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
February 15, 2018
Atlanta, Georgia

Record of the Proceedings

Contents

Meeting Agenda

Healthcare Infection Control Practices Advisory Committee
February 15, 2018
Centers for Disease Control and Prevention
Atlanta, Georgia
Teleconference

Time	Topic	Purpose	Presider/Presenter (s)
12:00pm	Welcome and Roll Call	Information	Daniel Diekema (HICPAC Co-Chair) Deborah Yokoe (HICPAC Co-Chair) Mike Bell (DFO, HICPAC; CDC)
12:10	Recommendation Categorization Workgroup Update	Information/ Discussion	Daniel Diekema (HICPAC Co-Chair) Deborah Yokoe (HICPAC Co-Chair)
12:30	Healthcare Personnel Guideline Workgroup Update	Information/ Discussion	Hilary Babcock (Subject Matter Expert)
1:00	NICU Guideline Workgroup Update	Information/ Discussion	Kristina Bryant (HICPAC)
1:30	Public Comment		
1:45	Vote and Call Summary	Discussion/Vote	Daniel Diekema (HICPAC Co-Chair) Deborah Yokoe (HICPAC Co-Chair)
2:00	Adjourn		

List of Attendees

HICPAC Members

Dr. Daniel Diekema, Co-Chair
Dr. Deborah Yokoe, Co-Chair
Ms. Vickie Brown
Dr. Kristina Bryant
Dr. Vineet Chopra
Ms. Loretta Fauerbach
Dr. Michael Howell
Dr. Lisa Maragakis
Dr. Jan Patterson
Dr. Selwyn Rogers

Ex officio Members

Ms. Yvonne Chow, Health Resources and Service Administration (HRSA)
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. Gary Roselle, US Department of Veterans Affairs (VA)
Dr. Daniel Schwartz, Centers for Medicare and Medicaid Services (CMS)

Liaison Representatives

Ms. Elaine Dekker, America's Essential Hospitals (AEH)
Dr. Mark Russi, American College of Occupational and Environmental Medicine (ACOEM)
Ms. Sharon Morgan, American Nurses Association (ANA)
Ms. Amber Wood, Association of periOperative Registered Nurses (AORN)
Ms. Darlene Carey, Association of Professionals of Infection Control and Epidemiology (APIC)
Ms. Lisa McGiffert, Consumer's Union (CU)
Dr. Marion Kainer, Council of State and Territorial Epidemiologists (CSTE)
Ms. Linda Spaulding, DNVGL Healthcare
Dr. Steven Weber, Infectious Diseases Society of America (IDSA)
Ms. Dana Nguyen, National Association of County and City Health Officials (NACCHO)
Ms. Kathleen Dunn, Public Health Agency of Canada (PHAC)
Dr. Craig Coopersmith, Society of Critical Care Medicine (SCCM)
Dr. Valerie Vaughn, Society of Hospital Medicine (SHM)
Ms. Kathryn Spates, The Joint Commission (TJC)

CDC/ Federal Representatives

Matthew Arduino, CDC/ DHQP
Michael Bell, CDC/ DHQP
Isaac Benowitz, CDC/ DHQP
Denise Cardo, CDC/ DHQP
Alicia Cole, CDC/ DHQP
Kendra Cox, CDC/ DHQP
Koo-Whang Chung, CDC/ DHQP
Mahnaz Dasti, CDC/ DHQP
Marie DePerio, CDC/ NIOSH
Katherine Fleming-Dutra, CDC/ DHQP
Cecilia Joshi, CDC/ DHQP
Wesley Kennemore, CDC/ DHQP
Stephen Kralovic, VA
David Kuhar, CDC/ DHQP
Kathleen Irwin, CDC/ DHQP
Kiran Perkins, CDC/ DHQP
Kristin Roberts, CDC/ DHQP
Nalini Singh, CDC/ DHQP
Erin Stone, CDC/ DHQP
Judy Trawick, HRSA
Taitainia Williamson, CDC/ DHQP

Members of the Public

James Arbogast, GOJO
Hilary Babcock, Washington University School of Medicine
Tammy Davis, TOPS Surgical Specialty

Hospital
Kathy Day, Safe Patient Project
Denise Graham
Maryellen Guinan, AEH
Nancy Hailpern, APIC
Lori Harmon, SCCM
Jessica Hayashi, Hayashi Infection Prevention Consulting
Kaitlin Heath, Becton Dickinson
Joan Hebden
Karen Hoffman, Infection Preventionist, Consultant
Eve Humphreys, SHEA
W. Charles Huskins, Mayo Clinic
Eric Jones, Sanofi Pasteur
Nadia Krasner, Cerus
Rachel Long, Becton Dickinson
Will Meade, 3M
Renee Odenhal, Ethicon US
Maria Rodriguez, Xenex Disinfection Services
Tina Seery, Washington State Hospital Association
Connie Steed, APIC
Keith St. John, PDI
Rachel Stricof, CSTE
Sylvia Quevedo, APIC
Angela Vassallo
David Weber, University of North Carolina

Executive Summary

The 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 teleconference meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on February 15, 2018. The Designated Federal Official (DFO) and co-Chairs confirmed the presence of a quorum of HICPAC voting members and *ex officio* members, which was maintained throughout the meeting.

Dr. Daniel Diekema provided an update on the Recommendation Categorization Workgroup efforts. He presented for HICPAC's approval the draft Recommendation Categorization scheme and Justification Tables. HICPAC unanimously voted to approve the draft scheme and tables.

Dr. Hilary Babcock updated HICPAC on the Healthcare Personnel Guideline Workgroup, including the progress of Section 1 through CDC clearance; draft recommendations and text for the Pertussis section of the Healthcare Personnel Guideline Section 2; and preliminary draft recommendations for Measles, Mumps, and Rubella. HICPAC unanimously voted to approve the draft recommendations and accompanying text for the Pertussis section of the Healthcare Personnel Guideline, Section 2.

Dr. Kristina Bryant described the work of the NICU Guideline Workgroup. HICPAC unanimously voted to approve the *C. difficile* systematic review and voted to approve Key Question 2 regarding *S. aureus*.

HICPAC stood in recess at 1:18pm on February 15, 2018.

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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)

February 15, 2018

Teleconference

Meeting Transcript

The United States 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 February 15, 2018, via teleconference.

Welcome and Roll Call

Coordinator: Excuse me, this is the operator. The conference line is now open you may begin.

Michael Bell: Thanks (Gabrielle). Hello everybody and welcome to our public HICPAC call. This is Mike Bell and I'm here with Koo Chung, Kendra Cox, and Erin Stone, and Debbie and Dan, are you on?

Deborah Yokoe: Yes.

Daniel Diekema: Yes.

Dr. Bell: So we have our co-Chairs. If it's all right with you then, I'll start with roll call and a request for any declarations of conflicts of interest. I'll start with HICPAC numbers, then the *ex officios*. Then I'll do roll call for the Liaison Representatives, and thereafter I will remind you a second time what I'm about to tell you now, which is that all of us need to send an email to HICPAC@cdc.gov confirming our attendance. This is how we can get formal recording of participation in this official meeting. I'll remind one more time of that email address after roll call. So with that I've already got Dan Diekema, Deborah Yokoe - do either of you have conflicts of interest that you need to declare?

Dr. Yokoe: This is Debbie. No conflicts.

Dr. Diekema: This is Dan, I receive research funding from bioMérieux.

Dr. Bell: Vickie Brown.

Vickie Brown: Yes present and no conflicts.

Dr. Bell: Kris Bryant.

Kristina Bryant: Present. I have been an investigator on clinical vaccine trials funded by Pfizer.

