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

Healthcare Infection Control Practices Advisory Committee
May 5, 2017
Atlanta, Georgia

Record of the Proceedings
## Healthcare Infection Control Practices Advisory Committee (HICPAC) Agenda
### May 5, 2017
#### Centers for Disease Control and Prevention
#### Teleconference

**Friday, May 5, 2017**

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List of Attendees:

**HICPAC Members**
- Dr. Daniel Diekema, Co-Chair
- Dr. Deborah Yokoe, Co-Chair
- Dr. Hilary Babcock
- Ms. Vickie Brown
- Dr. Kris Bryant
- Dr. Vineet Chopra

**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, Department of Veterans Affairs (VA)
- Dr. Daniel Schwartz, Centers for Medicare and Medicaid Services (CMS)

**Liaison Representatives**
- Dr. 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. Michael Anne Preas (Association of Professionals of Infection Control and Epidemiology (APIC))
- Dr. Marion Kainer (Council of State and Territorial Epidemiologists (CSTE))
- Ms. Linda Spaulding (DNVGL Healthcare)
- Ms. Dawn Tereshita (National Association of County and City Health Officials (NACCHO))
- Ms. Kathleen Dunn (Public Health Agency of Canada (PHAC))
- Dr. Louise Dembry (Society for Healthcare Epidemiology of America (SHEA))
- Dr. Sanjay Saint (Society of Hospital Medicine (SHM))
- Dr. Paulo Pontemayor (The Joint Commission (TJC))

**CDC Representatives**
- Ms. Kate Beagle, CDC/DHQ
- Dr. Michael Bell, CDC/DHQ
- Dr. Denise Cardo, CDC/DHQ
- Ms. Kendra Cox, CDC/DHQ
- Mr. Michael Craig, CDC/DHQ
- Ms. Mahnaz Dasti, CDC/DHQ
- Dr. Alex Kallen, CDC/DHQ
- Dr. Kathleen Irwin, CDC/DHQ
- Ms. Erin Stone, CDC/DHQ

**Members of the Public**
- Mr. Jim Arbogast, GoJo
- Dr. Philip Carling, Boston University School of Medicine
- Dr. Russ Castioni, 3M
- Dr. Cynthia Chang, Food and Drug Administration (FDA)
- Mr. Gary Evans, Hospital Infection Control & Prevention
- Ms. Ellen Evashwick, Cedars Sinai Medical Center
- Ms. Pamela Falk, Northside Hospital
- Ms. Stephanie Fedorinchik, Ethicon
- Mr. Hudson Garrett, Pentax
- Ms. Nancy Hailpern, Association for Professionals in Infection Control and Epidemiology (APIC)
- Ms. Lori Harmon, Society for Critical Care Medicine (SCCM)
- Ms. Jessica Hayashi, MS, BSN, St. Peter's Health Partners/ Trinity Heath
- Ms. Haley Horner, Cardinal Health
- Ms. Eve Humphreys, Society for Healthcare Epidemiology of America (SHEA)
- Mr. Richard Magana, Natividad Medical Center
Ms. Kaimi Maka, Citizens Memorial Healthcare
Mr. Charu Malik, Association for Professionals in Infection Control and Epidemiology (APIC)
Ms. Monique Mills, Down East Community Hospital
Ms. Renee Odehnal, Ethicon US, LLC
Ms. Antionette Olivarez, Tarzana Treatment Centers
Dr. Marco Paschoalini, BD
Dr. Barbara Purdon, Thrombolytics
Ms. Tunisia Peters, Bronson South Haven
Ms. Maria Rodriguez, Xenex Disinfection Services

Ms. Silvia Quevedo, Association for Professionals in Infection Control and Epidemiology (APIC)
Ms. Rachel Stricof, Council of State and Territorial Epidemiologists (CSTE)
Ms. Lisa Tomlinson, Association for Professionals in Infection Control and Epidemiology (APIC)
Ms. Kathy Warye, Infection Prevention Partners
Ms. Kristine Wilhelm, Evangelical Homes Senior Solutions
Mr. Hugo Xi, BD
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 May 5, 2017. 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.

The meeting was called to order at 1:02 pm on May 5, 2017. Dr. Thomas Talbot presented an update on the “2017 Draft Recommendations on the Use of Chlorhexidine-Impregnated Dressings for Prevention of Intravascular Catheter-Related Infections.” He reviewed public comments received via Regulations.gov and presented suggested actions in response to them. After HICPAC discussion, a vote was held to approve the three draft Recommendations as presented; HICPAC unanimously approved all Recommendations. Public comment was called for at 1:47 pm; no comments from the public were made.

HICPAC stood in recess at 1:54 pm on May 5, 2017.
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 May 5, 2017, via teleconference.

Friday, May 5, 2017

Welcome and Roll Call

Coordinator: Welcome to today’s conference call. At this time lines are open for committee members during our conference. Once again, lines for committee members are open. Public comments will be taken at the end of our presentation by pressing star, 1 and recording your name if you wish to make a public comment.

Our conference is also being recorded. If you have any objections, you may disconnect. I will now turn the conference over to Mr. Michael Bell. Sir, you may proceed.

Dr. Bell: Great. Thank you very much. Hello, everybody. Good afternoon or good morning and welcome to this telephone meeting of the Federal Advisory Committee, the Healthcare Infection Control Practices Advisory Committee.

I will be taking roll call and asking for any updated conflict of interests. And then after that, I will be handing it over to our chairs. So starting with roll call. Dan Diekema?
Dr. Diekema: Here. No.

Dr. Bell: Any conflicts?

Dr. Diekema: No updates.

Dr. Bell: Great. Dr. Yokoe?

Dr. Yokoe: I’m here. No conflicts.

Dr. Bell: Vickie Brown?


Dr. Bell: Great. Kris Bryant.

Dr. Bryant: Here. No updates.

Dr. Bell: Hilary Babcock?

Dr. Babcock: Here. No conflict.

Dr. Bell: Vineet Chopra?

Dr. Chopra: Here. No conflicts.


