



**Healthcare Infection Control Practices Advisory Committee (HICPAC)**  
**DRAFT: Guidelines for the Prevention of Intravascular Catheter-Related Infections**  
**May 17, 2010 Teleconference**



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## **List of Participants**

### **HICPAC Members**

Patrick Brennan, Chair  
David Pegues  
Lillian Burns  
Susan Huang  
Alexis Elward  
Tammy Lundstrom  
Yvette McCarter  
Denise Murphy  
Barbara Soule  
Dale Bratzler  
Bill Schechter

### **Designated Federal Official**

Jeff Hageman

### **Ex-Officio and Liaison Members**

William Baine (Agency for Healthcare Research and Quality)  
Ms. Nancy Bjerke (Association of Professionals of Infection Control and Epidemiology, Inc.)  
Ms. Joan Blanchard (Association of periOperative Registered Nurses)  
Sheila Murphey (Food and Drug Administration)  
Ms. Rachel Stricof (Advisory Council for the Elimination of Tuberculosis)  
Gary Roselle, Department of Veterans Affairs (VA)  
Roslyne Schulman, American Hospital Association (AHA)  
Mitchell Levy, Society of Critical Care Medicine (SCCM)  
Lisa Maragakis, Society for Healthcare Epidemiology of America (SHEA)



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Jeff Hageman: I want to thank everybody for joining the call today. We were having some technical glitches there at the beginning. That's why we're a bit delayed. But I would like to turn it over to the Chair of HICPAC, P.J. Brennan to give the opening remarks.

P.J. Brennan: Thank you Jeff. This is the HICPAC call to finalize the guidelines for Prevention of Intravascular Catheter-Related Infections.

Following our February call a few issues remain unresolved and the Writing Group has worked to address these issues.

During and following the last call information was received suggesting that some references may have been missing or that the research was incomplete.

And so as HICPAC has now adopted with other work it has done, the Penn Center for Evidence-Based Practice was enlisted to address the outstanding questions around this document.

To wrap up the unresolved issues, Dr. Ingi Lee who is with me here at Penn led the research into these questions. Eight questions were raised and for those of you with access to your computers or laptops the HICPAC Web page will provide you with access to both the research and the questions that needed to be resolved after the last meeting.

I should note at this point that HICPAC has adopted this method of research including the grade recommendations as its standard approach to resolving issues of data and evidence. The guideline that we were addressing here was initiated prior to HICPAC's adoption of that approach. Nonetheless we completed the work using that method.



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Our objective today is to finalize the issues that were unresolved after the last meeting. We are not reopening the rest of the document and we hope at the conclusion of this meeting to have it ready to go into clearance.

P.J. Brennan: Okay. So Jeff if you would handle the roll call and for the members of the call we'll be asked to make declarations of conflicts of interest that relate to this document in particular either a direct relationship to products that may be mentioned in the document or to competitor products with appropriate notation of the conflict and recusal if necessary.

Okay, go ahead Jeff.

Jeff Hageman: All right. So I'll start with you P.J., any conflicts?

P.J. Brennan: Present and no conflicts to report.

Jeff Hageman: Dale Bratzler.

Dale Bratzler: I'm here and I have no conflicts.

Jeff Hageman: Lillian Burns.

Lillian Burns: No conflicts.

Jeff Hageman: Alexis Elward.

Alexis Elward: I'm here. And I have received research support from Sage Products Limited and they manufacture the chlorhexidine wipes.



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Jeff Hageman: Susan Huang.

Susan Huang: Here. No conflicts.

Jeff Hageman: Tammy Lundstrom.

Tammy Lundstrom: Here. No conflicts.

Jeff Hageman: Yvette McCarter.

Yvette McCarter: Here. No conflicts.

Jeff Hageman: Denise Murphy.

Denise Murphy: I'm here. Have no new conflicts.

Jeff Hageman: Steve Ostroff.

Russ Olmsted.

David Pegues.

David Pegues: I'm present. And I have two potential conflicts. I'm a consultant for Access Technologies. They make an antimicrobial lock solution and VasoNova who makes an outpatient percutaneously inserted central catheter.

Jeff Hageman: Peter Pronovost.



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Barbara Soule.

Barbara Soule: I'm present. And I am doing consulting work for 3M which may have some products related to this guideline.

Jeff Hageman: Bill Schecter.

Bill Schecter: Present. No conflicts.

Jeff Hageman: Bill Baine.

Bill Baine: I'm present.

Jeff Hageman: Sheila Murphey (noted presence on call via email due to technical glitch).

David Henderson.

Jeff Hageman: Gary Roselle.

Gary Roselle: I am present and I don't have any conflicts.

Jeff Hageman: Rachel Stricof (noted presence via email during call).

Mark Russi

Sandra Fitzler.

Roslyne Schulman.



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Roslyne Schulman: Present. No conflicts.

Jeff Hageman: Joan Blanchard.

Barbara DeBaun.

Barbara DeBaun: Present. No conflicts.

