as the studies were not conducted in the current standard of care.
- **Benefits:** A reduction in definite CRBSI was seen in all three studies. No benefit was seen in the outcomes of suspected/ probable CRBSI, or BSI without a source.
- **Harms:** Harms that could result from this recommendation include hypoglycemia, adverse product related events, and the development of antimicrobial resistance to the agent used. The presence of a lock results in the interruption of fluid to the neonate, and asymptomatic hypoglycemia occurred in greater than 10% of infants during use of the locks whether the lock contained antibiotics-heparin or saline-heparin. Antibiotic levels in infants’ blood were not detected in the vast majority; and when antibiotic levels were detected, they were at very low levels that should not result in harm.

- **Resource Use:** The use of antimicrobial lock prophylaxis will result in increased human and material cost; however, in the context of high baseline rates these costs are likely to be lower than the costs of the infections.
- **Balance of Benefits and Harms:** The benefits of CRBSI reduction are balanced with the possible harms of hypoglycemia and the development of antimicrobial resistance. However, all three studies reported high baseline CRBSI rates, which may confound the benefit seen in these studies, since evidence-based insertion and maintenance practices have resulted in baseline CRBSI rates that are currently much lower than the baseline rates at the time of the studies. In the context of high baseline rates, these benefits may outweigh the harms.
- **Value Judgments:** Patient safety, facility rates, economic and human resource use, and the development of antimicrobial resistance.
- **Intentional Vagueness:** The antimicrobial agent is not specified in this recommendation. This is because each study used a different antibiotic. Each facility can review the hospital antibiogram and the causal bacteria for the high CLABSI rates in the unit and determine the optimal antibiotic agent. Not all catheters may be compatible with all antimicrobial agents.
- **Exceptions:** Infants who require continuous infusions that cannot be interrupted.

The Society for Healthcare Epidemiology of America (SHEA) has been asked to develop an implementation or practical guidance document to accompany each section of the NICU guideline. The SHEA document could describe choices for antimicrobial locks and provide practical guidance regarding how to use them.

Catheter Dwell Time: UVCs

The Workgroup proposes a change from existing recommendations that could drive practice in NICUs.

BSI Guideline 2011 Umbilical Catheter Recommendations:

1. Remove and do not replace umbilical artery catheters if any signs of CRBSI, vascular insufficiency in the lower extremities, or thrombosis are present [145]. *Category II*
2. Remove and do not replace umbilical venous catheters if any signs of CRBSI or thrombosis are present [145]. *Category II*
7. Remove umbilical catheters as soon as possible when no longer needed or when any sign of vascular insufficiency to the lower extremities is observed. Optimally, umbilical artery catheters should not be left in place >5 days [145, 154]. *Category II*
8. Umbilical venous catheters should be removed as soon as possible when no longer needed, but can be used up to 14 days if managed aseptically [155, 156]. *Category II*
9. An umbilical catheter may be replaced if it is malfunctioning, and there is no other indication for catheter removal, and the total duration of catheterization has not exceeded 5 days for an umbilical artery catheter or 14 days for an umbilical vein catheter. *Category II*

The Workgroup did not reassess Recommendations 1 and 2, but did reassess Recommendations 7, 8, and 9 related to optimum dwell time. The time periods of 5 days and 14 days have become “signposts” in the NICU for the length of time it is safe to leave UVC in place.

Key Question: In NICU patients, what is the optimal duration of umbilical catheters to prevent CLABSI?

One randomized controlled trial (RCT) and 4 non-randomized studies were retrieved. Each had a different study design:

- Sanderson 2017: n=3,985 infants (UVC vs peripherally inserted central catheters (PICC) vs UVC followed by PICC)

- Vachharajani 2017: n=201 infants >1000g and <1500g (QI initiative to reduce the number of PICCs inserted by updating feeding guidelines and increasing dwell time of UVCs from 5 to 7 days prior to changing to PICC)
- Butler O’Hara 2012: n=986 infants (Cohort comparing UVC in place for 7 days, followed by PICC when needed vs UVC in place for >7 days, followed by PICC when needed)
- Butler O’Hara 2006: n=210 infants <1250g (RCT) (Umbilical vein catheter in place up to 28 days (long-term) vs. umbilical vein catheter for 7–10 days followed by percutaneous central venous catheter (short-term))
- Bhandari 1997: n=2,091 infants (Risk factor analysis for vascular catheter types (UA: Umbilical Artery; UV: Umbilical Venous; CV: Central Venous Tunneled; PC: Percutaneous; PA: Peripheral Artery))

Two studies showed that longer use of an umbilical catheter was associated with an increased risk of CLABSI. The 2012 Butler O’Hara study showed that the CLABSI rate in UVCs rose rapidly for catheters in place >7 days, with a more than 20-fold increase in CLABSI risk in UVCs in place for 11-14 days. Beyond 14 days, there was a 30-fold increase in risk. This group acknowledged that their prior study suggested that longer durations were acceptable, but the data from the 2012 study showed that the longer UVCs are left in place, the higher the risk. The Sanderson study showed that the risk of CLABSI increased beyond 3-4 days of UVC dwell time, and that risk doubled every 2 days thereafter if the UVC was followed by PICC insertion. In the Vachharajani study, increasing UVC dwell time from 5 to 7 days before PICC insertion was not associated with an increase in CLABSI. However, the analysis was narrow.

Regarding CRBSI, Butler O’Hara 2006 showed that dwell times up to 28 days for UVC only had a higher rate of infection compared with UVC dwell times of 7-10 days followed by a PICC, but this was not significant. The Bhandari study showed that sepsis incidence increased with increasing duration; however, this increase did not reach significance until aggregating ≥ 8 days compared with ≤ 7 days. Regarding AEs, there was no difference in thrombosis, mortality, arrhythmia, embolus, hemorrhage, and pleural effusion between UVCs left in place up to 28 days and UVCs left in place 7-10 days, based on the Butler O’Hara 2006 study. However, most studies did not report AEs.

CLABSI: UVC Dwell Time *Draft Recommendation*

“Remove umbilical venous and umbilical arterial catheters as soon as possible and when no longer needed due to the concern for increasing risk of CLABSI associated with increasing dwell time. **Recommendation**”

- **Supporting Evidence:** One randomized controlled trial (Butler O’Hara, 2006), and 4 observational studies. (Bhandari, Butler O’Hara 2012, Sanderson, Vachharajani)
- **Level of Confidence in Evidence:** The level of confidence in this evidence is very low because observational studies are considered at higher risk of bias than randomized controlled trials and there was a loss of confidence due to imprecision. Only one study was conducted in the current standard of care.
- **Benefits:** The evidence reported increasing risk of infection with increasing UVC dwell time, suggesting a benefit to removing UVCs at the earliest opportunity.
- **Harms:** The evidence suggested that increasing dwell time for UVCs resulted in no difference in adverse events.
- **Resource Use:** The literature search did not retrieve evidence on resource use. Theoretically, reducing UVC dwell time could reduce material and human resource costs.
- **Balance of Benefits and Harms:** While the evidence did not indicate an optimal day by which to remove a UVC to prevent CLABSI, the benefits to removal of UVCs at the earliest opportunity

outweigh the harms. It is important to note that UVC dwell time and the risk of CLABSI is only one consideration to balance in the clinical needs of a patient.

- **Value Judgments:** The values considered in the formulation of this recommendation include patient safety and economic and human resource costs.
- **Intentional Vagueness:** There is no intentional vagueness in this recommendation.
- **Exceptions:** There are no exceptions to this recommendation.

The new recommendation removes the number of days. The existing recommendations imply that an umbilical artery catheter (UAC) can be safely left in place for 5 days, and that a UVC can safely be left in place for up to 14 days. However, the evidence indicates that infection risk increases the longer a catheter is left in place; therefore, the Workgroup decided to remove the number of days and focus on removing a catheter as quickly as possible. It is also important to note that UVC dwell time and the risk of CLABSI is only one consideration to balance in the needs of a critically ill NICU patient.

Insertion Site

Key Question: In NICU patients requiring a central venous catheter, does the use of one insertion site compared to another prevent CLABSI?

The retrieved studies address a number of different catheters inserted at different sites. Two non-randomized studies for percutaneously inserted central catheters were performed in overlapping populations at the same facility:

- Tsai 2009: n=518 lines in 334 very low birthweight (VLBW) infants (Femoral = 240 lines vs. Non-femoral = 278 lines)
- Tsai 2011: n=Tsai 2009 plus 290 lines in 200 infants (n=808 lines in 534 VLBW infants Femoral = 410 lines vs. Non-femoral = 398 lines)
- Both Tsai Studies: Femoral vs. non-femoral (greater & lesser saphenous veins of lower extremities, basilica veins or cephalic veins of the upper extremities) and femoral insertion performed when all other peripheral vascular access failed.

These 2 studies were conducted in the same NICU: they are essentially one study reported with overlapping time periods. It is important to note that the femoral insertion site was only used when peripheral access failed. When the outcome was catheter-related sepsis, there was benefit to using the non-femoral site. AEs were inconsistent across the studies. In Tsai 2009, non-femoral insertion was associated with an increased risk of AEs that included phlebitis, catheter site inflammation, or the need to remove the line early. However, there was no difference in thrombosis, occlusion, rupture, or leakage. In Tsai 2011, no differences were found in non-infectious complications including phlebitis, thrombosis, cholestasis, rupture, leakage, etc.

Three non-randomized studies on PICCs examined insertion in the upper versus lower extremity.

- Bashir 2016: 827 PICC lines in 827 preterm infants (upper extremity = 593 lines vs. lower extremity = 234 lines; insertion site selected at discretion of inserter based on accessibility of veins)
- Wrightson 2013: n=626 PICCs in 559 infants (upper extremity = 374 lines vs. lower extremity = 252 lines; insertion location based on vein quality, infant's condition, and inserter's skill and preference; Cephalic was most common at 49.7%)
- Hoang 2008: 477 PICCs in 396 infants (upper extremity = 370 lines vs. lower extremity = 183 lines; lower extremity PICCs inserted because of failure to insert in upper extremity or as primary selection site)

As in the Tsai studies, there was some bias in the apparent preference for the upper extremity. The lower extremity site was used if upper extremity access was not possible, or the decision was based on the skill of the inserter. No differences in infectious outcome measures were reported in any of the studies. The AE results were inconsistent across studies; AEs studied as outcomes varied:

- Bashir 2016 showed a greater risk of infiltration in the upper extremity, but no difference in phlebitis or occlusion.
- Wrightson 2013 showed no difference in phlebitis, clotting, and edema.
- Hoang 2008 showed greater risk of cholestasis and a shorter time to first complication in the upper extremity, but no difference in phlebitis.

Two non-randomized studies examined tunneled catheters, which are not used very often in NICU patients in 2019. These studies assessed internal jugular versus subclavian sites and then neck versus groin lines:

- Breschan 2007: n=236 (internal jugular n=129 lines vs. subclavian, n=107)
- Venguta 2005: n=137 (neck, n=88 (Left and right subclavian and internal jugular veins, and right internal and external jugular vein) vs. Groin, n=49 (left and right long saphenous vein))

Breschan 2007 showed a benefit to using the subclavian versus internal jugular, while Venguta 2005 surprisingly showed a benefit to using the groin versus the neck. Again, AEs were not consistently reported, and there were no clear signals. Breschan 2007 showed a reduction in clinical obstruction associated with the subclavian site and no difference in clinical thrombosis, pneumothorax, or hemothorax. Venguta 2005 showed a reduction in dislodgement associated with the groin site, and no difference in clinical thrombosis, leaks, and pleural/ pericardial complications.

CLABSI: Catheter Insertion Site Draft Recommendation

“Choose the insertion site appropriate to the central line type to be inserted in a NICU patient (eg, UVC, PICC, etc.) based on the clinical needs of the patient. The choice of central line insertion site for a NICU patient should not be based solely on CLABSI prevention. **Recommendation.**”

- **Supporting Evidence:** Seven observational studies (Bashir, Hoang, Wrightson, Breshan, Venguta, Bashir, Tsai 2011, Tsai 2009)
- **Level of Confidence in Evidence:** The level of confidence in this evidence was very low because observational studies are at higher risk of bias compared to randomized controlled trials, and studies reported heterogeneous outcome measures for infection, resulting in a loss of confidence due to imprecision. The two studies evaluating femoral lines vs. non-femoral lines were conducted in the same NICU with overlapping study periods (Tsai 2011, Tsai 2009). All studies were conducted prior to the implementation of insertion and maintenance bundles.
- **Benefits:** The evidence was either limited (percutaneous and tunneled catheters) or did not suggest a benefit to use of one insertion site over another (PICCs).
- **Harms:** Association between adverse events and an insertion site was limited and inconsistent, but suggested adverse events were associated with upper extremities, and non-femoral sites.
- **Resource Use:** The literature search did not retrieve studies comparing resource utilization associated with different insertion sites for tunneled catheters or PICCs. Theoretically, there would be no difference in human or materials costs to place a catheter in one site over another but in two studies, the femoral insertion site was chosen only if insertion in other sites failed. If placement in the first insertion site chosen is technically more challenging and results in multiple attempts, this could increase both human and material costs.

- **Balance of Benefits and Harms:** There was unclear benefit associated with different insertion sites. There is limited data to suggest an increase in adverse events associated with upper extremity site and non-femoral sites with PICCs. The choice of catheter insertion site is often limited by the availability of access in the neonate.
- **Value Judgments:** Value judgements considered in the formulation of this recommendation include patient safety and economic and human resource costs, as well as practical considerations. There may be logistical challenges to maintaining femoral catheters in diapered children.
- **Intentional Vagueness:** There is no intentional vagueness in this recommendation.
- **Exceptions:** There are no exceptions to this recommendation.

While this draft recommendation is presented as a “Recommendation,” the Workgroup considered other possibilities. For example, it could be stated that the choice of catheter site in a NICU baby is an unresolved issue; however, a “No Recommendation” is not helpful to the field. In practice, neonatologists place a UVC, PICC, or tunneled catheter based on the specific needs of the patient and typically not based on infection prevention concerns.

Dr. W. Charles Huskins, Workgroup member, commented that in the “big picture,” the insertion site is dependent upon the catheter: for example, an umbilical line goes in the umbilicus, not another site; a PICC goes in the arm or the leg; a surgically placed line goes into a central vessel. The first sentence of the draft recommendation is therefore to select the catheter type to be used, and to some extent, the insertion site is dictated by that selection. When the insertion site is not clear regarding upper versus lower extremity, there are no data to indicate that one is better than the other. While the data suggest no difference, the quality of the data is low. Making this statement a “Recommendation” implies that HICPAC has strong confidence in it.

Dr. Bryant clarified that the draft recommendation is divided for catheter insertion site and catheter type, and that similar data would be presented for catheter type. The Workgroup discussed the question of whether to include catheter insertion site at all. Given the effort that went into retrieving and reviewing the data and GRADEing the evidence, the Workgroup felt that it would be useful to make the data available. Without a recommendation or statement, it was not clear what to do with that information.

Catheter Type

Key Question: In NICU patients requiring a central venous catheter, does the use of one insertion site compared to another prevent CLABSI?

Three non-randomized studies compared UVCs and PICCs:

- Sanderson 2017: n=3985 lines (data collected from 2007-2009; UVC = 2668 lines vs. PICC = 3332 lines)
- Shalabi 2015: n=540 lines (data collected from 2010-2013: utilized bundle; UVC = 180 lines vs. PICC= 180 lines)
- Arnts 2014: n=203 lines (data collected from 2005-2006; UVC = 140 lines vs. PICC= 63 lines)

The studies largely showed no difference in infectious outcomes. AEs were reported only in the Arnts study, which found no difference in obstruction, extravasation, dislocation, and leakage.

Six non-randomized studies compared UVCs, PICCs, and tunneled catheters:

- Geldenhuys 2017: n=95 neonates (UVC = 55 lines vs. PICC = 23 lines vs. CVC = 14 lines)
- Soares 2017: n=400 lines (240 neonates) (UVC = 84 lines vs. UAC = 55 lines vs. PICC = 182 lines vs. short duration = 57 lines vs. tunneled = 22 lines)

- Greenberg 2015: n=15,567 lines (Tunneled = 1,116 lines vs. PICC= 14,451 lines)
- De Brito 2010: n= 461 (UVC = 33 lines vs. PICC= 20 lines vs. phlebotomy = 24 lines vs. intracath = 7 lines)
- Chien 2002: n=19,507 infants (Lines NR, data provided as rate)
- Bhandari 1997: n=3,107 lines (UAC = 1,699 lines vs. UVC = 617 lines vs. percutaneous= 308 lines vs. CVC: 294 vs. Peripheral Artery =189 lines)

Each study in this heterogeneous group asked a different question and studied it in a different way. Some, but not all, studies suggested that tunneled catheters had a higher incidence of CLABSI. Geldenhuys found a higher CLABSI incidence for tunneled catheters, PICCs, and CVCs compared with UVCs (insertion in operating theater = significant risk factor). Greenberg found CLABSI incidence for tunneled catheters to be 2.4 times than for PICCs. Soares found no difference in CLABSI.

For CRBSI, De Brito found a higher rate for PICCs than UVCs, intracath, and phlebotomy. For nosocomial BSIs, Chien found a higher rate associated with PICCs and tunneled catheters than UVCs. For nosocomial sepsis, Bhandari found a higher incidence with tunneled catheters and PICCs than UVCs. AEs were not reported in most studies. However, the Soares 2017 study conducted in Portugal reported higher rates of infiltration and no elective removal associated with PICCs compared with UAC, UVC, short duration venous catheters, or tunneled catheters.

CLABSI: Catheter Type *Draft* Recommendation

“Choose the central line type to be inserted (eg, umbilical venous catheter (UVC), percutaneously inserted central catheter (PICC), tunneled catheter, etc.) based on the clinical needs of the NICU patient. The choice of central line type to insert in a NICU patient should not be based solely on CLABSI prevention. **Recommendation.**”

- **Supporting Evidence:** Nine observational studies. (Arnts, Sanderson, Shalabi, Bhandari, Chien, de Brito, Geldenhuys, Greenberg, Soares)
- **Level of Confidence in Evidence:** The level of confidence in this evidence is very low because observational studies are considered at higher risk of bias than randomized controlled trials, and each study compared different interventions and reported different infectious outcome measures, resulting in a loss of confidence due to imprecision. Three studies compared umbilical venous catheters to with percutaneously inserted central venous catheters (Arnts, Sanderson, Shala). Six studies compared various catheter types that included umbilical arterial catheters, umbilical venous catheters, percutaneous arterial catheters, percutaneous venous catheters, peripherally inserted central catheters, intracath, phlebotomy catheters, and tunneled catheters. Only two studies were conducted in the era of insertion and maintenance bundles.
- **Benefits:** The evidence did not suggest a clear benefit of one catheter type over another, however studies evaluated different patient populations with varying clinical indications for central venous access and this was likely reflected in the evidence. The variations in dwell time according to catheter type was a confounding factor in interpreting the results seen in the evidence.
- **Harms:** One study suggested the risk of infiltration was higher with PICCs than with other catheters.
- **Balance of Benefits and Harms:** The balance of benefits vs harms was unclear in the evidence. Factors that influence catheter type selection include but are not limited to the chronologic and gestational age of the patient, patient size, the presence or absence of congenital abnormalities, prior device utilization and the projected duration of central venous catheterization. CLABSI prevention is not the primary consideration when choosing which catheter type to insert in a NICU patient.

- **Resource Use:** The literature search did not retrieve data on the comparative material costs of different catheter types. It is likely that material and human resource costs for insertion and maintenance of each catheter type will vary from facility to facility. Insertion of some catheter types (i.e. tunneled catheters) requires technical expertise that may not be available in all centers.
- **Value Judgments:** Value judgements considered in the formulation of this recommendation include patient safety and economic and human resource costs.
- **Intentional Vagueness:** There is no intentional vagueness in this recommendation.
- **Exceptions:** There are no exceptions to this recommendation.

Dr. Bryant explained that the Workgroup did not reach consensus on catheter type and site and hoped for HICPAC feedback regarding refining the draft recommendations for catheter type, site, and dwell time.

Additional CLABSI topics for this Guideline include 2 intervention categories from the 2012 work for which there is no new evidence:

- Antimicrobial systemic prophylaxis
- Anticoagulant systemic prophylaxis

The Workgroup is reviewing the 2012 data to ensure that outcomes are aligned and that the studies meet current inclusion criteria.

The remaining interventions with new evidence since 2012 are:

- Multi-intervention strategies, bundles, and checklists: 25
- PICC dwell time: 5
- Catheter manipulation (including Closed Medication Systems): 3
- Skin antisepsis: 3
- Chlorhexidine adverse events: 34
- Line maintenance: 2 (eg, catheter hub antisepsis)
- Other: 4 (eg, compliance measures; probiotic use)

The Workgroup will next review and update the remaining interventions, GRADE the evidence, and draft recommendations and narratives for HICPAC review, comment, and approval.

Respiratory Illness

Key Question: *What are effective strategies to prevent respiratory illness in NICU patients?*

The 2012 extraction tables have been updated, with 23 studies included. The updated literature search retrieved 557 studies, of which 112 studies were selected for full-text review, and 18 were ultimately included. The next steps are to review the relevant questions and review and aggregate the applicable evidence.

Challenges with this topic are becoming apparent. There is a disconnect between the important questions facing the NICU, and the evidence that is available to answer those questions. The Workgroup is grappling with whether it will be possible to develop actionable recommendations based on the available evidence.

If the evidence is insufficient to answer important questions about NICU infection prevention practice, the next steps are unclear. Recent HICPAC meetings have included discussion of the possibility of a NICU-specific Core Practices document, which could address important questions for the NICU and assemble existing NICU practices from different resources into a single document. However, such a document might not be the place to “break new ground” on topics for which evidence is lacking. If a

NICU Core Practices document were created using the same methodology as the primary HICPAC Core Practices document, it could include guidance from existing CDC publications pertaining to neonates in NICUs. This presentation might be important, but it would not address topics that HICPAC has identified as important, such as specific family and visitor education, specific environmental recommendations, and visitor screening. The question, therefore, is whether there is a role for a NICU Core Practices document, or a NICU Best Practices Document, and whether CDC, HICPAC, or a partner organization is best suited to creating it.

In closing, Dr. Bryant said that the *S. aureus* section of the NICU Guideline will enter initial CDC clearance and then be submitted to Regulations.gov for public comment. The public comments and updated drafts will be presented to HICPAC.

Discussion Points

Central Line Antimicrobial Locks

There was discussion regarding the meaning of, “when a unit is experiencing ongoing CLABSIs,” and whether this practice would be recommended in high-risk infants versus high-risk units.

Dr. Bryant said that the Workgroup discussed these issues. The data in NICU patients are not specific to high-risk infants, so the draft narrative does not refer to high-risk infants, but common sense would suggest the practice in high-risk infants.

Regarding the question of ongoing CLABSI and “how high is too high,” Dr. Bryant said that the Workgroup noted that most units in the US do not see rates as high as in most of the reviewed studies; however, most NICUs have not eliminated CLABSI. Therefore, the Workgroup felt that if a unit has CLABSIs, this approach is worth considering to “drive toward zero.”

HICPAC suggested adding an explicit statement that no studies were identified that used alcohol locks.

In the draft *S. aureus* section, additional verbiage regarding ongoing *S. aureus* states, “compared to baseline levels in the unit, as well as published data.” Similar verbiage could be added to the central line antimicrobial locks recommendation. A great deal of published data about CLABSI is available that could be utilized to determine whether a unit has a high rate. Consideration could be given to providing more specificity, given this available CLABSI data.

The Pediatric Infectious Disease Society (PIDS) asked whether studies on ethanol locks were reviewed. Dr. Bryant replied that no NICU studies that specifically assessed ethanol locks were retrieved; however, the narrative notes that not all agents may be compatible with all catheters.

Optimal UVC Duration

Many NICUs do not leave a UVC in as long as 14 days. While a UAC may remain in place for for 5 days, they are typically removed much earlier as a general practice in most places.

Perhaps the narrative and discussion of balance of benefits and harms could acknowledge the 2011 time points, with an explanation that they were removed in the new recommendation because no data support them.

There was concern that the phrasing “as soon as possible” may be interpreted too broadly and may result in catheters staying in longer: some facilities still do not remove them rapidly enough. Moreover, this message could be lost if users do not read the entire narrative. Therefore, it is important for the recommendation to state something to the effect of, “as soon as possible, but definitely no longer than X.”

Many NICU teams hold to that number of days, having been accustomed to them for years. It also is important to understand that catheters often are left in longer in babies for whom access is difficult and for whom peripheral access is not possible. This example raises concern about stating a “hard and fast” number of days.

It could be beneficial to articulate that the data show that there is an increase in risk every 2 days that the catheter remains in place. The narrative could describe situations in which a catheter may need to remain longer and address the importance of having an assessment schedule.

PIDS noted that it would be beneficial to discuss shorter- and longer-term complications, perhaps mentioning specifically the risk of thrombotic events, which often occur at a later time. The “Benefits and Harms” statement might include this statement.

Dr. Bryant agreed, noting that the studies in large part did not report on AEs such as thrombotic events. The longer a catheter is left in, risk of a thrombotic event increases. From a practical standpoint, this type of information has been included in other recommendations.

Dr. Bell supported the removal of permitted days, but wondered whether a statement could be made to “never leave it in more than X” days. It is clear that 14 days is too long, and the evidence suggests that risk escalates well before that time. This discussion could be incorporated into the narrative, addressing the former recommendation and indicating that the timeframe is too long, framing the issue so that it is not misinterpreted.

Dr. Bryant replied that the data do not support a statement of “never leave it in more than ...” The Workgroup was concerned that stating only “as soon as possible” may lead to the unintended consequence of some leaving the catheter in place for more than 14 days. The current strategy is to emphasize in the narrative that risk increases almost every day that the catheter remains in place, and the narrative could add that risk rises well in advance of 14 days.

Dr. Cardo pointed out that when CDC says “as soon as possible,” the timing is left open to interpretation. She suggested including an example so that interpretation does not vary so much, such as “(eg, within X days).”

Optimal Central Line Insertion Site

The surgical site infection (SSI) document included verbiage stating, “This practice is not helpful for SSI prevention.” This language clarifies that an intervention may be helpful for other reasons, but there is no specific link between it and the prevention of infection. The catheter insertion site recommendation could be structured in a similar way: “Selection of a specific insertion site is not necessary for prevention of CLABSI.”

The language was suggested, “The choice of central line insertion site should not be based solely on CLABSI prevention, but on the clinical needs of the patient and other potential adverse outcomes.”

The site should be addressed; in many institutions, the Medical Director of the Infection Prevention Program may not be familiar with pediatrics, especially the NICU, and will not be familiar with the evidence base. Sharing that information is beneficial. The second sentence could be deleted, as the issue is addressed under “Benefits and Harms.”

Basing a site recommendation on clinical judgment would be helpful. Some in the field may believe that one site is preferable to all others, but the studies yield no evidence to support one site over others. It may not be wise to imply that a site will never need to be selected based on the potential for infection. It may be helpful for HICPAC to say, “Use your clinical judgment based on what the patient needs. Currently, there is no evidence of one site being better than the other for infection.”

Dr. Bryant said that the Workgroup discussed the practical challenges associated with inserting a line in the femoral site. While there are no data in NICU patients to indicate an increased risk of infection, placing a line in a femoral site in a diapered patient poses practical challenges. This concept not reflected in the retrieved studies, but it is reflected in the narrative.

The response to the initial question, *In NICU patients requiring a central venous catheter, does the use of one insertion site compared to another prevent CLABSI?* is “No. Choose the insertion site appropriate to the central line based on clinical needs, not based on CLABSI prevention.”

Because the evidence is limited, it might be worth considering categorizing this recommendation as a “Conditional Recommendation.” Dr. Bryant said that the Workgroup wavered between a “No Recommendation” and stating that there is no clear signal for one site versus another for CLABSI prevention.

PIDS suggested that since site and type are intimately associated, it may be beneficial for the end user to combine the 2 recommendations.

Optimal Central Line Type

The logical order is to state type before insertion site. There was support for the potential of combining them into one recommendation. The last sentence in both probably could be deleted. Dr. Bryant observed that while presenting the data as a conglomerate is somewhat complex, it seems reasonable to combine the 2 recommendations.

The ability of the inserter and the elements of the bundle are important factors, but the data are not clear regarding what was included in the bundles for insertion or maintenance. It is difficult to state that something does or does not cause infection when the parameters are unknown. Until more data are available, the clinical needs of the patient will drive selection and placement.