Dr. Bell: Thank you. Lisa Maragakis?
Dr. Maragakis: I’m here. No updated conflicts.

Dr. Bell: Okay. Selwyn Rogers? Okay. Moving to our ex officios. Melissa Miller, AHRQ?

Dr. Miller: I’m here.

Dr. Bell: Thank you. Liz Claverie-Williams, FDA?

Ms. Claverie-Williams: Hi, I’m here.

Dr. Bell: Great. David Henderson, NIH?

Dr. Henderson: Here.

Dr. Bell: Yvonne Chow, HRSA?

Ms. Chow: Here.

Dr. Bell: Gary Roselle, VA?

Dr. Roselle: I’m here.

Dr. Bell: Dan Schwartz, CMS?

Dr. Schwartz: Here.

Dr. Bell: Excellent. Thank you, everybody. And then on to our liaisons. Do we have Elaine Dekker?

Ms. Dekker: Here. No conflicts.

Dr. Bell: Mark Russi?
Dr. Russi: Here.


Ms. Morgan: Here. No conflicts.

Dr. Bell: Sharon, welcome.

Ms. Morgan: Thank you.

Dr. Bell: Amber Wood, AORN?

Ms. Wood: Here.

Dr. Bell: Michael Anne Preas?

Ms. Preas: Here.


Ms. Dunn: Here.

Dr. Bell: Louise Dembry?

Dr. Dembry: Here.

Dr. Bell: Hi, Louise.
Dr. Dembry: Hi.

Dr. Bell: Let's see. Where am I? All right. Sanjay Saint?

Dr. Saint: Here.


Mr. Pontemayor: This is Paulo Pontemayor. Paulo Pontemayor calling for Margaret VanAmringe.

Dr. Bell: Oh, excellent. The Joint Commission is here then. Terrific. Let me go back to the folks that we missed from the membership roster. Has Sheri Chernestky Tejedor joined? Sheri Chernetsky Tejedor? Loretta Fauerbach?

Ms. Fauerbach: Yes.

Dr. Bell: Hi, Loretta.

Ms. Fauerbach: Hey. How are you?

Dr. Bell: Any new conflicts of interest?

Ms. Fauerbach: Yes. Clinical Advisory Board for PDI.

Dr. Bell: Say that once more please?

Ms. Fauerbach: Clinical Advisory Board for PDI.

Dr. Bell: Understood. Thank you. Mike Howell? All right. Well, the good news is we have quorum. We have more than 8 members and more than a total of 11 so we can have a call and we can vote. So thank you very much.
Just as a formal step, please, remember after this call, if everyone who’s on can send just a simple subject line email to HICPAC@cdc.gov. That’s simply HICPAC@cdc.gov to confirm your attendance on the call. That’s one of the rules for the advisory committee.

Great. With that, let me hand it over to our Chairs.

**Update: Chlorhexidine-Impregnated Dressings Recommendation Update**

**Dr. Yokoe:** Great. Thanks so much, Mike. This is Debbie Yokoe. I am the HICPAC co-Chair along with Dan Diekema. So I just want to echo Mike Bell’s welcome to all of the HICPAC members, *ex officios* and liaisons as well as to members of the public that are participating in this call.

As you all know, today’s teleconference is going to be focused on discussion on updating of the recommendation from the *2011 Guidelines for the Prevention of Intravascular Catheter-Related Infections* regarding the use of chlorhexidine-impregnated sponge dressings for prevention of bloodstream infections.

I’m very thankful for all the work that has been done by the writing group under the leadership of Tom Talbot. So I think at this point, I’d like to turn the discussion over to Tom.

**Dr. Talbot:** Sure. Hello, everybody. I think everybody has the slides so I’m going to walk through the slides. I’ll give slide numbers to let you know when I’m going to the next one just to keep everybody in the same universe of what we’re talking about.

So we’ll start with Slide 3, which gives a background just in case folks aren’t aware. Back in 2011, the CDC HICPAC bloodstream infection guideline had specific recommendations regarding chlorhexidine-impregnated dressings, specifically the use of a chlorhexidine-impregnated sponge dressing.
It was recommended that that dressing be used for temporary short-term catheters in those patients older than two months of age if CLABSI rates were not decreasing despite adherence to basic prevention measures that included education and training, appropriate use of CHG for skin antisepsis, and maximal serial barrier precautions.

That was a Category 1B recommendation that was defined in 2011 as strongly recommended for implementation and supported by some experimental clinical or epidemiologic studies and a strong theoretical rationale for an accepted practice supported by evidence.

There was no recommendation at that time in 2011 for any other type of chlorhexidine dressing—this was deemed an unresolved issue at that time.

Next slide, Slide 4. So a little bit more background. In part because of new technologies and data merged around other types of chlorhexidine data, actually in large part, our group was charged to review those recommendations in 2011 and update them.

So an updated literature search was conducted from 2010 to 2015. We applied the GRADE methodology to the results that consisted of seven RCTs for those 18 years and older and only two for those under 18 years of age.

This was presented at the HICPAC meeting in November. And we were advised that it was appropriate to evaluate these dressings as a single “product class.”

Next slide, Slide 5. The draft guidance, which I know everyone had received, was submitted for public comments. And we had 30 comments received between November 25 of ‘16 and January of ‘17. And we’re going to review the comments and the general topics noted on the bullets as well as the
review from the writing group and amendments to the guideline recommendations.

So the general topics that arose with public comments were around the product classification. The specific Recommendation One, around patients age 18 and older. Recommendation Two, in pediatric neonates less than two months, non-neonatal pediatric patients less than 18 years of age, the issue of adverse events, chlorhexidine resistance and some questions about methodology.

So let’s dive into that. Slide 6. In the Federal Register, HICPAC recommended assessing the chlorhexidine-impregnated dressings as a single product class based on the published evidence of efficacy as follows--this is the exact language from what was submitted in the Federal Register.

CHG was an active agent, CHG being chlorhexidine. Two, the same anatomic site of action, for example the skin around the catheter insertion site. The way that there was local elution of chlorhexidine directly to the catheter insertion site and surrounding skin. Four, a similar time span of delivery, e.g. while dressing present.