Dr. Bell: Thanks. Vineet Chopra.

Vineet Chopra: Present and no conflicts of interest to disclose.

Dr. Bell: Loretta Fauerbach.

Loretta Fauerbach: Present and no conflicts of interest.

Dr. Bell: Michael Howell. I'll come back to Mike Howell in just a minute. Lisa Maragakis.

Lisa Maragakis: Present, and I receive research funding from Clorox.

Dr. Bell: Thank you. Jan Patterson.

Jan Patterson: Present. No conflicts.

Dr. Bell: Selwyn Rogers. Let me go back to Michael Howell. So we're still missing two. Moving on to *ex officios*. Melissa Miller, AHRQ [Agency for Healthcare Research and Quality].

Melissa Miller: Present.

Dr. Bell: Thank you. Liz Claverie, we've already heard your voice. You're still here?

Elizabeth Claverie-Williams: Yes. Present.

Dr. Bell: Okay. David Henderson, NIH [National Institutes of Health].

David Henderson: I'm here.

Dr. Bell: Yvonne Chow, HRSA [Health Resources and Services Administration].

Yvonne Chow: Present.

Dr. Bell: Gary Roselle, VA [US Department of Veterans Affairs]. Dan Schwartz.

Daniel Schwartz: Yes, I'm here.

Dr. Bell: Was that Gary or Dan?

Dr. Schwartz: Dan.

Dr. Bell: Thanks Dan. All right, one more chance for Gary Roselle.

Stephen Kralovic: Mike, this is Steve Kralovic, I'm representing Gary Roselle and just got on. Sorry about that.

Dr. Bell: Terrific. Thank you, Steve. And then going to the Liaisons. America's Essential Hospitals, Elaine Dekker.

Elaine Dekker: I'm here and no conflicts.

Dr. Bell: American College of Occupational and Environmental Medicine, Mark Russi.

Mark Russi: Yes. I'm here.

Dr. Bell: Thanks Mark. Elizabeth Wick of American College of Surgeons. American Hospital Association, Evelyn Knolle. American Nurses Association, Sharon Morgan.

Sharon Morgan: Present.

Dr. Bell: Thank you. AORN [Association of periOperative Registered Nurses], Amber Wood.

Amber Wood: Present.

Dr. Bell: APIC [Association of Professionals of Infection Control and Epidemiology], Darlene Carey. Consumers Union, Lisa McGiffert. CSTE [Council of State and Territorial Epidemiologists], Marion Kainer.

Marion Kainer: Present.

Lisa McGiffert: Did you just call Consumers Union?

Dr. Bell: I did. Thanks, Lisa.

Ms. McGiffert: Yes, I'm here.

Dr. Bell: DNV Healthcare, Linda Spaulding.

Linda Spaulding: I'm here.

Dr. Bell: Thank you. IDSA [Infectious Diseases Society of America] Steve Weber. NACCHO [National Association of County and City Health Officials], Dana Nguyen.

Dana Nguyen: I'm here.

Dr. Bell: PHAC, Public Health Agency of Canada, Kathy Dunn.

Kathy Dunn: Hi, Mike. I'm here.

Dr. Bell: Thanks, Kathy. SHEA [Society for Healthcare Epidemiology of America], Louise Dembry. Society for Critical Care Medicine, Craig Coopersmith.

Craig Coopersmith: I am here.

Dr. Bell: Okay. Society for Hospital Medicine, Valerie Vaughn.

Valerie Vaughn: Here.

Dr. Bell: Thanks, Valerie. Surgical Infection Society, Rob Sawyer. The Joint Commission, Kathryn Spates.

Kathryn Spates: I'm here.

Dr. Bell: Thank you. Great. Is there anybody on the call whom I didn't call?

Dr. Diekema: Mike, I just got an email from Dr. Michael Howell that said that he is on the call, but he thinks he's being muted from your end or from the...

Dr. Bell: Okay. So Mike, there's another line. We'll send you by email the right line to call to be within the meeting as opposed to listening to the meeting. Please stand by and look for an email.

Okay. So at this point everyone except Dr. Selwyn Rogers, and all of our *ex officios*, we have everyone on board. Great. So, I think we have a quorum and that is excellent. I'll remind us all once more that the email address to send in the subject line, "attendee" or "present." It's HICPAC, H-I-C-P-A-C @cdc.gov and that's all you need to do. This will also give us an efficient way to get you the PDFs of the presentations. With that, if I may, I will turn it over to our co-Chairs. Dan.

Dr. Diekema: Thank you very much. I guess before I start, I also – do you also need to announce in the roll call the subject matter experts that are present or not?

Dr. Bell: No, I don't think that's required.

Recommendation Categorization Workgroup Update

Dr. Diekema: Yes, good. Okay. So, I'll start off with a review of what we hope to be - or what we'll be discussing is a potential final product of the HICPAC Recommendation Categorization Update Workgroup, and for those who have the meeting materials in front of them, if you open up the file that starts with my last name, Diekema-HICPAC-Rec-Cat-Workgroup, you can follow along where you are.

So moving in there to slide number 3 just for some background. As many of you know, this process started by way of a desire for us to simplify HICPAC's recommendation categories and improve transparency around the rationale behind why a specific category was chosen, address practices for which evidence is scant or absent, and to hopefully improve the way we can address bundled practices.

The activities of the workgroup to this point have included monthly workgroup calls. There were discussions at two HICPAC meetings in July and November of last year. So some of this should look quite familiar to you and we have also, or I should say the CAUTI [catheter-associated urinary tract infection] - the Workgroup has tested these draft category recommendations and the NICU [neonatal intensive care unit] Guideline Workgroup is also gaining some experience with this, as you will all see later on in the call.

So the next slide has an overview of - I'll be presenting three tables, one with the categories, the next with justification for choice of recommendation table, and the last table is the aggregate quality of evidence.

If you go to slide 5, I'll start with the strength category that is just Recommendation. And what we mean when we say this is, a Recommendation is that we're confident that the benefits of the approach exceed the harms or, in the case of a negative Recommendation, that the harms clearly exceed the benefits. These Recommendations ideally, of course, should be supported by

high- to moderate-quality evidence, but there may be times when a Recommendation can be made based on lesser evidence or expert opinion.

When high-quality evidence is either not forthcoming or impossible to obtain and the anticipated benefits strongly outweigh the harms, or when a recommendation is required by Federal law, we will also put it into the Recommendation category.

The implied obligation here is that healthcare personnel and healthcare facilities should implement the recommended approach unless there's a clear and compelling rationale for an alternative approach.

So the language that we want to use for a Recommendation would specify the setting and population to which it applies, for example, adult intensive care units, and use declarative verbs like use, perform, maintain, should, should not, and the language "we recommend" or "we recommend against," that this approach is "indicated" or is "not indicated."

So on the next slide would be the next category, which we would call a Conditional Recommendation, and this would be used in a situation where we've determined that the benefits of the recommended approach are likely to exceed the harms or for a negative recommendation, harms are likely to exceed the benefits.

These recommendations - Conditional Recommendations - can be supported by either low-, moderate- or high-quality evidence. For example, when there is high-quality evidence but the benefit/harm balance isn't clearly tipped in one direction, or the evidence is weak enough that it may cast doubt on whether the approach will consistently lead to benefit, or the likelihood of benefit for a specific patient population or situation has been extrapolated from relatively high-quality evidence demonstrating an impact in other patient or clinical situations, or the impact of the intervention it is difficult to disentangle from other simultaneously implemented interventions, as in a bundled approach to prevention of an adverse outcome, or there might be a benefit based on available evidence but with further research, it's anticipated that the benefit harm balance might change, or finally that the benefit is most likely if the intervention is used as a supplemental measure to basic practices.

