Healthcare Infection Control Practices Advisory Committee (HICPAC)
DRAFT: Guideline for Prevention of Surgical Site Infections

May 11, 2015 Teleconference

List of Participants

HICPAC Ex-Officios

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Dr. Hilary Babcock
Dr. Sheri Chernetsky Tejedor
Dr. W. Charles Huskins
Ms. Lynn Janssen
Dr. Lisa Maragakis
Dr. Jan Patterson Ms. Gina Pugliese
Dr. Tom Talbot
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HICPAC Ex-Officio Members

Dr. Melissa A. Miller, Agency for Healthcare Research and Quality
Ms. Elizabeth Claverie-Williams, Food and Drug Administration
Dr. David Henderson, National Institutes of Health
Dr. Gary Roselle, Veterans Administration
Dr. Daniel Schwartz, Centers for Medicare & Medicaid Service

HICPAC Liaison Representatives

Mr. Michael McElroy, America's Essential Hospitals
Dr. Mark Russi, American College of Occupational and Environmental Medicine
Dr. Elizabeth Wick, American College of Surgeons
Ms. Amber Wood, Association of periOperative Registered Nursed
Dr. Emily Lutterloh, Association of State and Territorial Health Officials
Dr. Marion Kainer, Council of State and Territorial Epidemiologists
Ms. Kathleen Dunn, Public Health Agency of Canada
Dr. Michael Howell, Society for Critical Care Medicine
Dr. Robert Sawyer, Surgical Infection Society
Ms. Margaret VanAmringe, The Joint Commission

CALL START

Coordinator: Welcome and thank you for standing by. At this time, all participant lines will be on a listen-only mode. Today's call is being recorded. If you object, you may disconnect at this time. And now, I'd like to turn the call over to Jeff Hageman.

Jeff Hageman: Thank you. It's May 11, 2015. This is call of the Healthcare Infection Control Practices Advisory Committee to discuss the remaining items for HICPAC input for the Surgical Site Infection Prevention Guideline.

Before we begin, just for those people on the call, if they haven't already looked, the materials for the call and the presentation are available at www.cdc.gov/hicpac.

For those people on the lines, please make sure that your phones are muted throughout the call, and because this is a public teleconference of an advisory committee that the transcript of the call will be available, will be publicly available on the HICPAC website following the meeting.

The first item for the agenda is to go through and make sure we have quorum to have the call. So, I will go through a roll call and if each member could say here, and then disclose any potential conflicts as it relates to the items to be discussed on the call today.

So, I'll start off with Dan Diekema.

Dan Diekema: Here. My potential conflicts are prior research funding from Cerexa and bioMérieux.

Jeff Hageman: Vickie Brown?

Vickie Brown: Present. No conflicts.

Jeff Hageman: Hilary Babcock?

Hilary Babcock: Present. No conflicts.

Jeff Hageman: Sheri Tejedor?

Sheri Tejedor: Present. No conflicts.

Jeff Hageman: Charlie Huskins?

Charlie Huskins: Present. Conflicts are or potential conflicts are research equipment and supplies from GOJO Industries.

Jeff Hageman: Lynn Janssen? Lisa Maragakis? Jan Patterson?

Jan Patterson: I'm here and no relevant conflicts.

Jeff Hageman: Gina Pugliese?

Gina Pugliese: Present and no conflicts.

Jeff Hageman: Tom Talbot?

Tom Talbot: Present. No conflicts.

Jeff Hageman: Debbie Yokoe?

Deborah Yokoe: Here. No conflicts.

Jeff Hageman: Let me just go through the members that I didn't announce. So, Susan Huang? Lynn Janssen? Lisa Maragakis? Mike Tapper? All right, so if there's a member that hasn't announced, please do so now. Now, I'll move to the Exofficios. David Henderson, NIH?

David Henderson: Here.

Jeff Hageman: Elizabeth Claverie-Williams, FDA?

Elizabeth Claverie-Williams: Here.

Jeff Hageman: Gary Roselle, VA?

Gary Roselle: Here.

Jeff Hageman: Dan Schwartz, CMS?

Dan Schwartz: Here.

Jeff Hageman: Melissa Miller, ARC?

Melissa Miller: Here.

Jeff Hageman: And we'll move to -is there any of the Ex-officios that I missed?

Margaret Vanamringe: Margaret Vanamringe.

Jeff Hageman: Oh, so we'll move onto the liaisons. So, that was Margaret Vanamringe from the Joint Commission? Michael McElroy from America's Essential Hospitals? Eliza Wick, American College of Surgeons? Okay. Amber Wood, Association of periOperative Registered Nurses?

Emily Lutterloh, Association of State and Territorial Health Officials?

Emily Lutterloh: Here.

Jeff Hageman: Marion Kainer, Council of State and Territorial Epidemiologists? Lisa McGiffert, Consumers Union? Janet Franck, DNV Healthcare? Kathleen Dunn, Public Health Agency of Canada? Mark Rupp, Society for Healthcare Epidemiology of America?

Mark Rupp: Here.

Jeff Hageman: Michael Howell, Society for Critical Care Medicine?

Michael Howell: Present. No conflicts.

Jeff Hageman: Robert Sawyer, Surgical Infection Society? Is there any HICPAC liaison that I missed that's in attendance?

Mark Russi: Hi Jeff, Mark Russi from American College of Occupational and Environmental Medicine. Jeff Hageman: Great, thank you Mark.

Lynn Janssen: Yes, this is Lynn Janssen. Can you hear me now?

Jeff Hageman: Yes we can.

Lynn Janssen: Thank you, I was...