Jeff Hageman: Marion Kainer.

Lisa McGiffert.

(Charlie) Huskins.

Shirley Paton.

Lisa Maragakis.

Lisa Maragakis: Present. No conflicts.

Jeff Hageman: Mitchell Levy.

(Mitchell) Levy: Present. No conflicts.

Jeff Hageman: Sanjay Saint. I think he was not going to be here.

Bob Wise.



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All right, so according to my count P.J. we do have quorum numbers.

P.J. Brennan: Okay. So for those of you on the public line, on the Web site ([www.cdc.gov/hicpac](http://www.cdc.gov/hicpac)) there are two documents. One is the Penn Center's research on the key questions and the center addressed eight questions although the version there reflects three key issues that were the ones that were most often commented on in the - I believe in the call and in the public comments that were received.

And those three questions were what is the appropriate level of chlorhexidine gluconate required for skin antiseptics prior to catheter placement; what type of chlorhexidine gluconate dressing should be used for temporary short term catheters in patients older than 2 months to reduce the risk of infection; and the third is do split septum needleless connectors have decreased risk of infection compared to all mechanical valve needleless connectors.

The other five questions, there was really very limited evidence and are not included in this document.

So we'll start with the second document on the Web page which is a table with the heading HICPAC Action, Suggested Revision, original text that is the Federal Register version and the author's revised text.

So the first section is catheter site dressing regimens.

Jeff, do you want to take it?

Jeff Hageman: Sure. So the first catheter site dressing regimens essentially reviews the comments during the public comment and during the February meeting were to consider increasing the



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recommendation for chlorhexidine impregnated sponge dressing to a 1A, amend conditional language to split the recommendation into two parts. One recommendation for the chlorhexidine sponge specific product and one for the chlorhexidine dressings, same amount of evidence differ for each.

And then the third comment was to modify, the conditional language noting catheter associated BSI rate reduction not catheter-related BSI rate reductions, the measure that most people are using.

So the original text had both. There were some discussion about the various products; one, chlorhexidine sponge and then chlorhexidine dressing. So the review that Penn did outlined the studies for both of those.

The original recommendation has use of chlorhexidine impregnated sponge dressing for temporary short term catheters in patients older than 2 months of age if the catheter-related BSI rate is higher than the institutional goal despite adherence to basic prevention measures including education and training, use of chlorhexidine for skin antisepsis and maximal sterile barrier precautions.

The Federal Register version had that recommendation as a Category IB. The authors revised text based on the public comments and HICPAC suggestions, revised that recommendation to use the chlorhexidine impregnated sponge dressing for temporary short term catheters in patients older than 2 months of age if the CA BSI rate has not been substantially reduced despite adherence to basic prevention measures including education and training, use of chlorhexidine for skin antisepsis and maximal sterile barrier precautions. The authors left it as a Category 1B.





P.J. Brennan: And for those of you who are trying to follow along in the evidence document, the evidence tables are on Page 12. And summarized at the top of Page 14.

And what the evidence showed there was that the RCTs only addressed sponge dressings. And so there is evidence that sponge dressing results in significantly decreased rates of infection compared to standard or no dressing.

Okay are there questions?

David Pegues: Yeah, this is Dave Pegues. Looking over the evidence tables, four of the randomized clinical trials showed a benefit of CHG sponges compared to standard dressings and reducing rates of catheter associated bloodstream infection. Two did not. No significant changes.

And I just want to clarify the Category IB ranking. Under what circumstances and what higher level of evidence will be required to make that a 1A recommendation?

Jeff Hageman: For this guideline, Category IA is strongly recommended for implementation and strongly supported by well designed experimental clinical or epidemiologic studies.

Category IB is strongly recommended for implementation and supported by some experimental clinical or Epi studies or strong theoretical rationale for an accepted practice.

Naomi O'Grady: I have re-discussed these issues prior to the call last week with the Writing Committee. And the reason that we made it a IB was because there are two trials that show no difference, two that show some difference.

And the trials that show a difference didn't use chlorhexidine as the skin antisepsis the way we currently do in standard practice.



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So the committee felt that until we have reliable data that's reproducible a IB would be the category that they would prefer. Although I would say that they didn't feel strongly enough to draw a line in the sand over this and, you know, if HICPAC felt strongly that it should be a IA we would be willing to do that.

But again the reason that we put it to a IB was because of the differences in skin antiseptics. One study used betadine, povidone-iodine, another study used alcohol.

Susan Huang: This is Susan Huang. Can I confirm that when we're talking about things that are to be used for a temporary short term issue when the CR BSI rate is higher than expected, I just want to make sure that there are a number of things that hospitals can do that might warrant either IA or IB or other categories.

And I want to make sure it's not construed that when you have rates that are high that everything needs to be done all at once, meaning impregnated catheter and sponge dressings and other things that have been shown to have benefit. I want to make sure that the guideline does specify that these are one of several things that can be done that have evidence behind them to be done in the study of high rates.