In addition to these product characteristics, HICPAC advised that these products should have published data pertaining to efficacy in preventing similar clinically relevant infection outcomes and product related adverse events.

Slide 7. So we got several comments around the issue of product class. And I think it’s fair to say, just as an editorial comment, that a lot of the work that we’ve done since the comments have come back around this issue of product class and to what degree the HICPAC guideline defines that class or not.
Suffice it to say, and the point is we do not feel that the CDC is the definer of product class and it really is the FDA. But I've got the punchline on that. Let me walk through the comments.

So you see there the comments about proposed changing to the product class; adding published evidence of efficacy to the class in two comments; emphasizing the method and amount of elution in site of action; changing the wording to be inclusive of other dressings and newer technologies; use the term chlorhexidine and not CHG; add FDA label indication for CRBSI reduction as an element of the class; add elements to increase consistency with FDA substantial equivalents.

So we actually had some good partnership with our FDA colleagues. And the FDA currently has no product class for these dressings. They're approved based on the demonstrated effectiveness of the device as a barrier to bacterial penetration to the catheter site and the effectiveness of the chlorhexidine for the reduction of bioburden within the dressing during use. The specific FDA label indication for preventing CRBSI is based on results from clinical testing data.

Next slide. There was a comment against creating a product class, noting chlorhexidine-impregnated dressings are all different in terms of amount and concentration of chlorhexidine and materials and that they should not be directly compared due to their different effects.

Our clarification was that the draft product class was based on the advice of HICPAC, and for the evidence review in this document the writing group appraised the best available evidence for the benefits and harms of chlorhexidine-impregnated dressings and consisted of RCTs evaluating a chlorhexidine-impregnated sponge and a chlorhexidine-impregnated gel dressing.
If the product class is removed, it would bring conflict with FDA’s forthcoming product class. Of note, they are developing a product class for these products.

The recommendation of the patients 18 years and older should be updated to clarify the need for efficacy in these products. And I’ll show you our final language at the end.

The proposed actions for this were to remove product class entirely from the document and update the class recommendations for adults 18 years and older to reflect the need for proof of clinical effectiveness in preventing CRBSI, catheter-associated BSI, or the like.

To highlight the need for evidence of both efficacy and preventing infections in an absence of harms, the FDA label indication for reduction of CRBSI and catheter-associated bloodstream infections is proposed as an addition to the recommendation for use in patients greater than 18 years see below.

Also recommended our actions were to add language framing the FDA equivalency requirements and class for these products in the document summary, which you see the language noted there that the US FDA has cleared chlorhexidine-impregnated dressings based on bench testing data, demonstrated effectiveness of the device as a barrier bacterial penetration to the catheter site and the effectiveness of the chlorhexidine for the reduction of bioburden within the dressing during use.

The FDA does not currently have a product class for these dressings. They are approved based on demonstrated effectiveness of the device as a barrier, bacterial penetration to the catheter site and the effectiveness of the chlorhexidine for the reduction of bioburden within the dressing during use.

The US FDA has cleared a subset of these dressings with the specific indications for preventing catheter-related bloodstream infections, CRBSI,
based on results from clinical testing data. So that’s a language that we’ve added to the document.

Dr. Yokoe: Tom, would you like to pause here and see if there are comments or questions from the members?

Dr. Talbot: I may need Erin to help me because she’s my product class extraordinaire and really has helped deal with navigations. So, yes, any questions. Probably the densest part of the slides.

Ms. Dekker: This is Elaine Dekker.

Dr. Yokoe: Hi, Elaine.

Ms. Dekker: Hi. It’s actually not a question. When reading Slide 9, it looks like where you start the FDA does not currently have a product. The word “not” is missing.

Dr. Talbot: Yes. I just saw that. That’s right.

Ms. Dekker: That’s my only comment so far.

Dr. Yokoe: Excellent.

Dr. Bell: It’s an important word though. Thank you, Elaine.

I’m also just going to nudge gently Liz from FDA to see if she feels comfortable with references to FDA at this point.

Ms. Claverie-Williams: Hi, Mike. Yes, I do. But if I may ask you, I actually have the lead group representative from FDA, Cynthia Chang, on the line. And may I ask FDA if they are, because they’re the regulatory group, if they are comfortable with it, if she can speak to that if that’s okay with you, Mike?
Dr. Bell: I defer to our chairs.

Dr. Yokoe: Absolutely. Okay.

Ms. Claverie-Williams: Thank you. Cynthia, if you can hear me, can you address all the questions since you are the regulatory group lead?

Dr. Yokoe: Cynthia may be muted.

Ms. Claverie-Williams: She probably is because she’s on the other line.

Dr. Yokoe: Yes, right. Operator, are you able to unmute her line?

Dr. Bell: Jill, did you catch that? We have somebody who is on the public line that needs to be allowed to speak.

Coordinator: Press star 0 and I will open your line.

Dr. Bell: Great.

Dr. Yokoe: Cynthia, are you unmuted?

Dr. Bell: In case it wasn’t clear, Cynthia, please press star 0 and the operator will activate your line.

Coordinator: Excuse me. Cynthia Chang’s line is open now.

Dr. Bell: Great.

Dr. Chang: Yes. Hello, this is Cynthia Chang.

Dr. Yokoe: Hello. Thank you.
Dr. Chang: And I am the Acting Branch Chief of the Plastic and Reconstructive Surgery Devices Branch in CDRH. And could you please repeat the question?

Dr. Bell: So it wasn’t a specific question. I just wanted to make sure that the language that was just presented and the sort of references to your agency didn’t cause any consternation from your perspective.

Dr. Chang: We currently do not have any concerns with the language.

Dr. Yokoe: Excellent. Thank you very much.

Dr. Bell: Terrific.

Dr. Yokoe: Are there any other comments or questions for Tom about the product class discussion? Okay, great. So please proceed.

Dr. Talbot: Sure. We’ll go to Slide 10 now. These were public comments related to draft Recommendation 1A for patients aged 18 years and older. In the Federal Register, the wording was that chlorhexidine-impregnated dressings are recommended to cover the site of short-term, non-tunneled central venous catheters for patients age 18 years and older, Category 1A.