Jeff Hageman: Lynn, do you have any conflicts to disclose?

Lynn Janssen: Nothing to disclose, thank you.

Jeff Hageman: Any other -anyone else that we missed? All right, so we have quorum to begin. Before we get into the presentation, just to remind that the presentation materials are up on the HICPAC website. If you don't have them, you can go find them there.

I do want to give a thank you, at the beginning of this call, to a lot of the members that have - and the core writing group and people both at CDC and externally that have been putting in a lot of effort to continue to move this guideline forward.

The guideline efforts started in June 2010, and we hope that this is the call to finalize the remaining two issues or at least get final input from HICPAC. I do want to make special notice just to thank several members of the core writing group both Dr. Sandra Berríos-Torres, who was critical in leading the majority of this effort for a number of years.

The Center for Evidence-Based Practice at University of Pennsylvania Health System, both Craig Umscheid and Brian Leas who have been providing methodology support and leadership throughout the process. Dale Bratzler, who a previous HICPAC member, who stayed on to continue moving the guideline forward.

And then here at CDC, Erin Stone, who's been putting in a lot of work over the many, many months to make sure that the guideline continues to move forward. The objectives of this call are for HICPAC to review the final two issues.

There will also be a review of some work that has been conducted since the December 2014 HICPAC meeting. There will be an opportunity after the HICPAC discussion for a public comment period.

We will also have, after the public comment period, any decisions or action by HICPAC will be decided upon after that comment period. After the call, there will be work to incorporate

that input as well as doing editorial and other changes to the actual draft documents to put together a final draft document that will be circulated to the co-authors of the guideline before it's submitted to CDC Final Clearance.

And, at this point in time, I'll turn it over to Erin Stone, who will walk through the presentation.

Erin Stone: Hi. If you'd like to start with the slide set, start with Slide 2. It lists the topics we're going to discuss. The first topic is -please put yourself on mute until we open it up for discussion. Thank you.

The topics for discussion include updates on the methodology which were re-reviewed, updates made to antimicrobial coated suture section, and updates on work conducted on the oxygenation section.

Slide 3 please. Briefly, we would like to provide an overview of the GRADE methodology and how recommendations are made. The overall quality of grades can be high quality evidence. This means that further research is very unlikely to change the confidence in the estimate of effect.

There can be moderate quality evidence. This means further research is likely to impact the confidence in the estimate of effect, and may change the estimate.

Low quality evidence which means further research is very likely to impact the confidence in the estimate of effect, and is very likely to change the estimate. Or a very low quality evidence, which could be any estimate of effect.

Slide 4 please. GRADING the evidence. RCTs start high and observational studies start low. Please note that we are reviewing two sections in the core section of the guideline and we will be reviewing RCT evidence only today.

Factors that lower the quality of evidence are study quality, also known as risk of bias, limitations, inconsistency, indirectness, imprecision, and publication bias. Factors that can increase the quality of evidence are large magnitude of effect, dose-response, and confounding.

If you move to Slide 5, this shows an example of a GRADE table. This will show how we get from a starting GRADE in a RCT to where we decrease the GRADE or increase the GRADE, based on the previously mentioned qualifiers, to get to the overall GRADE of evidence described as high, moderate or low.

Slide 6 please. This is how we formulate the recommendations via three key inputs. The values and preferences used to determine the critical outcomes, the overall GRADE of evidence for the critical outcomes, net benefits, net harms or trade-offs that result from weighing the critical outcomes.

Much of the time spent during the process is spent on the overall GRADE of evidence for the critical outcomes and the net benefits, net harms or tradeoffs. Recommendations can be for, or against, that's the direction, or strong or weak and that's the strength.

Slide 7. This is the categorization scheme for recommendations. Category IA and IB are both strong recommendations, supported by either high to moderate quality evidence or low quality evidence.

Category IC is a strong recommendation required by state or federal regulation. And, Category II, which is a weak recommendation supported by any quality evidence suggesting a trade-off between clinical benefits and harms.

Finally, there's the no recommendation. An unresolved issue for which there is low to very low quality evidence with uncertain trade-offs between benefits and harms. Also, no evidence falls under the no recommendation.

Slide 8. This is the review of the methods. Based on feedback received from co-authors, the methods were re-reviewed for the entire guideline. Publication bias was reviewed. It should be noted that there is no one right way to review for publication bias; however, there are a few generally accepted methods.

For all product specific recommendations, we re-reviewed the directionality of study results compared with the declared conflict of interests and funding sources. No pattern of publication bias was seen.

Forest plots were reviewed. For all large meta-analyses, they were reviewed and no evidence of publication bias was seen as the distribution of studies in the forest plot system metrical.

Quality assessments. The individual study quality assessments were re-reviewed for the entire guideline. This was done using a method similar to the Cochrane Risk of Bias Assessment. Examples of study qualities assessed include blinding, appropriate randomization, attrition, funding source, and conflict of interest.

Breakpoints for study quality were made more stringent throughout the entire guideline. The aggregate study quality for each comparator was re-reviewed for the entire guideline as well. Breakpoints for the aggregate study quality were also made more stringent.

All meta-analyses were re-reviewed. Large confidence intervals were reassessed. Heterogeneity was assessed for the meta-analyses in this guideline.

This was done by reviewing the I^2 value for each meta-analysis. The I^2 value describes the magnitude of variability rather than the statistical significance. That is, the percentage of variation across studies that is due to heterogeneity rather than to chance.

The overall numbers contributing to the meta-analyses were reviewed for accuracy. All of this additional methodologic work resulted in minor modifications of GRADES throughout the table.