Mike Bell: Susan that is the intended way. That's the intended message here. I don't think there's intent to say that everything must be implemented all together at the same time.

Susan Huang: Right. I just think the IA and IB classification was traditionally used for things that would be implemented routinely. And so when we start to talk about IA guidance for something that should be done if something's high, it really isn't. It makes it seem like the way people casually mention IA makes it seem like it must be done.



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Naomi O'Grady: Yeah, I agree with you. We have in the guideline language such that we do say if the rate has not been substantially reduced despite adherence to basic prevention measures which we talk about in the guideline the basic prevention measures which are - include education and training, maximal barrier precautions and chlorhexidine skin antisepsis.

So we do use that language reminding the reader that those are the basic things that need to be implemented and then there are other things outside of these core recommendations that could be implemented if the rate has not been substantially reduced.

Susan Huang: So maybe that's a clarification that there are several that could be considered with good evidence and there's no suggestion that all of these must be implemented together.

I mean it seems basic to us I think but it may not be basic coming across in the guideline.

Naomi O'Grady: So you're concerned that if we put it - if we recommend it at the IA level everybody will think this must be implemented.

Susan Huang: Yes, I am. And then my concern is that there are other things that are also there that have some supportive data. And so there are several things that could be done and I want to make sure it's not construed that anything that comes in the IA or IB category needs to be pursued.

Mike Bell: Yes, there is precedence for this in other devices for example silver-coated catheters and so on where we said that when everything else isn't enough these should be considered for addition.

It strikes me that we should stick with similar language here.



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Bill Baine: This is Bill Baine. I don't have a substantive comment. But I think that the text will say what you want it to say more clearly if you take out the comma after age and a comma after reduced.

P.J. Brennan: Okay, I think we can wordsmith this to make sure that it conveys that.

Jeff Hageman: So I didn't hear P.J. whether or not HICPAC chose- believe this is a IB or make this a IA based on the evidence.

P.J. Brennan: We haven't taken a vote on that. So the proposed revision is in the document as Category IB. So I'm going to suggest that we take the vote based on what is in the revision and then we can - if it passes we'll move on and if it fails we'll discuss further.

Barbara Soule: This is Barb Soule. I do want to support what Susan is saying in that out in the field if it comes out with IA recommendation people feel they must do it.

So the text in the recommendation is very important because that's how people will pretty much interpret a IA.

P.J. Brennan: Okay. Let's move onto the next item then.

Tammy Lundstrom: Sorry P.J. This is Tammy. Sheila Murphey can't get into the call. She's in a listening mode. She - I don't know if there's somebody technically that can help her. She sent an email that she can't get in.

Jeff Hageman: Thanks Tammy. We were trying to get her on.



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Susan Huang: And this is Susan. I'm sorry, but I have to - I dropped off. I have to drop off. I only have half an hour for this. But for this particular vote I vote to leave it as is.

P.J. Brennan: As a IB?

Susan Huang: Yes.

Susan Huang: Yes.

P.J. Brennan: Okay, thanks. Okay, let's go onto the next item. Timing of dressing changes.

Jeff Hageman: So this was just essentially revised text based on the - consider splitting gauze from transparent dressings and for gauze dressing there was a question about the category. The authors revised the text. Replace dressings used on short term central venous catheter sites every two days for gauze dressings, Category 2. And replace dressings used on short term CVC sites at least every seven days for transparent dressings except in those pediatric patients in which the risk for dislodging the catheter may outweigh the benefit of changing the dressing and that would be a Category 1B.

P.J. Brennan: Okay. So in this one the recommendation has been split and the language is really the same, isn't it Jeff? It was just split the first sentence out and made that a Category 2.

Jeff Hageman: Right.

P.J. Brennan: Yeah. Okay. Any comment on this one?

Tammy Lundstrom: This is Tammy. It makes it a lot clearer.



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P.J. Brennan: Okay.

Man: So do you want the distinction you made with regard to the pediatric patients between the short term; I'm sorry, the gauze and the transparent?

Jeff Hageman: I think it's fine.

Bill Schecter: This is Bill Schecter. Can I ask what page this recommendation is on?

P.J. Brennan: And it starts at the bottom of Page 1, the second row on Page 1.

Bill Schecter: Okay.

P.J. Brennan: And it carries over onto the first row of Page 2.

P.J. Brennan: Last column. Okay, let's go onto the needleless intravascular catheter systems.

Jeff Hageman: All right, so this one is an additional Penn Evidence Review was performed. There was some public comments about this recommendation that concern about recommending against all mechanical valve needleless connectors instead of - and so in addition the main point was that there was large differences between these devices that would seem to argue against general recommendations for all mechanical valve needleless connectors.

So the original text was when needleless systems are used the split septum valve is preferred over the mechanical valve due to increased risk of infection, a Category II. The language was modified slightly to say when needleless systems are used a split septum valve may be preferred over a mechanical valve due to increased risk of infection with some mechanical valves. And that stayed at a Category II.