PIDS suggested emphasizing the absence of recent data and considering opportunities for further studies to be conducted, perhaps by collaborations with partner organizations or through other means for conducting standardized, large-scale studies.

Next Steps

Dr. Bell commented on the options for addressing NICU Core Practices in a useful way. As Dr. Bryant noted, the HICPAC Core Practices document was designed so that every guideline does not need to restate recommendations related to, for instance, hand hygiene and staff training, for which additional research is unlikely to change practice. Some of the Core Practices apply to NICUs, and additional topics pertinent to the NICU for which additional research is unlikely may be added. Conversely, there are probably best practices for the NICU that are opinion- and circumstantially-driven, such as optimal spacing between isolettes. Opinions vary about this issue, facilities vary in how they address it, and it has not been studied. HICPAC focuses on the adult infection prevention end of the spectrum and may not have the clinician “heft” that a partner organization such as PIDS might, for example. The idea of a NICU Core Practices document is different from a newly developing theme, such as Middle East Respiratory Syndrome (MERS) or Severe Acute Respiratory Syndrome (SARS), on which HICPAC should quickly weigh in to render an expert opinion. For a more deliberate and specialized endeavor such as NICU Core Practices, there is value in determining how to work together to leverage the experts in professional societies. Frequently, they ask questions for which there are no data and become frustrated. A resource like a website for professional societies might enumerate high-level “wish lists” for new evidence generation to serve as an enticing starting point for new fellows who are looking for research projects.

HICPAC noted that the GRADE group has a process called a “Good Practice Statement” with specific criteria that may be worth considering. Other guideline groups have used that option for topics that need to be addressed, but for which no studies are available, and it is likely that no new studies will change practice.

Vote: Central Line Antimicrobial Locks

The central line antimicrobial locks recommendation was put forth for approval as presented, with the exception of two edits:

1. The Workgroup will include in the narrative how units might determine whether they have enough CLABSI to implement the recommendation.
2. The Workgroup will address ethanol locks in the narrative.

HICPAC voted unanimously to approve the recommendation, with no opposition and no abstentions. The disposition of the vote was as follows:

- 11 Favored: Anderson, Babcock, Bryant, Daniels, Dekker, Fauerbach, Huskins, Maragakis, Patterson, Preas, Yokoe
- 0 Opposed
- 0 Abstained

Bloodstream Infection Guideline Update Planning

Shannon Novosad, MD, MPH

Medical Officer

Hospital Infection Prevention Team

Division of Healthcare Quality Promotion

Centers for Disease Control and Prevention

Dr. Novosad shared an overview of planned updates to the *2011 Intravascular Catheter-Related Infections Guideline*.

Recent HICPAC-involved infection and prevention control guidelines include:

- 2002 *Hand Hygiene* (Standard Precautions, 2007)
- 2003 *Environmental Infection Control*
- 2003 *Pneumonia*
- 2006 *Multidrug-Resistant Organisms*
- 2007 *Isolation Precautions*
- 2008 *Disinfection and Sterilization*
- 2009 *Catheter-associated Urinary Tract Infections*
- 2011 *Intravascular Catheter-Related Infections*
- 2011 *Norovirus Gastroenteritis Outbreaks in Healthcare Settings*
- 2017 *Guideline for Prevention of Surgical Site Infection* (Updates 1999 Guideline)
- 2017 *Chlorhexidine-impregnated Dressing Recommendation Update*
- In progress: *Prevention of Infections in Neonatal Intensive Care Units*
- In progress: *Infection Control in Healthcare Personnel* (Updates *Guideline for infection control in health care personnel, 1998*)

2009 marks the beginning of the evidence-based era of HICPAC guidelines, when use of the GRADE method became standard and guidelines became more rigorously evidence-based. This approach has been applied to both new and updated guidelines.

The “targeted approach” to guideline updates includes new, priority topic areas with new data. This approach also includes updating current recommendations, such as:

- High-priority recommendations for which new data could inform clinical practice
- Recommendations that are unclear or outdated
- Recommendations that previously were “No Recommendation” or unresolved because of a lack of data.

As part of the approach, recommendations for which there are no new data, and which are standard of care, can be brought forward. In addition, out-of-date recommendations or recommendations that are no longer standard of care can be “sunsetting” or retired.

For example, to update the *Guideline for the prevention of surgical site infection, 1999*, the Workgroup did not conduct an intense evidence review for every recommendation in the 1999 document. Instead, they chose to carry forward some recommendations that were considered standard of care and for which no new data were available. The Workgroup developed a targeted list of questions based on their review of the remaining 1999 recommendations. Similarly, the 2017 *Chlorhexidine-Impregnated Dressing Recommendation Update* was based on the identification of an area in the 2011 *Guideline* for which there were new data, and for which recommendations were needed.

As noted earlier, the 2011 *Intravascular Catheter-Related Infections Guideline* is slated for update. The update process begins with a review of the approximately 90 recommendations in the current guideline: the recommendations will be categorized as Keep, Retire, or Review. Additionally, new topic areas that were not addressed in the prior guidelines, and for which new data are available that could inform clinical practice, will be identified. Existing and new topics will be prioritized to identify a targeted list of recommendations to update, questions will be formulated, and evidence will be reviewed. Possible topics for update include:

Section 2. Selection of Catheters and Sites

Current Recommendations

- 2.1.5 Use a midline catheter or peripherally inserted central catheter (PICC), instead of a short peripheral catheter, when the duration of IV therapy will likely exceed six days
- 2.2.2 Avoid using the femoral vein for central venous access in adult patients
- 2.2.3 Use a subclavian site, rather than a jugular or a femoral site, in adult patients to minimize infection risk for non-tunneled CVC placement
- 2.2.4 No recommendation can be made for a preferred site of insertion to minimize infection risk for a tunneled CVC

It is anticipated that questions could be formulated to consolidate these recommendations, or make them clearer. Questions could also consider selection of catheters and sites for specific groups such as pediatric patients - excluding the NICU patients addressed in the NICU Guideline - and for tunneled catheters.

Section 5. Skin Preparation

Current Recommendations

- 5.3 No comparison has been made between using chlorhexidine preparations with alcohol and povidone-iodine in alcohol to prepare clean skin

New data have been published since 2011 that could be used to update Recommendation 5.3.

Section 7. Patient Cleansing

Current Recommendations

- 7.1 Use a 2% chlorhexidine wash for daily skin cleansing to reduce CRBSI

A great deal of new data have been published since 2011 pertaining to the use of chlorhexidine bathing in ICUs versus non-ICUs, and in specific populations, that could be used to update Recommendation 7.1.

Section 14. Replacement of Peripheral and Midline Catheters

Current Recommendations

- 14.1 There is no need to replace peripheral catheters more frequently than every 72-96 hours to reduce risk of infection and phlebitis in adults
- 14.2 No recommendation is made regarding replacement of peripheral catheters in adults only when clinically indicated
- 14.3 Replace peripheral catheters in children only when clinically indicated

Section 14 can be made clearer in several ways. New data are available, the recommendations for adults can be consolidated, and it may be possible to evaluate whether replacement “only when clinically indicated” in Recommendation 14.3 can be applied to a broader group than just children.

Section 19. Needleless Intravascular Catheter Systems

Current Recommendations

- 19.1 Change the needleless components at least as frequently as the administration set. There is no benefit to changing these more frequently than every 72 hours
- 19.2 Change needleless connectors no more frequently than every 72 hours or according to manufacturers’ recommendations for the purpose of reducing infection rates
- 19.5 Use a needleless system to access IV tubing
- 19.6 When needleless systems are used, a split septum valve may be preferred over some mechanical valves due to increased risk of infection with the mechanical valves

It is anticipated that Recommendations 19.1 and 19.2 could be made clearer, and questions could be formulated regarding the timing of when needleless connectors should be changed; specifically, if they should be considered part of the administration set and changed accordingly or whether a different time period for changing is indicated. Additionally, Recommendations 19.5 and 19.6 could be incorporated into larger questions regarding whether needleless systems contribute to BSI risk.

Possible New Topic Area

A potential new topic area, with a number of potential questions, for this Guideline update is antiseptic-impregnated caps. Possible questions pertain to:

- The different types of antiseptic-impregnated caps (alcohol versus chlorhexidine caps),
- Use of the caps in different groups such as hemodialysis patients, and
- Use of the caps with different types of catheters (non-tunneled versus tunneled).

The process for updating this Guideline is likely to be similar to the process used for the Chlorhexidine-Impregnated Dressing update, in which the existing recommendations were replaced with new recommendations and links were provided to indicate where changes were made.

Dr. Novosad invited HICPAC feedback on these topics and other topics to consider for inclusion in the update.

Discussion Points

Dr. Bell emphasized that guidelines will no longer take the form of large, textbook-like documents. The goal of these efforts is to adjust only the components that need to be updated and to apply a web-based, interactive approach that reflects the changes, the evidence supporting them, and links to the previous, superseded recommendations.

Dr. Bell explained that the process for updating this Guideline is still in the formulation stage. CDC will follow up with a deliberate plan, which may include convening a HICPAC Workgroup, enlisting additional authors, etc.

HICPAC agreed with the proposed topics to address in this Guideline update and expressed appreciation for the “quick and nimble” nature of the new process. The following suggestions were offered:

- Examine or address whether antiseptic-impregnated caps need to be separately rescrubbed.
- Evidence has developed in the overuse of PICCs in adults since the 2011 guideline was published. HICPAC member Dr. Vineet Chopra is well-versed in this issue. It would be interesting to consider the issue in two ways:
 1. In terms of overuse; and
 2. Pertaining to statements that move away from traditional central venous catheters (CVCs) toward PICCs, which may lead to compromising future vascular access for people with chronic kidney disease.

Enhanced Barrier Precautions

Kara M. Jacobs Slifka, MD, MPH, MS
Medical Officer, Long-Term Care Team
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

Dr. Slifka said that CDC’s involvement in multi-drug resistant containment and response activities has alerted them to the immediate need to address MDRO prevention practices in nursing homes. Specific guidance has been developed for nursing homes on the use of personal protective equipment (PPE) to help prevent the spread of MDROs.

Current guidance for nursing homes comes from the Centers for Medicare and Medicaid Services (CMS) State Operations Manual, or the Interpretive Guidance for Surveyors in Long-Term Care Facilities, on Transmission-Based Precautions in Nursing Homes:

GUIDANCE §483.80(a),(e),(f)
INFECTIOUS PREVENTION AND CONTROL PROGRAM
TRANSMISSION-BASED PRECAUTIONS

“Transmission-based precautions must be used when a resident develops signs and symptoms of a transmissible infection, arrives at a nursing home with symptoms of an infection (pending laboratory confirmation), or has a laboratory confirmed infection and is at risk of transmitting the infection to other residents. For example, a resident with influenza and signs of infection should wear a facemask (eg, surgical or procedure facemask) when leaving his/her room for medically-necessary care (i.e., droplet precautions for the duration of the illness). The diagnosis of many infections is based on clinical signs and symptoms, but often requires laboratory confirmation. However, since laboratory tests (especially those that depend on culture techniques) may require two or more days to complete, transmission-based precautions may need to be implemented while test results are pending, based on the clinical presentation and the likely category of pathogens.^{40, 51}”

This language mirrors the CDC and HICPAC documents [Guideline for Isolation Precautions: Preventing transmission of Infectious Agents in Healthcare Settings, 2007](#) (<https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-guidelines-H.pdf>) and [Management of](#)

[multidrug-resistant organisms in healthcare settings, 2006.](https://www.cdc.gov/infectioncontrol/guidelines/mdro/index.html)

(<https://www.cdc.gov/infectioncontrol/guidelines/mdro/index.html>).

In order for CDC and HICPAC guidelines to be as broadly applicable as possible to multiple healthcare facilities and settings, including long-term care, the language must be flexible. Flexibility of language, however, leads to an absence of implementation guidance:

- “Healthcare is provided in various settings outside of hospitals, including facilities such as LTCFs... Each setting has unique circumstances and population risks... While this Guideline does not address each setting, the principles and strategies may be adapted and applied...”
- “Consider the individual resident’s clinical situation and prevalence or incidence of MDRO in the facility when deciding whether to implement or modify Contact Precautions in addition to Standard Precautions for a patient infected or colonized with a target MDRO.”

In the first example, concrete guidance on how to adapt and apply the principles and strategies is not provided. In the second example, it is not clear what “Modified Contact Precautions” are, or when nursing homes should implement modified versus strict Contact Precautions.

In practice, vague language and the lack of concrete implementation guidance lead to Standard Precautions and Contact Precautions not being applied as intended. The CMS regulations are somewhat more specific; however, they can be confusing, especially with regard to Contact Precautions and MDROs. The regulations focus on the signs and symptoms of infection, but colonization and infection are not the same, and the signs and symptoms of infection are not present in colonized individuals.

The CMS regulations also state that facilities must have policies that identify not only the type, but also the duration of transmission-based precautions, and that the precautions should be the least restrictive and for the least amount of time. The duration of MDRO colonization can be prolonged, however, which makes the regulations problematic. The regulations also state that when an individual is no longer at risk for transmitting the infection, precautions should be removed; however, colonized persons remain at risk for transmitting MDROs even when they are not actively infected. These examples illustrate why nursing homes either do not use, or minimally use, Contact Precautions, and why nursing homes experience pressure to identify a specific duration for the precautions that they use.

These concerns are even more problematic now because of the recognized burden of MDROs in nursing homes. Data obtained from point prevalence surveys in Southern California skilled nursing facilities (SNFs) demonstrate that as many as 6 out of 10 nursing home residents are colonized with MDROs, and less than 20% of them were recognized by the facility. MDRO burden is even higher among higher acuity residents, such as residents of SNFs that provide ventilator services, with as many as 8 out of 10 residents colonized with an MDRO. Again, the vast majority are not recognized by the facility.⁶

Typically, clinical cultures do not alert CDC to overall burden in these facilities. Clinical cultures underestimate true prevalence, and the degree of burden is often not realized until CDC is involved in response activities and conducts point prevalence surveys. Most facilities do not implement active surveillance, and no guidance instructs them to do so. In fact, especially clinically, it is suggested not to look for these pathogens except as part of a response: when colonized individuals are identified, repeated testing over a long period of time for clearance of MDROs is not practical and is often not accurate.

In preventing the spread of infections or infectious pathogens such as MDROs in nursing homes, a real and important balance must be struck among the factors of resident quality of life - including respecting the home-like environment; the importance of socialization; psychosocial well-being; and minimizing

⁶ McKinnell JA et al. *Clin Infect Dis*. 2019;Feb 11. doi: 10.1093/cid/ciz119. (Epub ahead of print)

stigmatization - and promoting resident safety. Facilities also face physical space limitations and the lack of private rooms: many facilities have triple- or even quad-occupancy rooms. Further challenges are associated with the difficulty of restricting movement around the facility for residents who are mobile, as well as the difficulty of moving residents from one room to another, such as for cohorting. Nursing homes need clarification about how to use PPE and apply room restrictions, especially given these unique challenges. They also need clarification about managing prolonged carriage of MDROs.

The goals of this guidance are to:

- Provide clarification and guidance for use of PPE and room restriction in nursing homes;
- Address the issues of prolonged MDRO colonization and the impact of room restriction and PPE use on resident quality of life; and
- Introduce a new approach known as “Enhanced Barrier Precautions.”

This guidance will help address some concerns specific to resident quality of life, safety, and rights. It also potentially allows for the ability to narrow the use of Contact Precautions among MDRO-colonized and -infected residents. Within this updated framework, Standard Precautions remain in place for all residents, regardless of their MDRO status. For MDRO-colonized and -infected residents, Contact Precautions are the approach only:

- When those residents have acute diarrhea, draining wounds, or secretions/ excretions that are unable to be covered or contained;
- With rare and highly resistant pathogens (eg, novel resistance mechanisms for which no current treatment options exist (pan-resistant); or
- On units or in facilities where, despite attempts to control the spread of MDROs, ongoing transmission is documented or suspected.

Enhanced Barrier Precautions expand the use of PPE beyond Standard Precautions and in situations when Contact Precautions do not apply. They also remove the need to make decisions about PPE use based on anticipated exposure by specifying high-contact care activities for which gown and gloves should be used, including:

- Dressing
- Bathing/ showering
- Transferring
- Providing hygiene
- Changing linens
- Changing briefs or assisting with toileting
- Device care or use of a device: central line, urinary catheter, feeding tube, tracheostomy
- Wound care: any skin opening requiring a dressing

Contact Precautions require the use of gloves and gowns upon every room entry and room restriction for the resident, except for medically necessary care. They also recommend the use of dedicated equipment and a private room. For Enhanced Barrier Precautions, glove and gown use are specifically for the high-contact care activities listed above. Activities not listed, unless otherwise addressed, would not require PPE use. There is no room restriction for these residents: they are able to leave their room and participate in group activities. These precautions are focused on MDRO-colonized and -infected residents. CDC Isolation Guidelines apply to other pathogens for which Contact Precautions are recommended, such as norovirus, *Clostridioides difficile* (*C. difficile*), and scabies.

It is important that guidelines give clear instructions on how to implement both Contact Precautions and Enhanced Barrier Precautions, such as posting clear signage outside of the resident room indicating the type of Precautions and required PPE. For Enhanced Barrier Precautions, signage should clearly indicate

high-contact resident care activities. PPE, including gowns and gloves, should be easily available immediately outside of resident rooms. Every resident room should have easy access to alcohol-based hand rub, ideally both inside and outside of the room: this access is not currently “the norm” in nursing homes. Trash cans for disposable PPE should be easily available, and a periodic monitoring and assessment process is also recommended to provide feedback and to determine the need for additional education and training.

Finally, to address the issue of unknown colonization status and the silent spread of MDROs, it is suggested that facilities consider using Enhanced Barrier Precautions based on easily identifiable resident risk factors, such as wounds and indwelling medical devices (eg, central line, urinary catheter, feeding tube, tracheostomy), regardless of MDRO status. Given that the immediate need for this guidance has arisen during MDRO containment and response activities, the guidance does not focus on this point; however, a risk factor-based approach is a future direction. Facilities are encouraged to make decisions regarding the use of additional practices to prevent the spread of MDROs in conjunction with their health department. CDC remains available for continued support, as strategies may differ slightly during these response and containment activities.

In summary, the Enhanced Barrier Precautions in this guidance fall somewhat “in between” Standard Precautions and Contact Precautions. In nursing homes, Standard Precautions and Contact Precautions often are not followed. Challenges associated with implementing precautions include access to PPE and making decisions regarding whether a potential exposure could occur. Enhanced Barrier Precautions will be helpful for facilities by removing the decision-making process and providing a list of activities that have been observed in nursing homes as high risks for transmission of both methicillin-resistant *Staphylococcus aureus* (MRSA) and resistant gram-negatives. Contact Precautions require PPE at every room entry, and the guidelines also state that patients should be restricted to their rooms, ideally private rooms. Implementing those recommendations is challenging in the nursing home setting, especially when residents are colonized for a prolonged period. Enhanced Barrier Precautions allow PPE use for high-risk activities, but do not carry the restrictions and challenges associated with Contact Precautions.

This guidance does not apply to acute care hospitals, long-term acute care hospitals (LTACs), group homes, and assisted living settings. While it could be applied in those settings, the guidance’s focus is on facilities that provide skilled nursing care, such as nursing homes and SNFs. The category of MDROs includes a number of pathogens: this guidance focuses on MDROs other than *C. difficile*, norovirus, scabies, or other pathogens for which Contact Precautions are recommended. While Enhanced Barrier Precautions are currently applied only to MDRO-colonized and -infected residents, ultimately CDC envisions this approach to be applied to residents at risk of MDRO colonization and infection.

Dr. Slifka asked for HICPAC’s general feedback, as well as HICPAC’s reaction to the questions:

- Are we missing any resident care activities for which the use of gown/gloves should be recommended?
- Is this list too extensive?

Discussion Points

Dr. Bell noted that this interim guidance is focused on long-term care, recognizing that acute care hospital practices do not translate easily to other settings. Challenges associated with Contact Precautions are not unique to LTCFs; acute care facilities question the use of Contact Precautions as well. The shift from isolation to a routine use of barriers is similar to the shift to universal gloving for vancomycin-resistant enterococci (VRE), which was demonstrated to be more effective than isolation in a long-term care setting. Removing the need to know which patients are under which precautions, and

requiring the use of a gown and gloves, might be beneficial. In addition to solving a clear problem, by piloting this guidance out of need, evidence can be gathered to support it. This alternative may help LTCFs with their practices, reserving Contact Isolation for more specific situations.

HICPAC noted that while the “stop sign” example for a patient room in an LTCF might be useful, assisted living centers are arranged like a home-type environment. It seems that another type of sign could be used in assisted living centers. For instance, in one facility, residents at risk for falls have a “falling star” sign on the door, which is less graphic than a stop sign.

Dr. Slifka answered that currently, the stop sign is by the most common sign used. Unfortunately, it communicates little and is confusing for staff and others. Therefore, CDC recommends clarifying what is expected of staff before they enter the room. She agreed with the infection control challenges associated with the home-like environment, but using clear signage is beneficial for decreasing the spread of pathogens.

Pilot data regarding Enhanced Barrier Precautions would be helpful, including how well people apply it, how it impacts use of gowns and gloves, the volume of materials being used, and whether it actually reduces transmission.

Dr. Slifka said that CDC has some pilot data from implementing Enhanced Barrier Precautions in community-based nursing homes that provide skilled nursing services. In this pilot setting, Enhanced Barrier Precautions were implemented for residents with broader risk factors for colonization and infection, not just MDROs. Previously, staff used gloves relatively regularly, but did not use gowns regularly. The addition of Enhanced Barrier Precautions helped identify residents at risk and increased both gown and glove use for high-risk activities. There was some evidence of decreased transmission. CDC is still collecting information, but initial feedback is that Enhanced Barrier Precautions are doable, feasible, and acceptable to staff.

Perhaps consideration could be given to performing a risk assessment of residents, including how they eat. Many caregivers help feed persons who cannot control their saliva or tongue action. Using aprons rather than the whole gown could be beneficial in these cases. Dr. Slifka replied that aprons provide only partial coverage and are not a full barrier. Some activities on the list are very high-contact, or are high- and prolonged-touch activities. CDC focuses on the full gown because it provides a full barrier.

The cost of implementing Enhanced Barrier Precautions is important to consider, particularly given that many facilities may not have sufficient resources to implement them. Some facilities cannot even afford to have alcohol gel in every patient room, much less gowns and gloves. Dr. Slifka indicated that CDC has made these observations as well. Facilities should still use PPE and alcohol-based hand rub as part of Standard Precautions and Contact Precautions. They hope to learn more about potential financial burdens.

Paradoxically, some studies have shown more environmental shedding with colonization than with infection. Perhaps a statement could be included to the effect of, “Whenever possible, even for patients who meet the criteria for Enhanced Barrier Precautions, single room, cohorting, or a similar approach may be appropriate.” Dr. Slifka replied that CDC has discussed these issues. The ideal of having a single room is impacted by the reality in nursing homes of having double, triple, and quad rooms. Cohorting also can be challenging in terms of whom to “mix and match” together in a Contact Precautions scenario, especially in settings where patients are colonized with multiple MDROs. CDC needs to continue to address other areas, including environmental cleaning and disinfection, training, and appropriate practices for all staff.

Perhaps Enhanced Barrier Precautions should be implemented for all residents. From an implementation perspective, it seems that this strategy would be easier to apply for all high-contact activity. While this approach sounds like an enormous burden, some residents have unknown status, and LTCFs do not tend to monitor or screen for MDROs regularly.

Some acute care settings are moving away from Contact Precautions for MRSA and VRE. It is not clear how to reconcile doing more in one setting and less in another. Dr. Slifka replied that CDC is concerned about unknown colonization status and recognizes, based on the data, that even when some residents are known to be colonized with MDROs, they “find more when they look.” The approach to decreasing transmission and spread of MDROs is tempered by the need not to overwhelm facilities with so many requirements that none of them are addressed. CDC is considering not only a known MDRO approach, but also ways to apply the approach more broadly to reach as many individuals as possible. Examining a risk-based approach is part of that consideration.

The California Department of Public Health (CDPH) is working toward implementing what they are calling “Enhanced Standard Precautions” for nursing home residents, based on the kind of activity and the patients’ risk category. Dr. Slifka said that CDPH is a pioneer in considering a framework shift to prevent the spread of these pathogens with a broader, more risk-factor-based approach.

HICPAC suggested adding high-contact physical therapy to the list of activities.

HICPAC wondered whether CDC had given consideration to testing how intended users interpret the term “Enhanced Barrier Precautions.” The term implies more intensity than Contact Precautions; branding efforts will be needed.

Dr. Slifka answered that some information was gleaned from the pilot work, but they hope to continue to collect feedback from staff about how the approach impacts their workflow, staff interpretations, how to educate staff, and how staff perceive this approach in terms of their current practices and ideal Contact Precautions. Consideration of how the name is heard and branding activities will be taken into consideration.

The number of children with healthcare needs has grown; there are approximately 100 pediatric LTCFs in the US. With that in mind, the guidance could specifically address children’s needs. Dr. Slifka said that children’s facilities are not specifically addressed in the guidance, although there is potential for it to be beneficial in those settings.

Better specificity is needed in terms of which patients are included in the Contact Precautions category versus the Enhanced Barrier Precautions category. Dr. Slifka indicated that this categorization could be specific to the setting. For example, *C. auris* differs across the country. Some locations may see none, while other locations see a great deal. CDC would likely work individually with heads of departments and facilities to understand the best approach. For new *C. auris* in an area, Contact Precautions may be best when determining whether transmission is ongoing. If transmission is found not to be ongoing, consideration could be given to applying Enhanced Barrier Precautions.

This work aligns with work in facilities that are considering more “horizontal” strategies and movement toward syndromic risk assessment based on Contact Precautions. Enhanced Barrier Precautions could apply in situations that are identified in which some barrier may be of benefit.

SHEA suggested examining the US Department of Veterans Affairs (VA) as a model, as they have nursing homes, many of which apply what they call “Enhanced Standard Precautions” for colonized patients. It is important to be careful regarding room restrictions, because these residents have belongings and other needs. Thus, managing the environment is challenging. It also is important to give instructions to

patients about what is expected of them. Dr. Slifka agreed and indicated that CDC has had conversations with the VA specific to Enhanced Standard Precautions and MRSA.

APIC suggested that before implementing Enhanced Barrier Precautions, facilities could adopt an audit perspective regarding how well Standard Precautions are performing. How well are hand hygiene and environmental disinfection working? A focus on a “back-to-basics” program can be preferable to implementing additional measures.

CSTE suggested considering adding details about environmental cleaning. The gowns in many nursing homes are flimsy and may not actually do the job that is intended. Perhaps greater specificity could be included about the quality of gowns. In addition, it is important for consistency between the CMS Interpretive Guidance and CDC guidance to avoid implementation issues.

Tuberculosis Healthcare Personnel Guideline Update

Sapna Bamrah Morris, MD, MBA

Division of Tuberculosis Elimination

Centers for Disease Control and Prevention

Dr. Morris acknowledged Dr. Gibril Njie from the Division of Tuberculosis Elimination (DTBE) and Drs. Lynn Sosa and Robert Belknap at the National Tuberculosis Controller’s Association (NTCA) for their hard work to produce *Tuberculosis Screening, Testing and Treatment of U.S. Health Care Personnel, Recommendations from the National TB Controllers Association and CDC (2019)*.

The CDC *Guidelines for Preventing the Transmission of M. tuberculosis in Health-Care Settings* were published in 2005. The recommendations from 2005 included:

- At Hire: Symptom screen and Interferon-Gamma Release Assays (IGRA) or tuberculin skin test (TST) testing in those without prior history of TB or latent tuberculosis infection (LTBI)
- Post-Exposure: Symptom evaluation and IGRA or TST testing for those with a negative test at baseline and without TB history
- Serial Screening and Testing: Recommended for HCP in medium-risk settings and settings with potential ongoing transmission
- Follow-Up of LTBI Positive: Treatment referral

Based on changes in the last decade, it was determined that the 2005 Guideline needed to be updated. Concerns about the efficacy of serial TB testing with declining TB incidence in the US were amplified by the purified-protein derivative (PPD) shortage in 2013 and multiple articles reporting IGRA poor performance in low-risk persons. In 2015, a joint National Society of TB Clinicians (NSTC) – National TB Nurse Coalition (NTNC) session was held at the 2015 National Tuberculosis Conference to discuss the issue. A Workgroup was created in Summer 2015, a systematic review began in January 2017, and updated recommendations were published on May 16, 2019. The research questions the Workgroup examined were:

- What is the prevalence and incidence of LTBI among healthcare workers (HCW) in the US?
- What is the incidence of TB disease among HCW in the US?
- Does annual or serial testing (via TST or IGRA) of US HCW reduce the risk of TB transmission in US healthcare settings?
- Does annual or serial testing (via TST or IGRA) of US HCW increase the detection of occult TB transmission in US healthcare settings?
- Are certain individuals who work within healthcare facilities at higher risk of TB than others based on occupational and non-occupational factors?

