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

August 19, 2021

Atlanta, Georgia

Record of the Proceedings

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Attendees

Healthcare Infection Control Practices Advisory Committee (HICPAC) Members
Hilary Babcock, MD, MPH, Co-Chair
Lisa Maragakis, MD, MPH, Co-Chair
Deverick Anderson, MD, MPH
Nicholas Daniels, MD, MPH
Elaine Dekker, RN
Mohamad Fakih, MD, MPH
Judith Guzman-Cottrill, DO
Colleen Kraft, MD, MSc
Michael Lin, MD, MPH
Michael Anne Preas, RN
JoAnne Reifsnyder, PhD, MBA, MSN
Sharon Wright, MD, MPH

***Ex Officio* Members**
Megan Hayden, RN, MS, CNS, CIC, CPH, Centers for Medicare and Medicaid Services (CMS)
Jonathan Merrell, RN, BNS, MBA, Indian Health Services (IHS)
Tara N. Palmore, MD, National Institutes of Health (NIH)
LCDR Scott Steffen, PhD, Certified Quality Improvement Associate (CQIA), Certified Quality Inspector (CQI), Food and Drug Administration (FDA)
Judy Trawick, Health Resources and Services Administration (HRSA)

Liaison Representatives
Holly Carpenter, American Nurses Association (ANA)
Paul Conway, American Association of Kidney Patients (AAKP)
Karen DeKay, MSN, RN, CNOR, CIC, Association of periOperative Registered Nurses (AORN)
Kristen Ehresmann, RN, MPH, Association of State and Territorial Health Officials (ASTHO)
Ashely Fell, MPH, Council of State and Territorial Epidemiologist (CSTE)
Hana E. Hinkle, PhD, MPH, National Rural Health Association (NRHA)
Keith Kaye, MD, MPH, Society for Healthcare Epidemiology of America (SHEA)
Alan Kliger, MD, American Society of Nephrology (ASN)
Chris Lombardozzi, America's Essential Hospitals (AEH)
Lisa McGiffert, Patient Safety Action Network (PSAN)
Adina Popalyar, RN, MPH, Public Health Agency of Canada (PHAC)
Mark Russi, MD, MPH, American College of Occupational and Environmental Medicine (ACOEM)
Sanjay Saint, MD, MPH, Society of Hospital Medicine (SHM)
Robert Sawyer, MD, Surgical Infection Society (SIS)
Christa Schorr, DNP, MSN, Society for Critical Care Medicine (SCCM)
Benjamin Schwartz, MD, National Association of County and City Health Officials (NACCHO)
Andrea Shane, MD, MPH, Pediatric Infectious Disease Society (PIDS)
Sarah Smathers, MPH, CIC, FAPIC, Association of Professionals of Infection Control and Epidemiology (APIC)
Margaret VanAmringe, MHS, The Joint Commission (TJC)
Stephen Weber, MD, ScM, Infectious Disease Society of America (IDSA)

Centers for Disease Control and Prevention (CDC) Representatives
Michael Bell, DHQP
Sydnee Byrd, DHQP
Denise Cardo, DHQP
Abigail Carlson, DHQP

Kendra Cox, DHQP
Ann Goding Sauer, DHQP
Rita Helfand, NCEZID
Alex Kallen, DHQP
Aaron Kofman, DHQP
David Kuhar, MD, DHQP
Jill Kumasaka, DHQP
Preeta Kutty, DHQP
Fernanda Lessa, DHQP
Devon Okasako-Schmucker, DHQP
Hanako Osuka, DHQP
Beth Pallo, DHQP
Ashley Payne, DHQP
Monica Payne, DHQP
LaTasha Powell, DHQP
Brajendra Singh, DHQP
Zachary Smith
Erin Stone, DHQP
Nimalie Stone, DHQP
Marwan Wassef, DHQP
J. Todd Weber, DHQP
Laura Wells, DHQP
Erin Whitehouse, DHQP

Members of the Public

Steven Brash, Infection Control and Prevention Consulting
Deborah Campbell
Pam Falk
Kaitlin Heath
Stephanie Henry, Cambridge Communications & Training Institute
Devin Jopp, EdD, MS, Association of Professional of Infection Control and Epidemiology (APIC)
Kevin Kavanagh, Health Watch USA
Betty McGinty
Chastity Myers
Silvia Quevedo, Association of Professionals of Infection Control and Epidemiology (APIC)
Gary Roselle, Department of Veterans Affairs (VA)
Keith St. John, Professional Disposables International
Rachel Stricof, Council of State and Territorial Epidemiologists (CSTE)

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 virtual meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on August 19, 2021 via Zoom for Government. The meeting was called to order at 12:00 PM Eastern Time (ET). The presence of a quorum of HICPAC voting members and *Ex Officio* members was confirmed, which was maintained throughout the meeting.

Dr. Babcock welcomed and introduced one new HICPAC member (Colleen Kraft, MD); one new *Ex Officio* member (LCDR Scott Steffen, PhD, CQIA, CQI representing FDA); and one new Liaison Representative (Patti Costello, MT-CHEST, MT-CSCT representing the American Hospital Association (AHA)).

Dr. Bell provided a DHQP update in which he noted that Koo Chung was not in attendance as he was engaged in multiple duties as part of the COVID-19 response structure. He emphasized that the South is experiencing frightening waves of hospital use related to COVID-19, and expressed empathy for others in similar situations. A *Morbidity and Mortality Weekly Report* (*MMWR*) was posted online on August 18, 2021 as an *MMWR* Early Release on vaccine efficacy (VE), for which he gave a nod to their National Healthcare Safety Network (NHSN) colleagues and their analysts across and outside the division who worked diligently to assemble the comparative data for vaccinated versus non-vaccinated nursing home residents. This report showed that although that ratio has been fairly stable over the past couple of months, there was quite a drop among facilities reporting back in March. That has led to current recommendations through the White House about boosters. Related to that, there is evidence showing that a highly vaccinated workforce was correlated with fewer infections amongst nursing home residents.

Dr. Babcock provided an update on the *Guideline for Infection Control in Healthcare Personnel* (HCP), including a reminder about what has been published and what is in progress. During this meeting, HICPAC voted unanimously to accept the workgroup's draft updated rabies recommendations, which are: 1) For healthcare personnel who have an exposure to rabies virus, administer post-exposure prophylaxis (PEP) in accordance with CDC recommendations and in consultation with federal, state, and local public health authorities; 2) Work restrictions are not necessary for healthcare personnel who have an exposure to rabies virus; and 3) For healthcare personnel who have a suspected or confirmed rabies infection, exclude them from work in consultation with federal, state, and local public health authorities.

Dr. Bell provided an Isolation Precautions Workgroup update. He reported that a description of the framing language has been completed and will be driven by key questions, systematic review processes, and evidence tables. HICPAC member, Dr. Sharon Wright, has agreed to serve as one of the Co-Leads of this group and the process is underway to identify the other Co-Lead. Within DHQP, subject matter experts (SMEs) have been identified and have agreed to provide support to this workgroup. Under the leadership of Erin Stone, the Evidence Review Team is preparing to work on this as well. Dr. David Kuhar has engaged in some background work to assess minor issues that can be tidied up in the previous document so that the workgroup can begin with a reasonably clean base. Once the internal workgroup is established for the committee, there will be a third round of recruitment to reach out to external individuals the workgroup thinks should be included. While a firm timeline has not yet been established, the hope is that workgroup membership will be complete within the next 6 weeks or so and that at

least the text-base of the framing and the transmission description will be completed within 12 months. The appendix and table updating can take place thereafter.