However, none of the final outcome GRADES were impacted in a way that would change the strength of recommendation for any of the current guideline draft recommendations.

Slide 9 please. For the question, how safe and effective are antimicrobial coated sutures, and when and how should they be used?

In December 2014, HICPAC made several recommendations to the CDC. Based on the evidence reviewed, no recommendation could be made regarding superficial and organ closures. This was an unresolved issue, and this will not change.

A strong recommendation was suggested for using triclosan-coated sutures in the deep and fascial layers in colorectal surgery, and a weak recommendation was made for surgeries other than colorectal.

This was based on multiple meta-analysis suggesting benefit to sutures overall, but specifically suggesting benefit in colorectal surgeries with no evidence of harms.

New information has arisen that has resulted in a reassessment of these results.

Slide 10. A letter to the author was written for one of the RCTs included in our original meta-analysis. This letter suggested sub-analyzing 1,185 abdominal surgeries in the RCT by the colorectal and abdominal surgery types within.

The RCT authors replied with this data. As a result, 690 patients with 122 infections, originally classified as abdominal surgeries, were reassigned to the colorectal surgery. Our guideline searches were limited to RCTs unless we did not pick up these letters when the original searches were updated last year.

Slide 11. The results have pointed out that HICPAC eliminated one of the original RCTs from the guideline in this section due to inadequate blinding, among other issues with this RCT. This reduced the total number of RCTs from 15 to 14. All of the meta-analyses were updated accordingly.

It should be noted that across these studies, there were varying lengths of follow-up and different definitions of infection. Studies largely compared deep layer closure with the same absorbable suture across arms, either polyglactin 910 or polydioxanone. And, this was in either triclosan-coated or non-antimicrobial coated versions.

Studies that used triclosan-coated sutures of the superficial layer used poliglecaprone 25 in triclosan-coated and non-antimicrobial coated versions. The meta-analyses were run for the composite outcome of all SSI for this section. This was deemed a critical outcome for these comparators, which has been denoted by the asterisks on Slide 11.

For the all surgeries comparator, 14 RCTs with 5,303 patients, high overall quality of evidence showed significant benefit to using triclosan-coated sutures with low heterogeneity.

The updated colorectal surgeries sub-analysis for all SSI involved five RCTs at moderate quality evidence. There's 1,912 patients and the odds ratio is 0.71 with a confidence interval that spans both sides of one. This shows no benefit to triclosan-coated -no significant benefit to triclosan-coated sutures for colorectal surgeries with moderate heterogeneity.

The updated abdominal surgeries meta-analysis. Five RCTs, 1,208 patients shows significant benefit to using triclosan-coated sutures with no heterogeneity.

We ran a sub-analysis of all surgeries except colorectal and abdominal to see if significant benefit was still seen. Nine RCTs of high quality evidence, 2,183 patients showed significant benefit to triclosan-coated sutures with low heterogeneity.

Slide 12. In summary, these meta-analyses showed high overall quality of evidence of benefit across procedures for closure largely at the deep and fascial layers with absorbable triclosan-coated sutures versus absorbable non-antimicrobial coated sutures with no evidence of harm.

It should be noted that we did not assess suture appropriateness and suture selection beyond the impact of the triclosan coating. Also, not all sutures indicated or selected for a surgical procedure have a triclosan-coated option.

Slide 13. This slide contains a proposed draft recommendation. That draft recommendation would be use triclosan-coated sutures for deep and fascial closure if a triclosan-coated option is available for the suture appropriate to the surgery type and the level of closure if triclosan is not contraindicated.

At this point in time, we would like to turn over the call to the HICPAC Chair Dan Diekema to facilitate HICPAC member discussion. This discussion will be followed by discussion including HICPAC Ex-officios and liaison representatives.

Please remember to identify yourself before you speak.

Dan Diekema: Thanks very much Erin. This is Dan. Can you hear me?

Erin Stone: Yes.

Dan Diekema: Okay good. So, I just want to reiterate the thanks that Jeff relayed earlier to an awful lot of people who put a lot work into not just this incredibly comprehensive guideline, but also the recent work going back to analyze some of these remaining thorny issues.

So, with that, I want to open it up for discussion of this proposed draft language, and the data that led to it.

Jan Patterson: Hi, this is Jan Patterson and I'm new to the committee. And so, I saw the data about the triclosan sutures and it looks, you know, like it is effective. I was concerned about whether the issue of the triclosan safety that's being looked at in household products and consumer products, whether that's being monitored and I understand that it is. And so, that's a good thing. And, I also just wondered if, since there's been some lab studies that have shown that triclosan resistance can be cross-resistant to other antimicrobial resistance. If there will be some kind of monitoring of any microbial resistance in triclosan sutures versus non?

Erin Stone: There wasn't any identified in the evidence we looked at, however, moving forward, we would like to keep an eye on that.

Jan Patterson: Yes, okay great. Thank you.

Dale Bratzler: Hi Erin, I think -this is Dale. I think it's also important to note that we are aware that FDA is looking into the whole question on the safety of triclosan, and may potentially regulate in the future.

Jan Patterson: Yes, that's great. Thank you.

Jeff Hageman: Yes, and Dale, and just, you know, and that's one of the important reasons why we have FDA Ex-officio participate as part of HICPAC, so they can communicate issues as they arise, as they might impact the Infection Control Guidelines in the future.

I think the main point is that FDA is looking at this issue broadly, you know, it's not for the suturing, as Erin stated that, there's currently in the evidence reviewed not identified harms.