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P.J. Brennan: So still Category II but it paints with a less broad brush. May be preferred on some mechanical valves.

Any comments?

Okay, let's go onto the next one, chlorhexidine and hub clean.

Jeff Hageman: Right. So there was a comment about avoid saying chlorhexidine is preferred for hub cleaning. And also they suggested stronger language about scrubbing versus wiping to indicate a more rigorous process.

So the original language was to minimize contamination risk by wiping the access port with an appropriate antiseptic chlorhexidine preferred and accessing the port only with sterile devices, Category IA.

The language changed slightly to be minimize contamination risk by scrubbing the access port with an appropriate antiseptic chlorhexidine povidone-iodine IOTA 4 or 70% alcohol and accessing the port only with sterile devices, remain a Category 1A.

Any comments on that change?

P.J. Brennan: So the language is less specific about chlorhexidine.

Lillian Burns: This is Lillian. I think that was the intent to make sure that it included other types of products. And also there was a lot of discussion about scrubbing the hub as opposed to wiping. And in the field they tend to use scrub the hub so we thought that would be - should be included.



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P.J. Brennan: Other comments?

Okay, let's go onto the section on recommendations for central venous catheters.

And the first item is at the bottom of Page 2, a modification of language related to femoral site selection.

Jeff Hageman: Right, so this one is essentially taking the same language as the original recommendation and splitting it to emphasize to avoid the femoral site.

So the original language was use of a subclavian site rather than a jugular or femoral site in adult patients to minimize infection risks for non-tunneled CVC placement, a Category 1A. That was split into two recommendations. Avoid using the femoral vein for central venous access in adult patients, Category 1A.

And the second use a subclavian site rather than the jugular in adult patients to minimize infection risk for non-tunneled CVC placement, Category 1B.

P.J. Brennan: Comments?

Okay, the next item is on Page 3, skin preparation relating to again to chlorhexidine and consideration of lower concentrations. And this is part of the Penn Evidence Review and was, let's see, included in the evidence review on Pages 8 through 12. This was the first question addressed in the evidence review I believe.

So Jeff, go ahead.





Jeff Hageman: Sure, there were some comments to consider lowering the concentrations for chlorhexidine with alcohol to 0.5% as an alternative for skin antisepsis. And then there was also a comment to recommend only alcohol-based chlorhexidine preparation for skin antisepsis and then HICPAC actually had suggested to prepare using chlorhexidine-based preparation of 2% or higher.

The original language was prepare clean site, skin site with a 2% chlorhexidine-based preparation before central venous catheter insertion and during dressing changes. If there's no contraindication to chlorhexidine, tincture of iodine or iodophor or 70% alcohol can be used as alternatives. That was all Category IA.

The authors revised text based on the comments was to prepare to clean skin with a greater than 0.5% chlorhexidine-based preparation before central venous catheter insertion and during dressing changes. If there's no contraindication the rest is the same Category IA.

So the main difference was changing the concentration of chlorhexidine from 2% in the original version. The authors revised the text to greater than 0.5%.

Barbara Soule: Say this is Barb Soule. As I'm looking at the analysis that we've done, it specifies chlorhexidine gluconate .5% alcohol versus the CG 2% aqueous.

But in the revised recommendation suggests that 0.5%. That's specific enough based on the evidence that we have?

P.J. Brennan: I'm going to ask Ingi to address that Barb.

Barbara Soule: Okay.



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Ingi Lee: So there are studies that show a benefit to chlorhexidine versus iodine. When you look at the different preparation whether it be the percentage or whether they're with or without alcohol there really are not lot of studies looking at (that).

So what I essentially found was just one of RCT that made this comparison that there was no difference.

And because there was such little evidence then I actually just looked at all studies comparing chlorhexidine versus iodine. And chlorhexidine faired better.

When you looked at the studies that were included in the meta-analyses they really ranged in percentages and it ranged from whether they used alcohol or not.

So I feel like this is a little bit of - it's not entirely clear which is the best preparation.

Mike Bell: Ingi the 1 RCT compared 0.5% chlorhexidine to an iodine-based product. Is that correct?

Ingi Lee: They compared - if you look on Page 9, so it made a couple of different comparisons. So it compared chlorhexidine 0.5% alcohol versus chlorhexidine 2% acquiesce and then iodine 10% acquiesce. And so I split them up comparing two at a time.

Mike Bell: Sounds good. So and my concern here is that if the proposed language is greater than 0.5 yet the one publication that we have is actually 0.5, shouldn't we say 0.5 or greater?

P.J. Brennan: Yeah.

Woman: Yeah.



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Ingi Lee: Yeah.

Woman: I believe.

Mike Bell: And that would be the alcoholic product, yes?

P.J. Brennan: Right. That's right.

Woman: Yeah, I think that would provide more clarity.

P.J. Brennan: So prepare clean skin with a 0.5% or greater chlorhexidine-based preparation.

Dale Bratzler: P.J. this is Dale.

P.J. Brennan: Go ahead Dale.