A *Community Guide* systematic review method was used to evaluate and summarize available evidence. A search was conducted for studies that screened and/or tested HCP for LTBI. MEDLINE, EMBASE, and Scopus were searched. The original search was from January 2006 - February 2017, with an updated search from February 2017 - November 2017 for MEDLINE only. Language was restricted to English only in order to focus on the low-incidence setting in the US. The original search identified over 1100 articles, but many were deemed not to be relevant or did not meet the inclusion criteria. After the updated search and screening process, a total of 36 articles were reviewed in the meta-analysis. Two reviewers independently screened and abstracted data for each included study. Disagreements were resolved by consensus, and data were analyzed using “metafor” and “meta” packages in R (v3.3.2).

The evidence indicates that a relatively low proportion (3% - 5%) of US HCP test positive for *M. tuberculosis* infection at baseline. Less than 1% of US HCP who previously tested negative convert to a positive test result during serial testing. Nearly 50% of US HCP who previously tested positive revert to a negative test result during serial testing. The evidence is insufficient to assess incidence and transmission of TB disease among HCP. No cases of TB disease were reported among the approximately 64,000 US HCP included in the studies reviewed.

Dr. Carla Winston, Associate Director for Science (ADS) of DTBE, is among the authors of an article published in *Infection Control and Hospital Epidemiology (ICHE)* in March 2019 titled, “Tuberculosis among healthcare personnel, United States, 2010-2016.” The article describes the incidence of TB disease among HCP. HCP with TB disease were more likely to be female, younger, and to have been born outside of the US. They were also less likely to have TB attributed to recent transmission. These findings indicate that these infections were remotely acquired, and that the incidence of TB actually occurs as a reactivation of TB, which could not have been prevented without initial LTBI treatment at baseline.

The updated recommendations include TB screening, testing, and treatment for HCP and were published as an *Morbidity and Mortality Weekly Report (MMWR) article* (<https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm>), co-written with NTCA.

Changes in the definitions from 2005 to 2019 include:

- “HCP” replaces HCW to be consistent with current preferred HHS and CDC language, but the definition itself is unchanged from 2005.
- “TB Screening” is defined as a broad process that includes a risk assessment, symptom evaluation, a test for LTBI (either a TST or IGRA), and additional work-up for TB disease as needed.
- “TB Testing” refers to an IGRA or TST.

Key changes in the recommendations are as follows:

- Pre-placement: IGRA or TST with symptom assessment and individual TB risk assessment has been added, with a focus on having confidence in baseline testing and to make sure that a complete evaluation is done at baseline (new).
- Post exposure: Symptom evaluation and IGRA or TST testing for those with a negative test at baseline and without TB history (unchanged).
- Serial Screening and Testing (new)
 - Screening/Testing not routinely recommended; can be considered for certain HCP groups
 - Annual TB education of all HCP, including TB exposure risks
- Follow-up of LTBI positive HCP: LTBI treatment strongly recommended unless a contraindication exists (new).

- This change reflects an effort to strengthen the treatment/referral piece and focus on encouraging HCP that have LTBI to receive treatment.

The facility assessment elements of the 2005 guideline are unchanged. Regarding high- or medium-risk assessment of a facility, a facility found to have higher risk or that is in a jurisdiction with an ongoing outbreak may wish to either target particular HCP populations that may be at higher risk or have more likelihood of exposure.

A companion document is planned for publication in 2019 that will expand on the *MMWR* article and include explanations, justifications, and operational recommendations. The document will describe implementation approaches and a number of scenarios for staff who will implement the guidelines or have discussions with state regulators.

To summarize, there is very little TB in the US. In the US, TB is mostly in 5 states, and approximately 80% of those cases are among persons born in countries where TB is endemic. Occupationally-acquired TB is rare. More than 96% of HCP TB tests are negative. This testing is financially, emotionally, and productively costly. Approximately 80% of active TB in HCP is reactivation of untreated LTBI; therefore, TB testing for HCP should be performed upon placement and post-exposure. Annual TB testing of HCP is not recommended. HCP with LTBI should be urged to take short-course treatment.

Plans to disseminate this information include a new infographic, an NTCA press release, a thoroughly updated website, a CDC “Dear Colleague” letter, social media (Twitter and Facebook), and a Medscape video.

Discussion Points

CSTE cautioned that contact investigation conducted by Employee Health after a TB exposure in a hospital must be thorough, as it will not detect persons who normally would be identified through annual screening. Without the “safety net” of the annual screening, there may be a need for additional training and skills-building for Employee Health.

ACOEM pointed out that this updated Guideline is an example of a product that will benefit from more detailed guidance. A sizeable section of the approximately 25-page companion document addresses risk stratification and other issues.

PIDS expressed appreciation for this work, which should be beneficial in a number of settings.

Dr. Bell expressed appreciation for the collegial way in which DTBE has worked with DHQP and HICPAC. The process was productive.

Day 1 Public Comment

Carla Warner Patient Advocate

Ms. Warner introduced herself and expressed her “thanks and congratulations.” She lost her husband, Willy “Bill” Warner, in 2013 to CRE following an endoscopic retrograde cholangiopancreatography (ERCP) procedure in North Carolina. He fought the infection for 8 long and excruciating months. It was difficult to go from wife to caregiver. He was only 55 years old when he died. During his long battle, she watched as a man who was once strong and innovative became unable to even lift himself off the couch or do even the simplest of tasks for himself. He lost 60 pounds in a matter of months despite daily tube feedings. She saw his knuckles turn white as he clenched the sheets in excruciating pain, she heard him gasp for air as his O₂ levels plummeted, and she heard him cry out, begging her not to leave his side due to hallucinations that he experienced during his delirium.

Ms. Warner testified at 2015 FDA meetings and reiterated the problems that her family experienced and the problems plaguing duodenoscopes. The outcome of that meeting was additional, more stringent cleaning protocols. They were recommended and implemented, but four years later, we are having the same conversation. She is grateful for having the conversation, keeping it in the forefront, and recognizing its importance, but infection transmission is still occurring. In light of the recently released surveillance data, it is of no surprise that the current practices have proven to be inadequate as a result of increasingly complex scopes and the complicated cleaning process that leads to human error. She has spent the last five years traveling the country and speaking at conferences and events to increase the awareness of the pitfalls of the current standards and stress the point of due diligence to clinicians. She is doing her part to spread the word, she asked that those present at the meeting do their part as well, to help her push for the only right answer in this scenario, which is sterilization of all scopes. This problem is not isolated to duodenoscopes. There are problems with all scopes.

It can be done. A small town hospital in North Dakota successfully introduced sterilization of all of their duodenoscopes as their standard of care: it can be done and it has been proven to be a possible, attainable, and a cost-effective model. The technology is available to sterilize scopes. Ms. Warner implored for sterilization to be the rule and not the exception. "Business as usual" is no longer working. Bill deserves that his death be a catalyst for change to protect others, not just a statistic of another life lost to CRE that was contracted after an ERCP procedure.

The day's presentations indicated that double HLD does not work and does not improve outcomes: Ms. Warner respectfully disagreed that currently, the benefits of an ERCP do not necessarily outweigh the risks. Regarding the discussion of how to address patients, she stresses to everybody - clinicians, administrators, physicians - that the standard consent process for care is no substitute for open and frank conversation. Patients need to know what they "are getting into."

Ms. Warner was grateful for this discussion because it is so important, and she recognized how hard it is to have those difficult conversations, and that sometimes they can be misunderstood. Please, she said, do not stop having that communication. Until those percentages are much lower, these issues must be discussed, and she hoped that others would join her in supporting the sterilization, the approach that will make her comfortable. She hopes to "put a face to the dangers plaguing these scopes that will resonate with each and every one of you."

Kevin Kavanagh, MD, MS
Health Watch USA

Dr. Kavanagh urged HICPAC to expand transparency initiatives for infectious disease and to encourage the rapid reporting of outbreaks of dangerous pathogens. As reported in the historical review *The Pandemic Century*, many nations, including the US, have inhibited the release of data. For example, in the 1924 plague epidemic in California, the word "plague" was not used in state newspapers. Instead, the illness was referred to as a "malignant form of pneumonia." There was poor communication between agencies, and state officials only became aware of the outbreak through news media reports. In the 2002 SARS epidemic, the Chinese government withheld the numbers of cases and critical information, which inhibited the realization that the problem was not the flu, but a more dangerous coronavirus. In the 2014 Ebola epidemic, the government of Guinea insisted that only laboratory-confirmed cases be reported in a country which had meager healthcare testing resources. This approach resulted in a vast underestimation of cases, a perception that the epidemic was on the wane, and inhibition of resources, which fueled the spread of Ebola to other nations, making it a world crisis. Specifically, in the United States, *C. auris* and CRE are organisms which pose extreme dangers both nationally and internationally. The WHO's *International Health Regulations (2005)* may enable the CDC

to mandate public reporting and oversee control of these pathogens in any state with an international airport or seaport.

Greater transparency is needed in other areas. Dr. Kavanagh said that CDC needs to publicly release infection control data regarding MRSA infections which are defined as “community” and that occur within the first three days of hospitalization. He further said that CDC should also gather and publicly report information regarding healthcare worker (HCW) infections and acquisitions of dangerous pathogens, including MRSA, and require routine testing of those workers exposed to dangerous pathogens. At a minimum, facilities should be required to maintain a log of HCW acquisitions and infections of dangerous pathogens. MRSA and *C. difficile* infections in all types of nursing facilities need to be reported. Any MRSA-positive culture or acquisition at a nursing facility is of importance. Long et al. in a *New England Journal of Medicine* article this year reported that carriers are at risk of future infections and that many of these can be prevented.

Dr. Kavanagh urged focus on actual numbers of infected patients and driving these numbers down through increased implementation of preventive strategies rather than mathematical adjustments.

Liaison Representative / *ex officio* Member Reports

American Association of Kidney Patients (AAKP)

AAKP’s target audience is the 40 million Americans who are at risk of kidney disease. AAKP is proud to be a founding member of the *Making Dialysis Safer for Kidney Patients Coalition*, with their allies, the American Society of Nephrology. AAKP will work as diligently with CDC as they do with other federal cabinet agencies, including DoD, the Department of Labor, the Department of Homeland Security (DHS), and others: AAKP works particularly closely with NIH and CMS. As the oldest and largest independent kidney organization in the US, AAKP is a strong advocate for the alignment of treatments for those with kidney disease to their aspirations: the focus is on more preemptive kidney transplants, and more at-home and more accessible dialysis. For HICPAC’s perspective, AAKP’s biggest agenda item is national policy in the direction of bringing kidney patients to organ transplants faster, and to home care solutions. Because of that, AAKP is not only strongly interested in safety in the hospital setting, but also in non-hospital settings, including clinics and homes. AAKP is also interested in maintaining the credibility of CDC among patient populations. Over the past 36 hours, AAKP conducted an online survey on the emerging issue of is patient concerns about measles outbreaks: highlights of that survey are that 1/3 of patients are concerned about measles, approximately 1/3 of them are concerned that measles might impact them, and 30% “do not know” about the issue. In terms of who patients view as the most credible source for information, 56% named CDC, 26% named nephrologists, approximately 5% named primary care physicians, and television and internet both rated below 5%. For immunocompromised patients and patients with numerous chronic conditions, CDC has disproportionate “weight.” AAKP is happy to work with CDC and HICPAC on safety standards for inside and outside the hospital setting.

American College of Occupational and Environmental Medicine (ACOEM)

ACOEM has voiced its support of H.R. 1309, the Workplace Violence Prevention for Health Care and Social Service Workers Act. Further, ACOEM has updated the guidance document for Medical Center Occupational Health, incorporating a section on physician burnout and depression. ACOEM is completing the companion document for the updated TB Guidelines published in the *MMWR* on May 16, 2019. The brief *MMWR* article represents a sea change in TB surveillance. Key issues, including individual risk assessments and annual surveillance for people with LTBI, present challenges in the workplace and are addressed in the companion document, as well as post-exposure evaluation.

America's Essential Hospitals (AEH)

AEH continues to care for vulnerable and under-served populations. A February 2019 campaign emphasizes to Congress ongoing work to expand access to care and improved population health. AEH is partnering with the National Association of County and City Health Officials (NACCHO) to conduct a webinar in late July 2019 to spotlight collaborative efforts between Essential Hospitals and their county health departments to combat antibiotic resistance.

Agency for Healthcare Research and Quality (AHRQ)

AHRQ continues to support research and implementation projects to develop improved methods and tools to combat antibiotic resistance in consort with the National Action Plan for CARB in 3 major domains:

1. Promoting antibiotic stewardship,
2. Preventing transmission of resistant bacteria, and
3. Preventing healthcare-associated infections.

This work is taking place in major healthcare settings, acute care hospitals, long-term care, and ambulatory care. AHRQ currently supports 3 large implementation projects:

The AHRQ *Safety Program for Improving Antibiotic Use* aims to improve antibiotic stewardship efforts in acute care hospitals, long-term care facilities (LTCFs), and ambulatory care settings. The Acute Care Cohort included over 400 hospitals, and preliminary data are promising. A long-term care cohort of over 480 LTCF will conclude at the end of November 2019. AHRQ is recruiting ambulatory care settings for the final cohort, which will start in December 2019, with an aim of 250 to 500 facilities. Toolkits will be available for each setting at the end of the project.

The AHRQ *Safety Program for Improving Surgical Care and Recovery* is a collaborative program to enhance the recovery of surgical patients. Funded and launched by AHRQ, the program is conducted by Johns Hopkins and partners at the American College of Surgeons. It aims to use an adaptation of the Comprehensive Unit-based Safety Program (CUSP) to improve patient outcomes by increasing the implementation of evidence-based enhanced recovery practices in hospitals, which include preoperative, interoperative, and postoperative practices to decrease complications in surgical patients. This 5-year project aims for implementation in 750 hospitals. To date, more than 290 hospitals are participating.

The AHRQ *Safety Program for Intensive Care Units (ICUs): Preventing CLABSI and CAUTI* is ongoing and aims to reduce CLABSI and catheter-associated urinary tract infection (CAUTI) rates in ICUs with persistently elevated infections. Over 500 ICUs have been recruited to participate nationwide, and one more one-year cohort will begin in early 2020.

Association of periOperative Registered Nurses (AORN)

Since the last HICPAC meeting, AORN's revised AORN Evidence Model has been applied to the newly-revised *Guideline for Surgical Attire and Prevention of Hypothermia*. The Model and the revised Guideline will be released on July 1, 2019. AORN is happy to report that the Surgical Smoke Protection Bill was signed into law in Colorado on March 2, 2019. AORN's 2020 Surgical Conference and Expo will be held in Anaheim, CA in March 2020. AORN invites submissions of education proposals, which will be accepted through the end of the month.

Association of Professionals of Infection Control and Epidemiology (APIC)

APIC has updated its *IP Competency Model* to include additional domains and sub-competencies to allow IPs to function optimally in healthcare settings. APIC's *Novice Roadmap for the Infection*

Preventionist accompanies the Competency Model and has been updated to be more dynamic to support IPs in any healthcare setting where consultation is provided. With regard to legislation, APIC responded to a request for information from the PACCARB of suggested strategies for the new plan. APIC's annual conference will be convened June 12-14, 2019.

Association of State and Territorial Health Officials (ASTHO)

ASTHO continues to work with CSTE co-leading the Council for Outbreak Response: Healthcare-Associated Infections and Antibiotic-Resistant Pathogens (CORHA). An in-person CORHA meeting is planned for June 2019. ASTHO has been proactively participating in CDC's AMR Challenge, reaching out to states to encourage participation. ASTHO has launched a newly-funded project on *Establishing Communities of Excellence in Addressing Antimicrobial Resistance and Advancing Antimicrobial Stewardship*, with several educational resources.

Centers for Medicare and Medicaid Services (CMS)

This summer, CMS is releasing an advance copy of the *Revised Surveyor Interpretive Guidance for Phase 2 and Phase 3 for Nursing Homes*. Along with this advance copy, CMS will release training for surveyors and providers to support compliance with the changes to be implemented in November 2019. New guidance for Phase 3 addresses requirements for the qualifications and role of an IP in a nursing home. CMS and CDC collaborated on the development of a free online training course in infection prevention and control for nursing home staff. The training, housed on CDC's training website, provides approximately 19 hours of continuing education credits, as well as a certificate of completion. CMS will soon release a *Nursing Home Antibiotic Stewardship* training webinar on the *Quality, Safety, and Oversight Surveyor Training* website. CMS's website is forward-facing; anyone can access the materials available for surveyors. An updated *Nursing Home Infection Control Worksheet* developed during a recent pilot will be released for use as a facility self-assessment tool. This version includes questions about facility water management efforts to reduce risk of *Legionella* infections. CMS will conduct a pilot survey to assess infection control practices in nursing homes with ventilator-dependent residents. They will look for gaps in assessment of infection control compliance and how well facilities prevent the transmission of MDROs between ventilator-dependent residents and other residents in the facility and during transitions of care.

Council of State and Territorial Epidemiologists (CSTE)

CSTE's Drug Diversion Workgroup developed a *Drug Diversion Toolkit* to provide guidance for state and local HAI programs during responses to drug diversion events. The Toolkit has been finalized and is anticipated for release in June 2019. The CSTE annual conference will be held June 2-6, 2019, in Raleigh, NC. A CSTE *Legionella* position statement includes an appendix that addresses incubation periods for healthcare-associated *Legionella*. Regarding CORHA, a Policy Workgroup has done quite a bit of work on disclosure of outbreaks, guidance to patients and others who were exposed, and potential greater public notification.

National Institutes of Health (NIH)

NIH has conducted ongoing surveillance of patients who present to the Clinical Center for CRE for 5 years, and this surveillance continues. NIH continues to assess the healthcare-associated epidemiology of VRE in the hospital and recently published a retrospective cohort study evaluating antibiotic exposures and VRE. Not surprisingly, colonization is associated with CRE infection and with increased mortality. Re-exposure to antibiotics increases the risk for VRE recolonization.⁷ NIH's investigation of *Sphingomonas koreensis* (*S. koreensis*) infections is published, and an abstract is submitted for IDWeek

⁷ *Infect Control Hosp Epidemiol*. 2019 Apr; 40 (4): 414-419

discussing ways of remediating hospital plumbing to obviate ongoing colonization with this organism.⁸ Karen Frank, MD, PhD, who was the Chief of Microbiology was selected as the new Chief of the Department of Laboratory Medicine. NIH is aggressively recruiting for a new Chief of Clinical Microbiology; submission of potential candidates is welcomed.

Public Health Agency of Canada (PHAC)

PHAC's focus is on AMR and the Canadian government's role as a global partner. Several years ago, PHAC released an AMR framework and is now creating an action plan. One of the pillars of the plan is infection control; it is anticipated to be released in Fall 2019. PHAC has finished a major piece of guideline work, *Prevention of Transmission of Bloodborne Viruses (BBVs) from Infected Healthcare Workers in Healthcare Settings*. PHAC thanked and acknowledged the contributions of Dr. David Kuhar and colleagues at CDC for not only helping PHAC scope this project, but also for the consultation process and review. The project involved 120 stakeholders nationally and internationally. Another major piece of PHAC's work is the *Guideline for Prevention and Control of Occupational Infections in Healthcare*, which is similar to CDC's work.

Pediatric Infectious Disease Society (PIDS)

PIDS's primary focus is on antimicrobial resistance and immunizations. PIDS has worked with the American Academy of Pediatrics and its Section on Infectious Diseases (SOID) and other stakeholders to develop a toolkit focused on pediatric antimicrobial stewardship. This product will be of assistance to those interested in developing pediatric antimicrobial stewardship programs. PIDS is collaborating with SHEA on its White Paper Series to accompany the HICPAC NICU Guideline. PIDS continues to advocate for immunization of children and those who interact with them in healthcare settings. PIDS published the *Handbook of Pediatric Infection Prevention and Control* in April 2019, which was edited by Drs. Kristina Bryant and Judy Guzman. This publication is one of the first handbooks specifically devoted to pediatric infection prevention and control. PIDS will hold its 10th Annual International Antimicrobial Stewardship Conference on May 30-31, 2019, at Washington University in St. Louis, MO. PIDS members will participate in the World Society of Pediatric Infectious Disease Conference in Manila in November 2019.

Society for Healthcare Epidemiology of America (SHEA)

SHEA has a new Executive Director, Kristy Weinshel. SHEA has a number of recent publications, including *Expert Guidance: Infection Prevention in Operating Room Anesthesia Work Area*; NICU White Paper Series (the first on *C. difficile* has been published, *S. aureus* is in development, and CLABSI Respiratory Infections will be next); *Evaluation and Management of Penicillin Allergy*; and materials from the Outbreak Response Training Program, a collaboration with CDC that is now available.

SHEA has several guidance documents in development, including: Sterilization and High-Level Disinfection; Initiation of Antibiotics; Healthcare Workers Infected with Bloodborne Pathogens, a white paper update; Infection Prevention in Long-Term Care (LTC); and the SHEA/IDSA Compendium 2020 Update, which helps to keep key guidance documents up-to-date. SHEA also conducted reviews with other groups, including the American Dental Association (ADA) recommendations for antibiotics for dental pain and swelling; and the HICPAC Draft Update to the CDC Infection Prevention and Control Recommendation Categorization Scheme.

SHEA recently held its spring meeting. The 2019 Epi Project Competition was won by Dustin Long, MD, for the project titled, "Molecular Epidemiology of Spinal Fusion Surgical Site Infection and Influence of

⁸ *N Engl J Med.* 2018; 379(26): 2529-39

Preoperative Patient Microbiome.” Questions persist in this area in the field, and there is a need for the next generation to develop concepts for how to study it. The SHEA Research Network has been active, with approximately 7 projects completed in the last year.

Regarding legislation, SHEA continues to advocate for the passage of the Pandemic and All Hazards Preparedness Act, which was recently reintroduced. SHEA also continues to advocate for the passage of legislation to lift spending caps mandated by the Budget Control Act of 2011. SHEA is working with stakeholder partners to advocate for more funding for CDC, specifically for NHSN. In addition, SHEA joined a coalition of stakeholders advocating for \$100 million over 10 years to modernize public health data infrastructure. Other activities include the launch of an *ICHE* Podcast series.

SHEA has published several textbooks, including *Practical Healthcare Epidemiology*, 4th Edition, released in Fall 2018; and the upcoming *Practical Implementation of an Antibiotic Stewardship Program*. IDWeek is coming up in October 2019. The 6th Decennial International Conference on Healthcare Associated Infections will be held March 26-30, 2020 in Atlanta, GA, at the Marriott Marquis.

Society of Hospital Medicine (SHM)

SHM continues its Fight the Resistance Campaign to target overprescribing of antibiotics. The High-Value Care Subcommittee is working on the Choosing Wisely 2.0 recommendations. The first recommendations targeted overuse of urinary catheters, and the next iteration of the recommendations will build on that work. SHM recently held a webinar that highlighted best practices to reduce hospital-acquired *C. difficile*, with a focus on antibiotic prescribing.

Adjourn

Dr. Yokoe thanked the group for a thought-provoking and productive first day of the meeting. With no additional comments or questions posed, HICPAC stood in recess at 5:00 pm.

Friday, May 17, 2019

Welcome and Roll Call

Dr. Yokoe called the second day of the HICPAC meeting to order at 9:05 am on Friday, May 17, 2019. A roll call by Dr. Bell of HICPAC members, *ex officio* Members, and Liaison Representatives established that a quorum was present. Quorum was maintained throughout the day.

Healthcare Personnel Guideline Section II Workgroup Update

Hilary M. Babcock, MD, MPH
Chair, HCP Guideline Workgroup

Dr. Babcock provided updates on progress of the individual sections in the update to the *Guideline for Infection Control in Healthcare Personnel (HCP), Section 2: Epidemiology and Prevention of Selected Infections Transmitted Among HCP and Patients*.

The HICPAC HCP Guideline Workgroup is charged with updating the pathogen-specific sections of the Guideline. Where information is out of date, the Workgroup makes updates using evidence-based methods where evidence is available.

HICPAC has voted to approve the following sections:

- Pertussis (February 2018)
- Mumps (May 2018)
- Rubella (May 2018)
- Measles (August 2018)

- Meningococcal Disease (November 2018).

At November 2018 HICPAC meeting, the Workgroup presented initial drafts of recommendations for the Diphtheria and Group A *Streptococcus* sections.

The methodology for these updates differs from the methodology applied to earlier guideline updates. For each section, the Workgroup reviews the 1998 recommendations and text to determine elements that can be deleted, updated, or continued. Specifically, the Workgroup looks for outdated recommendations that are already updated elsewhere (eg, ACIP), areas with significant gaps between the 1998 recommendations and current practices, areas with new data or literature that can inform updated recommendations, and areas of need where the 1998 guideline does not address a common issue or area of concern. The Workgroup engages SMEs within CDC to provide feedback on gaps, needed updates, and available literature. The CDC SMEs have been helpful partners for each of these sections. The Workgroup decides whether a Systematic Review or an Informal Review will be conducted.

For sections with full formal literature review, the Workgroup develops Key Questions to inform the literature review, and the review informs recommendations. Broader discussion takes place as well, as the Workgroup strives to capture a range of information. For pathogens with little to no new information, data, or literature, recommendations may be based on less formal reviews, expert opinion, other relevant guidelines, and harmonization with existing CDC resources and recommendations. The overarching goal of this work is to provide practical and thoughtful guidance where there is little directly applicable literature.

The guideline refers to the *HICPAC Core Practices Document*, particularly Section 8, which focuses on occupational health and includes key recommendations:

1. Ensure that healthcare personnel either receive immunizations or have documented evidence of immunity against vaccine-preventable diseases as recommended by the CDC, CDC's Advisory Committee on Immunization Practices (ACIP), and required by federal, state or local authorities.
2. Implement processes and sick leave policies to encourage healthcare personnel to stay home when they develop signs or symptoms of acute infectious illness (eg, fever, cough, diarrhea, vomiting, or draining skin lesions) to prevent spreading their infections to patients and other healthcare personnel.
3. Implement a system for healthcare personnel to report signs, symptoms, and diagnosed illnesses that may represent a risk to their patients and coworkers to their supervisor or healthcare facility staff who are responsible for occupational health.
4. Adhere to federal and state standards and directives applicable to protecting healthcare workers against transmission of infectious agents including OSHA's Bloodborne Pathogens Standard, Personal Protective Equipment Standard, Respiratory Protection standard and TB compliance directive.

The pathogens and infections to be addressed in Section 2 are:

- Conjunctivitis
- Cytomegalovirus
- Diphtheria
- Acute GI Infections (Norovirus, *C. difficile*, others)
- Hepatitis A
- Herpes Simplex
- Measles
- Meningococcal Disease
- Multidrug-Resistant Gram-Negative Bacteria

- Mumps
- Parvovirus
- Pertussis
- Poliomyelitis
- Rabies
- Rubella
- Scabies and Pediculosis
- *Staphylococcus aureus* (MSSA/MRSA)
- *Streptococcus* (group A)
- Tuberculosis
- Vaccinia
- Varicella
- Viral Respiratory Infections (Influenza, RSV, others)
- Potential Agents of Bioterrorism (eg, Anthrax)

The workflow is guided by the need for update with input from the Workgroup members, logical clusters of sections, and efficiency in working through CDC clearance.

Diphtheria

The Workgroup reviewed the 1998 recommendations for gaps and outdated recommendations. The group reviewed ACIP 2011 and CDC resources and reached out to the CDC SMEs for input. The Workgroup developed “draft” draft recommendations and a narrative section, which were presented to HICPAC for review and feedback in November 2018. The draft was then revised and updated.