Dr. Judith Guzman-Cottrill provided an overview of the proposed draft recommendations to the *Guideline for Infection Prevention in NICU Patients* for central line-associated blood stream infection (CLABSI) in NICU patients. The workgroup completed an updated review of the recent literature, which led them to propose two revised recommendations. She reviewed public comments that were received for this guideline during the public timeline period that was open between April 12, 2021 – June 8, 2021, along with clarifications and proposed actions. HICPAC unanimously approved the following updated recommendations: 1) **Draft Updated Recommendation 4.** Consider choosing the fewest number of lumens based on the clinical needs of the neonatal intensive care unit patient. **Conditional recommendation;** and 2) **Draft Updated Recommendation 11.** Consider implementing a dedicated catheter care team to prevent central line-associated blood stream infection (CLABSI) in neonatal intensive care unit (NICU) patients. **Conditional recommendation**

HICPAC stood adjourned at 1:39 PM ET.

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Division of Healthcare Quality Promotion

Healthcare Infection Control Practices Advisory Committee (HICPAC)

August 19, 2021
Atlanta, Georgia

DRAFT Minutes of the Meeting

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 remote meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on August 19, 2021.

Call to Order / Roll Call

Monica Payne, MS, Health Communications Specialist
Sydnee Byrd, MPA, Program Analyst
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Ms. Payne called to order the August 19, 2021 HICPAC meeting at 12:00 PM Eastern Time (ET), thanked everyone for joining, and reviewed housekeeping items.

Ms. Byrd then called the roll, establishing that a quorum was present. Quorum was maintained throughout the meeting. HICPAC members disclosed the following conflicts of interest (COIs):

- Dr. Guzman-Cottrill has a consulting contract with the Oregon Health Authority.
- Dr. Colleen Kraft is on the Scientific Advisory Board of Rebiotix.
- Dr. Michael Lin receives research support in the form of contributed products from OpGen, LLC and Sage Products, which is now a part of Stryker Corporation. He previously received an investigator-initiated grant from CareFusion Foundation, which is now part of Becton, Dickinson and Company.
- Dr. Lisa Maragakis has received research funding from The Clorox Company.

Ms. Byrd indicated that public comment was scheduled for after the presentations. She explained that when the comment period opened, the Coordinator would provide instructions for how members of the public may provide comments, that public comments would be limited to 3 minutes each, and that commenters should state their names and organization for the record before providing their comments. She noted that the public comment period is not a question and answer session.

Welcome / New Member Introductions

Hilary Babcock, MD, MPH
HICPAC Co-Chair
Medical Director of Occupational Health (Infectious Diseases)
Barnes-Jewish and St. Louis Children's Hospitals

Dr. Babcock welcomed everyone to the HICPAC meeting, noting that Dr. Maragakis would be in her car throughout the meeting and may or not be able to chime in at various times. She said she spoke for both herself and Dr. Maragakis in saying that they were happy everyone was able to be together—at least on Zoom. She expressed regrets that they still were not able to meet in person and continued to be in the midst of COVID-19 that they hoped would be better by now. She welcomed the following new member new HICPAC Members, *Ex Officio* Members, and Liaison Representatives:

HICPAC Members

- Colleen Kraft, MD, MSc is the Associate Chief Medical Officer at Emory University Hospital. Dr. Kraft splits her time between hospital leadership, clinical research, clinical care, patients, and teaching. She is a Professor in the Department of Pathology and Laboratory Medicine and in the Department of Medicine in the Division of Infectious Diseases. She is the President-Elect of the American Society of Microbiology (ASM), a role which she began in July 2021. Dr. Kraft is trained and Board Certified in Internal Medicine, Infectious Diseases, and Clinical Microbiology. She has clinical and diagnostic experience during 3 infectious disease epidemics, including the 2009 H1N1 influenza pandemic, the Ebola pandemic in 2014, and currently with COVID-19. She led system-wide coordination in the COVID-19 diagnostic testing and has served on national, state, and local advisory committees. Her experience in the clinical care of novel diseases led to the development of the Emory Healthcare Human Factors Lab (HHFL). She also works on antibiotic resistance elimination with the use of microbiome therapeutics, such as fecal microbiota transplant (FMT).

Ex Officio Members

- LCDR Scott Steffen, PhD, CQIA, CQI is the new *Ex Officio* member for the FDA. He obtained his Bachelor of Science and Doctoral Degrees in Biochemistry from Pennsylvania State University and Johns Hopkins Bloomberg School for Public Health, respectively. He completed a Post-Doctoral Fellowship studying enzymatic mechanisms of various Ebola proteins at Ft. Detrick. Afterward, he held various research positions investigating potential cancer targets and vaccine candidates at 3 different biotech companies. From 2008-2020, he served as a Microbiology/Sterility Reviewer and/or Team Lead for either the Center for Drug Evaluation and Research (CDER) or the Center for Devices and Radiological Health (CDRH), performing over 300 sterility assurance reviews of pre-market applications. Since 2020, he has been a Senior Program Management Officer with the All-Hazards Readiness, Response, and Cybersecurity (ARC) Team, serving in various lead roles during the center's response to the COVID-19 pandemic and ethylene oxide (EO) efforts, while serving also as the center's point of contact for device-related healthcare-associated infections (HAIs). LCDR Steffen holds 2 certifications as a Certified Quality Improvement Associate (CQIA) and a Certified Quality Inspector (CQI) from the American Society of Quality (ASQ).

Liaison Representative

- Patti Costello, MT-CHEST, MT-CSCT is representing the American Hospital Association (AHA). Ms. Costello was unable to join the call due to an emergency, so an introduction will be provided for her during the next HICPAC meeting.

Dr. Babcock noted that HICPAC is soliciting nominations for members, which is open until September 17, 2021. She invited everyone to submit nominations, emphasizing that HICPAC is always seeking great expertise, engagement, enthusiasm, and new members to help keep moving this important work forward.

Division of Healthcare Quality Promotion (DHQP) Update

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

Dr. Bell thanked Ms. Byrd and Ms. Payne for running the Zoom conference for this HICPAC meeting. He also offered a quick acknowledgement to Koo Chung who was not in attendance as he was engaged in multiple duties as part of the COVID-19 response structure. He emphasized that while they are extremely happy to receive any recommendations for potential new members as Dr. Babcock mentioned earlier, that does not mean that this necessarily leads to membership. There is a very complicated, byzantine process whereby members are ultimately selected. While potential members can be recommended to HHS, there is a governmental process that ultimately determines who can be selected. In addition, HICPAC needs to be diverse in terms of geography, fields represented, sex, race/ethnicity, et cetera. That calculus becomes extremely complex. Hence, if someone is recommended for nomination and DHQP likes them, that does not mean that things will happen right away. Even if everything goes smoothly, there could be other delays and it make take a couple of cycles before people who are nominated become official members.

In terms of DHQP updates, the South is experiencing frightening waves of hospital use related to COVID-19. Empathy goes out to all those who are in a similar situation. It is a crazy and very frustrating time, so Dr. Bell emphasized how grateful they were for people's participation in this HICPAC meeting. On a more technical level, a *Morbidity and Mortality Weekly Report* (*MMWR*) was posted online on August 18, 2021 as an *MMWR* Early Release on vaccine efficacy (VE).[1] He gave a nod to their National Healthcare Safety Network (NHSN) colleagues and their analysts across and outside the division who worked diligently to assemble the comparative data for vaccinated versus non-vaccinated nursing home residents. This report showed that although that ratio has been fairly stable over the past couple of months, there was quite a drop among facilities reporting back in March. That has led to current recommendations through the White House about boosters. Related to that, there is evidence showing that a highly vaccinated workforce was correlated with fewer infections amongst nursing home residents. This is another indicator of the value of appropriate immunization in the healthcare workplace.