But, you know, regardless of the recommendation that is in a CDC/HICPAC guideline, if harms for any recommendation were to surface whether that's through other sister agency work or through the literature. You know, those are times that CDC and HICPAC can reassess recommendations and reassess harms as they may come about.

Hilary Babcock: This is Hilary Babcock. I'm comfortable with this draft recommendation the way it is. I think adding the, if triclosan is not contraindicated, and adding some of the wording about being sure that you're still using the right type of suture so that choosing a triclosan-based suture does not override the need for the appropriate suture for your procedure is helpful, and I'm comfortable with this.

Dan Diekema: So, Hilary this is Dan. So, are you saying that the language as its written now addresses those two issues in your view?

Hilary Babcock: Yes.

Dan Diekema: Okay. Are there other comments or concerns from HICPAC committee members? If not, Jeff is it appropriate now to open it up to Ex-officio members...

Jeff Hageman: Or liaisons.

Dan Diekema: Liaisons.

Jeff Hageman: Yes.

Dan Diekema: So, any Ex-officio input, questions, concerns, comments?

Mark Rupp: Dan, this is Mark Rupp. I just wanted to clarify. This is for all surgical procedures or is it for intra-abdominal procedures? I know it's been expanded from just the colorectal procedures.

Dan Diekema: Yes, my understanding is that this would be for all surgical procedures for deep and fascial closure, not for superficial closures and there isn't -we're not specifying specific types of surgery.

Erin Stone: Yes. That is correct.

Marion Kainer: This is Marion Kainer. I like the wording with the (unintelligible) specifically like when you have the triclosan available for that type -appropriate for that type of closure. I think it is.

Dan Diekema: Thank you. Any other comments, questions, concerns?

Charlie Huskins: Dan, this is Charlie. Just to reemphasize because I think we talked about this before. In the text of the document, there will be some description about the types of procedures that were included in these RCTs, and some description of the rates of infection that were observed.

Erin Stone: This will be incorporated into the narrative summary. Absolutely Charlie.

Charlie Huskins: So, I think that addresses Mark's point a little bit, in that the types of procedures included will be described.

Dan Diekema: Any other comments, questions, clarifications? If not, then Jeff, would it be appropriate to open up the public comment period at this point, and then after that, return or actually, I'm sorry, I'm going out of order. Now, I guess I'm turning it back to you, Erin, to discuss the next issue.

Erin Stone: Yes, thank you. We're on Slide 14 now. We're going to start oxygenation. In December 2014, HICPAC was largely in agreement with the conclusions of the writing group regarding the benefits seen for increased inspired oxygen during the intra and postoperative periods for patients with normal pulmonary function undergoing general anesthesia.

However, HICPAC had requested that meta-analyses be conducted for the data in these studies.

Slide 15 please. This is the meta-analysis for the five RCTs for no nitrous oxide.

This is patients undergoing general anesthesia with intraoperative intubation and intraoperative and postoperative administration of increased inspired oxygen.

Five RCTs, moderate quality evidence for all SSI (the composite outcome). There were 2,604 patients showing significant benefit to increased inspired oxygen with moderate heterogeneity.

Slide 16. HICPAC had, specifically, requested a colorectal surgery sub-analysis. This was the same population: no nitrous oxide, general anesthesia, intraoperative intubation, intraoperative and postoperative administration of increased inspired oxygen. The sub-analysis of colorectal surgery patients for SSI all had 1,424 patients. This is moderate overall quality evidence. There was no significant benefit seen, and the heterogeneity was moderate to high.

Slide 17. This is the neuraxial anesthesia meta-analysis. Three RCTs, moderate quality evidence. The critical outcome with SSI endometritis, 1,559 patients: no significant benefit was seen, and there was no heterogeneity.

Slide 18. Of the results, the writing group proposes to stay with the Federal Register versions of the draft recommendation. 6A for patients with normal pulmonary function undergoing general anesthesia with endotracheal intubation administer increased fraction of inspired oxygen both intraoperatively and post-extubation in the immediate postoperative period. To optimize tissue oxygen delivery, maintain perioperative normothermia and adequate volume replacement. This is a Category 1A.

6B, RCT evidence suggests uncertain tradeoffs between benefits and harms regarding perioperative increased fraction of inspired oxygen in patients with normal pulmonary function undergoing either general anesthesia without endotracheal intubation or neuraxial anesthesia. That is spinal, epidural, or local nerve blocks for the prevention of surgical site infection. This is the no recommendation, unresolved issue.

And then, finally 6C: RCT evidence suggests uncertain tradeoffs between benefits and harms regarding the administration of increased fraction of inspired oxygen via facemask or nasal cannula during only the intraoperative period or the postoperative period for the prevention of surgical site infection in patients with normal pulmonary function.

Dan, I'd like to turn it back over to you for moderating HICPAC comments.

Dan Diekema: Thank you very much. So, this section, the draft recommendation and the data that led to it, are now open for comment from HICPAC committee members. So, I'm not hearing any comment. Just checking to make sure I'm not on mute. Can people hear me?

Erin Stone: We can hear you.

Dan Diekema: All right. Well, then next let's open it up for comment, questions, clarification from Ex-officio and liaisons. Just giving people a few seconds to get off mute if they're going to do that.

Mark Russi: So, Dan this is Mark. Will there be any specification with regard to the percent increased FiO2? It looks like the studies were all done 80% versus 30%, but it's certainly not specified in the recommendation.

Dan Diekema: Right, so, you know, right now this would just be in the narrative section in the tables, but are you suggesting perhaps it would be helpful to specify in the recommendation text itself?

Mark Russi: It seems like a natural question that folks will ask. And if the thought is that that's important, then maybe that should be part of the recommendation. I don't know though.