1998 Recommendation

- Encourage vaccination with Td every 10 years for health care personnel (Table 1) (9,19).
Category IB

DRAFT Update

Delete: Narrative will refer to *ACIP 2011 Recommendations for Immunization of Healthcare Personnel* and to CDC recommendations for adult vaccine schedules.

- Draft Narrative, Background: “Prevention of transmission of *C. diphtheriae* in healthcare settings involves (a) encouraging vaccination of healthcare personnel against diphtheria in compliance with routine adult vaccine schedules; ...”
- ACIP: “Tetanus and diphtheria toxoids (Td). All adults should have documentation of having received an age-appropriate series of Td-containing vaccine and a routine booster dose every 10 years...”
- HICPAC Core Practices, *Section 8 Occupational Health*: “1. Ensure that healthcare personnel either receive immunizations or have documented evidence of immunity against vaccine-preventable diseases as recommended by the CDC, CDC’s Advisory Committee on Immunization Practices (ACIP) and required by federal, state or local authorities.”

1998 Recommendations

- Obtain nasopharyngeal cultures from exposed personnel and monitor for signs and symptoms of diphtheria for 7 days after exposure (149). *Category IB*
- Administer antimicrobial prophylaxis to personnel who have contact with respiratory droplets or cutaneous lesions of patients infected with diphtheria. Also administer a dose of Td to previously immunized exposed personnel who have not been vaccinated within the previous 5 years (Table 1) (19,149). *Category IB*

- d. Repeat nasopharyngeal cultures of personnel found to have positive cultures at least 2 weeks after completion of antimicrobial therapy. Repeat antimicrobial therapy if personnel remain culture positive (149). *Category IB*
- e. Exclude exposed personnel and those identified as asymptomatic carriers from duty until antimicrobial therapy is completed and results of two nasopharyngeal cultures obtained at least 24 hours apart are negative (Table 3) (149). *Category IB*

DRAFT Updated Recommendations

1. For healthcare personnel who have an exposure to diphtheria, regardless of vaccination status,
 - a. Administer postexposure prophylaxis in accordance with CDC recommendations.
 - b. Exclude from work and obtain nasal and pharyngeal swabs for diphtheria culture.
 1. If nasal AND pharyngeal cultures are negative for toxin-producing *C. diphtheriae*, healthcare personnel may return to work while completing postexposure antibiotic therapy.
 2. If nasal OR pharyngeal cultures are positive for toxin-producing *C. diphtheriae*,
 - a. Complete postexposure antibiotic therapy.
 - b. Healthcare personnel may return to work when:
 1. Postexposure antibiotic therapy is completed AND
 2. At least 24 hours after completion of postexposure antibiotic therapy, two consecutive pairs of nasal AND pharyngeal cultures, obtained at least 24 hours apart, are negative for toxin-producing *C. diphtheriae*.
 - c. Implement daily monitoring for the development of signs and symptoms of diphtheria for 7 days after the last exposure.
2. For healthcare personnel with diphtheria infection, exclude from work until:
 - a. Antibiotic and antitoxin therapy are completed AND
 - b. At least 24 hours after completion of antibiotic therapy, two consecutive pairs of nasal AND pharyngeal cultures, obtained at least 24 hours apart, are negative for toxin-producing *C. diphtheriae*.

Each section's narrative follows a similar outline:

- Background
 - Prevention of transmission in healthcare settings
- Occupational Exposures
- Clinical Features
- Testing and Diagnosis
- Postexposure Prophylaxis

The Occupational Exposures section provides information about how to evaluate the risk for transmission and includes exposure statements, while the Postexposure Prophylaxis section provides information regarding treatment course and carrier state:

DRAFT Narrative: Occupational Exposures

“Transmission of diphtheria occurs through deposition of respiratory, oral, or nasal secretions, discharge from skin lesions, or, rarely, fomites, from an infected source person on the mucus membranes of a susceptible host. Unprotected (i.e., not wearing a facemask), close contact with an infectious source person or their secretions may be considered an exposure to diphtheria. Close contact may include performing a physical examination on; feeding or bathing a patient; bronchoscopy; intubation; or administration of bronchodilators.”

“Exposure to cutaneous diphtheria lesions may include unprotected contact with the lesions or their drainage, such as when changing lesion dressings or handling potentially infectious secretions without wearing recommended PPE (i.e., gown and gloves).”

DRAFT Narrative: Postexposure Prophylaxis

“Postexposure prophylaxis for diphtheria includes receipt of diphtheria vaccine and a single dose of intramuscular benzathinepenicillin G or a 7-to 10-day course of oral erythromycin. Detailed information regarding the dosage and administration of postexposure vaccine and antimicrobial therapy is available on the CDC website [link].

“Administration of postexposure prophylaxis does not always eliminate the carrier state. For HCP identified as *C. diphtheriae* carriers, positive post treatment cultures typically prompt administration of additional courses of treatment. The CDC website provides additional information on the management of *C. diphtheriae* carriers [link].”

Streptococcus, Group A Infection

The Workgroup reviewed the 1998 recommendations for gaps and outdated recommendations. The group also reviewed current CDC guidelines and recommendations in *Prevention of Invasive Group A Streptococcal Disease among Household Contacts of Case Patients and among Postpartum and Postsurgical Patients: Recommendations from the Centers for Disease Control and Prevention (2002)*. The Workgroup reached out to CDC SMEs for input and developed “draft” draft recommendations, which were presented for HICPAC review and feedback in November 2018. The Workgroup revised and updated the draft based on HICPAC feedback and CDC SME input.

1998 Recommendations

- a. Obtain appropriate cultures and exclude personnel from patient care or food handling if they have draining lesions that are suspected to be caused by *Streptococcus*. Work restrictions should be maintained until *streptococcal* infection has been ruled out or personnel have received adequate therapy for 24 hours (Table 3) (369,371,374). *Category IB*
- b. Do not routinely exclude personnel with suspected or confirmed carriage of group A *Streptococcus* from patient care or food handling unless it is shown epidemiologically that they are responsible for disseminating the organism in the health care setting (Table 3) (369,373,378). *Category IB*

The 1998 recommendations focus on draining wounds and do not explicitly address pharyngitis. They updated recommendations are more broad to encompass pharyngitis. In addition, the Workgroup reorganized the recommendations so that the situation that tends to occur most often is reflected in the first recommendation in the list.

DRAFT Updated Recommendations

1. Postexposure prophylaxis and work restrictions are not necessary for healthcare personnel who have an exposure to group A *Streptococcus*.
2. For healthcare personnel with known or suspected group A *Streptococcus* infection, obtain testing for group A *Streptococcus* and exclude from work until group A *Streptococcus* infection is ruled out, or until 24 hours after the start of effective antimicrobial therapy, provided that any draining skin lesions can be adequately contained and covered.
 - a. For healthcare personnel with known or suspected group A *Streptococcus* draining skin lesions that cannot be adequately contained or covered (eg, on the face, neck, hands, wrists), exclude from work until the lesions are no longer draining.

3. Work restrictions are not necessary for healthcare personnel with known or suspected group A *Streptococcus* colonization, unless they are epidemiologically linked to transmission of the organism in the healthcare setting.
4. For healthcare personnel with group A *Streptococcus* colonization who are epidemiologically linked to transmission of the organism in the healthcare setting,
 - a. Administer chemoprophylaxis in accordance with CDC recommendations AND
 - b. Exclude from work until 24 hours after the start of effective antimicrobial therapy AND
 - c. Obtain follow-up testing for group A *Streptococcus* 7 to 10 days after completion of chemoprophylaxis; if positive, repeat administration of chemoprophylaxis and again exclude from work until 24 hours after the start of effective antimicrobial therapy.

The narrative outline of this section adheres to the structure of the other sections; however, “Postexposure Considerations” is used rather than “Postexposure Prophylaxis,” as there is no recommended postexposure prophylaxis (PEP) for group A *Streptococcus*. A final statement about Outbreaks is added.

DRAFT Narrative: Background

“Prevention of transmission of GAS in healthcare settings involves:

- a. “in addition to using Standard Precautions, placing patients with known or suspected GAS infection in recommended transmission-based precautions according to their clinical manifestations of GAS disease and
- b. “excluding potentially infectious HCP from work.”

DRAFT Narrative: Occupational Transmission

“Healthcare-associated transmission of GAS has been documented from patients to healthcare personnel (HCP) and from HCP to patients. There are no recommended actions, such as administering postexposure prophylaxis (PEP) or work restrictions, after HCP exposure to GAS. Contact is the major mode of transmission of GAS in healthcare settings.”

DRAFT Narrative: Postexposure Considerations

“Although PEP is not administered after HCP exposure to GAS, if clinical symptoms compatible with GAS infection develop, GAS infection may be the underlying etiology and testing and treatment may be indicated.”

DRAFT Narrative: Outbreaks

“Even one case of postpartum or postsurgical GAS infection typically prompts an epidemiological investigation because of the potential for prevention of additional cases. CDC maintains recommendations for screening HCP during GAS outbreaks in healthcare settings, including which HCP to select for screening and which body sites to culture [link].

“When screening of HCP is performed, sites from which specimens are obtained and cultured include the throat, anus, vagina, and any skin lesions.

“Colonization with GAS does not necessitate treatment unless the carrier is epidemiologically linked to GAS transmission in the healthcare setting. Information regarding dosage and administration of chemoprophylaxis for GAS-colonized HCP who are epidemiologically linked to transmission is available on the CDC website [link].”

Varicella

The Workgroup reviewed the 1998 recommendations for gaps and outdated recommendations. The group also reviewed ACIP 2011 and reached out to CDC SMEs for input. The Workgroup presented “draft” draft recommendations and narrative text to HICPAC in August 2018. The draft was revised and

edited based on HICPAC feedback and in consultation with CDC SMEs, and for clarification and to align with Isolation Precautions.

1998 Recommendations

- a. Administer varicella vaccine to susceptible personnel, especially those that will have contact with patients at high risk for serious complications (Table 1). *Category IA*
- b. Do not perform serologic screening of persons with negative or uncertain history of varicella before administering varicella vaccine to personnel, unless the institution considers it cost-effective. *Category IB*
- c. Do not routinely perform post-vaccination testing of personnel for antibodies to varicella. *Category IB*

DRAFT Update

Delete: Narrative will refer to ACIP 2011 *Recommendations for Immunization of Healthcare Personnel* and to the HICPAC *Core Practices* Document.

- ACIP: “Healthcare institutions should ensure that all HCP have evidence of immunity to varicella.”
- HICPAC Core Practices, *Section 8 Occupational Health*: “1. Ensure that healthcare personnel either receive immunizations or have documented evidence of immunity against vaccine preventable diseases as recommended by the CDC, CDC’s Advisory Committee on Immunization Practices (ACIP) and required by federal, state or local authorities.”

1998 Recommendations

- e. Develop guidelines for managing health care personnel who receive varicella vaccine; for example, consider precautions for personnel who acquire a rash after receipt of varicella vaccine and for other health care personnel who receive varicella vaccine and will have contact with susceptible persons at high risk for serious complications from varicella. *Category IB*
- f. Develop written guidelines for postexposure management of vaccinated or susceptible personnel who are exposed to wild-type varicella. *Category IB*

DRAFT Update

Delete: Section 1 of the updated Healthcare Personnel Guideline addresses administrative issues related to immunization of healthcare personnel, including the development of policies and procedures. The draft updated recommendations address the development of rash after receipt of varicella vaccine.

1998 Recommendations

- l. Perform serologic screening for immunity to varicella on exposed personnel who have not had varicella or are unvaccinated against varicella. *Category IB*
- m. Consider performing serologic screening for immunity to varicella on exposed, vaccinated personnel whose antibody status is not known. If the initial test result is negative, retest 5 to 6 days after exposure to determine whether an immune response occurred. *Category IB*

DRAFT Update

Delete: Recommendations for vaccination of healthcare personnel, including serologic screening, are addressed in *ACIP 2011 Recommendations for Immunization of Healthcare Personnel*.

1998 Recommendations

- d. NO RECOMMENDATION for administering postexposure varicella vaccination for the protection of exposed, susceptible personnel. *UNRESOLVED ISSUE*
- g. Exclude personnel from work who have onset of varicella until all lesions have dried and crusted (Table 3). *Category IB*

- h. Exclude from duty after exposure to varicella personnel who are not known to be immune to varicella (by history or serology), beginning on the tenth day after the first exposure until the 21st day after the last exposure (28th day if VZIG was given; Table 3). *Category IB*
- i. Restrict immunocompetent personnel with localized zoster from the care of high risk patients until lesions are crusted; allow them to care for other patients with lesions covered. *Category IB*
- j. Restrict immunocompromised personnel with zoster from contact with patients until their lesions are crusted (Table 3). *Category IB*
- k. Restrict susceptible personnel exposed to zoster from patient contact from the tenth day after the first exposure through the 21st day after the last exposure (28th day if VZIG was given; Table 3). *Category IB*
- n. Consider excluding vaccinated personnel from work beginning on the 10th day after the first exposure through the 21st day after the last exposure if they do not have detectable antibodies to varicella, or screen daily for symptoms of varicella (Table 3). *Category IB*
- o. Do not routinely give VZIG to exposed susceptible personnel, unless immunosuppressed, HIV infected, or pregnant. If VZIG is given, exclude personnel from duty from the 10th day after the first exposure through the 28th day after the last exposure (Tables 1 and 3). *Category IB*

DRAFT Update

Delete/Reframe: For vaccine versus VariZIG for postexposure prophylaxis, the narrative provides a brief description and refers to ACIP 2011 and a 2013 Update document on administration of immune globulin. The draft updated recommendation addresses extension of work restrictions for personnel who receive immune globulin as PEP.

DRAFT Updated Recommendations:

1. For healthcare personnel **with** evidence of immunity to varicella who have an exposure to varicella or disseminated or localized herpes zoster:
 - a. Postexposure prophylaxis is not necessary.
 - b. Work restrictions are not necessary.
2. For healthcare personnel **without** evidence of immunity to varicella who have an exposure to varicella or disseminated or localized herpes zoster:
 - a. Administer postexposure prophylaxis in accordance with CDC and ACIP recommendations.
 - b. Exclude from work from the 8th day after the first exposure through the 21st day after the last exposure.
 1. Work restrictions are not necessary for healthcare personnel who previously received one dose of the varicella vaccine and *will receive the second dose of vaccine within 5 days after exposure.*
 2. If varicella-zoster immune globulin is administered as postexposure prophylaxis, exclude from work *from the 8th day after the first exposure through the 28th day after the last exposure.*
3. For healthcare personnel with varicella, exclude from work until all lesions have dried and crusted; or, for those who only have non-vesicular lesions that do not crust, exclude from work until no new lesions appear within a 24-hour period.
4. For healthcare personnel with disseminated herpes zoster, or for immunocompromised healthcare personnel with localized herpes zoster until disseminated disease has been ruled out, exclude from work until all lesions have dried and crusted.
5. For healthcare personnel with localized herpes zoster, including vaccine-strain herpes zoster and immunocompromised healthcare personnel with localized herpes zoster who have had disseminated disease ruled out:

- a. Cover all lesions and exclude from care of patients at increased risk for complications from varicella disease (eg, neonates, pregnant women, immunocompromised persons of any age) until all lesions are dried and crusted.
- b. If lesions cannot be covered (eg, on the hands or face), exclude from work until all lesions are dried and crusted.

Since the HICPAC review in August 2018, a sentence was added in the *Background* that cites and aligns with Isolation Precautions: “CDC recommends that susceptible HCP should not enter the room of a patient with varicella, disseminated herpes zoster, or localized herpes zoster if immune caregivers are available.” The headings were reorganized for clarity and readability.

DRAFT Narrative: Occupational Exposures

“VZV can be spread from person to person by direct contact, inhalation of aerosols from vesicular fluid of skin lesions of acute varicella or herpes zoster, and possibly through infected respiratory secretions from patients with varicella that also may be aerosolized.”

DRAFT Narrative: Occupational Exposures, Varicella and Disseminated Herpes Zoster

“Unprotected (eg, not wearing recommended personal protective equipment (PPE)) contact with patients with varicella or disseminated herpes zoster, their secretions, or air containing infectious particles may be considered an exposure to VZV. Exposures in healthcare settings may include unprotected entry into a source patient’s room and touching vesicular fluid from skin lesions without PPE. Experts differ regarding the duration of exposure to an infectious patient (eg, being in the same room) that is needed for transmission. Sources suggest time frames from 5 minutes to up to 1 hour. Brief, unprotected entry into a source patient’s room without touching the patient or surfaces is generally not considered an exposure.”

DRAFT Narrative: Occupational Exposures, Localized Herpes Zoster

“VZV can also spread from a person with active localized herpes zoster to cause varicella in a susceptible person (i.e., who has never had varicella or has not received varicella vaccine) from touching vesicular fluid from skin lesions without PPE. The lesions are infectious until they dry and crust over.”

DRAFT Narrative: Postexposure Prophylaxis

“Exposed HCP without evidence of VZV immunity should receive postexposure vaccination as soon as possible in accordance with CDC and ACIP recommendations. Vaccination within 3 to 5 days of exposure may modify the disease if infection occurs. Vaccination 6 or more days after exposure is still indicated because it induces protection against subsequent exposures.

“For HCP without evidence of immunity who have a contraindication to varicella vaccination and are at increased risk for severe disease (eg, pregnant, immunocompromised), varicella-zoster immune globulin should be administered as soon as possible (within 10 days) after exposure to VZV. Treatment with immune globulin can prolong the incubation period to 28 days after exposure. Detailed information regarding dosage and administration of PEP is available on the CDC website [link].”

Cytomegalovirus (CMV)

The Workgroup reviewed the 1998 recommendations for gaps and outdated recommendations and reviewed existing CDC guidance.

1998 Recommendation

- b. Ensure that pregnant personnel are aware of the risks associated with CMV infection and infection control procedures to prevent transmission when working with high-risk patient groups (Table 6) (3,117). *Category IA*

DRAFT Update

Delete: Section 1 of the updated Healthcare Personnel Guideline addresses administrative considerations, including counseling for populations that need to be aware of particular issues.

1998 Recommendations

- a. Do not restrict personnel from work who contract CMV-related illnesses (119). *Category IB*
- c. Do not routinely use workplace reassignment as a method to reduce CMV exposures among seronegative pregnant personnel (88,92,95-97,102,105,106,119,120). *Category IA*

“DRAFT” Draft Updated Recommendations:

1. Work restrictions are not necessary for healthcare personnel who contract CMV.
2. Routine exclusion of CMV seronegative pregnant or immunocompromised healthcare personnel from caring for patients with CMV is not necessary.

Parvovirus

The Workgroup reviewed the 1998 recommendations for gaps and outdated recommendations and reviewed existing CDC guidance.

1998 Recommendation

- a. Ensure that pregnant personnel are aware of the risks associated with parvovirus infection and of infection control procedures to prevent transmission when working with high-risk patient groups (Table 6) (274,275). *Category IB*

DRAFT Update

Delete: Section 1 of the updated Healthcare Personnel Guideline addresses administrative issues, including counseling.

1998 Recommendation

- b. Do not routinely exclude pregnant personnel from caring for patients with B19. *Category IB*

“DRAFT” Draft Updated Recommendation:

1. Routine exclusion of pregnant or immunocompromised healthcare personnel from caring for patients with Parvovirus B19 is not necessary.

Conjunctivitis

The Workgroup reviewed the 1998 recommendations for gaps and outdated recommendations, reviewed existing CDC guidance, and reached out to CDC SMEs for input.

1998 Recommendation

- a. Restrict personnel with epidemic keratoconjunctivitis or purulent conjunctivitis caused by other microorganisms from patient care and the patient’s environment for the duration of symptoms. If symptoms persist longer than 5 to 7 days, refer personnel to an ophthalmologist for evaluation of continued infectiousness. *Category IB*

DRAFT Update

Dr. Babcock explained that a 14-day exclusion is often used in practice: the [Red Book states](#) that “Health care professionals with known or suspected adenoviral conjunctivitis should avoid direct patient contact for 14 days after onset of disease in the most recently involved eye” (<https://redbook.solutions.aap.org/chapter.aspx?sectionid=189640035&bookid=2205>). CDC SMEs are unaware of literature to support the 14-day exclusion. The Workgroup proposes a Literature Review to determine whether transmission occurs in healthcare settings from HCP to others beyond resolution of symptoms of epidemic keratoconjunctivitis.

Poliomyelitis

The Workgroup reviewed the 1998 recommendations for gaps and outdated recommendations and reviewed existing CDC resources.

1998 Recommendations

- a. Determine whether the following personnel have completed a primary vaccination series: (1) persons who may have contact with patients or the secretions of patients who may be excreting wild polioviruses and (2) laboratory personnel who handle specimens that might contain wild polioviruses or who do cultures to amplify virus (Table 1) (21). *Category IA*
- b. For above personnel, including pregnant personnel or personnel with an immunodeficiency, who have no proof of having completed a primary series of polio immunization, administer the enhanced inactivated poliovirus vaccine rather than oral poliovirus vaccine for completion of the series (Table 1) (21). *Category IB*
- c. When a case of wild-type poliomyelitis infection is detected or an outbreak of poliomyelitis occurs, contact the CDC through the state health department. *Category IB*

DRAFT Update

The 1998 recommendations are related to vaccination and reporting, which are addressed elsewhere and therefore will not be carried forward. The Workgroup proposes a narrative section without recommendations.

Discussion Points

Diphtheria

HICPAC suggested clarifying the wording of draft Recommendation 1b:

- “obtain nasal and pharyngeal cultures for diphtheria and repeat nasal and pharyngeal cultures 24 hours later”
- “2 each nasal and pharyngeal cultures, total 4 specimens”

ACOEM suggested that “unprotected” should be specified each time “exposure” is defined.

Regarding an inquiry from HICPAC about whether polymerase chain reaction (PCR) is an acceptable testing method, if available, instead of culture, Dr. Babcock replied that the CDC SMEs indicated that culture is the preferred test.

The latest CSTE position statement clarifies that a PCR test or matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF) are not sufficient to confirm toxin production. Elek testing is needed.

Dr. Babcock said that the recommendation does not address the specifics of testing because testing modalities change over time; however, the narrative addresses confirmation of toxin production and will link to the CDC Diphtheria web page.

In response to a question from HICPAC regarding whether antitoxin is required for treatment, and the difficulty of obtaining antitoxin, Dr. Babcock said that antibiotic and antitoxin therapy are recommended for people who have diphtheria infection. The narrative provides information about treatment, and the CDC Diphtheria web page is linked for further details. The difficulty in acquiring antitoxin varies, but health departments should be able to assist, and the process for obtaining antitoxin is established.

HICPAC asked about toxin-producing versus non-toxin-producing *C. diphtheriae*. Dr. Babcock replied that the draft recommendations are for toxin-producing strains. If it is unknown whether a person has a

toxin-producing strain, the process is started, but can be stopped if the strain is found not to be toxin-producing.

Streptococcus, group A Infection

No additional questions, comments, or suggestions.

Varicella (Varicella-Zoster Virus)

Regarding draft Recommendation 2a, which states to give PEP “in accordance with CDC and ACIP recommendations,” there was discussion regarding clarifying the language so that it is clear that vaccine or an immune globulin product might be administered as PEP, and that the exclusion is longer for immune globulin.

Regarding draft recommendation 5a, HICPAC asked whether HCP with localized herpes zoster (shingles) whose lesions can be covered should be excluded from care of patients at increased risk for complications. It seems that the risk of transmission is close to zero if lesions can be covered, and this restriction can be logistically difficult to implement since individual patients can be immunocompromised in many different ways. Further, visitors with localized zoster are not typically restricted if the lesions can be covered, and people often do not know they have shingles until they are in the infectious state: would an exposure investigation be warranted?

Dr. Babcock replied that this recommendation was stated in the *1998 Guideline*, but there is variation in how these situations are managed. This document does not make recommendations about patient exposure management and when to launch an exposure investigation. In practice, most facilities address on a case-by-case basis what kind of investigation might be necessary. However, the point is well-taken that exposure evaluation might be implied if HCP work who should have been restricted from work.

HICPAC emphasized that even though there is variability in the field regarding how these situations are handled, the recommendation for exclusion is not a change; therefore, if the recommendation changes, it should be communicated clearly so that those who have followed the 1998 recommendations are aware of the change, and that the 1998 exclusions are not necessary.

Dr. Babcock added that if a substantial change is made to a recommendation, the Workgroup must review the literature and consult with the CDC SMEs. The section could either provide less clarity, with more permissive language so that facilities decide how to manage these situations, or the Workgroup could review the literature and consult with the CDC SMEs to determine whether this recommendation is not necessary for covered zoster that can be contained under clothes, etc.

NIH noted that part of the calculus associated with work restrictions is risk communication strategies. For example, a different decision might be made for HCP providing care for immunocompromised children. It may be difficult to capture this nuance in a recommendation.

Dr. Babcock said that the Workgroup will revisit these questions and discuss them with the CDC Varicella SMEs.

Regarding *Occupational Exposures: Varicella and Disseminated Herpes Zoster*, CSTE expressed discomfort about the statement, “Brief, unprotected entry into a source patient’s room without touching the patient or surfaces is generally not considered an exposure.” Anecdotally, transmission has occurred in similar situations. Varicella is highly infectious through an airborne route.

Dr. Bell appreciated the clarity of the statement, but wondered if the issue could be framed with an element of risk stratification so that practical issues are clear; that is, many people do not need to be actively evaluated because the likelihood of transmission is low.

Dr. Babcock replied that the Workgroup hoped that the wording “generally not considered an exposure” would allow for facilities to conduct that type of risk assessment. The occupational health field focuses on defining what is, or is not, an exposure. Risk assessment is important for an individual, but the language regarding what is or is not considered an exposure is common. A statement such as, “Brief, unprotected entry into a source patient’s room does not generally result in transmission” should be supported by literature. The Workgroup can revisit this question and consider how to structure the language to incorporate higher- and lower-risk exposures.

Dr. Bell answered that revisions may not be necessary if the Workgroup is comfortable with the word “generally,” and that it is meaningful across the field.

While there was some HICPAC support that “generally” addresses the issue, it was suggested that the Workgroup consult with the CDC SMEs to clarify risks. If there is variability in risk, a tighter, more explicit, and more specific recommendation could reduce the variability that may cause risk. Conversely, if the risk with a covered lesion really is low, perhaps the recommendation could be more permissive.

AEH expressed a preference for a stricter recommendation to better guide frontline HCP. Vagueness is difficult when decisions are being made in the field.

PIDS emphasized that not all neonates, pregnant women, or immunocompromised persons of any age are susceptible. While it may not be known at the time whether someone is susceptible, allowing for local adjudication is important.

Dr. Bell commended the Workgroup for the clarity and forthrightness of the language in the drafts, which will be helpful for users.

Cytomegalovirus

HICPAC pointed out that the term “routine exclusion” is unclear and implies that in some situations, a person might be excluded in “non-routine exclusion.” The phrasing, “Exclusion is not necessary,” was suggested. NIH supported the phrasing change.

Parvovirus

HICPAC observed that the 2018 *Red Book* states that “Pregnant health care workers should be informed of the potential risks to their fetus from human parvovirus B19 infections and about preventive measures that may decrease these risks (eg, attention to strict infection control procedures and not caring for immunocompromised patients with chronic parvovirus B19 infection or patients with parvovirus B19-associated aplastic crises, because patients in both groups are likely to be contagious).” The *Red Book* language seems to push facilities toward excluding pregnant HCP. It also addresses steps to undertake if pregnant HCP are exposed to a patient who is infectious with parvovirus B19. Some may perceive these recommendations as pointing in different directions.

Dr. Bell wondered a statement could be made, either in this section or in Part 1 of the *Guideline*, that while a practice might not be necessary, factors other than infectious risk, such as willingness of staff to work, may need to be considered. If these factors are the rationale for a facility’s policy, it should be clear that the policy is not related to risk, but to accommodate community preference.

ACOEM agreed that adding words like “willingness” into the guidance leads to a “slippery slope.” The intention may be good to support local decision-making when staffing is adequate to support the decision; however, indicating that “healthcare willingness needs to be taken into account” establishes a standard of unwillingness.

Dr. Babcock said that Part 1 addresses the involvement of HCP in the development of policies and procedures, which represents an opportunity to reflect the HCP experiences and expectations. These issues apply beyond the Parvovirus and CMV sections.

HICPAC observed that the word “ensure” is used frequently in the document and suggested that the narrative provide examples of how to “ensure,” or refer to examples.

Dr. Babcock replied that Section 1 addresses education and counseling, including the structure of education delivery, to ensure that HCP are aware of risks.