[1] https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e3.htm

Healthcare Personnel Guideline (HCP) Workgroup Update

Hilary M. Babcock, MD MPH
Chair, HCP Guideline Workgroup
Medical Director, BJC Infection Prevention and Epidemiology Consortium
Medical Director, BJC Occupational Health (Infectious Diseases)
Professor of Medicine, Infectious Disease Division
Washington University School of Medicine

Dr. Babcock provided an update on the *Guideline for Infection Control in Healthcare Personnel* (HCP). As a reminder, the original guideline was published in 1998 and has been under revision for about a decade. The HCP Workgroup's charge was to focus on pathogen-specific issues for Infection Control in Healthcare Personnel. Where information is out of date, the Workgroup will make updates using evidence-based methods where evidence is available. In terms of the status report, this Workgroup has been on pause for a while as everyone has been managing their way through the COVID-19 pandemic. Despite the continued COVID-19 pandemic, the HCP Workgroup is trying to get restarted and began meeting again on July 26, 2021. In the first two meetings, the group reviewed the progress of the update and where things left off, then restarted some work on the rabies draft recommendations and rabies narrative.

As an overall status reminder, **Section 1: Infrastructure and Routine Practices for Occupational Infection Prevention and Control Services** was completed and published in October 2019.[2] The Workgroup is now working its way through the pathogen sections to try to get them reviewed, approved, and posted. In terms of **Section 2: Epidemiology and Control of Selected Infections Transmitted Among HCP and Patients,** Diphtheria, Group A *Streptococcus*, Pertussis, and Meningococcal Disease have all been completed, reviewed, voted upon, approved, and are soon to be posted to the website. HICPAC already approved the following sections: Mumps, Rubella (May 2018); Measles (August 2018); and Varicella (August 2019) and those will be sent to the CDC Viral Pathogens Section for review and clearance. The Workgroup is waiting to submit to these sections in order to have a complete package, and the Viral Pathogens Section is busy at this point. Rabies and *Staphylococcus Aureus* (*S. aureus*) are in progress. Up next but on hold for the moment are: Respiratory Viral Pathogens, Conjunctivitis/Adenovirus, Scabies, and Pediculosis. On deck are: Hepatitis A, Hepatitis B, Hepatitis C, Herpes, Human Immunodeficiency Virus (HIV), and Tuberculosis (TB).

For Section 2, the Workgroup has proposed updated Rabies draft recommendations. The Rabies narrative section to support the draft recommendations is in progress. CDC Rabies subject matter experts (SMEs) have provided some initial input on the draft narrative and are continuing to work on that. Dr. Babcock reviewed the prior recommendations that were in the 1998 version, followed by the new draft updated recommendations.

1998 Recommendations

- Provide pre-exposure vaccination to personnel who work with rabies virus or infected animals in rabies diagnostic or research activities **Category IA**
- After consultation with public health authorities, give a full course of anti-rabies treatment to personnel who either have been bitten by a human being with rabies or have scratches, abrasions, open wounds, or mucous membranes contaminated with saliva or other potentially infective material from a human being with rabies. In previously vaccinated

[2] https://www.cdc.gov/infectioncontrol/guidelines/healthcare-personnel/index.html

individuals, post-exposure therapy is abbreviated to include only a single dose of vaccine on day 0 and one on day 3 **Category IB**

Draft Updated Recommendations

1. For healthcare personnel who have an exposure to rabies virus, administer postexposure prophylaxis (PEP) in accordance with CDC recommendations and in consultation with federal, state, and local public health authorities.
2. Work restrictions are not necessary for healthcare personnel who have an exposure to rabies virus.
3. For healthcare personnel who have a suspected or confirmed rabies infection, exclude from work in consultation with federal, state, and local public health authorities.

Dr. Babcock reminded everyone that every effort is being made not to duplicate recommendations. Specific recommendations about vaccination are handled primarily through the Advisory Committee on Immunization Practices (ACIP), so those are being removed as specific recommendations from the HCP Guideline with a reference pointing to the ACIP guidance instead. The updated recommendations focus on what to do in a healthcare setting for employees who have had an exposure. Pre-exposure vaccination recommendations and laboratory-specific recommendations are made separately through ACIP. As a reminder, the text pertaining to what constitutes an exposure and how to determine who has been exposed is included in the narrative and will be reviewed for HICPAC when that is completed.

The next steps for the HCP Workgroup will be to post the final Pertussis, Meningococcal Disease, Diphtheria, and Group A *Streptococcus* sections to the CDC Infection Control Guideline Website; finalize the Rabies section; and review the framing of key questions and updating literature search as needed for *S. Aureus*.

Discussion Points

Dr. Maragakis noted that the proposed recommendations apply only to post-exposure and requested further information about pre-exposure recommendations. She was thinking that there would be a formal recommendation for HCP who might be at risk for exposure.

Dr. Babcock indicated that pre-exposure recommendations apply largely to who qualifies for pre-exposure vaccination and when pre-exposure vaccination should be administered. All of that is covered in the ACIP Guidance with regard to the use of the rabies vaccines. Therefore, pre-exposure vaccination will be referenced in the narrative and people will be pointed to the ACIP Guidance. She did not recall HICPAC having a specific HCP recommendation.

PSAN observed that hospitals and HCP would see these guidelines and thought it would make sense to include everything having to do with rabies in the same guidance and not have it scattered in other places.

Dr. Babcock indicated that this was a decision made very early on with the goal of not having the same information in multiple places and then having to be sure that they all remained aligned as recommendations got updated in different ways. Because this document will primarily be living on the website with links that are embedded within it, it should be possible to have the recommendation and the places they want people to go look for more details embedded as a link that they can click on.

Dr. Bell added that the other rationale is that if everything is included in all of the documents, then every time something changes elsewhere, they will have to do a revision and update. Rather than trying to maintain all of those moving parts, the agency is making an effort to make all information as consistently located as possible in a single place with the links to updated material. To close the loop on PSAN's question, he looked at the ACIP pre-exposure information and there is not a recommendation for HCP. The general population is not recommended to have pre-exposure prophylaxis (PrEP). For rare exposures such as among veterinarians, there is a PrEP recommendation. For clinical care providers of human care, the expectation is that exposure to rabies virus should be a rare event and is more appropriately managed with PEP care. There are other recommendations for people who travel frequently to endemic areas such as for medical care abroad, but not for routine healthcare in the United States (US).

Dr. Babcock said that there are laboratories that are affiliated with hospitals and academic medical centers that may have people working with rabies virus, and she thought those recommendations were also included in laboratory worker guidance.

Dr. Bell indicated that they are also in the pre-exposure guidance for laboratory staff who are occasionally likely to handle rabies virus versus those who are routinely handling rabies virus in the course of conducting rabies research who are all on the higher part of the list for routine PrEP.

Dr. Maragakis clarified that her question came from looking at the 1998 recommendations since that was a Category 1A. She appreciated and supported the approach of not getting into the specific, but wondered if they wanted to call that out about the diagnostic and research activities and then point to ACIP in the recommendations versus the narrative. She said she was fine either way but wanted to raise the question.

HICPAC recalled that during the last Workgroup meeting, there was discussion about changing the second **and** in the first draft recommendation to read ". . . consultation with federal, state, **and/or** public health authorities so that people are not compelled to have to speak with every level of government as perhaps just one would be sufficient.