Dan Diekema: Other members have comment or input on that issue? Whether 80% since that's the data that was included in the meta-analysis with studies using that compared to 30%, 40%.

Erin Stone: 30%.

Charlie Huskins: This is Charlie. That seems very reasonable to me.

Dan Diekema: Would anyone object to including that language?

Gina Pugliese: No -this is Gina Pugliese. I think it would be helpful.

Dan Diekema: Okay.

Hilary Babcock: This is Hilary. I agree.

Michael Anne Preas: This is Michael Anne from APIC. So, does that apply -so, in the postextubation period, are you also saying 80% for that as well? That's going to be difficult to optimize I think. Unless you put them on a 100% re-breather.

Erin Stone: That is the way the rec would read if 80% was included in the recommendation.

Michael Anne Preas: Okay. Putting that out there.

Tom Talbot: This is Tom Talbot. Real quick, I think part of the challenge with this, we've been looking institutionally is that 80% -this is very different intraoperatively with general anesthesia, and then once you get postoperatively, it kind of addresses that last comment.

How do you attain levels of oxygen? And so, we went back and looked at some of the studies, and several of them just stopped delivering at extubation. Some do it for an hour or two.

So, we may want rethink if we're going to be prescriptive enough to say 80%. Do we want that for the post-extubation or not because that varies in the studies, and probably, the benefit is happening from the intraoperative administration of the 80% FiO2.

Dan Diekema: So, this is Dan. So, those are both very good points. I think there's two ways to deal with it. One is to add extra language to the draft recommendation. The other way to deal with it would be to leave the recommendation as is, and include this in the narrative section.

Vickie Brown: This is Vickie. Just one other comment is that recommendation has included, and I don't know from the studies that were re-done, is there a definition for the immediate postop period? What time period we're talking about?

Obviously, patients can spend different lengths of time in the PACU. So, that may be helpful as well if we're going to make some prescriptive recommendation is to include what is meant by immediate postoperative period.

Charlie Huskins: This is Charlie Huskins. Listening to this conversation, now, it seems actually more appropriate to me to leave it as is, and then deal with this more in the text because I think you can describe it better in the text.

And, I guess my feeling would be is that we don't want to be proscriptive on all of these details because there is variability in how the studies were done. Therefore, it's probably better to just describe it in the text.

Deborah Yokoe: This is Deb Yokoe. I agree with Charlie.

David Henderson: This is David Henderson. I agree with Debbie and Charlie.

Jan Patterson: Yes, and this is Jan Patterson. I agree.

Dan Diekema: So, this is Dan Diekema. Any other comments? I agree with that approach as well. I think this also would allow for institutions to take into account some of the variability in the studies that were done in developing their own approach to this.

Hilary Babcock: Yes, this is Hilary. I think that makes sense.

Gina Pugliese: Yes, Gina Pugliese. I agree as well, especially since the post-extubation period, as was pointed out, will vary depending on the patient and the conditions.

Dan Diekema: So, are there any other comments from committee members or from Ex-officio or liaisons about the draft recommendation? If not, I'm going to turn it back over to Jeff, I believe, to start the public comment period.

Erin Stone: Adrienne, if you're on the line, we would like to start the Operator moderated public comment portion of this call.

Coordinator: Thank you. At this time, if you would like to make a comment, you may press star 1 on your touchtone phone. Please unmute your phone and record your first and last name clearly when prompted. To withdraw your comment, press star 2.

And, once again, if you would like to make a comment, you may press star 1 and record your name. One moment for our first comment. We do have comments coming in. One moment. Our first comment comes from Sandra Berríos-Torres. Your line is open.

Sandra Berríos-Torres: Thank you. Hi, thank you very much for the update. My comment is regarding the triclosan-coated suture recommendation. I'm in disagreement with the Category I recommendation for the sutures and deep and fascial closure across all surgical procedures.

First of all, based on how the committee has addressed similar level of evidence in formulating other product related recommendations, it should be downgraded to a Category II and the language be modified to consider using.

It's important to keep in mind that this recommendation, as it stands, represents a real significant departure from all of the campaigns that we have in place to improve an antimicrobial stewardship.

We've ensured through the guideline that the parenteral prophylaxis be administered only when indicated, and based on published guidelines, this continued after a surgical incision is closed.

Yet, the triclosan suture kind of goes against all of this when the tissue absorption will continue long after the incision is closed. Regarding the no evidence of harm, the studies didn't really evaluate, appropriately most of them, for antimicrobial resistance.

And, in a lot of them, when you see evaluation of the pathogens, they were actually not pathogens that were necessarily supposed to be covered by the suture.

And, as we know, there were other potential adverse events to the triclosan that were not evaluated. For other product related recommendations, such as antiseptic irrigation, there's moderate to high quality evidence of benefit in the spine in the abdominal procedures without evidence of harm, but instead of giving it a Category I recommendation in favor of use, the committee downgraded it to Category II and applied the language of consider using.

On the other side of this, for platelet rich plasma, antimicrobial sealant and plastic adhesive drapes, all of which had moderate to high level of evidence of no benefit, and no evidence of harm which qualified for a Category I recommendation against their use. The committee, again, downgraded them to a Category II, and used the language of it's not necessary.

So, basically, I think it's important to keep in mind that this recommendation will impact, you know, the more than 80 million surgical procedures that are performed annually in the U.S., and not to mention the broader potential global impact as the guidelines inform future international SSI prevention guidelines. Thank you.

Coordinator: Our next comment is from Joseph Solomkin. Your line is open.