HICPAC pointed out that many pregnant HCP are immune, so a subset of HCP would be considered susceptible. The statements about counseling, or seeing one’s obstetrician, is typical in some organizations.

As with CMV, HICPAC pointed out that the term “routine exclusion” is unclear and implies that in some situations, a person might be excluded in “non-routine exclusion.” The phrasing, “Exclusion is not necessary,” was suggested.

Conjunctivitis

No additional questions, comments, or suggestions.

Poliovirus

No additional questions, comments, or suggestions.

Vote: Diphtheria

The draft “Diphtheria” section was moved for approval as presented, with the exception of one edit: The Workgroup will review the phrasing of 1.b.2.b.2 to determine whether the language can be clarified. HICPAC voted unanimously to approve the draft section, with no opposition and no abstentions. The disposition of the vote was as follows:

- 11 Favored: Anderson, Babcock, Bryant, Daniels, Dekker, Fauerbach, Huskins, Maragakis, Patterson, Preas, Yokoe
- 0 Opposed
- 0 Abstained

Vote: *Streptococcus*, group A Infection

The draft “*Streptococcus*, Group A Infection” section was moved for approval as presented. HICPAC voted unanimously to accept the draft section, with no opposition and no abstentions. The disposition of the vote was as follows:

- 11 Favored: Anderson, Babcock, Bryant, Daniels, Dekker, Fauerbach, Huskins, Maragakis, Patterson, Preas, Yokoe
- 0 Opposed
- 0 Abstained

Monitoring Healthcare Water Quality: From Plumbing to Patients

Why Water Matters

Joseph F. Perz, DrPH, MA

Division of Healthcare Quality Promotion

National Center for Emerging and Zoonotic Infectious Diseases

Centers for Disease Control and Prevention

Dr. Perz provided an update on DHQP's Water Workgroup's activities.

Wet environments support microbial growth, and water organisms in healthcare are recognized as sources for antibiotic-resistant pathogens and HAIs. Tap water meets stringent quality and safety standards in the US, but it is not sterile. While water quality rarely poses a risk in residential and community settings, healthcare settings pose additional concerns because of vulnerable patient populations; large, complex distribution systems; and varied water uses that lead to unique exposure pathways.

Hospital water quality depends upon the quality of municipal water entering the facility. Because healthcare water systems are large and complex, the water standards set by EPA for water entering the facility may or may not be met by the water in taps that are often many feet "downstream" in the operating room (OR), patient rooms, dialysis unit, food services area, waiting areas, etc. Further, the healthcare facility eventually influences and impacts the broader environment as its water returns to the municipal treatment facility.

Interest in healthcare water quality has been driven by outbreaks involving *Legionella* and other pathogens. A helpful review of healthcare outbreaks associated with water reservoirs was published by the University of North Carolina (UNC) in [Clinical Infectious Diseases](https://www.ncbi.nlm.nih.gov/pubmed/26936670) (<https://www.ncbi.nlm.nih.gov/pubmed/26936670>) in 2016. This article highlighted possible reservoirs and prevention strategies. Risks are not limited to the water coming out of the tap; it is important to be mindful of waste water in sinks, sink drains, toilets, etc.

CDC reviewed of the agency's experience in "[Investigation of healthcare infection risks from water-related organisms: Summary of CDC consultations, 2014-2017](https://reference.medscape.com/medline/abstract/30942147)" (<https://reference.medscape.com/medline/abstract/30942147>), which was published in *ICHE*. Over a 4-year period, 22% (134) of DHQP's 620 consultations involved a water-related organism:

- 40 (30%) involved non-tuberculous mycobacteria (NTM)
- 45 (35%) involved MDROs
- 24 (18%) were surgery-related
- 40 (30%) involved medical devices
- 13 (10%) involved medication contamination

The article includes a table describing exposure pathways and routes of transmission. The information from consultations is not always complete, but it is possible to observe patterns.

The presentation of information from this article at the recent SHEA Conference was well-attended and included robust discussion regarding facility design and human factors issues. Questions addressed included, for example, "why do staff sometimes feel compelled to store important, critical equipment next to a sink?" In addition to common exposure pathways, other pathways are emerging, such as dental water lines associated with NTM outbreaks. Unique pathways are also observed, such as surgical personnel using a hot tub before going to work and subsequently shedding NTM into the OR environment. Thus, there is a lot to be thinking about when it comes to the risks to patients from water. Outbreak experiences collected by groups such as UNC and CDC will begin to inform a "Water Infection Control Risk Assessment."

Water Management Programs (WMPs) are receiving more attention, in large part due to a CMS memo issued in June 2017 reminding hospitals and nursing homes of WMP expectations. At about the same time, CDC's *Legionella VitalSigns*™ was released. Healthcare facilities, particularly hospitals, are expected to have a WMP in place, and it is expected that they undertake some form of risk assessment for *Legionella* and other opportunistic pathogens in the facility's water. Implementation of the WMP

management is expected to consider the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) industry standard and the [CDC Legionella Toolkit: Developing a Water Management Program to Reduce Legionella Growth and Spread in Buildings](https://www.cdc.gov/legionella/wmp/toolkit/index.html) (<https://www.cdc.gov/legionella/wmp/toolkit/index.html>). The toolkit was released in June 2017, at the same time as the CMS memo, and continues to be an important reference for all types of buildings in the US. It includes specific guidance for healthcare facilities.

To learn more about the current state of healthcare facility water management, questions were added to the NHSN Annual Hospital Survey in 2017 (n=4929). An analysis representing a baseline was presented recently at the SHEA Conference. The survey was completed within 6 to 9 months after the CMS memo was released. At that time, approximately 1 in 5 facilities responded that they did not have a WMP: this result is concerning. Of those that did report having a WMP, approximately 5 out of 6 responded that they had performed a facility risk assessment, indicating that there is room for improvement. The facility types with the highest reported WMPs included cancer hospitals (94%), children's hospitals (87%), and VA facilities (99%); 83% of general hospitals reported having a WMP.

The survey asked about the composition of the water management teams. Environmental and Facilities representatives were included on 98.6% of the teams. Epidemiology & Infection Control departments were represented on 83% of the teams: this group should be included on all teams.

The survey found variability in facility monitoring approaches, which is not surprising given the lack of clear guidance in this area. Approximately two-thirds of facilities reporting having a WMP reported measuring disinfectant somewhere in the building. Many facilities monitor temperature, although it is not clear where and how. Approximately one-third of facilities with a WMP perform heterotopic plate counts (HPCs), and approximately two-thirds monitor for *Legionella*. As expected, facilities reporting not having a WMP have lower rates of these types of monitoring.

A paradigm shift in thinking is needed regarding WMPs in healthcare. Decreasing the risks to patients from potable water contamination involves traditional water management program activities, but those activities are not sufficient to address the problem: it is also important to decrease vector and device contamination through appropriate use, cleaning, and disinfection. In addition, patient exposure and host susceptibility to contaminated water must be considered. A 2014 article in *ICHE* by Dale Krageschmidt and colleagues, "[A Comprehensive Water Management Program for Multicampus Healthcare Facilities](https://www.ncbi.nlm.nih.gov/pubmed/24709725)," (<https://www.ncbi.nlm.nih.gov/pubmed/24709725>) emphasizes using a hazard analysis to build a water program. The article defines 4 risk levels and describes how components of the hospital and outpatient facilities were assessed:

- Highest-Risk Area (eg, bone-marrow transplant (BMT) units, solid-organ transplants, hematology, and medical oncology)
- Higher-Risk Area (eg, nontransplant ICUs and ORs)
- Medium-Risk Area (eg, general medicine or surgery)
- Low-Risk Area (eg, a hospital waiting room)

The CDC/DHQP [Plumbing to Patients Website](https://www.cdc.gov/hai/prevent/water-management.html) (<https://www.cdc.gov/hai/prevent/water-management.html>) is growing, with frequent additions of resources and information:

- An investigation discussion guide, "Tap Water Quality and Infrastructure Discussion Guide for Investigation," recognizes that problems can arise even in a well-run WMP. If the program is working well, early signals of sentinel cases and clusters can be detected. The multi-page guide helps organize approaches to this type of investigation.

- DHQP developed the “[Healthcare Facility Water Management Program Checklist](https://www.cdc.gov/HAI/pdfs/Water-Management-Checklist-P.pdf)” (<https://www.cdc.gov/HAI/pdfs/Water-Management-Checklist-P.pdf>) with input from CDC colleagues.

The [VA Directive](https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3033) (https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3033) specifically addresses water monitoring in healthcare. The VA has mandated WMPs throughout its system. Incoming water is continuously monitored for pressure, pH, solids, oxidants, and specific cold and hot water temperature requirements. Tap water is tested quarterly for growth of *Legionella pneumophila*, residual disinfectant, and pH. Water is sampled from at least 10 outlets on the hot water distribution system and at least 10 outlets on the cold water distribution system, from each building, for each quarterly testing cycle. In general, the following minimum detected oxidant residual levels at hot and cold water outlets are suggested as guidance:

- 0.5 milligrams (mg) per liter (L) for chlorine (as free chlorine)
- 0.5 mg/L for monochloramine
- 0.3 mg/L for chlorine dioxide.

It is beneficial when WMPs develop a close partnership with water utilities. System disruptions or pressure drops, loss of disinfection residual, and main breaks can impact the quality of water within the healthcare system. Within healthcare facilities, monitoring and testing can help WMPs carefully assess premise plumbing to assure water quality and mitigate *Legionella* and other water-related infection risks. By focusing “downstream,” WMPs can work with infection control and clinical partners to examine exposure pathways (eg, ingestion, diet, hygiene, or clinical care), higher-risk patient populations, and surgery and medical device use.

Context for a Water Monitoring Framework

L. Clifford McDonald, MD

Division of Healthcare Quality Promotion

National Center for Emerging and Zoonotic Infectious Diseases

Centers for Disease Control and Prevention

Dr. McDonald shared draft documents for discussion and input.

The DHQP Evidence Review Team, led by Erin Stone, has extracted water management guidance from a number of national, international, and prominent organization products. This work is setting the context for articulating a minimum framework for monitoring water quality in healthcare facilities. The focus on water quality in healthcare facilities is monitoring for all-hazards infection risks, not just one pathogen.

The extractions incorporate both baseline monitoring and intervention-related guidance and include prominent US *Legionella*-focused healthcare guidance. When the resources are specific, they are specific regarding implementing an intervention to improve water quality and then monitoring its effectiveness. The extractions incorporate more than potable water in healthcare settings and include the “what, when, and how” of implementation and monitoring. The Framework will likely focus on potable water and will include thresholds or action limits, and corrective actions if limits are not met. The extraction tables will be published online to provide context for the Framework.

To date, the resources that were extracted or are proposed include:

- ASHRAE Guideline 12: Proposed Revision of Guideline 12-2000, Managing the Risk of Legionellosis Associated with Building Water Systems
- ASHRAE Guideline 12: Legionellosis: Risk Management for Building Water Systems **EXCLUDED**
- CDC Guidelines for Environmental Infection Control in Health-Care Facilities (2003)

- WHO Water safety in buildings
- UK National Health Service/ Department of Health: Water sources and potential *Pseudomonas aeruginosa* contamination of taps and water systems
- Health technical memorandum 04-01: Safe water in healthcare premises, Part A: Design, Installation, and Commissioning
- UK Department of Health: Health Technical Memorandum 04-01: Safe water in healthcare premises. Part B: Operational management
- VHA Directive 2061 (2014)
- Microbiological standards for water and their relationship to health risk
- International Society for Infectious Diseases, ISID Infection Guide 2018
- HACCP Plan for Prevention of Legionellosis Associated with Building Water Systems
- Health Protection Surveillance Centre: Guidelines for the Prevention and Control of Infection from Water Systems in Healthcare Facilities
- Experimental based experiences with the introduction of a water safety plan for a multi-located university clinic and its efficacy according to WHO recommendations (Dyck 2007)
- Technologies for Legionella Control in Premise Plumbing Systems: Scientific Literature Review
- Overview and Comparison of Legionella Regulations Worldwide (Kenhove 2018)*

The relationship between water quality and infection risk is not linear and is influenced by other factors, such as water uses and patient risk; however, there is an imperative to consider water quality.

The Safe Drinking Water Act, the EPA standard for drinking water throughout the US, identifies minimum standards for water quality. Water quality in healthcare facilities should be of at least similar grade and quality as is found in a municipal drinking fountain. Minimum standards for healthcare facilities are important for a number of reasons. Good-quality water may come into a facility, but the water coming out of the tap may not be of good quality. Water age degrades water quality. Water ages in pipes and is there in contact with biofilms. The surface area and intricacies of plumbing fixtures are mitigating factors.

Water Monitoring Implementation Framework for Healthcare Settings

Matthew J. Stuckey, PhD, MPH

Division of Healthcare Quality Promotion

National Center for Emerging and Zoonotic Infectious Diseases

Centers for Disease Control and Prevention

Dr. Stuckey shared the draft Water Monitoring Implementation Framework approach.

The first page of the draft provides an introduction and information about basic and enhanced monitoring. The second page describes considerations for the “What, When and Where” of monitoring implemented as part of a WMP in a healthcare setting. This Framework exists within the structure of CDC’s checklist on the Patients to Plumbing website. As such, water monitoring practices are informed by:

- Environmental assessments to identify where waterborne pathogens could grow and spread, and
- Water infection control risk assessments (WICRAs) to
 - Recognize modes of transmission for specific pathogens,
 - Identify patient groups at increased risk, and
 - Consider the likelihood of water exposures resulting in HAIs.

One of the goals of the Framework is to provide definitions of basic monitoring practices that should be incorporated into all WMPs in healthcare facilities. If a WICRA determines that patients receiving medical care in a facility are only at a minimal or moderate risk for waterborne pathogens, then basic monitoring practices alone may be sufficient for that facility's program.

Water temperature should be monitored as part of basic monitoring, and monitoring practices should consider state regulations or codes. The water temperature control limit in cold water distribution systems should be <60°F (<20°C), and the control limit in hot water distribution systems should be ≥124°F (≥51°C). These control limits are informed by the extractions performed by the Evidence Review Team.

The "what" of basic monitoring includes pH and residual water disinfectant. The control limit should be monitored at the point of facility entry for:

- Chlorine (0.2 mg/L–4.0 mg/L free chlorine)
- Monochloramine (0.5 mg/L–4.0 mg/L total chlorine)
- Chlorine Dioxide (0.2 mg/L–0.8 mg/L free chlorine).

The control limit at the point of use should be ≥ trace/detectable. The water pH control limit should be 6.5–8.5.

It is important to ensure that a WMP is effective and is operating as designed. In healthcare settings, basic monitoring practices should include clinical surveillance of HAIs caused by water-related organisms (eg, *Legionella*, *Pseudomonas*, *Acinetobacter*, *Burkholderia*, *Stenotrophomonas*, NTM) at control limits defined in a facility's WMP. Clinical surveillance of HAIs caused by waterborne organisms can be used to validate the WMP.

Basic monitoring practices should be performed at least quarterly, but may be performed more frequently for all or some parameters as defined in a facility's WMP. As noted earlier, monitoring should be performed at the point of entry into a facility and at least at 10 outlets on both the hot and cold water distribution systems. Sample locations should be informed by environmental assessments (eg, sites where stagnation and biofilm are more likely to occur). Monitoring at representative fixtures close to, and far from, the central distribution point is recommended.

Some healthcare facilities should incorporate enhanced monitoring in addition to basic monitoring practices. This enhanced monitoring may be performed across a facility or within specific locations, and may be performed routinely or only during limited time periods as defined by a certain event. An enhanced monitoring program may be appropriate for circumstances including, but not limited to:

- A WICRA determines that medical care is provided to patients with compromised immune status, comorbidities, and exposure to certain procedures who are more vulnerable to infections caused by waterborne pathogens
- Clinical surveillance identifies an increase in or cluster of infections in patients caused by water-associated pathogens
- Water monitoring identifies that control limits are not maintained
- A water supply event occurs, such as a water main break
- Construction, renovation, or facility maintenance occurs

In addition to the physical and chemical characteristics of water monitored under basic practices, enhanced monitoring may incorporate other parameters, potentially including, but not limited to:

- HPC testing, for which the control limit should be <500 CFU/mL or as defined in a facility's WMP. HPCs may be considered an indicator of water quality, and interpretation of laboratory results should be appropriate for testing methodologies.
- Environmental pathogen testing, for which control limits should be defined in a facility's WMP. Interpretation of laboratory results should be appropriate for testing methodologies.

If a facility's WMP includes enhanced monitoring practices, additional validation steps beyond clinical HAI surveillance, such as environmental pathogen testing, may be appropriate. The frequency of enhanced monitoring practices should be defined in a facility's WMP. If a WICRA identifies vulnerable patients in a facility, increased monitoring frequency may be warranted. Increased monitoring frequency may also be warranted if circumstances require corrective actions, such as if control limits are not being maintained. The appropriate frequency of environmental testing, such as for specific pathogens, should be defined in a facility's WMP. Monitoring additional locations, either across a healthcare facility or within specific areas, may be warranted.

The next steps for the draft Framework are to continue incorporating internal and external feedback. When the Framework is finalized, it will be posted with the WICRA on the "From Plumbing to Patients" website. Future plans include developing and piloting new practical water tools, and publishing annual NHSN survey data on WMPs.

Discussion Points

HICPAC expressed appreciation for the additional guidance and anticipated that it will be helpful. The proactive and "all hazards" approach is encouraging and represents the gold standard of infection prevention.

There was discussion regarding guidance for the use of tap water in the NICU, such as for bathing. This issue is important, and it is beyond the NICU Guideline Workgroup's scope.

Dr. Perz agreed that water uses in the NICU are important to examine, and a standard approach is needed. This work is a "marriage" of water management and infection control. Protocols that carefully outline water uses in the NICU and address practices such as breast milk and formula preparation, maintenance and cleanliness of sink and counter spaces, patient isolettes with water reservoirs, and other potential pathways should be examined.

Dr. McDonald agreed and added that outbreak investigations could potentially inform a checklist tool or other considerations. NICUs would be reflected in the higher-tier of enhanced monitoring.

Dr. Stuckey commented on internal discussions about mitigation, which could be addressed in a separate tool as part of a modular approach to a larger toolkit. Dr. Perz agreed that they could move toward modules that address different high-risk areas, such as BMT, organ transplant units, NICUs, etc.

NIH commented on the construction of newer hospitals. NIH's new hospital was designed with "green water management," which circulates water for a long period of time, allowing disinfectant to dissipate. That structure represents a challenge. Secondly, the water system was charged some time before the hospital was occupied and functional: the water "sat" in the plumbing, unused, for a long period, allowing for biofilm growth. NIH commented on infections caused by sink splatter and noted that environmental pathogens are important considerations.

Dr. Perz agreed that green construction is an important element of these discussions. Improvements in one area - energy efficiencies and decreased water use - can introduce hazards in other contexts in terms of infection risk. Dr. Deverick Anderson and his colleagues at Duke University have published on a sepsis outbreak that stemmed at least in part from new construction and green water technologies.

AAKP was pleased with the focus on immunocompromised, solid organ transplant, and dialysis patients. Other issues for consideration include natural or manmade disasters at the point of recovery, and how a large hospital or healthcare system is restored to the municipal water system, as in New Orleans after Hurricane Katrina. In addition, in the “push” for more dialysis in the home, high-volume hemodialysis and water usage are concerns. These trends are important for policy and industry to address. AAKP is concerned for patients who want to be mobile, but whose water systems are not good and who are not well-informed regarding appropriate precautions.

Dr. Perz said that these issues serve as a reminder that their work aims to address water quality in all healthcare settings, and anywhere that care is delivered. Existing guidance is available for disaster recovery. Dialysis water quality is a good model.

APIC expressed appreciation on behalf of APIC and IPs across the nation for the toolkit and WICRAs. The Cooling Technology Institute (CTI) could be an additional partner for CDC to reach contractors who provide the oxidant levels, disinfection, and monitoring for cooling towers, which have been associated with outbreaks. From a public health perspective, it would be beneficial to learn about ongoing work at institutions with cooling towers. In a cluster investigation, it can be resource-intensive for a facility to continue to perform testing when data are insufficient, and other organizations with cooling towers may be the culprits.

Dr. Perz noted that a good WMP is based on a facility’s unique characteristics, such as the presence of cooling towers. It is reasonable for a good maintenance and monitoring plan to include the cooling towers. New York City instituted initiatives to regulate cooling towers based on community outbreaks of *Legionella* several years ago.

HICPAC observed that *Legionella* issues have arisen even after rain and flooding; perhaps these weather events should be added to water main breaks as a trigger of higher levels.

HICPAC expressed concern regarding the potential for a facility to experience a cycle of testing and detecting issues that are outside of a healthcare facility’s control, if enough corrective activities are not included in the Framework.

Dr. McDonald answered that the draft Framework does not attend to corrective actions, but additional tools are planned for development. This document is designed to be brief. It mentions that corrective actions are situational-dependent and beyond its scope. One caveat, for example, is local code: a facility may not be able to reach identified thresholds if they are not in harmony with local code. It is not uncommon for a facility not to reach identified thresholds for water entering the building. The first dialogue should be with a facility’s water provider, particularly since healthcare facilities are often one of their biggest consumers and customers.

Dr. Perz added that some of the described interventions and remedies may not be high-tech and or resource-intensive. For example, a utility may provide an appropriate level of residual disinfectant, but quarterly monitoring finds that some outlets are not reaching those levels. One of the “interventions” would be to consider flushing and assessing use levels to ensure that enough water is flowing and to address potential stagnation.

In response to a HICPAC question about whether elements of infrastructure, such as aerators, electronic eye faucets, blind loops, dry drains, central sterile processing and steam water quality, etc, are addressed in other guidance, Dr. McDonald indicated that these elements would not be the central focus of a monitoring framework. However, it is important to note that infrastructure elements are spread across facilities. CDC’s “From Plumbing to Patient” website will address drains.

Dr. Perz added that other standards are applicable to the reprocessing of devices and instruments; it is hoped that those standards are incorporated into a WMP.

HICPAC observed that many of the examples of situations in which basic or enhanced monitoring should be implemented are activities that occur all of the time, such as renovation or construction and care for immunocompromised and high-risk patients. With that in mind, it is not entirely clear how the Framework might be applied.

Dr. Stuckey said that the Framework is intended to enable individual facilities to have discussions and make nuanced decisions, and to allow flexibility for certain types of facilities where basic monitoring alone might be appropriate.

Dr. Perz emphasized that the WMPs must ultimately be tailored to the facility, building on information from its WICRA and current conditions. Each facility may have a unique monitoring plan, but it is hoped that the plan will reflect the foundation of basic monitoring.

Dr. McDonald added that some of the enhanced monitoring practices could be done locally in instances of construction, for example. The entire facility may need to be monitored, but for a short period. The broader message, informed by the NHSN survey, is that many facilities, even those with a WMP, have not performed any monitoring.

Given that new construction and green certification can be problematic from a water perspective, HICPAC wondered about an opportunity for collaboration on an alternative green, or Leadership in Energy and Environmental Design (LEED), certification for healthcare facilities that would recognize the need for water movement, certain temperatures of water, etc.

Dr. McDonald agreed that this discussion could take place on another level. Additionally, it would be beneficial to understand usual water quality across US healthcare facilities. The VA's work is shedding light on its facilities.

CSTE suggested that applying a modular approach with additional guidance for high-risk patients, such as NICU patients, would be helpful. Regarding construction of green, lean, LEED-certified facilities, it would be beneficial to work with the Facility Guidelines Institute to be proactive as new facilities are constructed to incorporate what is known thus far.

HICPAC pointed out that even in older buildings, water utilization may be lower for a variety of reasons. For example, alcohol-based hand sanitizers are frequently used. Staff use pre-packaged wipes not only for convenience, but also because of concerns about water quality. These practices may perpetuate a continuous cycle of low water utilization. The quality of water entering some facilities is often poor. Some facilities may constantly conduct enhanced monitoring due to low water use, old infrastructure, public works infrastructure, etc. Poor water quality also impacts sterilization: it can require a great deal to achieve better quality water for a variety of activities. Emphasizing partnership with the public works infrastructure is important to help facilities receive the best water, and implementation guides would be helpful to add to this Framework.

Dr. McDonald noted problems with organisms in the p-trap in sink drains and in p-trap toilets. Organisms living in one sink seem to be detected in other sinks or drains in the same "stack" due to retrograde flow of organisms. It is known that MDROs are exiting facilities into the sewage stream, not only directly from patients, but also from these p-traps and low-flow drains (with insufficient slope or grade given water usage) that, together, become like "bioreactors" in the facility.

Day 2 Public Comment

Kevin Kavanagh, MD, MS

Health Watch USA

Dr. Kavanagh commented on the recommendations for nursing homes from the perspective of a caregiver of 2 elderly relatives, one of whom is in a memory unit of a nursing home. Drug-resistant bacteria do not “respect” CDC guidelines. He reinforced his comments from the prior day of the meeting, particularly the comments regarding MRSA carriers being more infective than those who have infections. He further advised that recommendations should be tailored to different types of nursing facilities, as the recommendations “cannot be used across the board.” In memory care units, patients share shoes, glasses, and beds. It is important to move away from thinking how to control pathogens in a single patient, and to approach a facility as an entire “microbiome” to be managed. Residents in nursing home facilities, such as memory care units, are there for the long term. Not only should risks during admission be assessed, but in addition, residents’ microbiomes should be tested, and compatible new patients should become co-residents. If they are not compatible, then the microbiome could be modified, or the resident could be placed in a compatible environment. This approach is a modified, less restrictive, “reverse quarantine strategy” which was used in the 1918 Spanish flu epidemic. Recommendations that “do less” in a high-risk environment that is ideal for breeding and spreading pathogens is unlikely to succeed and may place segments of the nursing home industry at risk, and may encourage hospitals to become less aggressive in MDRO management. Dr. Kavanagh observed that the term “enhanced contact precautions” is misleading and may encourage facilities not to isolate patients with MRSA carriage and infections. “Enhanced standard precautions” is a better term, but he supported adopting a different strategy altogether.

Dr. Kavanagh further encouraged HICPAC to support that FDA require all over-the-counter formulations of polymyxins, the “last line of defense” drugs for CRE colistins in this category, to become prescription-only. These drugs are commonly found in US medicine cabinets as Polysporin[®], triple antibiotic ointment, etc. This step would be a strong move forward in antibiotic stewardship.

Jonathan Cooper

Environmental Services Division, Orlando Health Central Hospital

Mr. Cooper is the Environmental Services Infection Prevention Liaison for the Environmental Services Division of Orlando Health. He focuses on, among other areas, ultraviolet disinfection and perioperative suite monitoring. He commended the work on Enhanced Barrier Precautions. As the work progresses into PPE in nursing homes and preventing the spread of MDROs, he suggested that the recommendations include departments specific to areas such as Support Services Groups, Environmental Services, Linen Service Divisions, and Facilities Engineering. Those divisions touch the patient environment several times per day and are a potentially large risk factor.

Regarding the NICU Guideline and NICU Core Practices, Mr. Cooper noted that Orlando Health’s Winnie Palmer facility is the fourth-largest NICU in the world. They are focused on proper cleaning and disinfection of surfaces in the NICU and on linens. Orlando Health uses a contract service vendor and considers how those linens are cleaned and brought to its facilities, and also how the facility stores them and transports them to the units. Orlando Health is also partnering with GE regarding isolette cleaning.

Mr. Cooper commented on the multidisciplinary actions of Orlando Health’s water management program. The program tries to “bring all of the players to the table.” The Environmental Services team has been asked to promote and think about water movement every day, such as by adding a 90-second flush on the toilet, turning on the faucet, and running the shower in the patient room. Their work includes providing a “script” to manage patient satisfaction, because in a facility with 800 beds and 800 toilets flushing several times a day, and 800 showers running, patients have questions about the procedures.

Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the May 16-17, 2019, meeting of the Healthcare Infection Control Practices Advisory Committee, CDC are accurate and complete.