Dr. Kuhar added that for the previous cleared sections, they have similar recommendations that are framed exactly the same way. Given that this was approved, the decision was made between clearance and previous votes that this would be acceptable for consistency. He thought it was fine to discuss this further if people thought it should be changed for rabies. He suspected most places would not seek all 3 places for this, given that it is rare.

Dr. Babcock said she thought the intention was that there may need to be involvement of multiple levels. She did not think that there was an intent for the provider to call all 3 levels. Instead, the goal was to be sure that anyone who might need to know is included.

Dr. Bell further explained for audience context that there are different purposes for each notification. There are those who are close to the event who might need to do the work of figuring out who else was exposed or other ongoing work to address and contain any exposures. At the same time, there may be resources at the state or federal level that are specialized and could be accessed to make notifications. The ultimate goal is to make sure that everyone is in the loop.

Vote: HCP Guideline Section 2 Rabies
The HCP Guideline Section 2 Rabies recommendations were put forth for approval as presented. HICPAC voted unanimously to approve the recommendations, with no opposition and no abstentions. The disposition of the vote was as follows:

- 11 Favored: Anderson, Babcock, Daniels, Dekker, Fakih, Guzman-Cottrill, Kraft, Lin, Maragakis, Preas, Reifsnyder
- 0 Opposed
- 0 Abstained
- 1 Not Present: Wright

Isolation Precautions Guideline Workgroup Update

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

Dr. Bell reminded everyone that there has been discussion about the Isolation Precautions Guideline in preamble through the past year and a half or so and more recently in the description of a plan to go forward with a vision of the framing of infection transmission, something that everyone has felt has been due for quite some time. They are in the process of pulling together the group that does that. HICPAC member Dr. Sharon Wright has agreed to serve as one of the Co-Leads of this group. Regardless of how daunting the task might feel, it is a super exciting undertaking and one that Dr. Bell is extremely happy about. They are in the process of identifying other members for the Workgroup that will be led by Dr. Wright and a to-be-determined Co-Lead.

The systematic approach to the document already has been framed. Within DHQP, a group of SMEs have been identified and have agreed to support the workgroup. Under the leadership of Erin Stone, the Evidence Review Team is already honing its tools and getting ready to work on this as well. Dr. David Kuhar has engaged in some background work to assess “low-hanging fruit” for some of the minor issues that can be tidied up in the previous document so that the workgroup begins with a reasonably clean base. The approach will be to go through the existing document to ensure that they are able to identify either a new home or a replacement for each of the important components of the document. Some of that is in the context of components like the Core Practices, important background language, and replacement with new information.

As a reminder, this is not like the HCP Guideline in terms of undertaking the rewriting of a large textbook-like document. Instead, this will be very much in the format of more recent undertakings. The work beyond the framing language will be driven by key questions, systematic review processes, and evidence tables. While a firm timeline has not yet been established, Dr. Bell’s hope is that at least the text-base of the framing and the transmission description will be completed within 12 months. The appendix and table updating can take place thereafter, with the hope that this will not be as major an undertaking as the HCP document simply because the evidence base for this will not be mapped to the new description of transmission that is developed. They are not likely to find a great deal of information. There may be an interim step in which previous framing in the table will be labeled as a transitional document and then updated accordingly as evidence accrues. Most of this will focus on the framing of transmission processes as opposed to the nitty gritty isolation practices. Airborne and

contact isolation practices should not change. There may be some new information about enhanced barrier precautions that can be gleaned from the nursing home world, and there certainly will be a change in thinking through respiratory infection transmission. Beyond that, the categories of isolation are likely to be fairly similar.

In summary, there is about a year's worth of effort for the new framing. The cast of participants is currently being developed. Once the internal workgroup is established for the committee, there will be a third round of recruitment to reach out to external individuals the workgroup thinks should be included. Hopefully, this will be completed within the next 6 weeks.

Neonatal Intensive Care Unit (NICU) Workgroup Update

Judith Guzman-Cottrill, DO
NICU Workgroup Chair
Professor of Pediatrics
Division of Infectious Diseases
Oregon Health & Science University

Dr. Guzman-Cottrill provided an overview of the proposed draft recommendations to the *Guideline for Infection Prevention in NICU Patients* for CLABSI in NICU patients. In terms of the workgroup's activities for the CLABSI prevention guidelines, she said she was very pleased to share that the workgroup is in the final stretch of finalizing the CLABSI NICU prevention guideline. As a reminder, the draft recommendations, including the narrative, evidence reviews, recommendation justification tables, GRADE tables (Grading of Recommendations Assessment, Development and Evaluation), and evidence tables have been presented to HICPAC and the public already during public HICPAC meetings in November 2017; May and November 2018; and May, August, and November 2019.

The workgroup completed an updated review of the recent literature, which led them to propose two revised recommendations. As a reminder, the workgroup has followed GRADE methodology for all of the NICU guidelines. GRADE considers randomized controlled trials (RCTs) to be the gold standard. Non-randomized studies start low in terms of the confidence in the evidence. Many factors can lower the quality of evidence, including risk of bias, inconsistency, indirectness, imprecision, and publication bias. There also are factors that can increase the quality of evidence, including large magnitude of effect, dose-response, and confounding. Recommendations are broken down after the literature review to one of the following:

Recommendation
- Benefits clearly exceed the harms (or vice versa)
- Confidence in supporting evidence:
    - High to moderate
    - Low, very low, or expert opinion if high-quality evidence is impossible to obtain
- Federal regulation

Conditional Recommendation
- Benefits likely to exceed the harms (or vice versa)
- Confidence in supporting evidence is low, moderate, or high when:
    - High quality evidence exists, but benefit/ harm balance is not clearly in one direction
    - Weak evidence and the recommendation may not consistently lead to benefit

- Indirect high-quality evidence (e.g., benefit is seen in other populations & settings)
- Evidence of benefit (or harm) is in the context of simultaneously implemented interventions
- The evidence base is likely to change
- Benefit is most likely if intervention is implemented as a supplemental measure

No Recommendation

- Lack of evidence
- Unclear balance of benefits and harms

Each recommendation in the guideline follows this format to provide further information about how the recommendation was reached:

Draft Recommendations

1. *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:

Before going through the updated review of the recent literature and the two revised draft recommendations, Dr. Guzman-Cottrill first reviewed public comments that were received for this guideline during the public timeline period that was open between April 12, 2021 – June 8, 2021. Each comment is followed by any clarifications and proposed actions:

Comment	• No description of "adapted" GRADE approach is included.
Clarification	• None necessary.
Proposed Action	• Delete “adapted”.

Comment	• To improve clarity and utility for readers, the authors could provide additional explanation of how recommendation decisions were reached following a review of the evidenced-based and expert discussion, and which recommendations relied on expert consensus.
Clarification	• The justifications for expert discussion and consensus are captured in the recommendation justification table accompanying each recommendation. This was discussed at length during 4 HICPAC Meetings (2019-2020) and summarized in both HICPAC Recommendation Categorization Scheme for Infection Control and Prevention Guideline Recommendations and in the associated meeting minutes.
Proposed Action	• None.

Comment	• Providing Further Explanation of Low-Level Evidence & Recommendations: Recommendations in the chapter should be accompanied by an explanation of the strength of conditional recommendations and emphasize the associated implication that health care facilities or personnel “could” or “could consider” implementing these approaches.
Clarification	• The strength of recommendations is outlined in the HICPAC document Update to the CDC and the HICPAC Recommendation Categorization Scheme for Infection Control and Prevention Guideline Recommendations which is referenced in the document. CDC has not objectively quantified the strength of a conditional recommendation. We believe that "consider" is well understood by frontline healthcare personnel.
Proposed Action	• None.