In general, we had some support from eight individuals for the recommendation and only one individual noting concern in recommending against recommending these dressings due to resistance in wound healing concerns. The writing group appreciated those comments but did not feel that there was further clarification in the document to those issues.

There was a comment regarding other populations, five comments related to addressing use of these dressings in patients with other types of catheters, not central venous catheters, such as hemodialysis patients, arterial venous catheters, etc., that the recommendation should include new emerging CHG-impregnated products with proven efficacy as well as legacy products; and
then there was support for recommending the chlorhexidine-impregnated gel dressing.

Our clarification was that this update really addresses the use of chlorhexidine-impregnated dressings for patients with central venous catheters. And we felt that expanding this to other populations was not within the intended scope of the document. So no further change in language was made at that point.

Slide 11. There were comments about product specific recommendations. There was support for wording to specifically recommend only the chlorhexidine-impregnated sponge, suggesting that current evidence supported that product only.

The recommendation should include new emerging chlorhexidine-impregnated products with proven efficacy as well as legacy products, which we noted earlier; support for the gel dressing; and that products with an FDA label for catheter-related BSI reduction should receive a 1A recommendation.

So our clarification for that is that the draft document reviewed the best available evidence of benefits and harms of these dressings in patients with central venous catheters, which included assessment of efficacy of more than one type of dressing in preventing catheter-related BSI, catheter-associated BSI, and catheter-related infections.

The draft recommendations were based on this evidence and harmonized with FDA label indications. And the dressings were recommended if there was clinical evidence of a reduction in infectious outcomes supporting their use.

So our actions from those comments were to change slightly the wording of recommendation 1A saying chlorhexidine-impregnated dressings, with an FDA-cleared label that specifies a clinical indication for reducing catheter-
related bloodstream infection [CRBSI] or catheter-associated bloodstream infections [CABSI] are recommended to protect the insertion site of short-term, non-tunneled central venous catheters for patients 18 years and older as a Category 1A recommendation.

Dr. Yokoe: Let’s pause here and see if there are any questions or comments about Recommendation 1A, draft recommendations for patients aged 18 and older. Okay. Tom, sounds like this is crystal clear. I’m not hearing any questions or comments.

Dr. Talbot: Great. All right. The next section of comments are related to the draft recommendation for patients aged under 18 years of age. And on the slide it should say to date less than 18 and that should be less than 18 “years” for clarification.

In the *Federal Register*, the Recommendation 2A was that chlorhexidine dressings, and that should be CI dressings, are not recommended to cover the site of short-term, non-tunneled central venous catheters for neonates who are premature or less than two months of age due to risk of serious adverse skin reactions. And that was a Category 1A.

We did get several comments regarding the restriction for premature neonates and infants less than two months. And in reviewing the evidence base that supported this recommendation, it was based on two randomized control trials in neonates, one of which showed significantly higher incidence of severe dermatitis in the C-I dressing group.

The age of those with reactions was not specified clearly, but the incidence of reactions was higher in neonates that were under 1000 grams and the PCICU randomized control trial showed chlorhexidine-impregnated dressing related to adverse events occurred only in the neonatal patients. The FDA labeling says “do not use on premature neonates”.
So we did feel that we needed to clarify that recommendation to remove the under two-month restriction and to change from a Category 1A to a 1C to underscore harmonization with the FDA label indication.

So the new proposed language says that those dressings are not recommended to cover the site of short-term, non-tunneled central venous catheters for premature neonates due to risk of serious adverse skin reactions as a Category 1C recommendation.

Dr. Yokoe: Any comments or questions about 2A? Great.

Dr. Talbot: All right. Slide 13. Additional recommendations. So Federal Register version of the 2B recommendation was that no recommendation can be made about the use of these dressings to cover the site of short-term, non-tunneled central venous catheters for non-neonatal pediatric patients less than 18 years due to the lack of evidence from published high-quality studies about the efficacy and safety in this age group. And that was noted as an unresolved issue.

There were two individuals that questioned the lack of a recommendation in this population. And we did receive a comment to review a further study from Duzkaya of chlorhexidine dressings and prevention of catheter-associated BSI in a pediatric ICU that was not in our original search. So we did review that and grade that trial as well.

And in review of that trial, it did not suggest evidence of benefit to using these dressings in pediatric patients in the study and product-related adverse events were not assessed. The labels to the various dressings may differ regarding the non-neonatal pediatric age ranges cleared by FDA, but there is no current RCT evidence of benefit or harms in this population. And so there really still is no recommendation for this population.
So our actions were to incorporate the Duzkaya 2016 trial into evidence, GRADE, and risk of bias tables as they’ve been now added. They’re now in the narrative summary. But this study did not alter the recommendation language as you see submitted to the Federal Register.

Dr. Yokoe: Any comments about 2B? And, Kris Bryant, are you on the line?

Dr. Bryant: I am.

Dr. Yokoe: Just picking on you as a pediatrician. Any issues with either 2A or 2B?

Dr. Bryant: No. It does leave a gap for pediatricians. But I think we just have to rely on the evidence and so the recommendations fairly summarizes the evidence.

Dr. Yokoe: Great. Thank you. Any other comments, questions for Tom? Great.

Dr. Talbot: All right. Slide 14. The comments we received regarding product-related adverse events. In the evidence review, the evidence where you found moderate-quality evidence suggesting the use of C-I dressings is associated with an increase in the incidence of product-related adverse events in patients greater than or equal to 18 years of age.

In patients less than 18 years of age, moderate-quality evidence from two RCTs suggest that use of these dressings was associated with an increase in product-related adverse events in neonates.

One RCT, the Levy trial from 2008, found an increase in C-I-related adverse events in neonates and one RCT, the Garland 2005 trial, found an increase in severe contact dermatitis and other C-I dressing-related adverse events in neonates weighing less than or equal to 1000 grams.