Date

Deborah Yokoe, MD, MPH

Co-Chair, Healthcare Infection Control Practices Advisory
Committee, CDC

Date

Lisa Maragakis, MD, MPH

Co-Chair, Healthcare Infection Control Practices Advisory
Committee, CDC

Attachment #1: Acronyms Used in this Document

Acronym	Expansion
AAKP	American Association of Kidney Patients
ACIP	Advisory Committee on Immunization Practices
ACOEM	American College of Occupational and Environmental Medicine
AE	Adverse Event
AEH	America's Essential Hospitals
AHRQ	Agency for Healthcare Research and Quality
AMR	Antimicrobial Resistance
AORN	Association of periOperative Registered Nurses
APIC	Association of Professionals of Infection Control and Epidemiology
AR	Antibiotic Resistance
ARLN	Antibiotic Resistance Laboratory Network
ARSI	Antibiotic Solutions Initiative
ASHRAE	American Society of Heating, Refrigerating and Air-Conditioning Engineers
ASM	American Society for Microbiology
ASN	American Society of Nephrology
ASR	Alternative Summary Reporting
ASTHO	Association of State and Territorial Health Officials
BAA	Broad Agency Announcements
BMT	Bone-Marrow Transplant
BSI	Bloodstream Infection
<i>C. auris</i>	<i>Candida auris</i>
<i>C. difficile</i>	<i>Clostridioides difficile</i>
CARB	Combating Antibiotic-Resistant Bacteria
CAUTI	Catheter-Associated Urinary Tract Infection
CDC	Centers for Disease Control and Prevention
CDPH	California Department of Public Health
CDRH	Center for Devices and Radiological Health (FDA)
CFU	Colony-Forming Unit
CLABSI	Central Line-Associated Bloodstream Infection
CMS	Centers for Medicare and Medicaid Services
CMV	Cytomegalovirus
CORHA	Council for Outbreak Response: Healthcare-Associated Infections and Antibiotic-Resistant Pathogens
CRBSI	Catheter-Related Bloodstream Infection
CRE	Carbapenem-Resistant <i>Enterobacteriaceae</i>
CSTE	Council of State and Territorial Epidemiologists
CTI	Cooling Technology Institute
CUSP	Comprehensive Unit-based Safety Program
DASON	Duke Antimicrobial Stewardship Outreach Network
DCASIP	Duke Center for Antimicrobial Stewardship and Infection Prevention
DFO	Designated Federal Official
DHQP	Division of Healthcare Quality Promotion
DICON	Duke Infection Control Outreach Network

Acronym	Expansion
DoD	Department of Defense
DTBE	Division of Tuberculosis Elimination
<i>E. coli</i>	<i>Escherichia Coli</i>
EHR	Electronic Health Record
EIP	Emerging Infections Program
ELC	Epidemiology and Laboratory Capacity
EPA	Environmental Health Protection Agency
EtO	Ethylene Oxide
FDA	(United States) Food and Drug Administration
GAO	Government Accountability Office
GI	Gastrointestinal
HAI	Healthcare-Associated Infection
HCP	Healthcare Personnel
HCW	Healthcare Worker
HHS	(United States Department of) Health and Human Services
HICPAC	Healthcare Infection Control Practices Advisory Committee
HLD	High-Level Disinfection
HPC	Heterotrophic Plate Count
HRSA	Health Resources and Services Administration
ICHE	Infection Control and Hospital Epidemiology
IDSA	Infectious Diseases Society of America
IGRA	Interferon-Gamma Release Assays
IP	Infection Preventionist
IPC	Infection Prevention and Control
LEED	Leadership in Energy and Environmental Design
LTBI	Latent Tuberculosis Infection
LTCF	Long-Term Care Facility
MALDI-TOF	Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry
MAUDE	Manufacturer and User Facility Device Experience Database
MDR	Medical Device Reports
MDRO	Multidrug-Resistant Organism
MERS	Middle East Respiratory Syndrome
<i>MMWR</i>	<i>Morbidity and Mortality Weekly Report</i>
MRSA	Methicillin-Resistant <i>Staphylococcus aureus</i>
MSSA	Methicillin-Susceptible <i>Staphylococcus aureus</i>
NACCHO	National Association of County and City Health Officials
NARMS	National Antimicrobial Resistance Monitoring System
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NDM	New Delhi beta-lactamase-producing <i>Enterobacteriaceae</i>
NHSN	National Healthcare Safety Network
NICU	Neonatal Intensive Care Unit
NIH	National Institutes of Health
NTCA	National Tuberculosis Controllers Association
NTM	Non-Tuberculous Mycobacteria
OGHA	Office of Global Health Affairs

Acronym	Expansion
OHS	Occupational Health Services
OR	Operating Room
OSHA	Occupational Safety and Health Administration
<i>P. aeruginosa</i>	<i>Pseudomonas Aeruginosa</i>
PACCARB	Presidential Advisory Council on Combating Antibiotic Resistant Bacteria
PCR	Polymerase Chain Reaction
PEP	Post-Exposure Prophylaxis
PHAC	Public Health Agency of Canada
PICC	Peripherally Inserted Central Catheter
PIDS	Pediatric Infectious Disease Society
PMA	Premarket Approval
PPD	Purified-Protein Derivative
PPE	Personal Protective Equipment
RCT	Randomized Controlled Trial
<i>S. aureus</i>	<i>Staphylococcus Aureus</i>
SARS	Severe Acute Respiratory Syndrome
SCCM	Society of Critical Care Medicine
SESIP	Sharps with Engineered Sharps Injury Protection
SHEA	Society for Healthcare Epidemiology of America
SME	Subject Matter Expert
SNF	Skilled Nursing Facilities
SSI	Surgical Site Infection
TB	Tuberculosis
TST	Tuberculin Skin Test
UCSD	University of California, San Diego
UK	United Kingdom
UNC	University of North Carolina
UNGA	United Nations General Assembly
US	United States
USDA	United States Department of Agriculture
UVC	Umbilical Vein Catheter
VA	(United States Department of) Veterans Affairs
VRE	Vancomycin-Resistant Enterococci
VZIG	Varicella Zoster Immune Globulin
WHO	World Health Organization
WICRA	Water Infection Control Risk Assessments
WMP	Water Management Program

Attachment #2: *ex officio* Member and Liaison Representative Reports

Liaison Representative Report

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC) Centers for Disease Control and Prevention

Meeting Date: May 16-17, 2019
Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA
Liaison Representative: Mr. Paul T. Conway, Chair, Policy and Global Affairs
Organization represented: **American Association of Kidney Patients (AAKP)**

Interim Activities and Updates: (Past Six Months)

- In 2019, the AAKP awarded the CDC ***Making Dialysis Safer Coalition*** its 2019 Jenny Kitsen Patient Safety Grant Award – which provided grant funds to develop a patient safety/infection video (currently in production).
- In 2018, Dr. Priti Patel (an AAKP 2016 National Public Servant Award recipient), provided a presentation on public health and infection safety initiatives that improve the lives of kidney patients, especially those in the dialysis center setting, at the Inaugural AAKP National Policy Summit, attended by Congressional staff and Administration officials.

(Historic Notes & Context)

- AAKP was a founding partner of the CDC Making Dialysis Safer Coalition
- AAKP and CDC released (Sept. 2016) the co-branded *Conversation Starter to Prevent Infections in Dialysis Patients*. AAKP assisted in the creation of the document by coordinating a number of regional and national patient focus groups designed to offer patient input and practical insights on a variety of infection-related issues dialysis centers and patients confront on a daily basis. The most common and pressing concerns were used as the basis of the *Conversation Starter to Prevent Infections in Dialysis Patients*. The tool is now a highly popular way for patients and family members to initiate a discussion with dialysis facility staff about steps the facility takes to prevent infections
- The CDC has presented on infection prevention initiatives (inside and outside the dialysis facility) at every AAKP National Patient Meeting since 2015 – these are the largest kidney patient meetings in the United States.
- Since 2014, AAKP has regularly featured the mission and work of the CDC professional staff on its national social media platforms (Facebook @kidneypatient; Twitter @kidneypatients) and in its national bi-monthly magazine, aakpRENALIFE as means of highlighting the agency and building patient awareness and trust of CDC messaging on flu prevention, infection control standards and immunization best practices.

(AAKP Strategic Operations)

As part of AAKP's National Strategy, the Association developed and operates under two Centers:

- ***The Center for Patient Engagement & Advocacy:*** The Center for Patient Engagement and Advocacy works to engage, train, certify and activate kidney patients in ways that are the most effective at elevating the patient voice locally, nationally and on Capitol Hill. Major programs in this Center include the AAKP Ambassador Initiative with over 100 Ambassadors in nearly 50

states (<https://aakp.org/fellow-patients/>) and AAKP's Action Center (<https://aakp.org/action-center/>).

- **The Center for Patient Research & Education:** The Center for Patient Research and Education brings together all of AAKP's efforts to build existing and emerging patient education programs and research activities. Education is a simple and effective way to improve overall health and achieve better outcomes for patients. AAKP creates programs and materials, that are current, relevant and that address the most pressing issues patients and families face. In addition, AAKP has created a sophisticated database and expansive social media channels which allow the Association to better connect and learn from its constituents. In turn, AAKP provides education to patients and caregivers on what it means to be involved in research initiatives as well as opportunities to get involved in research to spur innovation. AAKP patients are driving research by providing qualitative and quantitative data on patient preference, perception and risk tolerance for new and innovated therapies.

Guidelines and Guidance:

Please include products that are in progress and planned for the coming year. Include Web links if appropriate.

- National Flash Survey of kidney patients (CKD, pre-dialysis, dialysis and transplant patients) is currently in the field gaining unique kidney patient insights on the measles issues, patient concerns and how proactive the medical community and patients have been in securing additional information about measles and immunosuppressed status.

Position Statements:

- AAKP formally endorses the full utilization of vaccines and immunizations, as recommended with CDC national guidelines and in coordination with transplant and nephrology teams, for all kidney patients, their families and their workplace colleagues as both a public health and a workforce protection measure.
- AAKP works very closely with the U.S. Secretary of Health and Human Services to expand transparency in drug pricing to commercially advertised prescription drugs, consistent with AAKP policy that informed patients are wise consumers of health care in their own right.
- AAKP worked closely with the U.S. Secretary of Labor and the U.S. Department of Labor to extend Family Medical Leave Act to organ donors. AAKP continues to educate the Congress on the importance of this policy, and supports Congressional efforts of the past 10 years to achieve passage of a similar policy.
- AAKP is opposed to Federal efforts, first announced in 2014, to remove patient consumer access to over-the-counter extra-strength acetaminophen and is a founding member of the 19-organization strong Patient Access to Pain Relief (PAPR) national coalition. Kidney patients cannot take NSAIDs and acetaminophen, safely dosed, remains the top recommended pain and fever relief option for the kidney consumer population.

Legislation:

- AAKP supports the Living Donor Protection Act
- AAKP supports a legislative effort (no bill introduced in current Congress) to extend Immunosuppressant Drug Coverage to kidney transplant patients beyond the current 36-month limit.
- AAKP has actively opposed the dialysis-industry sponsored Dialysis Patients Demonstration Act for the past three years on the basis it limits patient care choice via mandatory enrollments in

puts the dialysis industry in charge of kidney transplantation. AAKP patient members helped defeat this bill three times – and AAKP is in the process of educating the current Congress of patient concerns regarding re-introduction.

Campaigns and Related Activities:

- AAKP Inaugural Global Summit on Kidney Disease, a collaboration of AAKP and the George Washington University School of Medicine and Health Sciences (May 21-23, 2019 in Washington, D.C.)
- AAKP Second Annual Policy Summit (June 19-20, 2019 in Washington, DC)
- AAKP 2019 National Patient Meeting (Sept. 6-8, 2019 in Washington, DC)

Press Activities:

- AAKP conducts over 20 national media and background briefings per month on issues related to health policy, patient engagement, legislation and regulations that potentially impact patient health and public health outcomes.
- Our recent release referencing the CDC is here: <https://aakp.org/press-release/jenny-kitsen-patient-safety-award-recipient-grant-cycle-2019/>

Publications:

Over the course of the past year, AAKP national leadership has had multiple editorials published in the *Clinical Journal of the American Society of Nephrology*:

- AAKP National Ambassador Nichole Jefferson: *A Patient's View on Exercise and ESKD* <https://cjasn.asnjournals.org/content/14/2/171>
- AAKP National Ambassador Jonathan Haydak: *Patient Priorities for Research Involving Peritoneal Dialysis* <https://cjasn.asnjournals.org/content/14/1/3>
- AAKP Board Member Edward V. Hickey III: *12 Tips to Nephrology Teams Supporting Patients with Advanced Kidney Disease* <https://cjasn.asnjournals.org/content/13/7/971>
- AAKP Board Member Dave White: *Appropriate Use of Opioids in Patients with Kidney Diseases* <https://cjasn.asnjournals.org/content/13/5/675>
- AAKP Board Member Richard Knight: *An Evolving Continuum of Care for the Kidney Disease Patient Will Help the Transplant Center Patient Navigator* <https://cjasn.asnjournals.org/content/13/4/519>
- AAKP Board Member Kevin Fowler: *Accountability of Dialysis Facilities in Transplant Referral* <https://cjasn.asnjournals.org/content/13/2/193>
- AAKP Board Member BOD Paul T. Conway: *Trust Patient Insights at Both the Individual and National Level* <https://cjasn.asnjournals.org/content/13/1/1>
- AAKP Board Member Paul T. Conway & AAKP Board Member Kevin Fowler: *The New HHS Kidney Innovation Accelerator* <https://cjasn.asnjournals.org/content/13/11/1747>

Other Items of Note:

- AAKP HealthLine webinar: Hepatitis C (<https://www.gotostage.com/channel/6927452477730326277/recording/978b61d151654779bf4efd88b04ea345/watch?source=CHANNEL>)
- AAKP HealthLine webinar: Making Dialysis Safer for Patients: (<https://www.gotostage.com/channel/6927452477730326277/recording/b5ede0fa03964189a4b61893776fd8b4/watch?source=CHANNEL>)

Liaison Representative Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: May 16-17, 2019

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison Representative name: Mark Russi, MD, MPH

Organization represented: **ACOEM**

Interim activities and updates:

- ACOEM has issued additional guidance documents since the last meeting of HICPAC. In addition, public commentary has been made on a number of issues.
- ACOEM members are currently collaborating with NTCA on a companion document to be published in JOEM after new CDC guidance applicable to tuberculosis surveillance among healthcare workers is released.
- ACOEM voiced its support for H.R.1309, the Workplace Violence Prevention for Health Care and Social Service Workers Act on April 14, 2019.
- The ACOEM national meeting was held in Anaheim April 27-May 2. Scientific sessions with bearing upon medical center occupational health (MCOH) included offerings addressing the implementation of forthcoming CDC guidance for tuberculosis in healthcare settings, musculoskeletal injury, assaults among healthcare workers, mental health in the workplace, opiate abuse in the workplace, occupational health among animal care workers, burnout and depression among clinicians, safe handling of hazardous drugs, NIOSH health hazard evaluations and OSHA worksite inspections. An update to the Guidance for Occupational Health Services in Medical Centers was approved, incorporating a new section to address physician burnout and depression.

Guidelines and Guidance:

- Diagnostic Tests for Low Back Disorders 4/05/19
- Nanotechnology and Health 3/13/19
- Arsenic Exposure, Assessment, Toxicity, Diagnosis, and Management 12/10/2018
- Occupational Noise-Induced Hearing Loss 9/28/2018
- The Role of the Professional Supervisor in the Audiometric Testing Component of Hearing Conservation Programs 9/27/2018
- Fitness-for-Duty Assessments of Industrial Firefighters: Guidance for Occupational Medicine Physicians 2/10/2018
- Responsibilities of the Occupational and Environmental Medicine Provider in the Treatment and Prevention of Climate Change-Related Health Problems 2/8/2018
- Obesity in the Workplace: Impact, Outcomes, and Recommendations 1/30/2018
- Guidance for Occupational Health Services in Medical Centers 4/19/2017
- Global Trends in Occupational Medicine 3/15/2017

Position Statements:

- Patient Satisfaction Measurement in Occupational and Environmental Medicine Practice 5/11/2018
- Utilization Review in Worker's Compensation 10/31/2017

- Interaction of Health Care Worker Health and Patient Health and Safety in the US Health Care System: Recommendations From the 2016 Summit 8/29/2017
- The Personal Physician's Role in Helping Patients with Medical Conditions Stay at Work or Return to Work 6/12/17
- Advancing Value-Based Medicine: Why Integrating Functional Outcomes with Clinical Measures is Critical to our Health Care Future 4/14/2017

Legislation:

- ACOEM Voices Support for H.R.1309, the Workplace Violence Prevention for Health Care and Social Service Workers Act 4/14/2019
- ACOEM Responds to HHS Call for Comments on Pain Management Draft Report 4/02/2019
- ACOEM Comments on OSHA's Proposed Revisions to the Beryllium Standard 2/27/19
- ACOEM Comments on Healthy People 2030 1/21/2019
- ACOEM Addresses Proposed Rule Changes to Allow Teens to Use Patient Lifts in Health Care Settings 12/1/2018
- ACOEM Responds to OSHA Proposed Rulemaking on Tracking Workplace Injuries/Illnesses 10/2/2018
- ACOEM Responds to Proposed Changes to 2019 Medicare Physician Fee Schedule 9/21/2018
- ACOEM Expresses Concerns to EPA Regarding Agency's Proposed Rule on Strengthening Transparency in Regulatory Science 7/12/2018 ACOEM Comments to FDA on Opioid Prescribing Activity 3/21/2018
- ACOEM Applauds Proposed Legislation to Combat Opioid Epidemic 12/5/2017
- ACOEM Issues Commitment Statement on NAM Action Collaborative on Clinician Resilience and Well-being 12/5/2017
- ACOEM Urges DOT to Rescind Portion of Its Final Rule (49CFR Part 40) on Drug-Testing Procedures 12/1/2017
- ACOEM responded to proposed revisions to Medicare Physician Fee Schedule. 9/18/2017
- ACOEM commented on future direction of OSHA Voluntary Protection Programs. 9/11/2017
- ACOEM objected to proposed changes to EPA National Ambient Air Quality Standard. 9/7/2017
- ACOEM commented on OSHA proposal to revoke ancillary provisions of Beryllium Rule for Construction and Shipyards. 8/29/2017
- ACOEM issued statements urging Congress to maintain NIOSH funding, and supporting a proposed OSHA Standard addressing workplace violence. 4/26/2017

Campaigns and related activities:

Press activities:

- High Rate of Drug/Alcohol-Related Deaths in WTC Survivors 10/22/2018
- Computer Prompts to Take Breaks from Sitting Lead to Lower Blood Pressure 9/20/2018
- Time for Employers to Consider Social Determinants of Health 8/24/2018
- Wisconsin Physician New President of Occupational Medical Society 7/22/2018
- Defining Worker Well-Being – Experts Propose New Framework 7/20/2018
- Higher 'Culture of Health' Scores Linked to Lower Health Care Cost Trends 6/28/2018
- 'Productive Aging' Is Key to Addressing the Aging Workforce 5/31/2018
- 'Call to Action' on Mental Health and Well-Being in the Workplace 4/12/2018
- Concussions Are Common in Theater Workers 3/15/2018

- Nurses in Worse Health Make More Medical Errors 2/22/2018
- Managing Obesity in the Workplace – New Guidance from ACOEM 1/8/2018
- Influenza Leads to Increased Missed Work Time 12/7/2017
- New Compendium Highlights Development of Clinical Decision Support to Enhance Worker Health 11/17/2017
- 'Khamisiyah Plume' Linked to Brain and Memory Effects in Gulf War Vets 10/11/2017
- Occupational Health and the Arts -- Special Report in JOEM 9/21/2017
- ACOEM Urges OSHA Not to Revoke Ancillary Provisions of Beryllium Rule 9/1/2017
- ACOEM Disappointed DOT Has Withdrawn Proposed Rule to Screen Safety-Sensitive Personnel for Obstructive Sleep Apnea 8/21/2017
- Test May Help Identify Veterans with Deployment-Related Lung Disease 8/17/2017
- CDC Program Helps Smaller Companies Invest in Employee Health 7/14/2017 High Risk of Obstructive Sleep Apnea in Commercial Drivers 6/19/2017

Publications:

- As above

Other items of note:

Forthcoming guidance for management of tuberculosis surveillance in medical centers was discussed at the meeting of ACOEM's Medical Center Occupational Health Section. USP 800 and the need to comment upon medical surveillance recommendations applicable to those with potential for hazardous drug exposure were also discussed.

Liaison Representative Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: May 16-17, 2019

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison Representative name: Christopher Lombardozi, MD

Organization represented: **America's Essential Hospitals**

Interim activities and updates:

Guidelines and Guidance:

Position Statements:

Legislation:

Campaigns and related activities:

- In late February, America's Essential Hospitals launched a member awareness and unity campaign on social media with the hashtag **#WeAreEssential**. The campaign is primarily to educate members of Congress—especially the many new faces—about our hospitals and what it means to be essential. We've asked our hospitals to tag their members of Congress in social posts and to emphasize their work in the community to expand access to care and improve population health.
- America's Essential Hospitals continues to be a partner organization in the U.S. Stakeholder Forum on Antimicrobial Resistance (S-FAR), convened by the Infectious Diseases Society of America (ISDA), to support the principles that antimicrobial resistance (AR) is an urgent problem and to work with stakeholders from all industries to help inform policy and create awareness.

Press activities:

- America's Essential Hospitals actively promotes CDC information to our members via social media and through our website on timely topics such as updated vaccination guidance for at-risk groups for Hepatitis A, and recent educational webinar on cultural competency in preparedness planning. For this information and more, you can follow us on Twitter at @OurHospitals and on Facebook at facebook.com/essentialhospitals or visit our website at www.essentialhospitals.org.

Publications:

- **AMR Webinar (late July 2019)** – America's Essential Hospitals, along with the National Association of County and City Health Officials (NACCHO), will hold a webinar on collaborative efforts taking place between essential hospitals and their county health departments to combat antibiotic resistance. The webinar will showcase one California essential hospital and its county health department. Speakers will discuss lessons learned from their collaboration, as well as state and local funding that help make this work possible.
- **Population Health** – Essential hospitals around the country are targeting population health in their communities. The Essential Hospital's Institute has a [website](http://www.essentialcommunities.org)—www.essentialcommunities.org—to highlight the work of our members and provide resources

on public health partnerships, care coordination approaches, and data integration strategies to guide public health efforts.

Ex Officio Member Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: May 16-17, 2019

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Ex officio member name: Melissa A. Miller, MD, MS

Agency represented: **Agency for Healthcare Research and Quality**

Interim activities and updates:

- National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB)

AHRQ continues to support research and implementation projects to develop improved methods and tools to combat antibiotic resistance in three major domains: 1. Promoting antibiotic stewardship (AS); 2. Preventing transmission of resistant bacteria; and 3. Preventing healthcare-associated infections (HAIs) in the first place. These projects are combating antibiotic resistance in multiple healthcare settings: acute care hospitals, long-term care, and ambulatory care. AHRQ is participating in the working group to develop the next iteration of the National Action Plan.

- AHRQ Safety Program for Improving Antibiotic Use

The AHRQ Safety Program for Improving Antibiotic Use kicked off a one-year cohort of over 480 long-term care facilities in December 2018. An acute care cohort of the AHRQ Safety Program for Improving Antibiotic Use was completed in November 2018, with over 400 hospitals participating, including 80 critical access hospitals and 6 DoD facilities. An educational toolkit focused on this setting will be released in the coming year. An ambulatory cohort is planned to begin in December 2019. The AHRQ Safety Program for Improving Antibiotic Use is funded and guided by AHRQ, and led by Johns Hopkins University and NORC at the University of Chicago. This is a 5-year nationwide project aimed at adapting the Comprehensive Unit-based Safety Program (CUSP) for implementation of Antibiotic Stewardship in 250-500 acute care hospitals, 250-500 long-term care facilities, and 250-500 ambulatory care settings (i.e., clinics, physician's offices, and urgent care centers). This is a collaborative effort that is consistent with CDC Core Elements of Antibiotic Stewardship and involves coordination with CDC and CMS. The project aims to have a significant impact through the overall increase in AS activities it will produce.

- AHRQ Safety Program for Improving Surgical Care and Recovery

The AHRQ Safety Program for Improving Surgical Care and Recovery, a collaborative program to enhance the recovery of surgical patients, is a program funded and launched by AHRQ that is being conducted by Johns Hopkins University with partners including the American College of Surgeons. The program aims to use an adaptation of CUSP to improve patient outcomes by increasing the implementation of evidence-based enhanced recovery practices in hospitals. Enhanced recovery pathways include preoperative, intra-operative, and postoperative practices that can decrease complications, including surgical site infections, and accelerate recovery. This 5-year project aims for implementation in 750 hospitals nationwide, addressing a variety of surgeries in a phased approach. To date, more than 290 hospitals have been participating. Colorectal surgery was the initial focus starting with the first cohort of hospitals. Orthopedic surgery has been added starting with the second cohort. Gynecologic surgery has been added in the third cohort which began in March 2019.

- AHRQ Safety Program for Intensive Care Units (ICUs): Preventing CLABSI and CAUTI

The AHRQ Safety Program for Intensive Care Units (ICUs): Preventing CLABSI and CAUTI launched a fifth cohort of 150 ICUs in January 2019. Initiated in September 2015, this project aims to reduce central-line

associated bloodstream infections (CLABSI) and catheter-associated urinary tract infections (CAUTI) in ICUs with persistently elevated rates of these infections. This is a follow-up to AHRQ's nationwide projects of CUSP for CAUTI and CUSP for CLABSI. Implementation strategies tailored to such ICUs continue to be developed, including a modified set of CUSP training resources. Over 500 ICUs have been recruited to participate nationwide. An additional one-year cohort is planned in early 2020.

Publications:

Selected AHRQ-funded Publications:

- Colborn KL, Bronsert M, Hammermeister K, Henderson WG, Singh AB, Meguid RA. Identification of urinary tract infections using electronic health record data. *American journal of infection control*. 2018.
- Davis KK, Mahishi V, Singal R, et al. Quality Improvement in Ambulatory Surgery Centers: A Major National Effort Aimed at Reducing Infections and Other Surgical Complications. *Journal of clinical medicine research*. 2019;11(1):7-14.
- Gerber JS, Ross RK, Szymczak JE, et al. Infections after pediatric ambulatory surgery: Incidence and risk factors. *Infection control and hospital epidemiology*. 2019;40(2):150-157.
- Gross AE, Hanna D, Rowan SA, Bleasdale SC, Suda KJ. Successful Implementation of an Antibiotic Stewardship Program in an Academic Dental Practice. *Open forum infectious diseases*. 2019;6(3):ofz067.
- Huang SS, Singh R, McKinnell JA, et al. for the Project CLEAR Trial. Decolonization to Reduce Postdischarge Infection Risk among MRSA Carriers. *The New England journal of medicine*. 2019;380(7):638-650.
- Kempker JA, Kramer MR, Waller LA, Martin GS. Risk Factors for Septicemia Deaths and Disparities in a Longitudinal US Cohort. *Open forum infectious diseases*. 2018;5(12):ofy305.
- Kempker JA, Kramer MR, Waller LA, Wang HE, Martin GS. State-level hospital compliance with and performance in the Centers for Medicaid & Medicare Services' Early Management Severe Sepsis and Septic Shock Bundle. *Critical care (London, England)*. 2019;23(1):92.
- Khamash DF, Mongodin EF, White JR, et al. The Association Between the Developing Nasal Microbiota of Hospitalized Neonates and *Staphylococcus aureus* Colonization. *Open forum infectious diseases*. 2019;6(4):ofz062.
- Liang SY, Jansson DR, Hogan PG, et al. Emergency Department Environmental Contamination With Methicillin-Resistant *Staphylococcus aureus* After Care of Colonized Patients. *Annals of emergency medicine*. 2019.
- Monsees EA, Tamma PD, Cosgrove SE, Miller MA, Fabre V. Integrating bedside nurses into antibiotic stewardship: A practical approach. *Infection control and hospital epidemiology*. 2019:1-6.
- Morgan JR, Carey KM, Barlam TF, Christiansen CL, Drainoni ML. Inappropriate Antibiotic Prescribing for Acute Bronchitis in Children and Impact on Subsequent Episodes of Care and Treatment. *The Pediatric infectious disease journal*. 2019;38(3):271-274.
- Rhee C, Jentzsch MS, Kadri SS, et al. Variation in Identifying Sepsis and Organ Dysfunction Using Administrative Versus Electronic Clinical Data and Impact on Hospital Outcome Comparisons. *Critical care medicine*. 2018.
- Rhee C, Jones TM, Hamad Y, et al. Prevalence, Underlying Causes, and Preventability of Sepsis-Associated Mortality in US Acute Care Hospitals. *JAMA network open*. 2019;2(2):e187571.
- Rhee C, Wang R, Jentzsch MS, et al. Comparison of hospital surgical site infection rates and rankings using claims versus National Healthcare Safety Network surveillance data. *Infection control and hospital epidemiology*. 2018:1-3.