Comment	• Providing Further Explanation of Low-Level Evidence & Recommendations: Recommendations in the chapter should be accompanied by an explanation of the strength of conditional recommendations and emphasize the associated implication that health care facilities or personnel “could” or “could consider” implementing these approaches. • “To improve clarity for the readers, consider the addition of language to these recommendations such as adding the disclaimer “based on the clinical needs of the patient” or “The decision to… in a neonatal intensive care unit (NICU) patient should not be based solely on central line associated bloodstream infection (CLABSI) prevention,” which are already included in the document for other recommendations for conditional recommendations.
Clarification	• Providing Further Explanation of Low-Level Evidence & Recommendations: Recommendations in the chapter should be accompanied by an explanation of the strength of conditional recommendations and emphasize the associated implication that health care facilities or personnel “could” or “could consider” implementing these approaches. • "To improve clarity for the readers, consider the addition of language to these recommendations such as adding the disclaimer “based on the clinical needs of the patient” or “The decision to… in a neonatal intensive care unit (NICU) patient should not be based solely on central line associated bloodstream infection (CLABSI) prevention,” which are already included in the document for other recommendations for conditional recommendations.
Proposed Action	• Added "individual patient needs" to the introduction to clarify that all recommendations should take into account a patient-level risk assessment.

Comment	• Several key questions appear to be questions about general CLABSI prevention concerns and applying those practices to NICU settings, however they do not necessarily address the more granular questions that are posed in the NICU population. • NICU providers may be better aided by tailoring key questions and the resulting recommendations around NICU-specific concerns and interventions. Developing such recommendations likely requires additional research within the NICU population, and it may be of benefit to state that in the introduction.
Clarification	• The introduction already states that a companion paper will be published by SHEA that will address these questions. SHEA will further address questions for which there is limited evidence in neonatal populations.
Proposed Action	• No change.

Comment	• The introduction to the recommendations minimally recognizes the challenge of addressing key questions with available data from NICU patients, as well as the challenges of meeting the varied needs of NICU patients. For this reason, the authors have in some instances relied on strategies shown to prevent CLABSIs in adults or a specific population of infants. While evidence for NICU interventions has been graded by the authors, studies of adult populations have not been graded as part of this chapter. Grading the adult studies used as evidence may provide clinicians with useful context for their application to the NICU population.
Clarification	• Studies examining non-NICU patients were excluded from this literature review.
Proposed Action	• No change.

In terms of the literature search update, 46 studies met inclusion criteria up to 2018 in the original literature search. As mentioned earlier, the last time any NICU CLABSI recommendations were discussed in a HICPAC meeting was in 2019. As a final step, an updated guideline review was conducted using the same inclusion criteria as before, but included an updated literature search covering 2018 – 2021. This updated literature review included 451 titles and abstracts, 61 full text reviews, and inclusion of 10 studies. Of the 14 topics, 8 were reviewed for updates. As a reminder, the *NICU CLABSI Prevention Guidelines* include a total of 14 key questions (KQ). During this meeting, Dr. Guzman-Cottrill reviewed only the specific recommendations for which updated related literature was found and the workgroup reviewed those papers to determine whether the draft recommendations should be modified, including the following:

KQ 2 – Optimal Catheter Type: 1 study
KQ 3 – Optimal Insertion Site: 3 studies
KQ 4 – Number of Lumens: 2 studies
KQ 6 – Chlorhexidine Baths: 1 study
KQ 9 – Umbilical Catheter Dwell Time: 1 study
KQ 11 – Peripherally Inserted Central Catheter (PICC) Care Team: 1 study
KQ 12 – Optimal Bundle Elements: 2 studies

Draft CLABSI: *Catheter Type Draft Recommendation*
1 New Study Added to 9 original studies

Draft Recommendation 2.A. Choose the central line type (e.g., umbilical venous catheter (UVC), peripherally inserted central catheter (PICC), tunneled catheter, etc.) based on the clinical needs of the NICU patient. **Recommendation**

Draft Recommendation 2.B. The choice of central line type to insert in a NICU patient should not be based solely on CLABSI prevention. **Recommendation**

- Konstantinidi 2019; Cohort; N = 71 lines

Draft CLABSI: *Catheter Type Draft Recommendation*
NO CHANGE

- **Supporting Evidence:** Ten observational studies.
- **Level of Confidence in the Evidence:** The level of confidence in this evidence is very low due to imprecision: each study compared different interventions and reported heterogeneous outcome measures for infection. Three studies compared Umbilical Venous Catheters (UVCs) to Peripherally Inserted Central Catheters (PICCs). Six studies compared various catheter types that included umbilical arterial catheters (UACs), UVCs, percutaneous arterial catheters, percutaneous venous catheters, peripherally inserted central catheters, phlebotomy catheters, extended dwell peripheral intravenous catheters, and tunneled catheters. Four of these studies were conducted after the widespread implementation of central line insertion and maintenance bundles in 2010.
- **Benefits**: This evidence did not suggest clear benefit of one catheter type over another; however, the studies evaluated different patient populations with varying clinical indications for central venous access, which was likely reflected in the evidence. The variations in dwell time according to catheter type confounded interpretation of the results.
- **Resource Use:** One study reported that use of Extended Dwell Peripheral Intravenous (EPIV) catheter is more cost effective than PICCs, however this study did not incorporate line success or the cost of hyaluronidase to treat EPIV infiltration into their assessment. Other than this study, 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 facilities.
- **Benefit-Harm Assessment:** The balance of benefits and harms was unclear in this 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.
- **Value Judgments:** Value judgments considered in the formulation of these recommendations include patient safety and economic and human resource costs.
- **Intentional Vagueness:** There is no intentional vagueness in these recommendations.
- **Exceptions:** There are no exceptions to these recommendations.

Draft CLABSI: *Catheter Site Draft Recommendation*
3 New Studies added to 10 original studies

Draft Recommendation 3.A. Choose the insertion site appropriate to the central line type to be inserted in a neonatal intensive care unit (NICU) patient (e.g., UVC, PICC, etc.) based on the clinical needs of the patient. **Recommendation**

Draft Recommendation 3.B. The choice of insertion site in a neonatal intensive care unit (NICU) patient should not be based solely on CLABSI prevention.

- Garcia 2019; case control; N = 179 lines
- Litz 2018; cohort; N = 601 lines
- Elmekkawi 2019; cohort; N = 365 PICCs

Draft CLABSI: *Catheter Site Draft Recommendation*
NO CHANGE

- **Supporting Evidence:** Ten observational studies.
- **Level of Confidence in the Evidence:** The level of confidence in this evidence was low due to inconsistent results or no difference. The studies reported heterogeneous outcome measures for infection. The two studies evaluating femoral lines vs. non-femoral lines were conducted in the same NICU with overlapping study periods.[17,18] All studies were conducted prior to the widespread implementation of central line insertion and maintenance bundles in 2010.
- **Benefits:** The evidence was limited regarding the benefit of one insertion site versus another for percutaneous and tunneled catheters. No benefit of one site versus another was suggested for PICCs.
- **Risks and Harms:** Associations between adverse events and insertion sites were limited and inconsistent, but data suggested that 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. No difference in human or materials costs to place a catheter in one site or another are anticipated, 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, both human and material costs could increase.
- **Benefit-Harm Assessment:** The benefit associated with different insertion sites was unclear. Limited data suggest an increase in adverse events associated with inserting PICCs in upper extremity sites and non-femoral sites. The choice of catheter insertion site is often limited by the availability of venous access sites in NICU patients.
- **Value Judgments:** Value judgments 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 associated with maintaining femoral catheters in diapered children.
- **Intentional Vagueness:** There is no intentional vagueness in this recommendation.
- **Exceptions:** There are no exceptions to this recommendation.