Joseph Solomkin: Thank you. This has been a very nice discussion that I have greatly enjoyed. I have to, very strongly, echo Sandra's comments about triclosan. The -based on, I think, simply the description, the recommendation given today, the strongest data for this really has to do with abdominal surgery.

The data for (unintelligible) abdominal surgery, particularly (unintelligible) abdominal deep closures, is very limited, and certainly, I don't think justifies either by quality, number of studies or by strength of finding a IA recommendation for any place outside of the abdomen.

Within the abdomen, it only becomes significant if, actually, colorectal surgery which has the highest infection rate, and which in the data presented suggests no benefit or minimal benefit in that study, and then there's a more, less risk group of abdominal surgical procedures for fascial closure where, in fact, there was significance.

So, my take on this is, again, to agree with Sandra that this should be -I think she is very focused on stewardship issues, and I very much say that I'm concerned about the quality of data to support a recommendation that separates out subgroups the way this one does.

And, I would strongly request that this be considered as Sandra gave this a Level II recommendation, that it may be used or can be considered for use with that, but it certainly does not have IA evidence supporting and justifying this.

As far as oxygenation goes, I've looked through that very carefully and done separate analyses for another project. And, my concern is that with the all the studies to use regrading masks for the important group where there was no benefit found, which is in the neuraxial one, which, in fact, was really when undergoing elective caesarian section.

I would point out the extreme inconvenience and discomfort to the patient, postoperatively, having had a child and having to have a rebreathe non-rebreathing mask on for several hours.

I think that does go -that does create a certain degree of, well, actual harm to the patient, and I don't think there should be no recommendation in that area. I think there should be a recommendation against its use. Thank you.

Coordinator: Currently, there are no further comments. But as a reminder, if someone would like to make a comment, you may press star 1 on your touchtone phone and record your name.

To withdraw your comment, press star 2. One moment to see if we have any further comments. We do have another comment in queue. Our comment is from Elizabeth Wick. Your line is open.

Elizabeth Wick: Hi, and I'm representing the American College of Surgeons. I just wanted to echo what Sandra said, and also, I spoke to Dale about our concerns as well.

And, I think that especially with the antimicrobial sutures, that a Level IA support is quite strong to say in support of this when all sorts of emerging evidence and emerging bundles which have come out especially in colon surgery. None of them have had probably either of these interventions in them, but definitely not antimicrobial sutures and really seen significant improvement.

So, I'm concerned about the message that this is going to send to give such a high level evidence in support of antimicrobial sutures when it's certainly is questionable.

Coordinator: We have no further comments in queue.

Dan Diekema: Okay, thank you very much. This is Dan Diekema again. Can -am I on mute? Can people hear me?

Jeff Hageman: Yes we can hear you Dan.

Dan Diekema: Okay. So, I'd like to thank you all for those excellent comments, and I think they absolutely bear for the discussion. So, I would like to first invite some of those who are most closely involved in the data analysis to comment. I don't know if Craig and/or Dale is on the line at this point, and wishes to respond initially.

Dale Bratzler: Well, this is Dale. I'll just make a couple of quick comments, and believe me; we've had the same conversations as a writing committee working on this for quite some time.

With respect to antimicrobial sutures, we've looked at the data in multiple different ways, tried to analyze all the possible effects -well let me just first say that in the studies that we reviewed, we did not find evidence of harm.

Now, I understand the concerns of stewardship. So, I clearly understand that. But, at least, in the literature that we reviewed, we did not find evidence of harm using triclosan sutures.

We found -we did multiple meta-analyses, as I think Erin pointed out. We looked for any publication bias, we did not find that. We simply, you know, when we did multiple meta-analyses and looked at other meta-analyses that other authors had done also, they found similar findings that there seemed to be a fairly consistent reduction in surgical site infections.

I'm very aware of the data that Eliza Wick talks about, showing that a variety of different abdominal approaches to reducing surgical site infections have been very effective.

They have not included triclosan, but at least within the, you know, the studies that we looked at, the RCTs we looked at, we found this benefit consistently. I don't know, Craig or Brian, do you want to make any comments?

Craig Umscheid: This is Craig Umscheid from the University of Pennsylvania. I would just say that I agree with what Dale shared, and we've analyzed the data we identified in a number of different ways, and it's always difficult to understand the effect of a multi-component intervention versus a single intervention.

And as Dale said, all the studies that we analyzed that were available and the literature that addressed this question, really we're looking at the issue of antimicrobial suture versus no antimicrobial suture. So, there weren't necessarily other differences across the arms.

I will also agree with Dale that we did find no evidence of harms in the RCTs that we identified. That said, harms are notoriously difficult to identify in randomized controlled trials, and the vast majority of these trials were powered to find reductions in surgical site infections and were not looking at harm outcomes that we're talking about here.

I'll make one other comment about the FiO2. I agree with what many of the HICPAC members said on the line that ultimately including an exact percentage may not be a good idea.

We did have another key question in the guideline which asked about the specific FiO2, and we didn't find studies comparing one elevated FiO2 versus another. So, that's why we were left specific in our recommendations about the exact FiO2 to target.

Dan Diekema: Okay, this is Dan again. I first want to ask, Jeff or Erin, how much time we have on this line, and then, before I open up for comment from the committee members to respond to the public comments further.

Jeff Hageman: We can go over a bit. We just have to maintain if there's going to be any action by the committee to make sure that the members can stay on the call to maintain quorum. So, we're scheduled to end at 3:00, but if people are able to stay on for some minutes afterwards then we can continue.

Dan Diekema: So, I'd like to now open it up for other committee members, and I think, as you consider the objections that were raised in the public comment, I think the options of the committee include, after discussion, going ahead and voting on the draft recommendation as written, tabling it and going back and re-reviewing with these issues in mind.