So the implied obligation here for a Conditional Recommendation is that the healthcare facility or the healthcare personnel could or should consider implementing that approach, and the degree of the appropriateness of the approach will vary depending on the benefit/harm balance for that setting.

And so finally, this would be reflected in the language that would again specify the setting and population to which the Conditional Recommendation applies, and when it's relevant would include the selected settings. For example, something might be a Conditional Recommendation during an outbreak, but not during a non-outbreak setting, or in selected environments or selected populations, and the type of language would be "consider," "could" or "should consider," or "may," or "may consider."

Then on slide 7, the final category would be No Recommendation, and the definition here is obvious. It's that when there is both a lack of evidence and an

unclear balance between benefits and harm, and the language would just be "no recommendation can be made regarding" whatever the approach would be.

Dr. Yokoe: Dan, do you want to pause and see if there are any comments or questions?

Dr. Diekema: Sure. That's a good idea.

Ms. Wood: This is Amber Wood from AORN. Great job. I'm really excited about this. I do have a suggestion that the word "should" should be reserved for a Recommendation. The word "consider" may cause some confusion, and I would recommend taking that out of Conditional Recommendations.

Dr. Diekema: You mean taking the bullet point "should consider" out?

Ms. Wood: Of Conditional Recommendation, and reserving the use of the word "should" only when a Recommendation is made.

Dr. Diekema: Any other comments on that suggestion or concerns about removing that bullet?

Dr. Yokoe: This is Debbie. That sounds reasonable. And Amber, you don't have any concerns with the other bullets, "consider?"

Ms. Wood: No. AORN uses the same - we use the word "may" for the recommendation and I think there is some literature around the psychology around the word "should" versus "may," and I think it's appropriate to use that here.

Dr. Yokoe: Great. Good point.

Michael Howell: Debbie and Dan, this is Mike Howell, I just wanted to say that I've resolved my call-in difficulties and am both present, and also wanted to make sure that folks on the call knew my conflicts, which that I work for Google and am employed by Google and own equity in the company.

Dr. Yokoe: Excellent. Thank you. Thanks, Mike. Other comments regarding Table 1? Great.

Dr. Diekema: All right. So then I'll continue to slide number 8 in this file, which is to review Table 2. Table 2 is meant to be used by, well, initially the guideline workgroup and HICPAC to sort of specify what the justification is and the choice of recommendation.

And the components that we would like to include are in the left-hand column there, including aggregate evidence quality. We will discuss that in Table 3. The next component would be Benefit, where we would list the favorable changes and outcomes that would likely occur if the recommendation were followed.

The next would be Risks and Harms, where we include the adverse events or other unfavorable outcomes that may occur if the recommendation were followed. And here we want to be very explicit, both in Benefits and Risks and Harms, and clear about the pros and cons.

The next would be the Benefit/Harm Assessment, where we would want to classify as a preponderance of benefit over harm or vice versa, or a balance of benefit and harm, describing this either from the individual patient perspective,

the societal perspective, or both.

And in the Comments section, you can see that we really want to make a recommendation only when there's a clear benefit that's not offset by important harms or costs or vice versa, and when the benefit is small or offset by important adverse factors, the balance between benefit and harm would prevent a recommendation from being made.

The next component, I guess these are larger on slide 9, if you're still on slide 8, would be in the area of Resource Use, where you would want to describe if it's applicable, the direct costs, opportunity costs, material or human resource requirements, facility needs that could be associated with following the recommendation.

Recognizing in the comments section that HICPAC is not performing its own cost analysis and that costs change over time and in different settings. And so we're not obligating ourselves to address costs if these analyses are not available and no useful statements can be made, but we would like to state clearly if information is lacking.

So on the next slide, slide 10, moving on to the next component, which would be Value Judgments, summarizing value judgments used by the group in creating the recommendation or stating none if none were made. So what are we talking about with value judgments? So these might include guiding principles, ethical considerations, other beliefs or priorities, and we believe that stating them clearly will help users to understand what the influence was in interpreting the objective evidence.

The next component is one that is popular with all of us, Intentional Vagueness. Sometimes there is some vagueness in the recommendation that may be intentional. If so, and you know obviously recommendations should be clear and specific, but if there is a vagueness that's intentional, we ought to acknowledge the reasoning behind it. Reasons might include insufficient evidence and lack of consensus among the panel regarding evidence quality or anticipated harms and benefits, or the interpretation of the evidence, legal considerations, economic reasons, or ethical or religious issues.

The next category would be Exceptions, where the Workgroup or committee would list situations or circumstances where the recommendation should not be applied.

So before we open it up for discussion again, I'll point everyone to slide 11, which addresses the first category on Table 2, the aggregate quality of evidence. What do we mean when we say evidence - the quality of evidence is high, moderate or low?

So just to review quickly, "high" means we're highly confident that the true effect lies close to the estimated size and direction of the effect. So for example, that means that there might be a wide range of studies with no major limitations that come to the same conclusion, that there's little variation between the studies, and when summary estimates can be done, those estimates have a narrow confidence interval.

For the “moderate” quality of evidence, what we mean is that the true effect is likely to be close to the estimated size and direction of the effect, but there’s a possibility that it could be substantially different. Examples here would be that there might be only a few studies, or studies that have limitations but not major flaws, that there’s some variation between the studies, or that the confidence interval of any summary estimate is wide.

And then finally for “low” quality evidence, we mean that the true effect may be substantially different from the estimated size and direction of the effect. Examples here are when supporting studies have major flaws, that there’s an important or major variation between studies or that the confidence interval, the study estimate is very wide, or there are no rigorous studies.

So I think now we can open it up again for discussion of the last two tables.

Dr. Yokoe: Are there any comments or questions for Dan?

Dr. Diekema: So I guess I should mention if there aren’t any additional comments or questions - we’ll give you a couple more minutes. We would hope to vote on these tables at this point at the end of the call. And when we vote on it, it would be a vote with any modifications that we agree on, and the one that we have agreed on at this point is to remove “should consider” as a bullet in the language column of the Conditional Recommendation.

Ms. Wood: This is Amber Wood from AORN. I have a question. Some of these elements could be subjective, and I’m wondering is there going to be a process for coming to consensus on these components among the Workgroup, and will that be transparent in the consensus process in how these assessments were made?

Dr. Diekema: I’ll start by speaking to that. I think in general both the Workgroups and the committees certainly attempt to come to consensus, and we did have a discussion within this Workgroup around how transparent to be about any remaining disagreements or differences of opinion, which are reflected in the minutes and also have been reflected in the past in votes.

And we decided it was perhaps more useful not to include a separate category or component within this table that really got into the gory detail about specific differences of opinion. Rather, it would be addressed perhaps in the Intentional Vagueness component, where we might describe an inability to achieve consensus among the panel regarding different aspects of evidence quality or benefits and harms.

Ms. Wood: Thank you. That clarifies it and I appreciate the effort to move towards more transparency, and I think these components really address that.

Dr. Diekema: Debbie or anyone else that was part of that conversation, do you want to add?

Dr. Yokoe: No, you summarized it well. I think we just discussed the importance of transparency, including components of the discussion around elements where there is dissention, and the other elements in Table 2.

Dr. Howell: Dan this is Michael. I think this is really well done and moves us forward a lot

from where we've been and so I really appreciate the work that everyone has done to get it this far. I think it will add a lot to our process.

Dr. Diekema: Thank you. I agree.