We had comments regarding cases of fungal growth, irritation, epidermal necrosis when using the gel dressing, reports of allergy to standard
transparent adhesive dressings, but no issues with the actual chlorhexidine-impregnated product.

One issue was describing the dressings may be small and not adhere properly or keep access completely covered. And one suggesting choice of chlorhexidine skin antiseptics combined with dressing was shown to influence the risk of skin reactions in one comment.

On Slide 15, for clarification the writing group assessed the product-related adverse event findings related to C-I dressings from the evidence review. Again, the writing group did not consider issues related to dressing preferences or of providers or healthcare systems, provider opinions about ease of application, removal, or inspection for complications.

Of note, we do have language in the document about choosing dressings related to issues like covering site and adherence, but that’s not germane just to this type of dressing. We did not assess basic science or animal studies in this review.

We felt that it was outside the scope of the document to assess the combined effect of CHG, or chlorhexidine, excuse me, skin antisepsis and any type of dressing on adverse events. So there’s no change to the document than what was submitted to the Federal Register.

Dr. Yokoe: Any comments or questions for Tom around adverse events? Okay. Continue.

Dr. Talbot: Here we go. Next section, Slide 16. Comments regarding chlorhexidine resistance. The language submitted to the Federal Register from the evidence review stated in patients 18 years or older, low-quality evidence from two RCTs that compared C-I sponge dressings with standard dressings suggested no difference by dressing type and measures of resistance to
chlorhexidine and bacteria isolated from skin, CVCs, or blood cultures. No studies addressed as outcome in patients younger than 18 years.

There were comments submitted about the negative impact of chlorhexidine on antibiotic resistance and cross-resistance. A comment described the lack of resistance found with use of one product and suggested a study evaluating the effect of the chlorhexidine-impregnated gel in which the sample size was too small to evaluate infectious outcomes.

So the writing group received some clarifications in clarification to our evidence review above that there are preliminary data that show possible links between the use of chlorhexidine and subsequent elevated chlorhexidine minimum inhibitory concentrations [MICs]. There are also some preliminary data suggesting that use of chlorhexidine may be associated with resistance to other antimicrobials, such as colistin.

However, these data are preliminary and the clinical significance of the elevated MICs is not clear. Chlorhexidine has been shown to decrease the incidence of bloodstream infections and healthcare-associated infection with serious consequences.

This document also does not include RCTs that do not assess infectious outcomes. So if there are any trials that didn’t assess those outcomes, those were not in the inclusion of the document.

So Slide 17, we did wish to update the language that we had regarding resistance. And I’ll read the entire recommendation, but the new language is the italicized. So the current language in the limitations of evidence section is as follows.

The studies had limited power to detect chlorhexidine resistance associated with C-I dressing. Little is known about the influence of temporary C-I dressings on chlorhexidine resistance and the protective microbiome of
human skin, or the impact of using multiple chlorhexidine-based interventions, for example, chlorhexidine-impregnated dressings, chlorhexidine gluconate skin preparation and chlorhexidine gluconate bathing, on risk of chlorhexidine resistance.

The new text now is follows.

Preliminary studies describe associations between chlorhexidine products and clinical isolates with reduced susceptibility to chlorhexidine or other antimicrobials, i.e. colistin, or identified chlorhexidine resistance mechanisms, e.g. resistance genes and plasma mediated resistance.

These reports raise questions about how emerging resistance may affect the balance of benefits and harms of using C-I dressings in intravascular catheter-related infections. Given this uncertainty, surveillance and research should continue to assess the association between use of C-I dressings and resistance to chlorhexidine or other antimicrobials and to determine if emerging resistance might reduce the benefits of using C-I dressings to prevent intravascular catheter related infections.

Dr. Yokoe: Any comments or questions for Tom about the updated language? Okay.

Dr. Talbot: All right. Slide 18. We did get a couple comments on methodology regarding inclusion and exclusion criteria, not specifically the reliance on randomized control trials. The literature starts inclusion and criteria were as follows.

As titles were screened of abstracts and full text articles were retrieved if they were relevant to the key question they had to assess the efficacy of C-I dressings for the use with central venous catheters. They were randomized control trials, systematic reviews or met analyses, written in English and available as full text studies (excluding published meeting abstracts).
The reviewers also reviewed the full text articles and excluded articles that were conducted in dialysis settings and not RCTs. If there were numerous RCTs available, the literature search will stop at this point. The current methodology evaluates the aggregate quality of the best available evidence.

So we felt comfortable again reviewing our inclusion and exclusion criteria that we met those standards and those were the appropriate ones for the documents. We did not make any changes to the review or the final recommended guideline in the guideline.

Dr. Yokoe: Any comments? I think, keep going.

Dr. Talbot: Slide 19. There was concern for consistency across guidelines and seeks clarity on the level of evidence for each level of recommendation, 1A, 1B, 1C. That was one comment.

The clarification for that comment is that CDC and HICPAC methodology state the strength of the recommendation is based on quality of the best available evidence. The level of evidence supporting each recommendation category is described in Table 1 of the document.

The *Federal Register* version of the recommendation update evaluated the evidence of benefit and harms in patients with central venous catheters which consist of five RCTs: three large and one small RCT in adults with non-tunneled central venous catheters, and two small RCTs in pediatric neonatal patients.

The 2011 guideline evaluated the evidence of benefits and harms in patients with CVCs, which at the time consisted of one large RCT in adults and two small RCTs in pediatric and neonatal patients. It additionally excluded one meta-analysis although this meta-analysis included hematologic patients which was an exclusionary criteria.
The increase in the amount and strength of evidence between 2011 and to date determined the increase from Category 1B to 1A. So to clarify that and to address that comment, but we did not feel that additional changes needed to be made to the document itself.

Dr. Yokoe: Any comments on that? Yes.

Dr. Talbot: And the last one on methodologies are general document comments. There was a comment to avoid marketing language, product-specific references, product-specific chlorhexidine formulations or manufacturer specific recommendations or wording in the document in Table 2.

And there was a support for more rapid release of guideline updates. The clarification and the best available evidence assessed the efficacy of only two types of FDA cleared dressings on the market. And the reference of these products were a summary of the available evidence.