Dale Bratzler: Just one question. I do not have the benefit of participating in the previous discussion so I'm only seeing this discussion of the skin prep looking at the CHG concentration.

But when I look again at all of these studies that compare CHG prep to other preps, again when you look through this evidence review virtually all of them are CHG something or alcohol or aqueous versus plain iodine. The only one that showed a significant difference was Maki Study in '91 in terms of actual infection rates compared to povidone-iodine alcohol.

I don't want to raise that issue again. And I think, you know, I'm pretty comfortable with the recommendation to use a CHG-based prep for central lines.



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But in terms of direct comparisons most of them, the vast majority that I've seen have been CHG or CHG alcohol to plain iodine.

Ingi Lee: That's correct. There's only one study out of I think there were six RCTs, that compared different formulations, different percentages of chlorhexidine. You're correct. The rest of them compared chlorhexidine to iodine.

Naomi O'Grady: Right. Now there was one study. I believe it was the (Kumar) Study that didn't show any difference between 0.5% and povidone-iodine which is why the committee elected to go with greater than 0.5%. That also was consistent with the language that the ShEA Compendium used.

Mike Bell: (Naomi) could you clarify the paper that you're talking about, different - what was the...?

Naomi: It was a CID publication I think in 2000 (Kumar).

P.J. Brennan: Page 10 (Mike), (Kumar).

Mike: That one showed no difference between...

Naomi: BSI's, catheter tip colonization.

P.J. Brennan: And exit site, right.

Naomi: And exit site, yeah.

Woman: None of those were significant, right (results)?



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Woman: Correct.

Ingi Lee: So I just - I don't know if - how specifically we can comment because although chlorhexidine is better, it's just that most papers use different percentages and some use alcohol-based and some use non-alcohol based that there's not that much data for each of the individual products.

Naomi O'Grady: That's why we tried to err on the side of being conservative and they - greater than 0.5%.

Again this was the language that the SHEA Compendium used as well based on the same data.

P.J. Brennan: Okay. Are there any other comments?

(Naomi) is it your preference to keep it as it's written in the third column or I'm sorry, in the last column?

Naomi: I think to have consistency with the current recommendations that are out there I think that would be optimal.

But I think also I know for a fact that our committee is probably not willing to draw a line in the sand over this issue. But they do feel that the data really leans more towards a greater than 0.5% concentration of chlorhexidine with the caveat that products are not the same and the other components in the solutions are not equal.

Mike Bell: It's challenging given that we already have a publication that shows 0.5 is superior, right?



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Naomi: Yeah, I think the MICs - so the concerns are that the MICs for chlorhexidine and the 0.5% solution should be sufficient for common skin organisms.

The other concern is that with the use of so much chlorhexidine at lower concentrations there's concern about resistance and MIC creep.

P.J. Brennan: (Mike) which one are you referencing as showing superiority to the 0.5?

Mike Bell: Which one is that? The (Valent) Study 2008.

Naomi: One, 2008.

Woman: But that was for bacterial colonization of the catheter, right, it was not significant, the CRBSI.

Woman: That's correct.

Naomi: I think from our point of view it would be, you know, one study does not a recommendation make. And until again it can be reliably reproduced our committee would error on the side of going with greater than 0.5% but we could be convinced if you showed us a good reason to change the recommendation.

Mike: I think the rationale sounds good.

P.J. Brennan: So (Naomi) we're leaving it as its written then and greater than 0.5%.

Barbara Soule: And somebody had put in the words alcohol-based. Do we want to include those?



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P.J. Brennan: I don't think so.

Barbara Soule: Okay.

Naomi: I'm sorry, I didn't hear you Barbara.

The thing about the aqueous solutions they're not stable in the currently available packaging. So in truth the aqueous solutions just aren't available.

P.J. Brennan: Did you want the alcohol-based left in?

Dale Bratzler: I guess P.J. this is Dale. Again it goes back to this issue for me that unless there are other studies that I don't know about, for all of these CHG studies the predominant comparator is iodine alone. The Dennis Maki Study compared povidone-iodine to 70% alcohol and CHG. Had three different groups but did not have this iodine alcohol group combined.

So again raising that issue is iodine alcohol as effective as CHG alcohol.

And I just don't see those comparisons in this literature.

P.J. Brennan: Okay.

Dave Bratzler: The only one was the (Mima) Study and it was not significant although there was a trend. But the only one that I see that has that direct comparison.

P.J. Brennan: Dale so what are you suggesting?



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Dale Bratzler: Well it just seems to be the conventional wisdom today that you use the CHG prep for central lines. And I know it's part of all the bundles. I understand that.

And I definitely agree that a CHG prep versus iodine alone is clearly superior. I think that's been well demonstrated.

What I haven't seen is good comparisons of the iodine alcohol preps versus CHG alcohol. And I don't - I'm just not convinced those studies have been done. Again if it's best I clearly support it. It's just I haven't seen the good comparisons between iodine alcohol and CHG alcohol.