Draft CLABSI: *Chlorhexidine Bathing Draft Recommendation*
1 New Study added to 1 RCT & 2 OBS studies

Draft Recommendation 6.A. Consider use of chlorhexidine bathing to prevent central line-associated blood stream infection (CLABSI) in neonatal intensive care unit (NICU) patients in whom the benefits are judged to outweigh the potential risks. **Conditional Recommendation.**

Draft Recommendation 6.B. The identification of neonatal intensive care unit (NICU) patients who might benefit from chlorhexidine bathing remains an unresolved issue. **No recommendation.**

Draft Recommendation 6.C. If undertaken, the frequency of chlorhexidine bathing for neonatal intensive care unit (NICU) patients remains an unresolved issue. **No recommendation.**

- Westling 2020; cohort; N = 1,233 infants > 1,500g

Given that the presence of central lines is unknown in this paper, the workgroup discussed whether it should be included or excluded. However, the decision was made to include the paper because it did show that bathing was not associated with adverse events and it is known to be a concern for providers in using Chlorhexidine Gluconate (CHG) bathing in premature babies. The findings of this paper do not change the current recommendations for 6A, 6B, or 6C.

Draft CLABSI: *Chlorhexidine Bathing Draft Recommendation*
NO CHANGE

- **Supporting Evidence:** One randomized controlled trial and three observational studies.
- **Level of Confidence in the Evidence:** The level of confidence in this evidence is low due to imprecision. One of the studies was published prior to the widespread implementation of central line insertion and maintenance bundles in 2010.
- **Benefits:** The efficacy of CHG bathing to prevent CLABSI has been demonstrated in other populations. This evidence suggested a benefit to routine CHG bathing for NICU patients in facilities with high baseline rates despite implementation of, and adherence to, insertion and maintenance bundles and infection prevention and control practices. The evidence suggested no benefit to a single CHG bath.
- **Risks and Harms:** Hypothermia was not observed when using CHG washcloths for a single bath.[24] All three studies reported no skin reaction associated with CHG bathing with washcloths or solutions. CHG resistance was not assessed in any of the studies, nor was systemic absorption or effects on the microbiome.
- **Resource Use:** Implementing CHG bathing could result in an increase in human, education, and material cost, but it is anticipated that this cost could be offset by the decrease in costs associated with CLABSI.
- **Benefit-Harm Assessment:** The evidence suggested a benefit to routine CHG bathing in facilities with high baseline CLABSI rates despite implementation of, and adherence to, insertion and maintenance bundles and infection prevention and control practices. Other adverse events were not reported in association with CHG bathing. The long-term impact of CHG bathing on the development of resistance and cross-resistance was not adequately assessed in the evidence.
- **Value Judgments:** Value judgments considered in the formulation of these recommendations include the age of the studies compared to the current standard of care, and patient safety.

- **Intentional Vagueness:** The delivery method for CHG bathing (impregnated bath wipes vs traditional bath), the frequency of bathing, and the target population are left intentionally vague in these recommendations.
- **Exceptions:** CHG bathing will not be appropriate for all NICU patients.

Draft CLABSI: *Umbilical Catheter Dwell Time*
Draft Recommendation: UPDATE

Draft Recommendation 9.A. Remove umbilical venous and umbilical arterial catheters in neonatal intensive care unit (NICU) patients as soon as possible and when no longer needed due to the concern for increasing risk of central line-associated blood stream infection (CLABSI) associated with each day of increasing dwell time. **Recommendation**

New EVIDENCE: Draft Recommendation 9.B. Consider removal of umbilical artery catheters at or before 7 days of dwell time in neonatal intensive care unit (NICU) patients. **Conditional Recommendation**

NEW EVIDENCE: Draft Recommendation 9.C. Consider removal of umbilical venous catheters at or before 7 days of dwell time in neonatal intensive care unit (NICU) patients. **Conditional Recommendation**

Draft Recommendation 9.D. Consider removal of umbilical venous catheters and inserting a peripherally inserted central catheter (PICC) or other long-term central venous catheter at or before 7 days of umbilical venous catheter dwell time for neonatal intensive care unit (NICU) patients requiring long-term central venous access. **Conditional Recommendation**

New evidence was found for 9B and 9C with the new papers and further supporting information listed below for each recommendation. Based on the new evidence, no change was made to either 9B or 9C.

Draft Recommendation 9.B. Consider removal of umbilical artery catheters at or before 7 days of dwell time in neonatal intensive care unit (NICU) patients. **Conditional Recommendation**

NEW EVIDENCE: Levit 2020, cohort; N = 2,017 UACs

- **Supporting Evidence:** Four observational studies.
- **Level of Confidence in the Evidence:** The level of confidence in this evidence is very low due to imprecision and inconsistency across studies. Half of the studies were conducted in the current standard of care.
- **Benefits:** Increasing risk of infection was reported in association with increasing UVC dwell time, suggesting a benefit to removing UVCs at the earliest opportunity. One study suggested the risk of CLABSI was significantly different at 4 days; however, this study used data collected before the widespread implementation of central line insertion and maintenance bundles in 2010. Two studies were conducted in this era, one of which noted no difference in CLABSI when UVC duration was extended from 5 to 7 days as a part of a quality improvement (QI) initiative, and the other reported an increase in risk at 7 days followed by a three-fold increase in risk at 14 days.
- **Risks and Harms:** The evidence suggested that increasing dwell time for UVCs resulted in an increase in the risk of infections, and one of the two studies suggested adverse events such as occlusion were associated with increasing dwell time.

- **Resource Use:** The impact of reducing UVC dwell time on material and human resource costs is unknown.
- **Benefit-Harm Assessment:** While the evidence did not suggest an optimal day by which to remove a UVC to prevent CLABSI, the benefits of removal of UVCs at the earliest opportunity outweigh the harms. The data also did not support extending UVC dwell time past 7 days. 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:** Value judgments considered in the formulation of this recommendation include patient safety and economic and human resource costs.
- **Intentional Vagueness:** Facilities can determine the need for longer-term access based on patient characteristics.
- **Exceptions:** There are no exceptions to this recommendation.

New EVIDENCE: Draft Recommendation 9.C. Consider removal of umbilical venous catheters at or before 7 days of dwell time in neonatal intensive care unit (NICU) patients. **Conditional Recommendation**

Levit 2020, cohort; N = 2,017 UVCs

The workgroup discussed the Levit paper in terms of the first week of life being <1% cumulative incidence and 3.6% cumulative incidence at Day 14. Some might say that that the dwell time could be longer based on that paper, but it is not known from Day 7 to Day 14 when that risk increases. Therefore, the workgroup chose to keep the recommendation as currently stated.

Bandahari 1997, cohort; N = 2,091 UVCs

- **Supporting Evidence:** Two observational studies.
- **Level of Confidence in the Evidence:** The level of confidence in this evidence is low because observational studies start at low quality evidence in the GRADE methodology. One study was not conducted in the current standard of care.
- **Benefits:** Increasing risk of infection was reported with increasing UAC dwell time in one study, suggesting a benefit to removing UACs at the earliest opportunity. The study suggested the risk of sepsis was higher in UACs in situ for ≥8 days when compared with those in situ for ≤7 days. The other study reported 19 CLABSI over ten years and suggested a more than three-fold increase in risk between the first week of use and day 14.
- **Risks and Harms:** The evidence suggested that increasing dwell time for UACs was associated with a higher proportion of infections including occlusion and thrombosis.
- **Resource Use:** The impact of reducing UAC dwell time on material and human resource costs is unknown.
- **Benefit-Harm Assessment:** While the evidence suggested the optimal duration for UACs may be up to 7 days, the data did not provide certainty regarding the optimal day for UAC removal to prevent CLABSI. It is important to note that UAC dwell time and the risk of CLABSI is only one consideration to balance in the clinical needs of a patient.
- **Value Judgments:** Value judgments considered in the formulation of this recommendation include patient safety and economic and human resource costs.
- **Intentional Vagueness:** Facilities can determine the need for longer-term access based on patient characteristics.
- **Exceptions:** There are no exceptions to this recommendation.