The proposed action was to remove the product-specific language describing the products and chemical formulations from the main document sections but maintain the descriptions of dressings analyzed in the evidence summary, and Table 2 was removed from the document.

Dr. Yokoe: Any comments about these changes? Okay. Great.

Dr. Talbot: Okay. All right. So, with all that, Slide 21, these are the updated draft recommendations for your consideration. Recommendation 1 for patients aged 18 years and older: Chlorhexidine-impregnated dressings with an FDA cleared label that specifies a clinical indications for reducing catheter-related bloodstream infections, CRBSI, or catheter associated bloodstream infections, CABSI, are recommended to protect the insertion site of short-term non-tunneled central venous catheters, Category 1A.
Of note, there is a Section 5.0, “Implementation Considerations,” for these patients which address things we’ve talked about in the public meeting as well regarding utilization of this tool and ensuring adherence to other basic practices around line care and maintenance.

Recommendation 2, patients younger than 18 years, 2A: Chlorhexidine-impregnated dressings are not recommended to protect the site of short-term, non-tunneled central venous catheters for premature neonates due to risk of serious adverse skin reactions, Category 1C.

And Recommendation 2B, no recommendation can be made about the use of chlorhexidine-impregnated dressings to protect the site of short-term, non-tunneled central venous catheters for pediatric patients less than 18 years old and non-premature neonates due to lack of sufficient evidence from published high quality studies about efficacy and safety in this age group, unresolved issue.

Dr. Yokoe: Thank you so much, Tom, for that amazing summary. I thought that was really great. And again, I want to thank you and the whole writing group for your very careful literature review and your thoughtful crafting of the revised language around these recommendations.

So now that we’ve seen the full updated draft recommendations, I just want to open it up again to the HICPAC members, *ex officios* and liaisons to see if you have any questions or comments for Tom.

Ms. Brown: This is Vickie. I just have one quick question. In the category of short-term non-tunneled central venous catheters, would we include in that category temporary dialysis catheters, vascular catheters?

Dr. Talbot: Erin, correct me, but I believe, I think, that was an earlier comment that those catheters are not included.
Ms. Stone: They are not...

Ms. Brown: So when you say you excluded dialysis settings, it would include those catheters, too?

Dr. Talbot: Right. Erin, is that right?

Ms. Stone: That's correct. They would be excluded.


Dr. Chopra: Tom, this is Vineet. Fantastic presentation. Just a quick point of clarification here on the temporary central venous catheters, non-tunneled CVCs. I assume that includes peripherally inserted central catheters as well, is that correct?

Dr. Talbot: Yes.

Dr. Chopra: Okay. Thank you.

Dr. Yokoe: Other comments or questions for Tom?

Dr. Maragakis: Hi. It's Lisa Maragakis. Tom and the writing group, thank you so much for all your work on this. I guess mine is a comment and not really a question. But it's about the topic that we've discussed many times about how the evidence, the available evidence, really addresses the issue of a whole bundled approach to CLABSI prevention.

And I guess I just want to go on the record as saying that I still feel a little uncomfortable with this one product getting a Category 1A recommendation based on the available evidence that may be drawn from studies that didn't have full implementation of the other evidence-based interventions to prevent CLABSI at the time that the study happened.
Dr. Talbot: We've had a lot of discussion on that. I knew at one point we had an implementation flowchart to help guide that. I can read some - the language that's in that Section 5, it's referred to in 1A, I can read you what has been landed on that we think kind of gets to this.

And it's basically the last paragraph that states, every healthcare facility in the United States that uses CVC should track CLABSI outcomes and process measures to identify opportunities to prevent patient harm. Facilities should ensure high adherence to existing CLABSI prevention policies, practices, and bundles using regular audit and feedback and other means regardless of which type of dressing is chosen. In healthcare settings that are demonstrating success in preventing CLABSI, the addition of C-I dressings is optional.

We really had a much longer section. Then we went back, it was gone. It was back in. That's the kind of language we landed with to at least address your point about really the basics and the bundle of ensuring compliance should happen. But, you know, the level of evidence is very strong for this product. But it doesn't necessarily mean that you always need to use this product, as we note in that paragraph.

Erin, I don't know if you want to - if I said that wrong or if you want to add to that. But I think that's where we kind of landed with that discussion. We spent a lot of time on that piece. And I was a big proponent of that for sure.

Ms. Stone: I don't have anything to add. I think you explained it well.

Dr. Babcock: This is Hilary Babcock. And I, you know, agree with Lisa, which is known from our prior conversations as well. I do appreciate having the specific references to see Section 5 sort of right there in the recommendation so that it doesn't get overlooked and potentially lost as people look at just the
recommendations and don’t always read the entire text. So I do think having that specific call out to go look at that specific place is helpful.

Dr. Yokoe: So definitely a very important point and I know this is the point that we had spent a fair amount of time discussing amongst the HICPAC members and others.

Ms. Janssen: Hi. This is Lynn Janssen. I just want to be clear that I understood that PICC lines are included in the recommendation for the C-I dressing or excluded?

Dr. Talbot: They would be considered a central venous catheter. So they would be included.

Ms. Janssen: Okay, I thought - I assumed so. But then a comment made me think I needed to ask the question. Thank you.

Dr. Talbot: Yes.

Ms. Morgan: Hi. This is Sharon Morgan from ANA. The original look of the situation, it seems as if we were using the sponges as a way of trying to reduce CLABSI for those situations where there was continued resistance despite all the standard protocols.

And it seems like in the end product there was relaxation of that language to just use it. Is that a fair assumption or are we still just saying that for those situations where there is continued resistance?

Dr. Talbot: Mike might want to add a comment, too. I think part of the challenge with recommendations like we had in 2011 is that the kind of language that was in there was a little bit problematic.

And I think the desire of CDC is to move away from that in their guideline recommendations. But as we’ve had discussions and, as Lisa and Hilary
have mentioned as well, we definitely felt there needed to be something in there about the implementation test. So that’s that reference to that Section 5.0 where we say, you know, you may not need to use these.