Dr. Yokoe: Right. Are there other comments or questions for Dan? Excellent. Okay shall we move on to the next topic? Our next discussant is Hilary Babcock, who will be providing an update on the Healthcare Personnel Guideline Workgroup.

Healthcare Personnel Guideline Workgroup Update

Hilary Babcock: Hello. So also as Dan mentioned, the slides for my presentation are in the materials you received under Babcock-HICPAC-Guideline-Workgroup-Update. So we'll go through those slides and then I'll pause for questions a couple of times in the middle as we go through.

If you click through the slides, there's the disclaimer and then just a reminder about the Workgroup and the Workgroup charge, this has not changed.

And then on slide 4, we have a little status report. Section 1, which came through the committee for moving on to clearance, has completed the clearance review, and the items from clearance are being incorporated into that.

As a reminder, that's the infrastructure and routine practices, overview of occupational infection prevention services, and the next step after the clearance edits for that part will be public comments.

And then Section 2 is the part that we're working on now, the pathogen-specific sections, and so today we have the formal draft Pertussis recommendations and narrative to be presented and we have sort of the "first pass," "draft, draft" recommendations of the measles, mumps and rubella recommendations and then we are starting the next bolus of pathogens, and the *S. aureus* [*Staphylococcus aureus*] literature review is near completion.

So a quick update on the literature review for *S. aureus*, we've reviewed the Key Questions. In the past, there were over - about 4,000 articles identified, 3400 excluded at title and abstract, 300 excluded at full text, and we now have 119 included for extraction, and data extraction for those is ongoing.

So we'll move on to Section 2. This is the update for Pertussis. On slide number 6, we have the full 1998 Guideline language. This is really just for reference and we'll look at each one of these as we update them.

Slide 7 shows the full updated recommendations and they're being presented for approval on the next few slides in a bigger font so that you can read them. They have undergone revisions since the last HICPAC meeting to incorporate feedback from HICPAC, internal subject matter experts, and Workgroup discussion, and so these are now the formal draft recommendations and not "draft, draft."

The "a" recommendations, a1 through a3, all address exposure management, and then "b" is about ill healthcare workers, and "c" is a clarifying point about

work restrictions after exposure.

So starting with "a" draft recommendations, each of the next three slides, recommendations start with the same stem - they all start with "for asymptomatic healthcare personnel, regardless of vaccination status, who have had unprotected exposure to pertussis," and then we have the specific situation addressed by the recommendation.

So for a1, for asymptomatic healthcare personnel regardless of vaccination status who have had unprotected exposure to pertussis and are likely to interact with persons at risk for severe pertussis, administer postexposure prophylaxis, and if not receiving postexposure prophylaxis, restrict from contact, for example through furlough, duty restriction, or reassignment, from patients and other persons at risk for severe pertussis for 21 days after their last exposure.

I will just mention on this slide, that as I read these for the 100th time preparing for this call, it occurred to me it might be better to have a modifier before the "at risk." In theory, everyone is at risk for pertussis, but some people are at an increased risk compared to others, or at particular risk, and the language might be better reflective of that by updating to say "by persons at increased risk for severe pertussis," or "at particular risk for pertussis."

And in the text of the section, which I'll show you in a minute, we do note that. So I'll just mention that and then when we talk about it at the end, I'm interested in people's feedback on that point.

So the second recommendation, the same stem, "for asymptomatic healthcare personnel regardless of vaccination status who have had unprotected exposure," and they're not likely to interact with persons at risk, or at increased risk, for severe pertussis, administer postexposure prophylaxis or implement daily monitoring for 21 days after the last exposure for development of signs and symptoms of pertussis.

And then a3, the third exposure-related recommendation, again has the same stem and then for people - healthcare personnel who have themselves pre-existing health conditions that may be exacerbated by a pertussis infection to also administer postexposure prophylaxis in that setting. Those are the three exposure recommendations.

Next slide, slide 11 just as a reference point, I included the text section that addresses this question about particular risk or at high risk, and you can see the language that's been used and the text there on the slide. It states that the objective of postexposure prophylaxis is to prevent transmission and disease in others, and we recognize populations at particular risk for serious complications and mention what those are.

And we mention healthcare settings that may have patients at higher risk or increased risk for severe pertussis and what those might be, but are not limited to, as they can be in other places. And we tried to balance the discussion from the group last time about providing this information, but not be overly prescriptive so that healthcare facilities could identify these areas for themselves.

Then the “b” pertussis draft recommendation is about symptomatic healthcare personnel, so this recommendation reads, exclude from work symptomatic healthcare personnel with suspected pertussis for 21 days from the onset of cough or until five days after the start of effective antimicrobial therapy.

And then “c” clarifies our common question about work restrictions. This is now on slide 13 and reads, work restrictions are not necessary for asymptomatic healthcare personnel after an unprotected exposure who received postexposure prophylaxis, regardless for their risk for interaction with persons at risk, or at increased risk, for severe pertussis. I'll go through the whole pertussis section and then pause for questions there.

The pertussis draft narrative, we did distribute the full text of this section with the call materials so if you haven't already reviewed them, you can review that at your leisure. But just some bullet points from that, we do include a summary of pertussis epidemiology overall and in healthcare settings, in particular we refer to ACIP [Advisory Committee on Immunization Practices] guidelines for pertussis vaccination for healthcare personnel and note the limits of the current vaccine.

Specific recommendations, as we’ve mentioned before, for vaccination are not going to be included in the healthcare worker guideline, and they will reference ACIP instead. There’s a little discussion about healthcare-associated outbreaks and then in response to HICPAC’s concerns on the last presentation, we did also include a discussion of criteria to consider in a definition of exposure, and I’ve included the language there. It’s primarily to give some examples to help people provide an exposure definition and then we note populations at particular risk of complications.

And then on the next slide, slide 15, in response to the discussion that HICPAC raised last time around parapertussis and non-pertussis *Bordetella* species, we did add a section in the text with some feedback and input from the Pertussis section at CDC and from the Workgroup as a whole.

So we added some notes that these species are being found more often. Now with molecular diagnostics, we added a few lines specifically about parapertussis, mentioning that it usually causes fewer symptomatic infections, has less frequent clinically severe disease, lacks the pertussis toxin, which may be an explanation for those findings. But there are very few data on defining high-risk populations for this infection, few data on the impact of antibiotics, and less consistent susceptibility to macrolides.

And we do note that some states have specific guidance around exposures and management of parapertussis. It is often similar to pertussis guidance. And so we provide that information primarily as our reference within the text. So I'll go ahead and pause and see if there are any comments or feedback from that first part of the presentation before we move on to measles, mumps, and rubella.

Dr. Yokoe: Do we have any comments or questions for Hilary?

Ms. Dekker: This is Elaine Dekker.

Dr. Yokoe: Hi Elaine.

Ms. Dekker: Hi. I have a question and I wasn't sure if you consider this at all. Just from past experience when we've had difficult years of pertussis, many times there are similar locations where there may be more than one exposure by staff over a period of time.

Wondering if it's possible, or is there any information around if they receive postexposure prophylaxis at this point and they've been re-exposed within a certain period of time, no postexposure prophylaxis may be indicated. Is that something that's even feasible or available with an option?

Dr. Babcock: So I don't think that there's a lot of data to drive that recommendation or change the recommendation based on that type of event. I definitely sympathize and we have that kind of event here as well.

Ms. Dekker: Okay.

Dr. Babcock: We'll look to see; I think that's a good question and it may be something that we could address in the text to acknowledge that that is a situation that happens. But there isn't a lot of data to drive understanding the use of Tdap in that setting.

Ms. Dekker: Okay. So it might be helpful if you could.