Draft CLABSI: *Optimal Bundle Elements Draft Recommendation*

2 new studies (Balla and Savage) were added to 1 existing study
NO CHANGE

Draft Recommendation 12. Use "bundled" interventions for central line insertion and maintenance as part of a single or multiple intervention quality improvement effort to reduce rates of central line-associated blood stream infection (CLABSI) in neonatal intensive care unit (NICU) patients. Elements of insertion and maintenance bundles for all patients have been recommended by the Centers for Disease Control and Prevention.[42] **Recommendation**

- Balla 2018; before after; N = Not Reported (NR)

- Savage 2018; before after; N = NR

- **Supporting Evidence:** 3 observational studies.
- **Level of Confidence in the Evidence:** The level of confidence in this evidence is low due to imprecision. One of the studies was published prior to the widespread implementation of central line insertion and maintenance bundles in 2010.
- **Benefits:** The efficacy of CHG bathing to prevent CLABSI has been demonstrated in other populations. This evidence suggested a benefit to routine CHG bathing for NICU patients in facilities with high baseline rates despite implementation of, and adherence to, insertion and maintenance bundles and infection prevention and control practices. The evidence suggested no benefit to a single CHG bath.
- **Risks and Harms:** Hypothermia was not observed when using CHG washcloths for a single bath.[24] All three studies reported no skin reaction associated with CHG bathing with washcloths or solutions. CHG resistance was not assessed in any of the studies, nor was systemic absorption or effects on the microbiome.
- **Resource Use:** Implementing insertion and maintenance checklists or bundles could result in an increase in material and human resource cost, but it is anticipated that this cost could be offset by the decrease in costs associated with CLABSI.
- **Benefit-Harm Assessment:** Even though harms were not assessed, the evidence suggested a benefit to implementing insertion and maintenance bundles as part of infection prevention and control practices with the potential to decrease CLABSI.
- **Value Judgments:** Value judgments considered in the formulation of this recommendation include the age of the studies compared to the current standard of care, and patient safety. Use of insertion and maintenance bundles has become the standard of care in patients with central lines, including NICU patients.
- **Intentional Vagueness:** The components of insertion and maintenance bundles studied in NICU patients vary, and no study has compared the effectiveness of one bundle versus another in this population. The optimal components of NICU-specific bundles, above and beyond the standard measures recommended by CDC, cannot be determined from the available evidence.
- **Exceptions:** There are no exceptions to this recommendation.

Draft CLABSI: *Number of Lumens Draft Recommendation*
Two new studies added to one study

Previous Draft Recommendation 4. The choice of single versus double lumen umbilical venous catheter solely for the purpose of preventing CLABSI in neonatal intensive unit care patients remains an unresolved issue. **No recommendation.**

Pre-existing Evidence: 1 RCT

- Catheter-associated Sepsis:
  - No infections reported in either group
- Adverse events
  - No difference in leaks around catheter site, occlusion of one lumen, difficulty with insertion, or mechanical problems between groups
- This study may have been underpowered

New Evidence: 2 observational studies

- Garcia 2019; case control study; N = 179 Central Venous Catheters (CVC)

- Levit 2020, cohort; N = 2,017 UVCs

Concerns exist for confounding by indication in both studies despite adjusted estimates of effect. The workgroup recommended changing Recommendation 4 from No Recommendation to a Conditional Recommendation.

Previous Draft Recommendation 4. The choice of single versus double lumen umbilical venous catheter solely for the purpose of preventing CLABSI in neonatal intensive unit care patients remains an unresolved issue. **No recommendation.**

Draft Updated Recommendation 4. Consider choosing the fewest number of lumens based on the clinical needs of the neonatal intensive care unit patient. **Conditional recommendation**

- **Supporting Evidence:** One randomized controlled trial, and two observational studies
- **Level of Confidence in the Evidence:** The level of confidence in this evidence is low due to imprecision.
- **Benefits:** Two observational studies reported an increase in the adjusted risk or odds of CLABSI with the use of double lumen catheters, compared with single lumen catheters, however there is concern for confounding by indication in these studies. The RCT was small and reported no infections; however, a reduction was found in the number of additional intravenous catheters required with the use of double-lumen catheters.
- **Risks and Harms:** One observational study reported a non-significant increase in complications with double lumens compared with single lumens, however limited conclusions can be drawn from this because this increase also included CLABSI. The RCT reported no difference in adverse events. Notably, increasing number of lumens in other types of catheters has been associated with an increased risk of infection in adults.
- **Resource Use:** No difference in human or material costs associated with the insertion and maintenance of single versus double-lumen catheters was reported.
- **Benefit-Harm Assessment:** The balance of benefits or harms was inconsistent across studies; however, the confidence in this evidence is low because patients requiring more care will likely have more CVC inserted or more lumens in their CVCs. Thus, it is likely these studies are subject to confounding by indication. Future publications may change the strength and direction of this evidence. Increasing the number of lumens has been associated with increased risk of thrombotic and other infectious complications in adult populations.
- **Value Judgments:** Value judgments 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.

Draft CLABSI: *Catheter Care Team Draft Recommendation*
1 new study added to 1 study

Previous Draft Recommendation 11. The efficacy of having a dedicated peripherally inserted central catheter care team to prevent central line-associated blood stream infection (CLABSI) in neonatal intensive care unit (NICU) patients remains an unresolved issue. **No Recommendation**

Draft Updated Recommendation 11. Consider implementing a dedicated catheter care team to prevent central line-associated blood stream infection (CLABSI) in neonatal intensive care unit (NICU) patients, when baseline rates are high. **Conditional recommendation**

New Evidence: 1 observational study
Holzmann-Pazgal 2012; cohort study; N = NR CVC

Existing Evidence: 1 observational study
Taylor 2011; cohort study; N = 200 CVC

- **Supporting Evidence:** Two observational studies.
- **Level of Confidence in the Evidence:** The level of confidence in this evidence is very low due to imprecision.
- **Benefits:** The evidence suggested a decrease in risk of CLABSI with the use of a catheter care team to in NICU patients. One study suggested Catheter-related Bloodstream Infections (CRBSI)reductions when patients were stratified by duration of catheter, patients with an indwelling central line ≥30 days had a 50% lower risk of CRBSIs, while there was no difference in risk of CRBSI for patients with an indwelling catheter
- **Risks and Harms:** Harms attributable to the catheter care team were not reported.
- **Resource Use:** Implementing a catheter care team could result in an increase in human resource cost, but it is anticipated that this cost could be offset by the decrease in costs associated with CLABSI.
- **Benefit-Harm Assessment:** Even though no harms or benefits were reported from implementing a catheter care team, the evidence suggested a reduction in the risk of all CLABSI, or CRBSI in patients with indwelling central lines placed ≥30 days.
- **Value Judgments:** Value judgments considered in the formulation of this recommendation include the age of the studies compared to the current standard of care, and patient safety.
- **Intentional Vagueness:** The composition of the catheter care team the composition of the catheter care team and assigned duties are not specified.
- **Exceptions:** Exceptions do not apply to an unresolved issue.