And of all the series of studies in the evidence review there's only one that has that comparison and it was a non-significant difference though potentially the trend.

P.J. Brennan: And that was (NEMO)'s?

Dale Bratzler: Yes. Because Dennis Maki Study, I actually pulled it up real quick to look at it. Dennis Maki Study actually had three limbs to the study, iodine...

P.J. Brennan: Yes.

Dale Bratzler: ...alcohol or CHG alone.

Woman: ...the comparison between CHG alcohol and iodine alcohol is an unresolved issue (as) evidence.

Dale Bratzler: Right.



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P.J. Brennan: So if we leave in greater than 0.5% alcohol-based - alcohol chlorhexidine-based preparation and add a sentence on the unresolved comparison, does that resolve it for you Dale?

Dale Bratzler: Yeah, absolutely. That would.

P.J. Brennan: Any comment on that point? Any more comment on that point?

Woman: That's good.

Jeff Hageman: All right, let's move to the next one. So this is - there was a recommendation for maximal sterile barrier precautions. HICPAC had actually decided to modify this recommendation from full body drape to large drape such as a half sheet because the literature didn't really specify the size of the drape. However the authors chose not to make this change. I can let, you know, (Naomi) speak to this.

But essentially because this has not been the standard practice and although it's not specified the size of the drape in the literature, those familiar with the specific studies looking at that noted that a full body drape was actually used.

There was also some concern about changing kind of standard practice today when we don't really have a specific drape size that we would move to.

Does that summarize the points, (Naomi)?

Naomi: Yes. The standard in the - in clinical practices, the full body drape, that's the language that's been used in most of the other studies.



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And the fact is we don't actually have data on what the appropriate size is and so to say a half sheet didn't seem reasonable to the committee.

P.J. Brennan: Questions about this or comments?

All right let's move on Jeff, administration sets at the top of Page 4.

Jeff Hageman: Sure, this was another one where the one recommendation was split into the three different parts. There was also some refining of it to specifically state this can only be for continuously used administration sets.

So it went from inpatients not receiving blood, blood products or lipid emollients, replace administration sets including secondary sets and add-on devices no more frequently than 96 hour intervals but at least every seven days, Category 1A. It was split into inpatients not receiving blood, blood products or lipid emollients, replace administration sets that are continuously used including secondary sets, add-on devices no more frequently than at 96 hour intervals but at least every seven days, Category 1A.

And then there was two additional items added. The frequency for replacing intermittently used administration sets as an unresolved issue as well the frequency for replacing needles to access implantable ports as an unresolved issue.

P.J. Brennan: Okay, comments?

Okay, replacement of peripheral and midline catheters at the bottom of Page 4.

I think this is similar. Isn't it Jeff?



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Jeff Hageman: Yes, this is similar. So this again is splitting of the recommendations based on comments. The original recommendation was replace peripheral catheters every 72 to 96 hours to reduce the risk of infection and phlebitis in adults, Category 1B. It was - that recommendation was modified to 2. Replace peripheral catheters no more frequently than 72 to 96 hours to reduce risk of infection and phlebitis in adults, Category 1B. And added replacing peripheral catheters in adults only when clinically indicated as an unresolved issue due to lack of evidence.

P.J. Brennan: Comments?

Bill Baine: It sounds - this is Bill Baine. It sounds as though you're saying that if you replace the peripheral catheter more frequently than 72 to 96 hours it would increase the risk of infection.

You might consider saying replace peripheral catheters to reduce risk of infection (in) phlebitis in adults but not more frequently than every 72 to 96 hours.

Naomi: Well but there are studies that indicate you may not have to replace them at all. There's one study which is why we left it an unresolved issue because in the face of all these other studies that indicate 72 to 96 hours, you know, some people would argue that maybe we shouldn't be replacing them at all.

Bill Baine: Well that's fine but that's different. As it's worded now, it sounds as though gee should I replace the catheter. Well maybe but don't do it more than 72 to 96 hours because you'll increase the risk of infection. It's just that the order that they're coming in and...

Naomi: So there's no need to replace a peripheral catheter more frequently than 72 to 96 hours to reduce the risk of infection.



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Bill Baine: I think that's the less ambiguous and less confusing about what it is that's reducing - what it is that's increasing risk of infection.

Naomi: Okay.

Bill Baine: The other thing that I would urge is that whatever the finished wording is doesn't sound as though you're saying oh gee the guy's got this infection obviously where his IV is. But we shouldn't replace it more frequently because it hasn't been 72 hours yet. That would make it even more dangerous or something.

Naomi: Okay.

Jeff Hageman: Let's move to the last comment for the catheter securement devices. There were comments that catheter securement devices should be recommended for all catheters. HICPAC had actually suggested a sub-bullet to emphasize that the evidence support extending securement devices to other catheter types is currently lacking. The original recommendation was use a sutureless securement device to reduce the risk of infection for PICCs, a Category 2.

Authors actually revised to be more inclusive to use a sutureless securement device to reduce risk of infection for intravascular catheters.

(Naomi) did you want to comment on that?