Although, as you've heard, they have been considered and, of course, also be cognizant of the fact that, however we approach this particular recommendation, we have to make sure that we have a level playing field and are approaching all the other recommendations similarly.

So, with that I'll open it up for comment.

Tom Talbot: Yes Dan, this is Tom Talbot. I think the issue about the sutures and application to all surgeries versus subset of surgeries, I think, we need to be consistent how we've been across the guideline.

And, I know for other interventions, namely oxygen for example, and glucose control I believe, we were comfortable with enough studies with enough selection of procedures, enough not necessarily defined, to broaden those recommendations out for all procedures.

So, I think we have to be careful, here, if we start to go back and be restrictive when, you know, the analyses stay as they are. I think, well when you look at the point estimates, they're all pretty solid right there around 0.6, 0.7 which I think is interesting.

So, I'd be a little bit uneasy to start limiting that if we didn't do that for other initiatives, to your point in being consistent across the guideline.

Jan Patterson: Yes, this is Jan Patterson and I understand that rationale. I guess that the instance in this case is that it's this is an antimicrobial which, you know, is very resistant.

There can be cross-resistance to antibiotics, you know, for serious infection. So, that would be my reservation to making it across the board and I, you know, I seriously consider what the surgical colleagues added through the public discussion.

Dan Diekema: Are there other comments?

Charlie Huskins: Yes, this is Charlie Huskins. It seemed like in the comments by the surgical colleagues that part of that discussion involved the fact that these are surgeries with higher rates of infection than many types of surgery.

And, that is, as we've discussed in the past too, that's a little bit difficult to incorporate based on how we've handled other things in the guideline, at least to my understanding.

So, I guess the question would be whether there's any better way we could do that? That is address the fact that most of the studies that have been done here on this topic were done in procedures that have somewhat higher rates of infection, including colorectal and abdominal.

I don't see it myself right now, but I'd be open to thinking about if there's any different way to describe this. Noting that even the subset of surgeries that excluded abdominal and colorectal still had a positive or excuse me a protective effect overall, which was significant.

Dan Diekema: Yes. Other comments from the committee members? Is it appropriate to ask Ex-officio or liaison to...

Jeff Hageman: Yes.

Dan Diekema: ...comment if they have input as well, Jeff?

Jeff Hageman: Yes

Dan Diekema: Any other comments?

Tom Talbot: Hey Dan, this is Tom Talbot. Erin, can you remind us what, in the other studies, what were the breadth of procedures they looked at? Do you have that off?

Erin Stone: There was one study in pediatric mix surgery, one study in general mix surgery, there were several CABG studies one looking at the sternal and leg, and the others looking at leg infections. Then, there was a pediatric cerebral spinal shunt surgery study, and a leg revascularization study. And a breast cancer study.

Tom Talbot: That was for the sutures, right? Just clarifying.

Erin Stone: Yes.

Tom Talbot: Yes, so those aren't necessarily ones that would be higher, ones we'd say with higher infection rates like we would with colorectal. Some of them, I mean, I just throw that out there.

Hilary Babcock: Yes, this is Hilary. I agree. I think looking at the summary of the metaanalyses on the Slide 11; it's hard to pull out an area that we don't appear to have pretty high quality evidence of benefit.

Craig Umscheid: This is Craig Umscheid. Just from the method's point of view, we did look at baseline risk of infection and how the results differed across baseline risk.

The challenge is the vast majority of the RCTs in this analysis have a baseline infection rate of 10% or higher.

We only had two RCTs that had a baseline infection rate of 5% or less. Neither of those RCTs showed a compelling result. But, it was tough to do stratified analyses by baseline risk because most of them had, at the least, a moderate risk of infection at base point.

Charlie Huskins: Jeff, this is Charlie. Is there any way that any of the people making public comment could provide additional comment.

Jeff Hageman: Sure. One comment on the baseline infection rate is, you know, we would need to look at - right now, we haven't looked at across all elements and, you know, in order to take that into consideration which we might need to, but look how it influences the other recommendations or how it plays into the other recommendations as well.

But, we can open it up for public comment if, Dan, you would like to do that now.

Dan Diekema: Yes, I think, in particular, I mean we all are cognizant of the fact that the first public comment comes from a key co-author of this guideline and so, I'm very uncomfortable proceeding in the face of a strong objection from someone who's been so integrally involved in this process.

So, yes, I would invite additional public comment, and then we can come back and decide what action the committee, if any, the committee wants to take today.

Jeff Hageman: Adrienne, could you ask for public comment one more time please?

Coordinator: Yes, thank you. If anyone would like to make a comment, you may press star 1 on your touchtone phone and record your first and last name clearly when prompted. To withdraw your comment, press star 2. And we do have a comment in queue already from Elizabeth Wick. Your line is open.

Elizabeth Wick: Hi, it's Eliza, again, from the American College of Surgeons and I guess, we know, the -if it's going to be recommended for deep and fascial closures other than abdominal surgery, it just, I don't think this is going to make sense to people.

Because, inherently, you usually think of -it's sort of referring to an abdominal procedure. And, it just doesn't make sense, I don't know -Sandra might have thoughts about the wording of that, but I think it needs to be rethought.

Jeff Hageman: And, I did just want to clarify, so Eliza Wick, American College of Surgeons, she is one of the HICPAC liaisons. That we just had some trouble with the lines, so that's not a public comment per se.

Dan Diekema: Thank you. Are there additional public comments? Or, I'm sorry, are there public comments I should say?