Dr. Babcock: Yes. We can definitely…

Ms. Dekker: We should give some people information to say it's really more of a personal choice at that time by the organization and the individual who was exposed maybe.

Dr. Babcock: Yes we can definitely do that.

Dr. Yokoe: Sure. Other questions or comments?

Darlene Carey: This is Darlene Carey with APIC. Just one comment regarding on the section 2 for your pertussis-based narrative - I guess it's on slide 14. Just want to give you my appreciation for discussion for the criteria for consideration for the exposure definition. I think a lot of infection prevention and occupational health staff members have concerns about that whenever an exposure happens. So I just wanted to let you know I appreciate that.

Dr. Babcock: Great. Thank you.

Dr. Yokoe: Are there any other comments for Hillary regarding pertussis?

Dr. Babcock: Does anyone have any comments or questions in particular or feedback about including the "at increased risk" or "at particular risk," or have a preference between those two for the higher-risk population?

Dr. Bell: Hilary this is Mike. I think what you're trying to do makes sense. I think that whatever language is chosen, it will be important to be able to give people a sense of what they need and if there is an accepted list of patient types or individual types who are considered to be at particular or increased risk, I think we would need to include that in addition to that indicator.

Dr. Babcock: Yes, so it is addressed in the text and we do have that summary in the text about which groups have been identified in the literature of being at risk for severe disease. So there is definitely data to define those populations and I think really it's more of a question of trying to reflect that in the recommendation so that we don't just say "at risk of severe disease" when really everyone is technically at risk of severe disease, but could sort of call out the specific populations in the recommendation to reflect that we do identify those in the text.

Dr. Bell: If it's not too large, if that could be captured parenthetically in the recommendation I think that would help users.

Dr. Babcock: Okay. That sounds good. Any other comments, feedback? So we will be hoping to get a vote on the pertussis recommendations from the full committee at the end of the call as well, with the addition of the word "increased" in front of the "at risk" for all of the recommendations, so keep that in mind as we come to that vote at the end of the call.

I'll move on next to measles, mumps, and rubella recommendations starting on slide 16. Just as a reminder, these are really a first "draft, draft" stage where we're presenting to the committee for any initial thoughts or feedback. The text for these sections has not yet been updated.

So for each of these we'll show the 1998 recommendation and then the preliminary draft update of that recommendation on the same slide. It does make the font a little small, but it is easier to review with all the information that way.

On slide 17, has the 1998 Guideline recommendations a1 through a3, they are all about the use of the vaccine, and that will all be deleted with a reference to following the ACIP recommendations and with a reference to the HICPAC Core Practices about ensuring the healthcare personnel receive their immunizations and follow ACIP recommendations. So that is what will happen for each of these organisms as we go along.

On slide 18 is an update of the postexposure prophylaxis recommendation, which was to administer postexposure measles vaccine, and we've just sort of de-specified that a little bit to administer postexposure prophylaxis in accordance with ACIP and CDC recommendations, because that is a vaccine-based recommendation that will again defer back to ACIP.

And then on slide 19, so this is the work exclusion for people who do not have presumptive evidence of immunity to measles who have been exposed to measles from the fifth day to the 21st regardless of receipt of postexposure prophylaxis. This is not - we reworded slightly, but it is not a change in content. Then slide 20, again is the exclusion from work of people who develop known or suspected measles.

There is a duration of work exclusion. This reflects what has already been updated, and existing guidances are already up to four days instead of the seven days, so this will be updating to match that guidance. It has consideration about extending the duration of work exclusion for immune-suppressed personnel longer than that four days.

Then on slide 21, this is a new recommendation that for all healthy personnel who have evidence of immunity to measles, they are not excluded from work, but they should be monitored for signs and symptoms of measles infection for 21 days after their last exposure, though they would still be allowed to work.

And then again, a new recommendation just to note that during an outbreak, vaccination or additional vaccines should be managed in accordance with CDC/ACIP recommendations. So that's measles.

The next section is mumps. So again "a" and "b" in the mumps guideline in 1998 was about the use of the vaccines, which will again be deleted with reference for ACIP and the Core Practices document.

Slide 23 is an update of work exclusion for people without presumptive evidence of immunity to mumps who have unprotected exposure, and the work exclusion for people who have known or suspected mumps.

Again the number of days are slightly different between the two, but an update is reflecting the current CDC guidance that is in place and we are reviewing the rationale and justification for that change when it was made so that we can address it in the text and be sure that we explain it and make sure that it's clear.

And then rubella, so again recommendations "a" through "e" in the old guidelines were all about vaccine and that will be deleted with reference to ACIP. And then the draft recommendations on slide 25 are the work exclusions for non-immune employees with an unprotected exposure and for people who develop known or suspected rubella, and again the stages are slightly different.

The old recommendation was 21 days, and the updated recommendation is 23, and that is reflecting the current recommendation from CDC and we'll provide rationale in the text. And the text will also clarify that there is no postexposure prophylaxis for rubella.

So those are the updated recommendations for measles, mumps, and rubella. I'll just go on to the next slide as my last slide on the next steps.

Slide 26. The *S. aureus* data extraction and evaluation is continuing. We're going to incorporate any feedback and finalize the draft update to the recommendations and text for measles, mumps, and rubella based on any of your feedback today and then we hope to have final draft recommendations and text ready for committee review and vote for those three pathogens in May.

And then next up we have diphtheria and meningococcal disease. We have an acknowledgement slide about the people who have been working on this and then I'll pause there for discussion, comments or questions about the measles, mumps, or rubella, or if anything about pertussis has occurred to you while we're talking about those. Happy to hear that feedback as well.

Dr. Yokoe: Thanks so much Hilary. Terrific work by the whole Workgroup. Any comments or questions for Hilary regarding measles, mumps, or rubella. Okay. Any other feedback or questions for Hilary regarding any of the Workgroup efforts? Okay. Terrific. Thank you so much Hilary.

Dr. Babcock: Okay. Thanks.

Dr. Yokoe: Great work. I'm going to pause for a moment just to acknowledge that Selwyn Rogers has joined the call. Selwyn, are you there?

Selwyn Rogers: I am. Sorry for the hiccup. I was leaving out of Chicago to Indianapolis. I'm in the Indianapolis airport, so bear with me.

Dr. Yokoe: Welcome. Do you have any conflicts of interest to report?

Dr. Rogers: No, I do not have any conflicts of interest to report.

Dr. Yokoe: Great. Our next discussion is Kris Bryant. She'll providing the NICU Workgroup update.

NICU Guideline Workgroup Update

Dr. Bryant: Good afternoon, everyone. My slides were distributed before the call. They're entitled Bryant-HICPAC-NICU-Guideline-Workgroup-Update.

I have three topics to talk to you about today. *Clostridium difficile* [*C. difficile*], *S. aureus*, and CLABSI [central line-associated bloodstream infection].

For *Clostridium difficile*, I'm happy to report that the Workgroup has a final work product for review and vote today. It's a systematic review. For *S. aureus,* we have draft recommendations for Key Question 2, and I'll give you an update on our progress on Key Questions 1 and 3.

And then for CLABSI, I'll give a preview of what you are likely to hear at the May meeting. So on slide number 3, I'll just remind you that we had three key questions for *Clostridium difficile*. The first Key Question, what clinical demographic or other criteria have been shown to prompt diagnostic testing for *C. difficile* that result in identifying symptomatic *C. difficile*-infected NICU patients.

Key Question 2 was a little simpler. What test or sequence of tests for *Clostridium difficile* performed best in detecting CDI [*Clostridium difficile* infection] among NICU patients?