Naomi: Well I guess we were - the public comment said catheter securement devices should be recommended for all catheters. And the issue is that catheter securement devices are - include the - a small plastic disk that sits on the patient's arm or neck or at the subclavian site or wherever and it is secured in site with adhesive.



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But a securement device also includes a suture. So the public comment didn't really make sense to us and I wasn't really - we weren't really clear on what they were getting at.

But it seemed that the comment indicated that they wanted securement devices recommended for all catheters.

And so we recommended a sutureless securement device for all intravascular catheters and that extends to peripheral IVs, to PICCs and to central venous catheters.

Given that there's no biologically plausible explanation for why it would reduce infections in PICCs and not central venous catheters, I think that the user just has to assess the risk benefit ratio when it comes to risk of dislodging the catheter versus the benefit of not having that additional suture as a (9 to 7) infection.

P.J. Brennan: Okay, are there any objections to that?

Okay Jeff I think we've completed all of the issues that we needed to review. Is that correct?

Jeff Hageman: That's correct.

P.J. Brennan: Okay, should we open up the line to public comment then?

Jeff Hageman: Yes. So Operator can you please open the line for public comment?

Coordinator: Yes. Thank you. At this time for any questions or comments please press star 1 on your touchtone phone. Once again that's star 1 for comments or questions.



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At this time there are no comments or questions.

P.J. Brennan: Okay. Jeff and (Mike) would you like - should we vote item by item or can we vote unmassed on these...?

Jeff Hageman: Probably best to do item by item.

P.J. Brennan: Okay. All right, then let's start and do we need to do a roll call or can we just have a voice vote?

Coordinator: Excuse me. We do have one comment that came up. Did you want to take that now?

P.J. Brennan: Yes.

Coordinator: Joseph Boyle your line is open.

Joseph Boyle: Thank you very much. Can you all hear me?

Woman: Yes.

P.J. Brennan: Yes.

Jeff Hageman: Yes. Could you speak your name one time for the record please.

Joseph Boyle: Yeah, this is Joseph Boyle. I'm with the Johnson & Johnson Company Ethicon.

And, you know, obviously my comments are a little prejudice but I hope you will take that into consideration.



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You know I just wanted to comment and we're very, very pleased, you know, with the recommendation for CHG sponge dressing.

But I did just want to make a general comment because we're very proud of the research and the clinical studies that have been done for the - you know on this technology. And it's been on the market for over 15 years with approaching 3,000 hospitals using it.

But the key point is, you know, the - I heard discussions about four randomized controlled trials. And in fact there's well over a dozen randomized controlled trials and realizing some of them weren't empowered enough to reach significant, you know, significant - statistical significance. But with that said quite a few of them were.

And of course you've all you referenced in your draft document, you know, all the references are - refer to the different studies like the (Tin System) and the (Reshalt).

But I just wanted to make the fact number one there's quite a few more than before. Number two, the comment was that it would be a 1B because in some of the more recent significant studies a CHG prep was not used.

And I wanted to make the - make it clear to all and on the record that these studies were done in Europe and the ones that were published in - one that was published in JAMA.

And as you all know a CHG was not available over there. But what they did use they were using and this was discussed earlier on a different product line but what they were using was a povidone-iodine with alcohol.



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And all the studies that we've seen that there hasn't been any data really showing that CHG number one is, you know, significantly better than povidone-iodine with alcohol, number two.

And finally, the, you know, the fact that, you know, we're calling for hospitals to start using - leaving dressings on, leave the (side on) for five to seven days and not do the daily dressing changes and as you all know the efficacy of the bio-patch or the efficacy of the sponge dressing that is effective for seven days.

So whether or not in these studies they use CHG or not shouldn't be an issue related to what the level of recommendation is because after 12 to 48 hours all of those CHG preps no matter which company it is they, you know, they no longer are efficacious after, you know, 12 to 24 hours. So that's where the sponge dressing really kicks in.

And so I would like the committee to consider that number one, that we feel it should be a 1A irrespective of whether or not these studies utilized a CHG prep because we feel that is not important in considering that this product, it's sweet point, it's efficacy is within - is after that 12 to 24 hour period to 48 hour period from Day 2 to Day 7.

So thank you for the opportunity for - to make a few comments. And I would appreciate it if you would at least give that some consideration.

P.J. Brennan: Thank you for those comments. I think one of the beauties of the method that we're using now is that you can see the processes that we went through in terms of searching for this.

So you can see the search terms used the document were very broad. So I'm not sure why these studies would have fallen out if they're European. Perhaps they were not English language. And that was one of the exclusions.



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So, you know, we'll be happy if you send us those references, we'll be happy to take a look.

Alex Kallen: P.J. just one point of clarification. Some of those studies -- this is Alex Kallen from CDC -- might have been in epidural catheters and in orthopedic pins and not specific for intravascular catheters, therefore would have not been included.

Coordinator: Yes, our next comment. One moment.