Coordinator: We do have two additional comments in the queue. Our next comment is from Bill Schecter. Your line is open.

Bill Schecter: Hi, this is Bill Schecter. I was the previous American College of Surgeons representative to HICPAC and I was the HICPAC representative, I think that was correct term, when the guidelines were formulated. And, or when the revisions were formulated, and I agree, completely, with Sandra's comments. Thank you.

Jeff Hageman: Thank you Bill.

Dan Diekema: Thank you Bill.

Coordinator: Our next comment comes from Joseph Solomkin. Your line is open.

Joseph Solomkin: Thank you again. I just wanted to comment on the, particularly, the subgroup and, again, the numbers of the studies in each and the particular issue actually is the infections reported in the cardiac surgery study.

Most of those -nearly all of the infections that are noted in those studies and studies of leg wounds, in particular, I think really confound the data. Firstly, where it's turned out to be infections involving the chest, the external closure maybe between 1% to 2%.

And the leg used to harvest vein grafts, now done actually endoscopically without incisions. Those were infection rates and report about 8%. On the other hand, those are not really -and many of those are not infections, they're wound healing breakdowns because of the (onanatomic) incisions, difficulty in wound closure, and distil extremities in people with underlying vascular disease.

So, those studies and there's -one of the driving studies for this is a Swiss cardiac study. Actually, was driven almost completely by the leg thing. So, I think what this goes to is the absence of breadth of data to support going outside of, in my own strong preference, abdominal incisions.

The surgery that they're typically describing in non-colorectal abdominal surgery -they're things like hysterectomies, pancreaticoduodenectomy, and then some, for example, mesh repairs.

And I wouldn't challenge the validity of those -of that as abdominal extra colorectal. But again, I think, then, that the data package is not as tight as the numbers are. Thank you.

Coordinator: We do have one additional comment in queue. The comment is from Sandra Berríos-Torres. Your line is open.

Sandra Berríos-Torres: Thank you. And, just one other thing to keep in mind with these studies, at least looking at the risk of bias assessment from the version that was sent to us before the HICPAC meeting.

The quality in a lot of these studies, including some of the bigger ones, which, actually, the overall risk of bias in those was sort of moderate, and the quality in some of these studies was not that great.

The other thing to keep in mind is a majority of these studies are not using a lot of the perioperative standards that we use currently in the United States. That's something else to keep in mind.

And, the question as to how to best address this, again, I just kind of bring it back to the way that the committee has addressed some of the other high level evidence issues that have been downgraded from a Category I to a Category II was to consider that's something to continue to keep in mind. Thank you.

Coordinator: We have no further comments in queue.

Dan Diekema: Okay. So, thank you all again. I think we're -the hour's getting late and I think that the decision, at this point, that we have to make as a committee is whether we're comfortable in moving forward to vote on the draft language for these two recommendations. One of the two or none of them.

I'll just say that I'm not comfortable. I would prefer to table the draft language for the recommendation related to the triclosan-coated sutures, so that we can circle back, fully consider these public comments, including comments from co-authors on the guideline, and consider how to move forward.

I would be comfortable voting on the oxygen draft recommendation language, but if there is disagreement on that from HICPAC committee members, I'm happy to hear it.

Deborah Yokoe: This is Debbie Yokoe, I agree with Dan. I think we should vote on supplemental oxygenation, but table the antimicrobial suture question.

Dan Diekema: Any other comment?

Hilary Babcock: This is Hilary. That plan sounds good to me.

Dan Diekema: Okay then...

Sheri Tejedor: This is Sheri, I agree.

Dan Diekema: So, Jeff, do you call out the role in terms of voting on the draft recommendation language on Slide 18 for...

Jeff Hageman: Oxygenation.

Dan Diekema: ...oxygenation?

Jeff Hageman: Yes, I'll do that. So, the wording as is for the 6A, 6B, and 6C on Slide 18. So, I'll go through each member and say if you approve or not approve or recuse.

So, Dan Diekema?

Dan Diekema: Approve.

Jeff Hageman: Vickie Brown?

Vickie Brown: Approve.

Jeff Hageman: Hilary Babcock?

Hilary Babcock: Approve.

Charlie Huskins: Approve.

Jeff Hageman: Sheri Tejedor?

Sheri Tejedor: Approve.

Jeff Hageman: Lynn Janssen?

Lynn Janssen: Approved.

Jeff Hageman: Jan Patterson?

Jan Patterson: Approved.

Jeff Hageman: Gina Pugliese?

Gina Pugliese: Approved.

Jeff Hageman: Tom Talbot?

Tom Talbot: Approved.

Jeff Hageman: Debbie Yokoe?

Deborah Yokoe: Approved.

Jeff Hageman: And, Lisa Maragakis? And I know Lisa is on, but wasn't able to speak for reason. Have I missed any members? That's ten approves pending Lisa's communication to me by e-mail, but that ten is enough to pass that motion, and so, the oxygenation draft recommendations are approved, and we'll be tabling the triclosan suture recommendations at this point.

I do want to make one comment. Even though they are approved here, all of the recommendations throughout the entire guideline, and the guideline is not final; it's still a draft form.

So, we will see what the remaining work is for the triclosan suture recommendations, and given that work, and it may also need to impact in some of the other recommendations, so that we're applying the methods consistently across the guideline and recommendations.

So, Dan, any remaining comments?

Dan Diekema: None, except to thank everyone who joined the call, and to thank, also, those who provided public comment.

Jeff Hageman: All right. Thank you. We're adjourned.

Coordinator: Thank you for your participation. This concludes today's conference and you may disconnect at this time.

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