And Key Question 3, what is the significance of a positive *C. difficile* test in a NICU patient. Unfortunately, we were not able to identify evidence to answer these questions, but rather we identified a number of gaps which are listed on the next two slides, slides 4 and 5.

Very briefly, the gaps include what is the potential for toxigenic *C. difficile* to cause diarrhea in young infants. We know that colonization is common, but we don't know the potential really to cause clinically significant diarrhea. If *C. difficile* can cause diarrhea in young infants, are there are any biomarkers for clinical or laboratory factors that can differentiate diarrhea due to another cause from diarrhea due to *C. difficile*.

Gap number 3, if *C. difficile* infection occurs in neonates, what is a valid definition of *C. difficile* infection in this population? Gaps 4 and 5, are on the next slide.

Is it possible to clearly identify diarrhea from *C. difficile* or if it is possible to clearly identify diarrhea from *C. difficile*, what are the risk factors based on a valid definition of CDI in these infants, including risk factors associated with changes in the microbiome? And which traditional interventions that enhance the protective effects of the normal microbiome, prevent infection, and decrease transmission are also effective in the NICU?

So just as a summary, while we didn't identify evidence to answer the questions, we felt like it was really important to highlight these gaps. These gaps address issues that are relevant to clinicians and can impact the care of NICU patients.

The systematic review has been distributed. It's ready for a vote. The next steps are CDC clearance, online publication, and coordination with the practical guidance document that is being developed by SHEA in collaboration with other professional society partners.

That is the summary for *C. difficile*. So I'll stop there and ask if there are any questions or comments.

Dr. Yokoe: Any questions for Kris?

Dr. Bryant: Okay. I'll guess I'll move on to *S. aureus*. Just as a reminder, our Key Question 2 for *S. aureus* is, which anatomic sampling sites in laboratory assays most effectively identify *S. aureus* colonization in NICU patients? The Key Question 2 appears on slide 7, and you'll note we retrieved four diagnostic studies. Four dealing with MRSA [methicillin-resistant *Staphylococcus aureus*], and one dealing with *S. aureus* in general.

Slide number 8 is just a reminder about overall quality grades for the evidence, and then on slide number 9 you'll see the evidence summary for the question about laboratory assays for the detection of *S. aureus*. There was one diagnostic study that compared PCR [polymerase chain reaction] to culture for the detection of *S. aureus*.

Overall the quality of evidence was moderate. PCR had higher sensitivity when compared to culture, 96% compared to 92%, and there was moderate overall quality of evidence that PCR and culture have identical specificity and positive predictive value and similar negative predictive value.

On the next slide, slide 10, you'll see the evidence summary for laboratory assays in the detection of MRSA comparing real-time PCR to culture. The evidence summary includes two diagnostic studies that are highlighted on this slide, and the quality of evidence overall was moderate.

There was high-quality evidence for higher sensitivity, specificity, and negative predictive value of PCR for the detection of MRSA compared to culture. However, there was moderate-quality evidence suggesting a low positive predictive value of PCR with wide confidence intervals. And the driving factor behind this is that in one study, PCR identified MRSA in seven samples that were subsequently negative for MRSA on culture, but five of the seven actually yielded MSSA, or methicillin-susceptible *S. aureus*.

On slide 11, you'll see the evidence summary for the anatomic sampling sites. Just as a reminder, the question was, which anatomic sampling sites most effectively identify *S. aureus* colonization in NICU patients?

The evidence summary includes two diagnostic studies, and there was moderate-quality evidence from these studies that suggested that the sensitivity is higher for nares samples than samples obtained from other anatomic sites.

The study by Huang, I'll highlight in particular the sensitivity for a nares sample alone with 71%, for umbilicus alone with 60%, but there was a suggestion that sensitivity could increase to 90% if both sites were sampled.

Dr. Diekema already walked you through the proposed recommendation scheme, and that is highlighted on slide 12. The justification tables that you saw earlier are summarized again on slide 13, and I'll show you how the justification tables will look when used in practice.

I'll just walk you through the justification tables for these two Key Questions and our draft recommendations. So for our draft recommendation for laboratory assays, if screening for *S. aureus* colonization in NICU patients is performed, use PCR or culture-based detection methods.

On slide 15, you'll see the top of the justification table, the boxes for Benefit, as well as Risks and Harms. I think worthwhile pausing for just a minute to talk about the benefit.

As I've mentioned, PCR offers increased sensitivity over culture for detecting *S. aureus*. It's a marginal benefit, but a benefit. But there are times when culture may be better. Culture has the advantage that if you have an isolate you can do molecular typing, you can conduct susceptibility tests, and this can be important. So our draft recommendation allows facilities to select the laboratory test that best fits their needs and the needs at hand.

On the next slide, you'll see the justifications for Resource Use and the Benefit versus Harm Assessment. In terms of resource use, PCR can be more expensive than culture. Costs will likely vary by a facility and benefits versus harms, there is a benefit to using PCR versus culture-based methods to detect *S. aureus* colonization.

But this benefit is offset by important considerations, and that's really what drove the Workgroup decisions. We wanted facilities to balance the performance characteristics of the test, the clinical management consideration, susceptibility testing, and the other factors that are listed on this slide.

On slide 17, you'll see what went into the Value Judgments and Intentional Vagueness. We again, as Dr. Diekema mentioned, this is a favorite of the committee. The reasons for not making a firm recommendation for one test versus the other, included interpretation of the available evidence, the possibility that future research could change this recommendation, and really insufficient evidence on the impact that test characteristics would have on patient outcomes.

So we really did not think that recommending one test versus the other would

have significant impact on patient outcomes.

In terms of the second part of Key Question 2 that addresses anatomic sampling sites, our draft recommendation appears on slide 18. If screening for *S. aureus* colonization of NICU patients is performed, collect samples from at least the nares of NICU patients.

Slide 19 lists the justification table and Resource Use. Slide 20 highlights the Benefit versus Harm Assessment, Value Judgments, and Intentional Vagueness. On slide 21, we have draft recommendation 2b2, "consider also collecting samples from the axilla, rectum, and umbilicus to increase yield."

Under Benefit, we note that the yield from collecting additional samples offers a small and incremental increase in sensitivity and note that during outbreak settings with a highly virulent strain, sampling additional sites might provide greater benefit. There is no harm, as you see.

Under Benefit versus Harm, we note that benefit is possible, but that might not outweigh the additional cost and resources required for sampling additional sites.

Slide 22 just summarizes Resource Use, Value Judgments, Intentional Vagueness and any exceptions, and under Exceptions it's noted, again, during outbreak settings, sampling additional sites might provide greater benefit.

All right, so the next steps for *S. aureus* include voting on these draft recommendations at the May HICPAC meeting. We hope to have draft recommendations for Key Question 1 and Key Question 3 - those are summarized on slide 23. I can pause just a minute before going on to CLABSI. If there are any questions or comments.

Ms. McGiffert: Hey, this is Lisa McGiffert. Can you hear me all right?

Dr. Bryant: I can.

Ms. McGiffert: I had a question about when you looked at PCR versus culture, whether you looked at issues related to timing and the effect that has on antibiotic use, because from the patient's perspective, I don't know if one of this quicker than the other. I may be misunderstanding, but if one of them is faster to get results, that can really have an impact on patients and antibiotic use.

Dr. Bryant: Thank you for that question. Just as a clarification, we were looking at screening for *S. aureus* and so not for diagnostic use if you think a patient has an infection.

Ms. McGiffert: Got it. I'm sorry I misunderstood that. I wasn't thinking about that.

Dr. Bryant: No, I appreciate that clarifying question, because that would be an important consideration if we were using that to make clinical treatment decisions. Timing is also a relevant question with regard to screening.