Dr. Guzman-Cottrill indicated that the following updated recommendations in the CLABSI Section on which HICPAC would be asked to vote included the following:

Draft Updated Recommendation 4. Consider choosing the fewest number of lumens based on the clinical needs of the neonatal intensive care unit patient. **Conditional recommendation**

Draft Updated Recommendation 11. Consider implementing a dedicated catheter care team to prevent central line-associated blood stream infection (CLABSI) in neonatal intensive care unit (NICU) patients, when baseline rates are high. **Conditional recommendation**

Discussion Points

Dr. Babcock observed that there appeared to be separate recommendations for 9A, 9B, and 9C that all ended up saying pretty much the same thing, that if there is an umbilical artery or venous catheter, it should be taken out before 7 days. She asked whether there had been any discussion about lumping these together.

Dr. Guzman-Cottrill responded that 9A states to remove the line as soon as possible, which is the guiding principle for all CLABSI prevention. The workgroup wanted to make sure that was up front and stated clearly. Historically for umbilical arterial catheters versus venous catheters that are used in premature babies, there has been a mix of recommendations in the literature, whether it is umbilical venous or arterial, in terms of how many days it can be kept in safely and the maximum number of days. Some of the guidelines used by clinicians say 7 days, some say 10 days, and some say 14 days. This was a key question that was requested of many stakeholders in terms of making specific different recommendations for the venous catheters and the arterial catheters with regard to the maximal number of days to be able to keep it in. For extremely premature babies, it is often very difficult to get another type of access in other than the umbilical artery and vein. That is why the workgroup opted to separate it into A, B, and C.

In terms of Draft Updated Recommendation 11, Dr. Babcock asked about the use of the word "baseline" in that this should be considered only when baseline rates are high. She asked what the protocol would be if baseline rates were okay, but there was an increase in the rates over the last couple of years. She suggested a modification to, "when rates are high."

Dr. Lin pointed out that if this intervention works, it also could be a prevention measure even when there is not an outbreak. Therefore, he suggested removing the clause "when baseline rates are high."

Dr. Guzman-Cottrill agreed with the suggestion to remove "when baseline rates are high."

Ms. Dekker said that based on what she is used to seeing in her ICU, they have such a rarity that they say one is a problem for them because they do not have a lot of line days and do not see a lot of infections. She suggested stating "when any increase is noted" for Recommendation 11. If they wait until it is high, the prevention piece is missed.

Dr. Guzman-Cottrill emphasized that a dedicated catheter care team, if it is possible, should be thought of as a prevention measure not a reaction. Perhaps "when baseline rates are high" could be removed from the recommendation and discussion could be included in the narrative about how this should be used to prevent CLABSI. Her institution has gone many months without a CLABSI in the NICU. That does not mean they should not even consider this.

Vote: Guideline for Infection Prevention in NICU Patients: CLABSI Section
The proposed updated recommendations in the CLABSI Section of the *Guideline for Infection Prevention in NICU Patients* were put forth for approval, with the HICPAC suggestion to remove the clause "when baseline rates are high" from Recommendation 11 and further discussion in the narrative pertaining to how this should be used to prevent CLABSI. HICPAC voted unanimously to approve the recommendations with the suggested modification, with no opposition and no abstentions. The disposition of the vote was as follows:

- 11 Favored: Anderson, Babcock, Daniels, Dekker, Fakih, Guzman-Cottrill, Kraft, Lin, Maragakis, Preas, Reifsnyder
- 0 Opposed

- 0 Abstained
- 1 Not Present: Wright

Federal Entity Comment

No federal entity comments were provided during this meeting.

Public Comment

No public comments were provided during this meeting.

Summary and Work Plan

Dr. Babcock thanked everyone for taking time out of their busy schedules, particularly in the midst of the continuing COVID-19 pandemic and surges. She summarized that during this meeting, HICPAC heard a DHQP update, an update from the HCP Guideline Workgroup that included a HICPAC vote on a rabies recommendation, an update from the Isolation Precautions Guideline Workgroup that is getting underway, and an update from the NICU Guideline Workgroup that included a vote on two amended recommendations. There were no federal entity or public comments.

Adjournment

Dr. Bell thanked the HICPAC members, Co-Chairs, *Ex Officios*, and Liaison Representatives for their participation and thoughtful input during this meeting. He also expressed gratitude to Ms. Payne and Ms. Byrd for running an efficient Zoom meeting and Dr. Maragakis for joining them while in transit in her automobile. He thanked Dr. Babcock for her leadership in keeping HICPAC efforts moving forward despite a crazy year and a half with the COVID-19 pandemic.

With no additional business raised or comments/questions posed, HICPAC stood adjourned at 1:39 PM ET.

Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the August 19, 2021 meeting of the Healthcare Infection Control Practices Advisory Committee, CDC are accurate and complete.

_____ _____

Date Hilary Babcock, MD, MPH
Co-Chair, HICPAC / CDC

_____ _____

Date Lisa Maragakis, MD, MPH
Co-Chair, HICPAC / 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
AEH	America's Essential Hospitals
AHA	American Hospital Association
ANA	American Nurses Association
AORN	Association of periOperative Registered Nurses
APIC	Association of Professionals of Infection Control and Epidemiology
ARC	All-Hazards Readiness, Response, and Cybersecurity
ASM	American Society of Microbiology
ASN	American Society of Nephrology
ASQ	American Society of Quality
ASTHO	Association of State and Territorial Health Officials
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CHG	Chlorhexidine Gluconate
CLABSI	Central Line-Associated Bloodstream Infection
CMS	Centers for Medicare and Medicaid Services
COI	Conflicts of Interest
CQI	Certified Quality Inspector
CQIA	Certified Quality Improvement Associate
CRBSI	Catheter-related Bloodstream Infections
CSTE	Council of State and Territorial Epidemiologists
CVC	Central Venous Catheter
DHQP	Division of Healthcare Quality Promotion
EO	Ethylene Oxide
EPIV	Extended Dwell Peripheral Intravenous
ET	Eastern Time
FDA	(United States) Food and Drug Administration
FMT	Fecal Microbiota Transplant
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HAI	Healthcare-Associated Infection
HCP	Healthcare Personnel
HHFL	Healthcare Human Factors Lab
HHS	(United States Department of) Health and Human Services
HICPAC	Healthcare Infection Control Practices Advisory Committee
HIV	Human Immunodeficiency Virus
HRSA	Health Resources and Services Administration
IDSA	Infectious Disease Society of America
IHS	Indian Health Services
KQ	Key Questions
MMWR	*Morbidity and Mortality Weekly Report*
NACCHO	National Association of County and City Health Officials
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NHSN	National Healthcare Safety Network

Acronym	Expansion
NICU	Neonatal Intensive Care Unit
NIH	National Institutes of Health
PEP	post-exposure prophylaxis
PHAC	Public Health Agency of Canada
PICC	Peripherally Inserted Central Catheter
PIDS	Pediatric Infectious Disease Society
PrEP	Pre-Exposure Prophylaxis
PSAN	Patient Safety Action Network
RCT	Randomized Controlled Trial
S. Aureus	*Staphylococcus Aureus*
SCCM	Society for Critical Care Medicine
SHEA	Society for Healthcare Epidemiology of America
SHM	Society of Hospital Medicine
SIS	Surgical Infection Society
SME	Subject Matter Expert
TB	Tuberculosis
TJC	The Joint Commission
US	United States
UAC	Umbilical Arterial Catheters
UVC	Umbilical Venous Catheter
VA	Department of Veteran Affairs
VE	Vaccine Efficacy
QI	Quality Improvement