And then we had a lot of discussion even with that of what’s the acceptable level where you wouldn’t use them. Is it zero? For how long a time? Is it when rates are decreasing? Is it when rates fall below your own institutional benchmark? But what if that benchmark is not aggressive enough?

And so we spent a lot of time really trying to tease that out and landed with that language of demonstrating success at CLABSI, which is admittedly vague as well. But we didn’t feel, and, Mike, you may want to comment about this, that it’s better not to have that kind of language in recommendations. That is different from back in 2011 when the old guideline was developed.

Ms. Morgan: Thank you for the clarification. If I may, just one more comment. Two things with regard to education. I would like to see it stressed, if it’s not already stressed, that it is very, very important that the evidence-based protocols are not changed. Because when you look at the efficacy of this product and, you know, the insert says good for ten days, there may be this assumption that I don’t need to be changing what is an evidence-based protocol for changing dressings.

And then the other thing to make sure that, you know, in reading through articles on the use of these products is that they have to be put in place correctly or there is less efficacy.

So I don’t know whether that is going - any type of that type of language that is going to be included in the final presentation.

Dr. Talbot: I think that’s a fair point and I have to look back if there are, in that section of implementation considerations, if that’s explicitly spelled out.
But I think in general, like with all the guidelines, like they just released as a side guideline, there is still some need for additional implementation guidance and education guidance that synergized with these recommendations. So this is a much smaller scope than the SSI guideline, but you can envision it probably needs some of that to help guide education as well. So those are really good points.

Ms. Morgan: Thank you.

Ms. Dekker: This is Elaine Dekker from AEH.

Dr. Yokoe: Go ahead, Elaine. Thank you.

Ms. Dekker: I just wanted to clarify to my own mind. This is a document that’s meant to just specifically address the dressings but it’s kind of like a supplement to our already existing intravascular document, correct? The prevention of the - I can’t think of the formal title, but this is a supplement to that?

Dr. Talbot: Yes. It expands just that section. In the introduction of the document it spells it out that the rest of BSI Guideline recommendation still apply. It was not a full guideline update. And even in regards to recommendations of that guideline about non-C-I dressings, we didn’t go back and review literature on that either. So it’s just really this specific slice for C-I dressings has been updated.

Ms. Dekker: And that was my thought, too. It might be helpful in the education to really emphasize that one key piece that this is not meant to supplant but rather to enforce and help give more guidance on one specific topic only.

I think a lot of people may assume that this kind of updating all of that guidance, not just the one piece if they skim it too quickly.
Dr. Talbot: And I think - so just to give you a sense of language in the document, it says these draft recommendations -- so after the ones we just went over -- supersede only the two statements about chlorhexidine dressings and the section on catheter site dressing regimens, Recommendations 12 and 13 in the 2011 guidelines.

The updated recommendations on use of C-I dressings for short-term non-tunneled CVCs do not supersede other recommendations about tunneled CVCs, peripheral intravenous catheters or geo catheters and other topics covered in the 2011 guidelines.

So really, and that’s right after the recommendations that this is just replacing those prior recommendations from the old guideline.

Ms. Dekker: Excellent.

Dr. Talbot: So it needs to be emphasized in education.

Ms. Dekker: Yes. Definitely. And thank you for making that connection between the two documents.

Dr. Yokoe: Are there either comments or questions for Tom? Okay, great. And Dan or Mike, do you want to take over the discussion? I think it’s maybe time for the public comments?

Dr. Diekema: Yes, I think so. So thanks again to Tom and the writing group. And I think at this point I will turn it over to the operator to moderate the public comments section.

Coordinator: Thank you. If you would like to make a public comment, please press star 1 on your touch-tone phone. Please record your name so that I may introduce you. Please limit your public comment to three minutes. Once again, please
press star 1, record your name if you wish to make a public comment at this time.

Once again, if you wish to make a public comment, please press star 1 at this time and record your name.

Dr. Diekema: I think we’ll just give a couple of minutes here just in case someone needs to jolt themselves out of - so while we wait to see if there are any public comments, I would ask the committee to refer to Slide 21 that Dr. Talbot just presented. After the public comment period and any discussion that ensues from there, we will be voting on these updated draft recommendations.

Are there any public comments?

Coordinator: We have no public comments at this time, sir.

Dr. Diekema: Okay. Erin, could I ask you to read through the roster and then the response would be approve or disapprove?

Ms. Stone: Okay. I can do that. So I’m going to run through the roll. Dan Diekema. Do you want to do this recommendation by recommendation or as a package?

Dr. Diekema: Why don’t do them separately, 1A, 2A and 2B?

Ms. Stone: Great. So for patients aged 18 years and older, chlorhexidine-impregnated dressings with an FDA cleared label that specify the clinical indication for reducing catheter-related bloodstream infections, CRBSI, or catheter associated bloodstream infections, CABS, are recommended to protect the insertion site of short-term, non-tunneled central venous catheters. This is a Category 1A.

Dan Diekema, do you approve or do you...
Dr. Diekema: Yes.

Ms. Stone: Yes?

Dr. Diekema: Approve.

Ms. Stone: Debbie Yokoe, approve or?

Dr. Yokoe: Approve.

Ms. Stone: Okay. Vickie Brown?

Ms. Brown: Approve.

Ms. Stone: Kris Bryant?

Dr. Bryant: Approve.

Ms. Stone: Hilary Babcock?

Dr. Babcock: Approve.

Ms. Stone: Vineet Chopra?

Dr. Chopra: Approve.

Ms. Stone: Loretta Fauerbach? Loretta Fauerbach, are you on the line? I'll come back to you.

Ms. Fauerbach: I am. But I'm having trouble unmuting.

Ms. Stone: Thanks. Do you approve of the adult recommendation?
Ms. Fauerbach: Yes.

Ms. Stone: Lynn Janssen, approve or disapprove?

Ms. Janssen: Approve.

Ms. Stone: Lisa Maragakis?

Dr. Maragakis: Approve.