Is one quicker than the other? And the answer there is, it really depends on what technology a particular facility has, what methodology they're using for PCR, what they're doing for culture, and so that variability played into our decision to

say use one or the other depending on local resources, local needs.

Dr. Yokoe: Other questions, comments for Kris?

Dr. Diekema: I just wanted to really thank the group and thank you during this presentation for showing so nicely how you are applying the guideline categorization changes that we're implementing. I think it's really a nice example of how you would couch your Recommendation versus a Conditional Recommendation. So thanks for that.

Dr. Bryant: Thank you. We found the process of completing the justification table to be really useful. It generated a lot of discussion and we hope that the justification tables really portray all of the things, all the ideas that went into developing the recommendation.

So the last couple of slides relate to central line-associated bloodstream infections, or CLABSI. We have updated the Key Question. Just as a reminder, the initial Key Question developed in 2011 was, "What are the most effective strategies to prevent CLABSI in neonatal intensive care patients?"

The updated question is, "What are effective strategies to prevent CLABSI in NICU patients?" It's a subtle difference, but our goal is to identify all effective strategies and not necessarily offer the most effective strategy.

So our next steps are updating the literature search, and we'll present progress at the May meeting.

Slide 26 just highlights the references used for the *S. aureus* question and the almost-final slide includes workgroup members. I'd like to acknowledge all the workgroup members, Loretta Fauerbach and Charlie Huskins are HICPAC members.

Alexis Elward has shepherded this project from the beginning. It's been many years in progress now. And I'd like to thank all our CDC technical advisors. Any questions?

Dr. Yokoe: Thanks so much, Kris. I just want to echo Dan's thanks to you and the Workgroup for this terrific work and also for testing out the new recommendation categories and the justification table.

Dr. Bryant: Thank you. We're looking forward to using it for the remaining Key Questions for *S. aureus*.

Dr. Yokoe: Any other comments for Kris? Okay, great. I think we are entering the public comment period, and I will turn this over to the operator to open up the session for public comment.

Public Comment

Coordinator: Thank you. At this time if you would like to give a comment, please press "star, one" and record your name to enter the comments queue. Once again, for public comments too, please press "star, one" and record your name to enter that

queue. Those will take one moment to queue, do please stand by.

Once again for public comments, do please press “star, one” at this time. Please stand by. So I’m showing at this time, we have no comments from the public.

Dr. Yokoe: Okay. Thank you very much. I will take this time to mention that we did receive one written public comment, which was submitted by Dr. Mark Stibich from Xenex Disinfection Services. This comment will be added to the minutes, and these minutes will be published within 90 days of this meeting.

Operator, have you received any public comment?

Coordinator: I have no comments from the public at this time.

Dr. Yokoe: Okay. Great, then at this point, I guess I’ll turn the discussion over to Mike and Erin. I think we have several items to vote on.

Vote and Call Summary

Dr. Bell: Thanks Deborah. At this point, we’re able to move on to voting and summarizing the call according to my agenda, after the public comment, of which we have identified one written submission. We can move on to vote on today’s items.

Erin Stone: Great. So this is Erin, and I can take the vote. We’ll start with the Recommendation Categorization Update votes. The committee is voting on the three recommendation categories as written, with the modification of the removal of “should” as discussed on today’s call. I will call the members’ names, and if you will just respond that you are in favor of, or against. I’ll start with Dan Diekema.

Dr. Diekema: In favor.

Ms. Stone: Deborah Yokoe.

Dr. Yokoe: In favor.

Ms. Stone: Vickie Brown.

Ms. Brown: In favor.

Ms. Stone: Kris Bryant.

Dr. Bryant: In favor.

Ms. Stone: Vineet Chopra.

Dr. Chopra: In favor.

Ms. Stone: Loretta Fauerbach.

Ms. Fauerbach: In favor.

Ms. Stone: Michael Howell.

Dr. Howell: In favor.

Ms. Stone: Lisa Maragakis.

Dr. Maragakis: In favor.

Ms. Stone: Jan Patterson.

Dr. Patterson: In favor.

Ms. Stone: Selwyn Rogers.

Dr. Rogers: In favor.

Ms. Stone: Perfect. Then with a unanimous vote, the committee has approved the new Recommendation Categorization scheme. Thank you. We're going to move on to the next vote, which is the Healthcare Personnel Guideline Section 2, Pertussis Recommendations.

The recommendations were reviewed thoroughly in the presentation. It appears that the only edit made, would be the addition of "increased" to persons at risk for severe pertussis for recommendations a1 and a2. Now I will take the committee's votes on the bundle of recommendations. If you have any dissenting opinion on any of the recommendations, please let me know when I call your name. Otherwise, let me know if you are in favor. Dan Diekema.

Dr. Diekema: In favor.

Ms. Stone: Deborah Yokoe.

Dr. Yokoe: In favor.

Ms. Stone: Vickie Brown.

Ms. Brown: In favor.

Ms. Stone: Kris Bryant.

Dr. Bryant: In favor.

Ms. Stone: Vineet Chopra.

Dr. Chopra: In favor.

Ms. Stone: Loretta Fauerbach.

Ms. Fauerbach: In favor.

Ms. Stone: Michael Howell.

Dr. Howell: In favor.

Ms. Stone: Lisa Maragakis.

Dr. Maragakis: In favor.

Ms. Stone: Jan Patterson.

Dr. Patterson: In favor.

Ms. Stone: Selwyn Rogers.

Dr. Rogers: In favor.

Ms. Stone: Thank you. The committee has unanimously approved the draft recommendations for Section 2, Pertussis, for the Healthcare Personnel Guideline.

We will move on to the NICU *C. difficile* systematic review. The committee is voting to approve entering the *C. difficile* systematic review and appendix to CDC clearance, and the subsequent publication of this document on the CDC website. Please let me know when I call your name if you approve or not. Dan Diekema.

Dr. Diekema: I approve.

Ms. Stone: Deborah Yokoe.

Dr. Yokoe: Approve.

Ms. Stone: Vickie Brown.

Ms. Brown: Approve.

Ms. Stone: Kristina Bryant.

Dr. Bryant: Approve.

Ms. Stone: Vineet Chopra.

Dr. Chopra: Approve.

Ms. Stone: Loretta Fauerbach.

Ms. Fauerbach: Approve.

Ms. Stone: Michael Howell.

Dr. Howell: Approve.

Ms. Stone: Lisa Maragakis.

Dr. Maragakis: Approve.

Ms. Stone: Jan Patterson.

Dr. Patterson: Approve.

Ms. Stone: And Selwyn Rogers.

Dr. Rogers: Approve.

Ms. Stone: Thank you. The committee has unanimously approved to finalize the *C. difficile* systematic review.

Finally, the last vote is for the NICU guidelines *S. aureus* section draft recommendations and recommendation justifications for Key Question 2. The proposed draft recommendations are comprised of three separate recommendations. When I call your name, let me know if you disapprove of any part of those recommendations; otherwise, please note that you approve. Dan Diekema.

Dr. Diekema: Approve.

Ms. Stone: Deborah Yokoe.

Dr. Yokoe: Approve.

Ms. Stone: Vickie Brown.

Ms. Brown: Approve.

Ms. Stone: Kris Bryant.

Dr. Bryant: Approve.

Ms. Stone: Vineet Chopra.

Dr. Chopra: Approve.

Ms. Stone: Loretta Fauerbach.

Ms. Fauerbach: Approve.

Ms. Stone: Michael Howell.

Dr. Howell: Approve.

Ms. Stone: Lisa Maragakis.