Hudson Garrett: Hudson Garrett, PDI Healthcare. Yes, actually I just wanted to offer a very positive comment and really commend Dr. (O'Grady) and Lillian. I know that's been a long road. And I just could not be more pleased with the final language. And just wanted to commend the author group on that.

Jeff Hageman: All right, let's go forward with the voting P.J.

P.J. Brennan: Okay. So the first item is a revision to state that use of chlorhexidine impregnated sponge dressing for temporary short term catheters in patients older than 2 months of age if the catheter associated bloodstream infection rate has not been substantially reduced despite adherence to basic prevention measures including education and training, use of chlorhexidine for skin antisepsis and MSB. And it's a Category 1B.

All those in favor of the language as stated.

HICPAC members: Aye.

P.J. Brennan: All right, and Susan Huang was an aye as well. Are there any objections?



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P.J. Brennan: Any recusals?

P.J. Brennan: Okay. So that is unanimous.

The second item is the timing of dressing changes. Replace dressings used on short term central venous catheter sites every two days for gauze dressing. This is a Category 2.

And replace dressings used on short term central venous catheter sites at least every seven days for transparent dressings except in those pediatric patients in which the risk for dislodging the catheter may outweigh the benefit of changing the dressing. And that's a Category 1B.

All those in favor?

HICPAC members: Aye.

P.J. Brennan: Any opposed? Any recusals?

Okay, the next one relates to needleless intravascular catheter systems. And is a modification of the language to state when needleless systems are used a split septum valve may be preferred over some mechanical valves due to increased risk of infection. And this is a Category 2.

All those in favor?

HICPAC members: Aye.

P.J. Brennan: Any opposed? Any recusals?



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Thank you.

The next item addresses port scrubbing. Minimize contamination risk by scrubbing the access port with an appropriate antiseptic (chlorhexidine povidone-iodine and IOTA 4 or 70% alcohol) and accessing the port only with sterile devices. This is a Category 1A.

All those in favor?

HICPAC members: Aye.

P.J. Brennan: Any opposed? Any recusals?

The next relates to catheter location. Avoid using the femoral vein for central venous access in adult patients. That's a Category 1A.

Use a subclavian site rather than a jugular in adult patients to minimize infection risk for non-tunnel central venous catheter placement. And that's a Category 1B.

All those in favor?

HICPAC members: Aye.

P.J. Brennan: Any opposed? Any recusals?

Okay, the next item and Jeff if you have - if you can help me with the language here. I'm not sure I captured it all but I'll take a stab at it.



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Prepare clean skin with a greater than 0.5% chlorhexidine alcohol-based preparation before central venous catheter insertion and during dressing changes.

If there's a contradiction to chlorhexidine a tincture of iodine, iodophor, or 70% alcohol used as alternatives.

The issue of a comparison of chlorhexidine gluconate alcohol and povidone-iodine alcohol is an unresolved issue.

All those in favor of that language?

HICPAC members: Aye.

P.J. Brennan: Any opposed? Any recusals?

Okay, the next item is maximal barrier precautions. And we made no change in this language. We will not use the - we will continue to use the full body drape but use maximal sterile barrier precautions including use of cap, masks, sterile gowns, sterile gloves and a sterile full body drape for insertion of CVC, PICCs or guide wire exchange, Category 1B.

All those in favor?

HICPAC members: Aye.

P.J. Brennan: Any opposed? Any recusals?

All right. The next category splits out a much shorter recommendation. And introduces two unresolved issues and to replacing administration sets.



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In patients not receiving blood, blood products or lipid emollients replace administration sets that are continuously used including secondary sets and add-on devices no more frequently than at 96 hour intervals but at least every seven days, Category 1A.

The frequency reported replacing intermittently used administration sets is an unresolved issue.

Frequency for replacing needles to access implantable ports is an unresolved issue.

All those in favor of this language? Aye.

HICPAC members: Aye.

P.J. Brennan: Any opposed? Any recusals?

Okay, the next one relates to peripheral and midlines. Replace peripheral catheters (unintelligible). Oh that's right, okay so this is - there's no need to replace peripheral catheters more frequently than 72 to 96 hours to reduce the risk of infection and phlebitis in adults, Category 1B.

Replacing peripheral catheters in adults only when clinically indicated is an unresolved issue.

All those in favor? Aye.

HICPAC members: Aye.



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P.J. Brennan: Opposed? Any recusals?

And the final one is - final item is securement devices. Use a sutureless securement device to reduce the risk of infection for intravascular catheters. And that's Category 2.

All those in favor? Aye.

HICPAC members: Aye.

P.J. Brennan: Any opposed? Any recusals?

Okay. Thank you. Jeff do we have any other business?

Jeff Hageman: We don't. I just want to thank everybody for the extra time because of the technical problems getting started.

P.J. Brennan: And I want to thank Naomi and the Writing Group and Lillian for their patience and hard work on this document. And Ingi and her colleagues in the Center for Evidence-Based Practice for helping us resolve these issues.

Okay, we're adjourned.

END



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