- Rhee C, Zhang Z, Kadri SS, et al. Sepsis Surveillance Using Adult Sepsis Events Simplified eSOFA Criteria Versus Sepsis-3 Sequential Organ Failure Assessment Criteria. *Critical care medicine*. 2019;47(3):307-314.
- Sick-Samuels AC, Woods-Hill CZ, Fackler JC, et al. Association of a blood culture utilization intervention on antibiotic use in a pediatric intensive care unit. *Infection control and hospital epidemiology*. 2019;40(4):482-484.
- Tamma PD, Miller MA, Cosgrove SE. Rethinking How Antibiotics Are Prescribed: Incorporating the 4 Moments of Antibiotic Decision Making Into Clinical Practice. *Jama*. 2018.
- Wilmont S, Hessels AJ, Kelly AM, Larson EL. Family Experiences and Perspectives on Infection Prevention in Pediatric Long-Term Care. *Rehabilitation nursing : the official journal of the Association of Rehabilitation Nurses*. 2018;43(6):307-314.

Liaison Representative Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Report Date: 4/30/19

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison Representative name: Holly Carpenter

Organization represented: **American Nurses Association**

Interim activities and updates:

- ANA signed on to the National Adult and Influenza Immunization Summit's Quality and Performance Measurement Working Group letter urging inclusion of the maternal and adult immunization composite measures as part of the Medicaid Child and Adult Core Sets.
- Currently updating [ANA Immunization webpages](#) and [Infection Prevention & Control webpages](#)
- ANA recently reinstated funding for an ANA member to attend the ACIP meetings in person.
- ANA is an active participant in the Sharps Injury Prevention Work Group which meets quarterly via teleconference.
- ANA participates in the weekly National Adult and Influenza Immunization Summit calls and the monthly National Adult and Influenza Immunization Summit's Organizing/Steering Committee meeting time permitting.

Guidelines and Guidance:

Please include products that are in progress and planned for the coming year. Include Web links if appropriate.

- No updates at this time.

Position Statements:

- No updates at this time.

Legislation:

- On February 27, 2019, the Oversight and Investigations Subcommittee of the House Committee on Energy & Commerce held a hearing regarding ongoing measles outbreaks affecting certain in the United States. ANA sent a letter to the Subcommittee Chair and Ranking Member regarding our position on vaccines: [E and C Measles Letter 2019.02.28 FINAL](#)

Campaigns and related activities:

- Active participant in Infant Immunization Week: used graphics and blurbs from toolkit in multiple ANA and Healthy Nurse, Healthy Nation social media and e-newsletters

Press activities:

- No updates at this time.

Publications:

- No updates at this time.

Other items of note:

- No updates at this time.

Liaison Representative Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: May 16-17, 2019

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison Representative name: Karen deKay

Organization represented: **AORN**

Interim activities and updates:

- Revised AORN Evidence Model to align with the CDC Infection Prevention and Control Recommendation Categorization Scheme. We utilized the new model in the revised Guideline for Surgical Attire and Prevention of Hypothermia and will apply new format to all guidelines for the 2020 print book, which will be electronically released throughout 2019.
- ECRI Guidelines Trust has accepted 27 AORN guidelines for inclusion.

Guidelines and Guidance:

- AORN guidelines are available in print and through electronic access. Information on how to obtain the guidelines can be found at www.aorn.org.
- Guidelines are posted for a 30-day public comment period at www.aorn.org
- The 2019 *Guidelines for Perioperative Practice* include 6 new evidence-rated guidelines: Safe Patient Handling and Management, Design and Maintenance of the Surgical Suite, Sterilization, Safe Environment of Care, Sterile Technique, and Transmission-Based Precautions.
- Guidelines in development for 2020 print publication
 - Surgical Attire: approved, release electronically July 1, 2019
 - Hypothermia: approved, release electronically July 1, 2019
 - Sterilization Packaging Systems: public comment May 10- June 9, 2019
 - Sharps Safety: public comment June 3- July 3, 2019
 - Autologous Tissue Management: public comment July 3- August 3, 2019
 - Environmental Cleaning: public comment July 31- August 31, 2019

Position Statements:

- Available at <http://www.aorn.org/guidelines/clinical-resources/position-statements>
- March 2019 membership approval:
 - Perioperative Registered Nurse Circulator Dedicated to Every Patient Undergoing an Operative or Other Invasive Procedure (revision)
 - Perioperative Registered Nurse Residency Programs (new)
- Under revision:
 - Standards of Perioperative Nursing
 - Advanced Practice Registered Nurses in the Perioperative Environment
 - Managing Distractions and Noise During Perioperative Patient Care
 - Environmental Responsibility
 - Perioperative Care of Patients with Do-Not-Resuscitate or Allow-Natural-Death Orders

Legislation:

- AORN legislative priorities for 2019 are RN as circulator, preserving and protecting the Perioperative Registered Nurse's scope of practice, supporting workplace safety and patient

safety initiatives, and advancing positive health care improvements.

- Surgical Smoke Protection bill (HB19-104), was signed into law in the state of Colorado on March 28, 2019

Campaigns and related activities:

- Nursing Infection Control Education (NICE) network
- Surgical Smoke Safety. Go Clear Award recognizes health care facilities committed to a surgical smoke-free environment for their perioperative team and patients: <http://www.aorn.org/aorn-org/education/facility-solutions/aorn-awards/aorn-go-clear-award>

Press activities:

- Recent AORN press releases can be accessed at <https://www.aorn.org/Aorn-org/About-AORN/AORN-Newsroom/Press-Releases>

Publications:

- 2019 *Guidelines for Perioperative Practice*, AORN Journal, Perioperative Job Descriptions and Competency Evaluation, Perioperative Policies and Procedures, & Ambulatory Surgery Center Resources

Other items of note:

- AORN Global Surgical Conference & Expo 2020, March 28 – April 1, Anaheim, CA
 - Education Session Proposal submission deadline is May 31, 2019

Liaison Representative Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: May 16-17, 2019

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison Representative name: Darlene Carey MSN RN CIC NE-BC FAPIC

Organization represented: **Association for Professionals in Infection Control and Epidemiology Inc. (APIC)**

Interim activities and updates:

- **Convened a consensus conference**, “The Role of the Infection Preventionist in a Transformed Healthcare System: Meeting Healthcare Needs in the 21st Century,” in November 2018. The conference brought together leaders and experts from both the IP profession and the broader IPC field to imagine the future role of IPs and develop consensus recommendations that the profession can implement.
- **Partnered with SHEA on inaugural leadership development course**, with faculty from the American Association for Physician Leadership.
- **Re-designed Certification Review online course** was launched in April 2019, which is now mobile-friendly with updated content.
- **New IP Competency Model** to be launched Spring 2019. Additional domains and subcompetencies have been developed, and the model itself will be more interactive.
- **APIC’s Novice Roadmap for the Infection Preventionist** is being re-designed as a fully online checklist with embedded resources. This will also be better aligned with the Competency Model and focus more on the core competencies than the traditional learning stages and time periods.
- EPI Intensive will become the **EPI Intensive Certificate Program**, a hybrid in-person/online course series. The first offering is scheduled for Fall 2019.
- IP Academy program will become the **Applied Learning Conference**, a more interactive and engaging in-person program on key topic areas of interest to the IP. First offering is October 2019
- Developing an **Ambulatory Care Essentials online course** that serves as foundational training to those starting in infection prevention in the ambulatory setting. Course is scheduled to launch late 2019

Guidelines and Guidance:

Please include products that are in progress and planned for the coming year. Include Web links if appropriate.

- N/A

Position Statements:

- N/A

Legislation:

- Submitted [comments to CMS on proposed regulatory provisions to promote program efficiency, transparency, and burden reduction](#).
- Submitted [comments to the HHS Office of the National Coordinator for Health IT on its draft](#)

[strategy on reducing regulatory and administrative burden relating to the use of health IT and EHRs.](#)

- Submitted [comments to the UN Interagency Coordination Group on draft recommendations on antimicrobial resistance.](#)
- Submitted [comments to CMS on proposed revisions to the Hospital Quality Star Ratings system.](#)
- Submitted [response to CDC Request for Information on NHSN Outpatient Procedure Component and Bloodstream Infection Surveillance Protocols.](#)
- Submitted [comments to the National Quality Forum on draft approaches to future core measure set prioritization.](#)
- At request of CMS, provided review and comments on draft Long-Term Care interpretive guidance on F880, F881, F882, and F868.
- Submitted [response to request for information from the Presidential Advisory Committee on Combating Antibiotic-Resistant Bacteria \(PACCARB\) on suggested strategies for new National Action Plan.](#)
- APIC President Karen Hoffmann [delivered public comments to PACCARB](#) on need for CMS to finalize proposed update to infection prevention and control Condition of Participation that includes requirement for antibiotic stewardship programs in hospitals.
- APIC and SHEA sent joint letters to [PACCARB](#) and [HHS Secretary Azar](#) requesting finalization of the proposed Medicare infection prevention and control Condition of Participation.

Campaigns and related activities:

- Supported WHO World Hand Hygiene Day via social media and eNews articles.

Press activities:

- Issued press releases on AJIC studies focusing on:
 - Infection prevention staffing needs
 - The impact of HAIs on patients
 - Hospital privacy curtains as potential vector of pathogen transmission
 - High-risk staph transmission in the OR
 - Sink drains next to toilets in patient rooms: a reservoir of bacteria
 - Need for antibiotic stewardship in the outpatient setting
 - Children's ball pits as germ breeding grounds
 - Home healthcare nurses' knowledge and attitudes toward infection control

Publications:

- Published [article](#) in the April issue of the *American Journal of Infection Control* summarizing APIC 2018 Consensus Conference on "The Role of the Infection Preventionist in a Transformed Healthcare System: Meeting Healthcare Needs in the 21st Century."
- Published [Consumer Alerts](#) on preventing infections during an outpatient procedure, chickenpox versus shingles, adenovirus, norovirus, measles, and RSV.
- *Prevention Strategist* 2018 Winter issue included articles on influenza, fungal laundry, the changing role of the IP, emerging modes of ambulatory care, hand hygiene data, tools for CLABSIs in oncology, infection prevention in dental setting, and the LEAN thinking A3 method.
- *Prevention Strategist* 2019 Spring issue included articles on ASC consulting, sterile processing and cleaning, an IP internship program, the next generation of IPs, diagnostic stewardship, AFM, and the APIC Consensus Conference.

- *Prevention Strategist 2019* Summer issue includes articles on APIC-SHEA Leadership Development Course, APIC's updated Competency Model for the IP, retiring *AJIC* editor Elaine Larson, APIC's pro-vaccine advocacy work, qualitative data, quality improvement in endoscope reprocessing, accreditation focus on sterilization-focused system tracers, annual IPC plan and risk assessment framework, and Group A Strep in LTC facilities,
- APIC Text Online published a brand-new chapter on Antimicrobial Stewardship and an updated chapter on Sterile Processing.
- Recently published *Infection Prevention in Long-Term Care*, 2nd edition. This completely updated reference now includes guidance on regulatory compliance, antimicrobial stewardship, and water management programs for facilities such as nursing homes, assisted living, and continuing care communities.

Other items of note:

Liaison Representative Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: May 16-17, 2019

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison Representative: Alan Kliger

Organization represented: **American Society of Nephrology**

Interim activities and updates:

- A Nephrology Self-Assessment Program (NephSAP) special edition on infection prevention has been submitted to the NephSAP editors, with publication projected for July 2019
- An infection prevention Curriculum for fellows and practicing nephrologists is in development, and projected for publication in fall 2019
- Human factors assessments: the ASN is partnering with engineers at Virginia Polytechnic Institute to conduct human factors assessments at six dialysis facilities in the US. The project will conclude with an analysis of the data generated at all six dialysis facilities to determine barriers and facilitators to infection prevention in the following areas:
 - Catheter care and access
 - Injection safety
 - Environmental decontamination
 - Hand hygiene

Guidelines and Guidance:

Please include products that are in progress and planned for the coming year. Include Web links if appropriate. (The ASN does not issue guidelines. However, under its contract with CDC, ASN is developing recommendations for improved infection prevention practices, including the following.)

- Hepatitis C monitoring and testing algorithm and recommendations
- Blood Culture Standardization: compilation of best practices and a summary of existing literature. This is accompanied by a SBAR template, competency checklist, and competency testing recommendations.
- Study addressing preventing the transmission of *Clostridium difficile* in out-patient dialysis facilities

Position Statements:

- (none this term)

Legislation:

- (none this term)

Campaigns and related activities:

- Pilot project to address improving leadership and supporting cultural change in dialysis facilities through the education and engagement of the dyad of medical director and nurse manager
- Partnerships with state and federal HAI professionals to educate about the infection prevention challenges in dialysis facilities

- Vascular access pilot project implementing chairside electronic checklists and audit tools for patients with catheters
- hand hygiene awareness

Press activities:

Publications:

- Published in CJASN: “Management of the Hemodialysis Patient with Catheter-Related Bloodstream Infection” (Crystal A Farrington and Michael Allon, 2019)
- Submitted to Kidney News: “ASN and CDC’s *Nephrologists Transforming Dialysis Safety* (NTDS) Team Up With Human Factors Engineers to Target Zero Infections in Hemodialysis” (Alan S Kliger MD and Sarah Parker PhD)

Other items of note:

- The Targeting Zero Infections webinar series includes five webinars to date. The webinar series is available on the ASN Learning Center; CME/CNE credits are available. The series includes:
 - “Targeting Zero Infections: Where Do We Begin?” (May 23, 2017)
 - “Targeting Zero Infections: MDROs and Antimicrobial Stewardship in the Dialysis Facility” (September 27, 2017)
 - “Targeting Zero Infections: Infectious Disease Reporting: State Requirements & Resources” (March 29, 2018)
 - “Targeting Zero Infections: Environmental Decontamination” (June 19, 2018)
 - “Targeting Zero Infections: Hepatitis C Detection, Prevention, and Treatment” (December 6, 2018)
 Upcoming webinar: The next webinar is tentatively titled, “Blood Culture Standardization” (September 5, 2019).
- Participation in ASN Kidney Week (November 2019):
 - NTDS Annual Session: “Is Dialysis Safe? A Critical Look at Hemodialysis and Peritoneal Dialysis in the United States” (November 7, 2019)
 - “Keeping the Bugs Away: Preventing, Diagnosis, and Treating Common Infections in the Dialysis Unit” (November 8, 2019)

Liaison Representative Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: May 16-17, 2019

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison Representative name: Kristen (Kris) Ehresmann

Organization represented: **Association of State and Territorial Health Officials (ASTHO)**

Interim activities and updates:

- ASTHO continues to enhance the capacity and performance of state and territorial health officials and other state public health leaders to effectively monitor and address the growing threat of healthcare-associated infections (HAIs) and emerging antibiotic-resistant (AR) infections through building strong partnerships and promoting HAI/AR prevention and control standards and policies. Key areas of ASTHO's HAI/AR work include:
 - Co-leading the Council for Outbreak Response: Healthcare-Associated Infection and Antimicrobial-Resistant Pathogens, (CORHA), with the Council of State and Territorial Epidemiologists (CSTE). CORHA's Workgroups on Detection and Reporting, Investigation and Control, and Policy and Laboratory Practices are tasked with developing resources and tools to support HAI outbreak response activities across the public health-healthcare continuum. [The CORHA website](#) features a "Resource Hub" that includes CORHA-developed products and external resources.
 - Providing capacity building and technical assistance to State and Territorial Health Officials, other state public health leaders and HAI/AR Program Directors and Coordinators through the dissemination of tools, resources and learning opportunities on HAI/AR, including containment of MDROs, prevention and control best practices, and priorities from the CDC and other state-level partners.
 - Conducting assessments of existing policies to develop recommended practices on state HAI/AR outbreak reporting to public health, sepsis awareness and prevention, and implementing policy change to prevent HAI and reduce AR.
 - Participating in CDC's AMR challenge in collaboration with affiliate partners.
 - Launching a newly-funded project on *Establishing Communities of Excellence in Addressing Antimicrobial Resistance and Advancing Antimicrobial Stewardship*.

Guidelines and Guidance:

- ASTHO's [Healthcare and Infection Control Gateway](#) provides guidance to state health agencies on controlling and preventing HAIs.

Other items of note:

- ASTHO's podcast episode on "[Policy Approaches to Containing Antimicrobial Resistance](#)" highlights national and state perspectives on the prevention and containment of unusually resistant bacteria.

Liaison Representative Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: May 16 – 17, 2018

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison Representative Name: Marion Kainer

Organization represented: **Council of State and Territorial Epidemiologists**

Interim activities and updates:

- **CSTE annual conference** will be held June 2 – 6 in Raleigh, North Carolina and will include Sunday workshops. <https://www.csteconference.org/2019/>
- **Provided comments for:**
 - National Action Plan for President’s Advisory Council on Combating Antibiotic-Resistant Bacteria
 - USP 797
 - FDA’s Guidance for Industry addressing Insanitary Conditions at Compounding Facilities

Guidelines and Guidance:

Please include products that are in progress and planned for the coming year. Include Web links if appropriate.

- **The Council for Outbreak Response: Healthcare Associated Infections and Antibiotic Resistant Pathogens (CORHA)** held its last in-person meeting in November 2018. In addition to the detection and reporting and investigation and control groups, CORHA has contracted with APHL to support the new laboratory group. The new policy work group held their first meeting at the in-person full council meeting at the CSTE national office in November 2018 and is currently working on a guidance for public disclosure of outbreaks. Cross communications surfaced between the HAI Subcommittee, the SHEA policy committee, and CORHA's policy work group to have Marion Kainer, Maureen Tierney, and Joe Perz present a late breaker at SHEA Spring 2019 in light of the NY Times article on *C. auris* that claims the lack of transparency in healthcare.
- A one-pager describing the mission, vision, membership can be found here <http://corha.org/>
- The Council is co-chaired by CSTE and ASTHO; CDC, NACHO. APIC, SHEA, APHL, CMS and FDA also are members of the Council. There are multiple workgroups including:
 - **CORHA Workgroup A (Outbreak Detection and Reporting):**
 1. Create standard definitions for outbreaks and exposure events and thresholds for reporting;
 2. Improve reporting of outbreaks and exposure events to public health;
 3. Improve the use of existing surveillance systems to detect outbreaks.
 - **CORHA Workgroup B (Outbreak investigation and control)** will work on
 1. Defining appropriate levels of response;
 2. Improve response to investigation and control of outbreaks to public health;
 3. Improve data management for outbreak investigation and tracking
 - **CORHA Laboratory Workgroup (charge)**
 1. Contribute knowledge and support activities to optimize laboratory practices in support of identifying and investigating possible HAI/AR outbreaks.
 2. Support effective interactions among laboratory partners and between laboratories, healthcare facilities, and state/local health departments in the context of HAI/AR

response activities.

- **CORHA Policy Workgroup (charge)**
 1. Improve policy and legal standards for reporting, investigation, notification and disclosure of HAI/AR outbreaks and exposure events
 - *Outbreak Reporting, Notification, and Disclosure*. For the purposes of this workgroup, the following definitions are important:
 - *Outbreak reporting* is defined as activities that occur when a facility reports a possible outbreak to a local and/or state health department(s).
 - *Notification* occurs when individuals, including patients potentially affected by an outbreak or otherwise have a right to know are informed of their risk.
 - *Disclosure* is defined as activities that occur to inform individuals beyond the patients potentially affected by an outbreak.
 2. Explore options to enhance legal authority and policy options to support best practices
- **Antimicrobial Resistance Surveillance Taskforce (ARSTF):**
 - The Antimicrobial Resistance Surveillance Task Force (ARSTF) is a collaboration of the CDC, the Association of Public Health Laboratories (APHL), and the Council of State and Territorial Epidemiologists (CSTE). It consists of thirty-plus individuals from clinical care, public health, laboratories, and informatics. It began in 2016, and after a full year of work, developed a vision statement, strategic map and profile, and a schema of roles and responsibilities for various levels of public health agencies for the next three years, including specific objectives for this year. The objectives address infrastructure building, collaborative alignments, and several specific initiatives (such as ensuring that antimicrobial susceptibility data do not get suppressed for public health purposes).
 - The ARSTF has released its year 2 Report and Recommendations. It is available at: https://cdn.ymaws.com/www.cste.org/resource/resmgr/arstf/ARSTF_Year_2_Report_and_Reco.pdf
 - Other key documents are:
 - Vision: https://cdn.ymaws.com/www.cste.org/resource/resmgr/pdfs/pdfs2/ARS_Vision.pdf
 - Strategic Plan: https://cdn.ymaws.com/www.cste.org/resource/resmgr/pdfs/pdfs2/ARS_Strategic_Map.pdf
 - Strategic Profile: https://cdn.ymaws.com/www.cste.org/resource/resmgr/pdfs/pdfs2/Strategic_Profile_for_Nation.pdf
 - Roles and Responsibilities Table: https://cdn.ymaws.com/www.cste.org/resource/resmgr/pdfs/pdfs2/ARS_Roles_and_Responsibiliti.pdf
- The Task Force wants to align and keep in communication with other planning bodies, such as HICPAC. There are various ways interested organizations and individuals could keep informed about the work of the Task Force: the Task Force email list, the Task Force's newsletter, or by checking the CSTE website. Individuals could also participate on one of the Task Force's working groups. For more information, contact Brooke Beaulieu at brooke@cste.org
- **Colonization Surveillance Workgroup** – Small focus group of State Epidemiologists and ARSTF members to provide insight into the broad issue of surveillance for colonization. Initial

conversations arose from discussion on how to classify people in whom there is laboratory evidence of illness but no signs/symptoms. Proposed a small subset from this group to further discuss and consider a policy brief. This group would also engage with the ARSTF Workgroup 5 (AR Surveillance Scope) for relevant pieces.

- **Drug Diversion toolkit**
 - The Drug Diversion Workgroup Developed a toolkit to provide guidance for state and local HAI programs during response to drug diversion events. It is near finalization and is expected to be released at the CSTE Annual Conference.
- **Data analysis and Presentation Standards (DAPS) toolkit**
 - Work is underway to update/ expand the DAPS toolkit. Current toolkit available at: <http://www.cste.org/general/custom.asp?page=HAIToolkit>. Topics include presentation of dialysis data, NHSN AU/ AR data; consumer-friendly language around the re-baselining, guidance on trending (especially with re-baselining). The DAPS work groups has acquired new leadership and plans to continue updating the 2015 DAPS Toolkit.

Position Statements (Upcoming 2019 meeting):

- **No new HAI/AR position statements**
- **There will be 10 position statements for member consideration at the 2019 CSTE Annual Conference**
 - **19-ID-01** – Public Health Reporting and National Notification of Plague
 - **19-ID-02** – Standardized Surveillance Case Definition for Blastomycosis
 - **19-ID-03** – Case Definition for Non-pestis Yersiniosis
 - **19-ID-04** – Revision to the Case Definition for National Legionellosis Surveillance
 - There is a Legionellosis Surveillance Workgroup (with some member overlap with CSTE HAI Subcommittee) that has been working on a revision to case definition
 - Amend NAAT testing to be confirmed
 - Provide new language to help with case classification of Legionnaire’s vs Pontiac Fever
 - Three new appendices to include information on incubation period an considerations for healthcare-associated and travel-associated cases (meant to be tools for health departments, not binding)
 - **19-ID-05** – Revision to the Standardized Case Definition, Case Classification, Public Health Reporting, and National Notification for Acute Flaccid Myelitis
 - **19-ID-06** – Revision of the Case Definition for Hepatitis C
 - **19-ID-07** – Changes to Public Health Reporting and National Notification for Spotted Fever Rickettsiosis (including Rocky Mountain spotted fever)
 - **19-ID-08** – Revision to the case definition for national pertussis surveillance
 - **19-MCH-01** – Neonatal Abstinence Syndrome Standardized Case Definition
 - **Interim-CC-19** – Nonfatal Opioid Overdose Standardized Surveillance Case Definition

Ex Officio Member Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: May 16-17, 2019

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Ex officio member name: Yvonne Chow

Agency represented: **HRSA/FORHP**

Interim activities and updates:

- FORHP has conducted focus groups with over 30 critical access hospitals with some that are independent and part of systems. The purpose of these groups is to identify and compile strategies and best practices from CAHs that have successfully implemented all seven of the core elements of antibiotic stewardship.
 - Product: Suggested strategies, tools, and resources will be summarized and distributed as a guide for state Flex programs and CAHs seeking to implement or enhance antibiotic stewardship programs.

Guidelines and Guidance:

Position Statements:

Legislation:

Campaigns and related activities:

Press activities:

Publications:

Other items of note:

Liaison Representative Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: May 16-17, 2018

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison Representative name: Dana Nguyen, BSN, RN, CIC, Clark County Public Health (WA)

Organization represented: **National Association of County and City Health Officials (NACCHO)**

Interim activities and updates:

- July 30, 2019: NACCHO will co-host a webinar with American Essential Hospitals (AEH) to highlight a local health department partnering with an essential hospital to improve antimicrobial stewardship and HAI prevention/response.
- June 2-6, 2019: NACCHO will host a roundtable session at the CSTE conference. This session will feature examples of local health departments participating in regional containment strategies
- January 31, 2019 -March 1, 2019: NACCHO launched a nationwide assessment of local health departments to identify HAI/AR activities locals are involved in, which entities they partner with to conduct this work, and challenges and barriers they encounter. The assessment also aims to identify opportunities for technical assistance to support local capacity. NACCHO anticipates having preliminary results by the summer of 2019.
- January 30-31, 2019: NACCHO staff participated in the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB)
- Ongoing: NACCHO promotes HAI prevention and infection control news and resources via NACCHO's regular communication channels that reach nearly 3,000 LHDs.
- Ongoing: NACCHO staff and four local health department representatives participated on The Council for Outbreak Response: Healthcare-Associated Infections (HAIs) and Antimicrobial-Resistant Pathogens (CORHA) workgroup and All-Member calls. Stephanie Black, MD, MSc (Chicago, IL) and Hillary Hanson, MS, MPH, CIC (Flathead County, MT) participate on Workgroup A: Detection and Reporting which aims to identify standardized approaches to detection and reporting of infectious disease outbreaks and exposure events within healthcare facilities and in various ambulatory settings. Dawn Terashita, MD, MPH (LA County, CA) serves on the governance committee and participates in Workgroup B: Investigation and Control Workgroup, developed to identify consistent and coordinated approaches to investigation and control of infectious disease outbreaks and exposure events within healthcare facilities and in various ambulatory settings.
- Ongoing: NACCHO hosts a quarterly call to convene the ELC HAI/AR directly funded cities to discuss project updates, share lessons learned, and troubleshoot challenges.
- Ongoing: NACCHO provides funding and technical assistance to demonstration projects with three local health departments to increase their capacity in preventing HAIs, and combatting antimicrobial resistance including through containment of novel resistant pathogens. These demonstration sites are DuPage County Health Department (IL), Florida Department of Health in Orange County (FL), and Lubbock County (TX).

Guidelines and Guidance:

Please include products that are in progress and planned for the coming year. Include Web links if appropriate.

- No guidelines in development at this time

Position Statements and Joint Letters:

- Ongoing: NACCHO's policy statement on Antimicrobial Resistance and Stewardship is under current review and is set to be finalized by June 2019
- March 22, 2019: NACCHO signed a letter in support of S-FAR recommendations for FY2020 AMR funding
- January 7, 2019: NACCHO submitted comments to the U.S. Department of Health and Human Services (HHS) on the National Action Plan (NAP) for Combating Antibiotic-Resistant Bacteria recommendations

Legislation:

- No legislative updates at this time.