Dr. Maragakis: Approve.

Ms. Stone: Jan Patterson.

Dr. Patterson: Approve.

Ms. Stone: Selwyn Rogers.

Dr. Rogers: Approve.

Ms. Stone: Thank you. The committee has unanimously voted to approve the *S. aureus* section, Key Question 2 draft recommendations. Thank you. I turn it back over to you, Dan and Debbie, for the call summary.

Dr. Yokoe: Thanks so much Erin, and thank you for this very productive meeting. Just to briefly recap, Dan Diekema updated us on the Recommendation Categorization Workgroup efforts and some of the minor revisions that have taken place since the last discussion. And we have voted to approve the current Recommendation Categorization scheme and the justification table.

And secondly, Hilary Babcock provided an update to the Healthcare Personnel Guideline Workgroup - updated us on the clearance process for the infrastructure section. We voted on Section 2, Pertussis, and approved with a minor revision of specifying persons at "increased" risk for severe pertussis, and Hilary also updated us on the measles, mumps, and rubella recommendations.

And then finally, Kris Bryant provided an update on the NICU Guideline Workgroup. We voted to approve the *C. difficile* systematic review and voted to approve Key Question 2 regarding *S. aureus*. So again thank you to all. Dan, anything you'd like to add?

Dr. Diekema: No, I think that's a good summary, and I'd just like to echo your thanks to all the members, Liaisons, *ex officios*, and in particular to our Workgroups for the progress that we're making on these guidelines. Thank you very much.

Dr. Bell: And I'll just add my thanks, this is Mike. I'm very, very happy with the work that you've done for this call. In particular, I'm extremely excited about the implementation of the categorization scheme and the upgrades we're enjoying at this point. I look forward to seeing it applied again on our next discussion. Thank you everybody. Hugely appreciated here. Erin.

Ms. Stone: That's all I have on our end. Thank you everyone so much for a great call.

Dr. Yokoe: Thank you.

Dr. Bell: Thank you.

((Crosstalk))

Coordinator: And once again that will end today's conference. Thank you for participating. You may disconnect at this time.

Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing transcripts of the February 15, 2018, teleconference of the Healthcare Infection Control Practices Advisory Committee, CDC are accurate and complete.

_____ _____

Date

Daniel J. Diekema, MD, MS
Deborah Yokoe, MD, MPH
Co-Chairs, Healthcare Infection Control
Practices Advisory Committee, CDC

Attachment #1: Acronyms Used in this Document

Acronym	Expansion
ACIP	Advisory Committee on Immunization Practices
AHRQ	Agency for Healthcare Research and Quality
AORN	Association of periOperative Registered Nurses
APIC	Association of Professionals of Infection Control and Epidemiology
C. difficile	*Clostridium difficile*
CAUTI	Catheter-Associated Urinary Tract Infection
CDC	Centers for Disease Control and Prevention
CDI	*Clostridium difficile* Infection
CLABSI	Central Line-Associated Bloodstream Infection
CSTE	Council of State and Territorial Epidemiologists
DFO	Designated Federal Official
DHQP	Division of Healthcare Quality Promotion
HHS	(United States Department of) Health and Human Services
HICPAC	Healthcare Infection Control Practices Advisory Committee
HRSA	Health Resources and Services Administration
IDSA	Infectious Diseases Society of America
MRSA	Methicillin-Resistant *Staphylococcus aureus*
MSSA	Methicillin-Susceptible *Staphylococcus aureus*
NACCHO	National Association of County and City Health Officials
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NICU	Neonatal Intensive Care Unit
NIH	National Institutes of Health
PCR	Polymerase Chain Reaction
PHAC	Public Health Agency of Canada
S. aureus	*Staphylococcus aureus*
SHEA	Society for Healthcare Epidemiology of America
VA	(United States Department of) Veterans Affairs

Attachment #2: Public Comment Received

From: Mark Stibich, PhD, Chief Scientific Officer, Xenex Disinfection Services, LLC

Public Comment: Healthcare Infection Control Practices Advisory Committee (HICPAC) for Feb 2018 meeting

After reviewing the HICPAC product group slides and proposed process that was presented at the November 2017 HICPAC meeting, I have several concerns that I would like to bring to your attention:

1. The process slides state that only products with a status of FDA approved, cleared, or granted, or products that are EPA registered will be evaluated. This leads to unfair eligibility for review in some product categories. For example, in the “no touch” disinfection space, products exist that are EPA registered (hydrogen peroxide vapor devices) as well as products that are currently classified as pesticidal devices (ultraviolet based disinfection systems). Pesticidal devices are not EPA registered and therefore would not be eligible for review even though these many of these products are essential for removing pathogens from the healthcare environment in order to reduce the occurrences of Hospital Acquired Infections. This would cause any review of this product category by the HICPAC product workgroup to be incomplete and inequitable.

2. Historically, HICPAC has used an evidence hierarchy that favors randomized control trials. This approach, while expedient, neither fully considers all the sources of reliable evidence nor does it reflect the decision-making approach undertaken by hospitals and healthcare facilities. While a reliance on randomized controlled trials is understandable for product categories that have a direct impact in the field of “no touch” disinfection, we estimate that well over 700 hospitals have invested in a form of ultraviolet disinfection. Those hospitals’ product selection and infection control committees use evidence from multiple sources to make a decision.

3. The HICPAC process does not define products nor does it discuss what products will be grouped together. For example, one could group products that solve a particular problem together. One could also group products that use a particular technology together. Sometimes, products within a space are vastly different and used so differently within that space that to group them would not make sense. For example, one could group all “no touch” disinfection technologies together - but doing so would neglect the fact that the body of evidence, the user experience, environmental safety and the operational impact of hydrogen peroxide vapor devices, mercury ultraviolet devices and pulsed xenon devices are vastly different in some cases.

4. Additionally, in terms of defining the product, the evidence standards for different products should be different. Hand hygiene interventions should be evaluated using evidence about human factors, behavior change and integration into workflow, while diagnostic devices should be evaluated with a different set of evidence (such as sensitivity and specificity). The assumption that recommendations can only be made when a certain level of published evidence is available will lead to HICPAC recommendations that are disconnected from the reality of the hospitals and the purchasing decisions they make.

5. The HICPAC process does not consider the voice of the customer and end-user experience. In the case of “no touch” disinfection, there are over 700 hospitals using this

technology. For HICPAC to evaluate these products without considering that vast real-world experience is a large oversight.

6. The HICPAC process does not seek to define the best practice with a particular product. For example, in the case of “no touch” disinfection, some evidence in the literature shows “no touch” devices being used in outbreaks only, others being used for isolation discharge disinfection only and still others used for all discharges on a targeted unit. The results, reported in the literature, are vastly different depending on both the technology used and the method of use. The HICPAC process does not define best practice nor is there consideration of whether the evidence being examined represents the current thinking in terms of best practices.

7. The HICPAC process does not involve manufacturers and yet suggests that cost will be a factor in evaluation. Cost cannot be determined from published studies or other information. Studies do not provide information regarding resources provided and bundled services that may be included in the cost. Additionally, manufactures will have important insights as they will be most familiar with the collective experience of their users and their considerations when evaluating the products.

8. The HICPAC process states that transparency is a goal and yet we, despite attending HICPAC meetings, have been told that we should “do more” to communicate with the group and have been pointed to other manufacturer representative as examples of what we should be doing. Emails posing questions to HICPAC members from myself and my colleagues have gone unanswered. We are a small but important company, we don’t have a team of lobbyists to help and we are respectful of your time and procedures. We would like clarification concerning the routes of communication to HICPAC for this process.