Ms. Stone: Great. So then for patients younger than 18 years, Recommendation 2A, chlorhexidine-impregnated dressings are not recommended to protect the site of short-term, non-tunneled central venous catheters for premature neonates due to risk of serious adverse skin reactions.

Dan Diekema, do you approve or disapprove?

Dr. Diekema: I approve.

Ms. Stone: Debbie Yokoe?

Dr. Yokoe: Approve.

Ms. Stone: Vickie Brown?

Ms. Brown: Approve.

Ms. Stone: Kristina Bryant?

Dr. Bryant: Approve.

Ms. Stone: Hilary Babcock?
Dr. Babcock: Approve.

Ms. Stone: Vineet Chopra?

Dr. Chopra: Approve.

Ms. Stone: Loretta Fauerbach?

Ms. Fauerbach: Approved.

Ms. Stone: Lynn Janssen?

Ms. Janssen: Approved.

Ms. Stone: And Lisa Maragakis?

Dr. Maragakis: Approve.

Ms. Stone: All right. For the final recommendation, 2B, no recommendation can be made about the use of chlorhexidine-impregnated dressings to protect the site of short-term, non-tunneled central venous catheters for pediatric patients less than 18 years old and non-premature neonates due to the lack of sufficient evidence from published high-quality studies about efficacy and safety in this age group. This is an unresolved issue.

Dan Diekema, do you approve or disapprove?

Dr. Diekema: Approve.

Ms. Stone: Deb Yokoe?

Dr. Yokoe: Approve.
Ms. Stone: Vickie Brown?

Ms. Brown: Approve.

Ms. Stone: Kristina Bryant?

Dr. Bryant: Approve.

Ms. Stone: Hilary Babcock?

Dr. Babcock: Approve.

Ms. Stone: Vineet Chopra?

Dr. Chopra: Approve.

Ms. Stone: Loretta Fauerbach?

Ms. Fauerbach: Approved.

Ms. Stone: Lynn Janssen?

Ms. Janssen: Approve.

Ms. Stone: And Lisa Maragakis?

Dr. Maragakis: Approve.

Ms. Stone: Great. Thank you.
Vote: 2017 Draft Updated Recommendations on the Use of Chlorhexidine-Impregnated Dressings for Prevention of Intravascular Catheter-Related Infections

The 2017 Draft Recommendations on the Use of Chlorhexidine-Impregnated Dressings for Prevention of Intravascular Catheter-Related Infections was approved unanimously, with no opposition and no abstentions. The disposition of the vote was as follows:

9 Favored: Babcock, Brown, Bryant, Chopra, Diekema, Fauerbach, Janssen, Maragakis, Yokoe
0 Opposed: None
0 Abstained: None

Dr. Diekema: All right. Well, thank you very much. I would like to thank everyone for joining the call, the committee, ex officios, liaisons and in particular thanks to Tom Talbot and the rest of the writing group for all the work they put into this.

With that, I think I'll turn it back over to either Erin or Mike. Do you want to comment at all on next steps? Where this goes next in terms of CDC clearance and then eventual publication?

Dr. Bell: You just did a very good job of explaining the next steps. So this will end up being cleared and posted on our Web site. We'll be following up with liaisons as well as committee members in terms of notifying partners and other organizations of the update.

I will say one last thing, in addition to echoing the thanks of everybody else for the hard work that was put into this, and that is to remind everybody that if you participated today please remember to send that email to hicpac@cdc.gov.

Dr. Diekema: Okay. Debbie or Erin, do you have anything else?

Dr. Yokoe: No. Again, thanks to everyone.

Dr. Diekema: All right.
Dr. Talbot: Thanks to Erin. She needs to be shouted out to specifically. She did a great job...

Dr. Diekema: Oh, absolutely.

Dr. Yokoe: Thank you, Erin.

Dr. Diekema: Thank you very much. So with that, I think this call is adjourned.

Dr. Bell: Thanks, everybody. Bye-bye.

((Crosstalk))

Coordinator: This does conclude today’s conference call. We thank you all for participating. You may now disconnect and have a great rest of your day.

The meeting adjourned at 1:54 pm.
Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing transcripts of the May 5, 2017 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

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Expansion</th>
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<tbody>
<tr>
<td>AEH</td>
<td>America’s Essential Hospitals</td>
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<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
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<td>ANA</td>
<td>American Nurses Association</td>
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<td>AORN</td>
<td>Association of periOperative Registered Nurses</td>
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<td>ASTHO</td>
<td>Association of State and Territorial Health Officials</td>
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<tr>
<td>BSI</td>
<td>Bloodstream Infection</td>
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<td>CABSI</td>
<td>Catheter-Associated Bloodstream Infection</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>Chlorhexidine Gluconate</td>
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<td>C-I</td>
<td>Chlorhexidine-Impregnated</td>
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<tr>
<td>CLABSI</td>
<td>Central Line-Associated Bloodstream Infection</td>
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<td>Centers for Medicare and Medicaid Services</td>
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<td>CRBSI</td>
<td>Catheter-Related Bloodstream Infection</td>
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<td>CSTE</td>
<td>Council of State and Territorial Epidemiologists</td>
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<td>CVC</td>
<td>Central Venous Catheter</td>
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<td>DFO</td>
<td>Designated Federal Official</td>
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<td>Division of Healthcare Quality Promotion</td>
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<td>FDA</td>
<td>(United States) Food and Drug Administration</td>
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<td>GRADE</td>
<td>Grading of Recommendations Assessment, Development and Evaluation</td>
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<td>(United States Department of) Health and Human Services</td>
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<td>Health Resources and Services Administration</td>
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<td>Intensive Care Unit</td>
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<td>Minimum Inhibitory Concentration</td>
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<td>National Association of County and City Health Officials</td>
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<td>National Institutes of Health</td>
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<td>PCICU</td>
<td>Pediatric Cardiac Intensive Care Unit</td>
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<td>PICC</td>
<td>Peripherally-Inserted Central Catheter</td>
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<td>Randomized Controlled Trial</td>
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<td>Surgical Site Infection</td>
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<td>VA</td>
<td>(United States Department of) Veterans Affairs</td>
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