Campaigns and related activities:

- November 13, 2019: NACCHO committed to support the Antimicrobial Resistance (AMR) Challenge led by the U.S Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC). NACCHO will increase the awareness and capacity of the nearly 3,000 local health departments across the country to fight antimicrobial resistance and promote stewardship by sharing tools, resources, and lessons learned through the NACCHO website, blogs, and communications materials, and will facilitate opportunities for local health departments to identify local-level commitments in support of the AMR challenge. NACCHO will continue to leverage its work with local health departments on healthcare-associated infections and with local STD clinics on resistant gonorrhea to advance detection, treatment, prevention, and containment of resistant infections
- NACCHO continues to participate in the following campaign meetings, conference calls, and committees related to (1) obtaining updates on HAIs, injection safety, antimicrobial resistance, and infection control; and (2) determining how NACCHO can support national efforts to address related issues
 - Safe Injection Practices Coalition
 - Making Dialysis Safer for Patients Coalition
 - Compounding Quality Coalition

Press activities:

- November 13, 2018: NACCHO published a press release to announce its organizational commitment to the [AMR Challenge](#)

Publications:

- December 5, 2018: NACCHO published a [blog](#): *Against Antimicrobial Resistance: A Local Commitment to Fighting a Global Threat* featuring an interview with The Long Beach Department of Health and Human Services on their antimicrobial resistance (AMR) Challenge commitment.

Other items of note:

Ex Officio Member Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: May 16-17, 2019

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Ex officio member name: David K, Henderson, M.D., Tara N. Palmore, M.D., Alternate

Agency represented: **National Institutes of Health**

Interim activities and updates:

- The Clinical Center continues to conduct ongoing surveillance of our patients at admission and during ongoing hospitalization for carbapenemase producing organisms (CPO). We are now completing five years of active surveillance for CPO and are assembling the data to characterize our experience.
- The Clinical Center also continues to assess the healthcare-associated epidemiology of Vancomycione-Resistant Enterococci (VRE) in our hospital, We recently published a retrospective cohort study evaluating antibiotic exposure and VRE recolonization (*Infect Control Hosp Epidemiol* 2019 Apr; 40 (4): 414-419).
- The Clinical Center investigation of *Sphingomonas koreensis* infection and colonization has identified the source as our potable water supply. Eleven clonal infections were identified over a 12-year period. A manuscript describing these findings was recently published (*N Engl J Med.* 2018;379(26):2529-39). We have attempted several interventions, most notably assuring adequate chlorine levels in both hot and cold water, as well as a 'plumbing intervention'. An abstract describing six months' experience with the novel plumbing intervention has been submitted to ID Week. Though our patient population continues to be substantially immunosuppressed, no additional infections have been detected for the past 27 months.
- We have completed the search for a new Chief of our Department of Laboratory Medicine and have chosen Karen Frank, M.D., Ph.D. as the new Chief. Dr. Frank has been the Chief of the Microbiology Section in the Department of Laboratory Medicine. Dr. Frank came to NIH from the University of Chicago. In that role she has led and/or participated in several collaborative research projects related to specific issues and threats for our patients, due to resistant Gram-negative bacteria. Her research team has investigated the horizontal transfer of the carbapenemase-encoding plasmids that are contributing to the spread of these resistance pathogens. We are now actively searching for a new Chief of Clinical Microbiology

Guidelines and Guidance:

Position Statements:

Legislation:

Campaigns and related activities:

Press activities:

Publications:

1. Daniel-Wayman S, Fahle G, Palmore T, Green KY, Prevots DR. Norovirus, astrovirus, and sapovirus among immunocompromised patients at a tertiary care research hospital. *Diagn Microbiol Infect Dis.* 2018 Oct;92(2):143-146.

2. Kadri SS, Adjemian J, Lai YL, Spaulding AB, Ricotta E, Prevots DR, Palmore TN, Rhee C, Klompas M, Dekker JP, Powers JH 3rd, Suffredini AF, Hooper DC, Fridkin S, Danner RL; National Institutes of Health Antimicrobial Resistance Outcomes Research Initiative (NIH-ARORI). Difficult-to-Treat Resistance in Gram-negative Bacteremia at 173 US Hospitals: Retrospective Cohort Analysis of Prevalence, Predictors, and Outcome of Resistance to All First-line Agents. *Clin Infect Dis*. 2018 Jul 23. doi: 10.1093/cid/ciy378. [Epub ahead of print]
3. Johnson RC, Deming C, Conlan S, Zellmer C, Michelin A, Lee-Lin S-Q, Thomas P J, Park M, NISC Comparative Sequencing Program, Weingarten RA, Less J, Dekker JP, Frank KM, Musser KA, McQuiston JR, Henderson DK, Lau AF, Palmore TN, Segre JA. Genomic and epidemiologic investigation to identify *Sphingomonas koreensis* point sources in an indolent hospital outbreak. *N Engl J Med* 2018; 379 (29): 2529-39.
4. Hughes HY, MD, Odom RT, Michelin AV, Snitken ES, Sinai N, Milstone AM, Henderson DK, Palmore TN. A Retrospective Cohort Study of Antibiotic Exposure and VRE Recolonization. *Infect Control Hosp Epidemiol* 2019 Apr; 40 (4): 414-419.
5. Dulanto Chiang, A, Sinai N, Palmore TN. Risk Factors for Viridans Group Streptococcal Bacteremia in Neutropenic and Non-neutropenic Patients: A Single Center Case-Case-Control Study. *Open Forum Infect Dis* 2018 5(1): ofx260.

Book Chapters:

1. Garg M, Mufti N, Palmore TN, Hasni SA. Recommendations and barriers to vaccination in systemic lupus erythematosus. *Autoimmun Rev*. 2018 Oct;17(10):990-1001.
2. Palmore TN, Parta M, Cuellar-Rodriguez J, Gea-Banacloche JC. "Infections in the cancer patient." in DeVita VT, Lawrence TS, Rosenberg SA eds. *DeVita, Hellman, and Rosenberg's Cancer: Principles and Practices of Oncology*, 11th ed., 2018. *In press*.
3. Beekmann SE, Henderson DK. Chapter 41, Vascular Infection. In *Clinical Infectious Diseases*, Schlossberg, D. (Ed). Cambridge University Press, Cambridge, UK. 2019: 139-44.

Other items of note:

Liaison Representative Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: 16-17 May 2019

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison Representative: Andi L. Shane

Organization represented: **Pediatric Infectious Diseases Society (PIDS)**

Interim activities and updates:

- This is the second HICPAC meeting attended by a representative from the Pediatric Infectious Disease Society (PIDS). PIDS is delighted to have representation

Guidelines and Guidance:

- A collaborative effort among the Pediatric Infectious Diseases Society (PIDS) and the American Academy of Pediatrics (AAP) and its Section on Infectious Diseases (SOID), and Health Care without Harm Clinician Champions in Comprehensive Antibiotic Stewardship Group resulted in development of the Pediatric Antibiotic Stewardship Program (ASP) Toolkit, <https://www.pids.org/asp-toolkit.html>
- PIDS is continuing to collaborate with SHEA on the white paper series to accompany the HICPAC NICU guideline. Aaron Milstone is the PIDS representative on the writing group and is leading work on the *S. aureus* white paper.

Campaigns and related activities:

PIDS members continue to advocate for immunization of children and those who interact with them in healthcare settings.

Publications:

- Publication of the *Handbook of Pediatric Infection Prevention and Control* occurred in April 2019. Edited by Kris Bryant and Judy Guzman- Cottrill with contributions by PIDS members, <https://global.oup.com/academic/product/handbook-of-pediatric-infection-prevention-and-control-9780190697174?cc=us&lang=en&> This handbook seeks to “address the nuances and challenges specific to pediatric infection prevention, providing expert guidance on topics where evidence-based guidelines don't currently exist”.

Other items of note:

- PIDS will co-sponsor the 10th Annual International Antimicrobial Stewardship Conference to be held May 30-31, 2019 at Washington University in St. Louis, Missouri. Conference organizers are currently finalizing another outstanding program including the Thursday morning basics of antimicrobial stewardship session targeted toward medical and pharmacy residents and fellows as well as clinicians involved in the startup of antimicrobial stewardship programs.
- PIDS members will participate in the World Society of Pediatric Infectious Disease (WSPID) Conference in Manila in November 2019 as invited speakers addressing the global challenges of pediatric infection prevention in healthcare settings.

Liaison Representative Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: May 16-17, 2019

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison Representative name: Christa A. Schorr, MD

Organization represented: **Society of Critical Care Medicine**

Guidelines and Guidance:

Please include products that are in progress and planned for the coming year. Include Web links if appropriate.

- **In Development (*related to CDC work)**

- *1) Guidelines for the evaluation of adult new fever in the ICU: a 2008 update SCCM and IDSA

- 2) Management of the critically ill adult patient with liver disease

- 3) Surviving Sepsis Campaign guidelines for the management of adult sepsis and septic shock

- 4) Surviving Sepsis Campaign guidelines for the management of sepsis and septic shock in children

- 5) Failure to rescue

- 6) Update 2004: Inter- and intra-hospital transport of critically ill patients

Legislation:

- None

Campaigns and related activities:

- The Surviving Sepsis Campaign resolved issues related to the [Hour-1 bundle](#) and the website has been updated with infographics, videos and resources for clinicians.
- The Surviving Sepsis Campaign (SSC) released findings from the internationally focused research committee revealing the top six clinical priorities for sepsis research. The manuscript on these findings, [Surviving Sepsis Campaign Research Priorities for Sepsis and Septic Shock](#) was co-published in Critical Care Medicine and Intensive Care Medicine. Presentation of the findings were offered at the ESICM annual congress meeting in Paris and at the SCCM Congress in February located in San Diego.
- SCCM continues collaboration with ESICM via the SSC on guidelines for recognition and treatment of sepsis and septic shock for children with a release in late 2019. Since sepsis continues to be a devastating consequence of infection, SCCM has commissioned a task force to develop and disseminate a definition for children's sepsis and continues to consult with the World Health Organization on initiatives and policies to address this global health crisis. The task force will meet in Salzburg, Austria on June 21 & 22, 2019 immediately following the European Society of Pediatric and Neonatal Intensive Care Congress.
- SCCM completed work on a guide aimed to support the practice of screening for sepsis patients on inpatient hospital wards. The guide which included contributions from a meeting held at the CDC, will be posted to the Surviving Sepsis Campaign website in June. It will be available as an open access, free download.
- SCCM offered an open mic networking session at the SCCM Congress in San Diego in collaboration with AHRQ and the American Hospital Association HRET on teamwork to reduce CAUTI and CLABSI in intensive care unit. The session was recorded, and proceedings are being available as approved by AHRQ. Approximately 60 ICU clinicians were present for the session.

Publications: See above content.

Annual Congress

49th Critical Care Congress
February 16-19, 2019
Orange County Convention Center
Orlando, Florida, USA

Liaison Representative Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: May 17-18, 2019

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison Representative name: Louise-Marie Dembry, MD, FACP, MS, MBA, FIDSA, FSHEA

Organization represented: **Society for Healthcare Epidemiology of America (SHEA)**

Interim activities and updates:

- After an external search facilitated by an executive search firm, the search committee, chaired by Dr. David Henderson, interviewed multiple candidates with excellent credentials and skills. The SHEA Board of Trustees selected Kristy Weinschel, MBA as Executive Director in February. Since 2012, she has served as Director of Membership, Marketing and Operations, and as the staff liaison for several member committees. Since November 2018, she had served as the Interim Executive Director of SHEA.
- Through the sad loss of Gina Pugliese, a committed Editorial Board member for *Infection Control and Healthcare Epidemiology* and strong SHEA contributor, SHEA collected donations to fund many additional scholarships for the Gina Pugliese Scholarship Fund at the Decennial 2020.

Guidelines and Guidance:

- **Recently Published:**
 - SHEA Expert Guidance: Infection Prevention in Operating Room Anesthesia Work Area
 - Chair Silvia Munoz-Price
 - Guidance, webinar series, pocket card: <http://www.shea-online.org/index.php/practice-resources>
 - SHEA NICU White Paper Series
 - *C. difficile*
 - Co-Chairs Tom Sandora and Allison Bartlett
 - <https://doi.org/10.1017/ice.2018.209>
 - In development: *S. aureus*
 - Pending: CLABSI, Respiratory Infections
 - AAAAI-IDSA-SHEA Evaluation and Management of Penicillin Allergy
 - SHEA Representative Theresa Rowe; SHEA member Erica Shenoy
 - Consensus paper, tool kit, podcast, patient guide: <https://jamanetwork.com/journals/jama/article-abstract/2720732>
 - Outbreak Response Training Program
 - Tool Kits: Incident Management, Horizontal Strategies, Emerging Pathogens, Implementation, Communication, Negotiation (<https://ortp.guidelinecentral.com/>)
 - HICS: The Insider's Perspective (<https://learningce.shea-online.org/content/course-10>)
 - Outbreak Communications (<https://learningce.shea-online.org/content/podcast-outbreak-communications>)
- **In Development:**
 - Sterilization and High Level Disinfection (Co-Chairs Erica Shenoy and David Weber)
 - Initiation of Antibiotics (Co-Chairs Chris Crnich and Theresa Rowe)

- SHEA Healthcare Workers Infected with Bloodborne Pathogens (white paper, Co-Chairs Louise Dembry and David Henderson)
- Infection Prevention in LTC (Co-Chairs Lona Mody and Rekha Murthy)
- SHEA/IDSA Compendium 2020 Update (Co-Chairs Deborah Yokoe and Lisa Maragakis)
- Undergoing revisions: SHEA Handbook for SHEA-Sponsored Expert Guidance
- **Recently Reviewed:**
 - ADA recommendations for antibiotics for dental pain and swelling
 - HICPAC Draft Update to the CDC Infection Prevention and Control Recommendation Categorization Scheme

(Reviewed for “current” status) ASHP, SHEA, IDSA, SIS Clinical Practice Guidelines for Antimicrobial Prophylaxis in Surgery (ASHP planning update, to start this year)

Research:

- The winner of the 2019 Epi Project Competition is Dustin R. Long, MD of the University of Washington, Seattle, WA for his proposed research project, “Molecular Epidemiology of Spinal Fusion Surgical Site Infection and Influence of Preoperative Patient Microbiome.”
- **SHEA Research Network June 2018-May 2019:**
 - In Queue:
 - Assessment of Utilization of Rapid Molecular Diagnostic Tests in Hospitals (PI: David Calfee)
 - Completed:
 - SHEA Needs Assessment: Infection Prevention Training for Frontline Personnel Prevention Course for HAI Knowledge and Control of HAIs (Prevention CHKC Program Committee)
 - Post-Procedural Antimicrobials (PI: Daniel Livorsi)
 - Denominator Validation for NHSN Metrics (PI: John O’Horo)
 - Perceptions of Data Management in Infection Prevention (PI: Carlos Figueroa-Castro)
 - CLABSIs in Home Infusion Therapy (PI: Sara Keller)
 - Assessing the composition and function of existing antimicrobial stewardship committees in the practice-based setting as compared to published guidelines (PI: Matthew Weissenbach)
 - Antifungal Stewardship (PI: Margaret Fitzpatrick)
 - Submitted:
 - SHEA Research Network Survey of FY2018 (PIs: Kathleen Choitos - SHEA Research Network Leadership Team)
 - Hospital Epidemiologists’ and Infection Preventionists’ Opinions Regarding Hospital-Onset Bacteremia and Fungemia as a Potential Healthcare-associated Infection Metric (PI: Clare Rock)
 - Antibiotic Prescribing during End-of-Life Care (PI: Rupak Datta)
 - Published:
 - Do Experts Understand Performance Measures? A Mixed-Methods Study of Infection Preventionists, Govindan S, Wallace B, Iwashyna TJ, Chopra V. Infect Control Hosp Epidemiol. 2018 Jan;39(1):71-76. doi: 10.1017/ice.2017.243. Epub 2017 Dec 5. PubMed PMID: 29202884.
 - Use of diagnostic stewardship practices to improve urine culturing among SHEA Research Network hospitals, Sullivan KV, Morgan DJ, Leekha S. Infect Control

Legislation:

- Continue to advocate for the passage of the Pandemic and All Hazards Preparedness Act (PAHPA), which was re-introduced bill for the 116th Congress.
- Continue to advocate for passage of legislation that will lift spending caps mandated by the Budget Control Act of 2011.
- Working with stakeholder partners to advocate for increased funding for CDC, specifically for NHSN.
- Joined a coalition of stakeholders advocating for \$100 million over 10 years to modernize public health data infrastructure.

Campaigns and related activities:

- Launched an ICHE Podcast. The ICHE Podcast series will summarize and discuss a select number of articles published each month within the ICHE Journal. Our hope is that the podcast allows listeners to stay up-to-date on the latest ICHE research and gives authors a chance to highlight their work. This series is developed by the Managing Editor of ICHE, Lindsay MacMurray.

Press activities:

SHEA has released the following press statements in 2019. Full text can be found at <http://www.shea-online.org/index.php/journal-news/press-room/press-release-archives>

- New Infection Prevention and Control Training Opportunity for Clinicians in Development
Date Published: April 24, 2019
- Electronic Health Records Decision Support Reduces Inappropriate Use of GI Test
Date Published: April 24, 2019
- Information Technology Can Support Antimicrobial Stewardship Programs
Date Published: April 23, 2019
- New Study Finds Higher C-section Infection Risk for Mothers on Medicaid
Date Published: April 09, 2019
- Vaccine Avoidance Endangers Individual and Public Health
Date Published: April 01, 2019
- Improper Removal of Personal Protective Equipment Contaminates Health Care Workers
Date Published: March 20, 2019
- Antibiotics and Proton Pump Inhibitors Linked to Increased Risk of Infectious Diarrhea in Children
Date Published: March 07, 2019
- Infectious Diseases Experts Urge Increased Focus on Preventing Deadly Infections
Date Published: March 05, 2019
- Simple Change to Standard Orders Reduces Urine Testing in Asymptomatic Patients
Date Published: February 21, 2019
- CDC Investments Keep Antibiotic Resistance in Check Throughout U.S.
Date Published: January 17, 2019
- Infectious Diseases Experts Call for Coordinated Response to Global Health Issues
Date Published: January 07, 2019

Publications:

- SHEA is still actively promoting our textbooks released in 2018:

- Practical Healthcare Epidemiology, 4th Edition: <https://doi.org/10.1017/9781316597170>
- Practical Implementation of an Antibiotic Stewardship Program
<https://doi.org/10.1017/9781316694411>
- ICHE has launched a new podcast, available [here](#) and [here](#).

Other items of note:

- **SHEA Spring 2019: Science Guiding Prevention** was hosted April 24-26 in Boston, MA. The Program Committee Chair, Dr. Judy Guzman-Cottrill and Vice Chair, Dr. Thomas Sandora oversaw a program with over 900 attendees and 200 posters of original science in infection prevention and antibiotic stewardship.
- **IDWeek 2019** is scheduled for October 2-6, 2019 in Washington, DC. Drs. Kristina Bryant, MD (chair), Tom Talbot (vice-chair), and SHEA committee representatives: Drs. Robin Jump, Ebbing Lautenbach, Shelley Magill, Tara Palmore, and identified the sessions for IDWeek 2019. SHEA is also working with Drs. Emily Spivak and Jason Newland to execute our ‘Best Practices for Antimicrobial Stewardship Programs’ pre-meeting workshop which usually bring in over 200 registrants. There will also be an additional half day Pre-Meeting Workshop, “Expanding Antibiotic Stewardship into Outpatient Settings”, chaired by Lauri Hicks and David Hyun. The primary objective of this didactic and active learning workshop is to give attendees effective tools that can be used to expand the world of stewardship into the outpatient arena.
- **Online Education Center - LearningCE** houses all of SHEA’s online learning. This system is available to both members and non-members. Users can learn about innovative topics at their own pace and track their progress while earning CME credits. Top programming includes the Healthcare Associated Infections (HAI) Surveillance webinar series, Journal CME 2019, the ICHE Podcast, and the Quality Improvement for the Hospital Epidemiologist webinar series. New educational programs in development include a newly revised version of SHEA’s Primer for Healthcare Epidemiology, Infection Control & Antimicrobial Stewardship and a webinar series on Implementation Science. This easy-to-use platform offers a variety of education, with new programs being developed every month, all located in the Course Catalog, and provides unique user transcripts to keep track of all completed courses, CME earned, and certificates. Most of the programs are available at no charge to SHEA members.
- **6th Decennial International Conference on Healthcare Associated Infections** will be held March 26-30, 2020 in Atlanta, GA at the Marriott Marquis. The Steering Committee, including Drs. Denise Cardo, Arjun Srinivasan, Keith Kaye, Linda Green, Bill Powderly, Didier Pittet, and John McGowan, have developed a mission and vision for the next Decennial. The Conference’s theme is *Global Solutions to Antibiotic Resistance in Healthcare*. The Program Committee with direction from the Program Chairs, Drs. Daniel Diekema, John Jernigan, Deborah Yokoe, and Benjamin Park have begun developing a program. Speaker invites go out early summer 2019.

Liaison Representative Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: May 16-17, 2019

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison Representative name: Valerie Vaughn, MD

Organization represented: **Society of Hospital Medicine (SHM)**

Interim activities and updates:

- SHM continues to promote its Fight the Resistance Campaign dedicated to promoting awareness and behavior change related to antimicrobial stewardship and appropriate prescribing practices.

Guidelines and Guidance:

Please include products that are in progress and planned for the coming year. Include Web links if appropriate.

- SHM's High-Value Care Subcommittee is currently working to develop the second iteration of the Choosing Wisely topics (Choosing wisely 2.0). This guideline will build on top of the original choosing wisely recommendations. [See original Guide here](#)

Position Statements:

- None at this time

Legislation:

- None at this time

Campaigns and related activities:

- None at this time

Press activities:

- [SHM aids national infection prevention and control effort](#)

Publications:

- [Contact Precaution for MRSA and VRE, Kristen Young, DO, MEd , Sarah B Doernberg, MD, MAS, Ruth Franks Snedecor, MD, Emily Mallin, MD, SFHM](#)
- [Contact Precautions for Multidrug-resistant Organisms, Including MRSA and VRESA, Lisa L Maragakis, MD, MPH , John A Jernigan, MD, MS](#)
- [Prevalence of Staphylococcus aureus and Use of Antistaphylococcal Therapy in Children Hospitalized with PneumoniaCVBC, Jennifer M. Frush, BA, Yuwei Zhu, MD, MS, Kathryn M. Edwards, MD, Carlos G. Grijalva, MD, MPH, Isaac P. Thomsen, MD, MSCI, Wesley H. Self, MD, MPH, Seema Jain, MD, Evan J. Anderson, MD, Krow Ampofo, MD, Andrew T. Pavia, MD, Sandra R. Arnold MD, Jonathan A. McCullers MD, Derek J. Williams, MD, MPH](#)
- [The Association of Inpatient Occupancy with Hospital-Acquired Clostridium difficile Infection, Mahshid Abir, MD, MSc , Jason Goldstick, PhD, Rosalie Malsberger, MS, Claude M. Setodji, PhD, Sharmistha Dev, MD, Neil Wenger, MD, MPH](#)
- [Things We Do For No Reason: Blood Cultures for Uncomplicated Skin and Soft Tissue Infections](#)

[in Children, Eric Zwemer, MD , John R. Stephens, MD](#)

Other items of note:

- On April 30th, 2019 SHM Hosted an online webinar highlighting QI best practices and success stories reducing infection rates of Hospital Acquire Clostridium difficile. Click [HERE](#), and search QI Enthusiast Forum to view the webinar recording.
- [Infective endocarditis isn't what it used to be](#)
- [Delaying antibiotics in elderly with UTI linked to higher sepsis, death rates](#)
- [Topical antibiotic decolonizes S. aureus in NICU infants](#)
- [Non-TB mycobacteria infections rising in COPD patients](#)

Liaison Representative Report
HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC)
Centers for Disease Control and Prevention

Meeting Date: May 16-17, 2019

Meeting Location: Centers for Disease Control and Prevention, Atlanta, GA

Liaison Representative name: Margaret VanAmringe

Organization represented: **The Joint Commission**

Interim activities and updates:

- Ambulatory antimicrobial stewardship standards to be published in July 2019
- Conducted education and awareness activities (surveyor training, advisory board meetings, blog posts, speaking engagements) about the risk of legionella/waterborne pathogens and the need for effective water management programs.
- Conducted education and awareness activities (surveyor training, advisory board meetings, blog posts, speaking engagements) about reducing the risk of mold infections in health care settings.
- Launched education and awareness campaign on the need for compliance with personal protective equipment (PPE) standards to protect health care workers.

Guidelines and Guidance:

Please include products that are in progress and planned for the coming year. Include Web links if appropriate.

- Issued clarification in Joint Commission's *Perspectives* publication that infection control policies must be based on a hierarchy of references (including manufacturers' instructions for use, evidence-based guidelines, and local rules and regulations) to be scored as compliant with Joint Commission standards.
- Developing clarification for Joint Commission requirements regarding the removal of alcohol-impregnated products in the operating room.
- The Joint Commission provided production support for *Guide to Infection Prevention for Outpatient Podiatry Settings* (CDC)
- The Joint Commission provided production support for *Guide to Infection Prevention in Outpatient Orthopedic and Pain Management Settings* (CDC)
- The Joint Commission Department of Research completed work on a three-year project funded by the CDC titled, *Adaptation and Dissemination of Outpatient Infection Prevention (ADOPT) Guidance*. This project was designed to prevent healthcare associated infections in outpatient settings by identifying gaps and inconsistencies in current infection control materials for selected outpatient settings, and by developing adapted infection prevention and control guides for specific outpatient settings (podiatry, and orthopedics and pain management). This three-year project was completed in September 2018. The ADOPT Guidance team worked with 12 ambulatory-focused professional associations and 11 ambulatory health care systems on all project-related activities. Project deliverables included adapted guides, companion pocket guides, and a general outpatient infection prevention customizable, fillable checklist (based on the existing *CDC Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care*).

Links to project deliverables:

- [Guide to Infection Prevention in Orthopedic and Pain Management Office Settings\[PDF – 1.66 MB\]](#)

- [Pocket Guide Version: Guide to Infection Prevention in Orthopedic and Pain Management Office Settings\[PDF – 3.70 MB\]](#)
- [Guide to Infection Prevention for Outpatient Podiatry Settings\[PDF – 3 MB\]](#)
- [Pocket Guide Version: Guide to Infection Prevention for Outpatient Podiatry Settings\[PDF – 1.53 MB\]](#)
- Guide to Infection Prevention for Outpatient Settings Checklist: fillable form https://www.cdc.gov/infectioncontrol/pdf/Fillable-Outpatient-Checklist_508.pdf

Other items of note:

- The Joint Commission Department of Research recently completed work on the 12-month CDC BAA 2016 supported project (contract #200-2016-92276) entitled “Implementing standardized measurement of infections in nursing homes: challenges and facilitators.” We enrolled 36 nursing homes and supported them through the process of NHSN enrollment and data submission in the *C. difficile* Lab-Id module for nursing homes. A manuscript is in development in collaboration with CDC partners.
- The Joint Commission Department of Research completed a collaborative research project related to respiratory protection. This project was supported through a contract with the Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), National Personal Protective Laboratory (NPPTL). The project had two aims: (1) To assess the usefulness of two resources related to respiratory protection, and (2) to identify clinical situations whereby clarification regarding clinical use of respiratory protection might be needed. The team worked with an eight-member Technical Advisory Panel and a scientific officer to identify clinical conundrums related to respiratory protection, as well as continuing operational challenges. The findings are reported in “Opportunities to bridge gaps between respiratory protection guidance and practice in US health care.” *Infection Control & Hospital Epidemiology*; 2019 Feb 18:1–6.
- The Joint Commission and Pfizer Independent Grants for Learning and Change (IGLC) have successfully collaborated for over five years on projects to identify, fund, and oversee projects related to specific improvement objects that align with mutual interests of patients, health care providers, and stakeholders. Pfizer IGLC provides the funding while The Joint Commission provides oversight of the project in an administrative capacity. Phase I resulted in three antimicrobial stewardship projects, and Phase II resulted in four projects related to venous thromboembolism (VTE). These projects have resulted in relevant research and peer reviewed publications. Phase III builds on this collaboration and is focused on an international audience, specifically antimicrobial stewardship in the Asia-Pacific region. At the end of 2018, six grantees were selected by an expert panel to receive funding for their research with the projects starting in first half of 2019. The timing of these projects coincides nicely with the release of the antibiotic stewardship international standard, which can help to heighten awareness and promote further research around the issue of antibiotic stewardship in international settings (e.g., Asia-Pacific).
- Staff from the Joint Commission Divisions of Healthcare Improvement and Healthcare Quality Evaluation are working with CDC DHQP staff to summarize 2017 infection control breaches identified during the accreditation survey process in ambulatory care settings which were reported to state health departments as required by CMS. These breaches related to unsafe injection practices and use of sharps, problems with sterilization and high-level disinfection, or other deficiencies that could potentially expose patients to the blood or bodily fluids of another. Manuscript is in development.