

FTS-CDC-OD

**Moderator: Dr. Patrick Brennan
September 10, 2010
12:18 pm CT**

Coordinator: Hello and thank you for standing by. All lines will be on listen-only until the question and answer portion. To ask your question, please press star then 1 on your phone.

Today's conference is being recorded. If you have any objections you may disconnect. I would like to introduce your host for today's call, Dr. Brennan and Jeff Hageman. Please begin.

Dr. Patrick Brennan: Thank you. Good afternoon and welcome to this HICPAC teleconference. The subject of today's call is a review of a Norovirus Guideline for healthcare facilities that has been developed by a writing group constituted by HICPAC and its consultants.

The plan for this afternoon's session is a scheduled 90-minute teleconference. Immediately after this we will have a roll call and review of conflicts of interest.

And then we'll do a follow up discussion of this Guideline for the Prevention and Control of Norovirus Gastroenteritis Outbreaks in Healthcare Settings that has been posted in the Federal Register and previously reviewed by HICPAC.

Following the discussion there will be a period of public comment during which those in listening mode on the phone will be able to ask questions of the panel.

Committee members will then vote on the Guideline and then we'll wrap up the call. So I just want to review that during the June meeting of HICPAC in Atlanta, this Guideline was reviewed by the Committee and there was extensive discussion, some words missing and suggested changes were made.

As I mentioned this document has been posted in the Federal Register for public comment, and that the issues we'll discuss on the call today are those arising both from the public comments and from the June HICPAC meeting.

During the meeting we'll review the issues and approve changes to the Federal Register Version of the Guideline. You should be aware that all of the materials, the issues table and the Federal Register Version of the Guideline are available on the HICPAC Web site at www.cdc.gov/hicpac.

With that I'll turn the call over to Jeff Hageman, and Jeff will conduct the roll call and conflicts of interest. Jeff?

Jeff Hageman: Thanks PJ. So I'll go down the roll and state whether or not you're here and for HICPAC members only, please state if you have any conflicts of interest related to this Guideline that we'll be talking about today. Dr. Brennan?

Dr. Patrick Brennan: Present, no conflicts.

Jeff Hageman: Dale Bratzler?

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

Jeff Hageman: Lillian Burns?

Lillian Burns: Present, no conflicts.

Jeff Hageman: Alexis Elward?

Alexis Elward: Present. I receive research support from Sage Products.

Jeff Hageman: Susan Huang?

Susan Huang: Here and no conflicts.

Jeff Hageman: Tammy Lundstrom? Yvette McCarter?

Yvette McCarter: Here, no conflicts.

Jeff Hageman: Denise Murphy? Russ Olmsted? Steve Ostroff?

Stephen Ostroff: Yes present, no conflicts.

Jeff Hageman: David Pegues?

David Pegues: Present, no conflicts.

Jeff Hageman: Peter Pronovost? Bill Schecter? Barbara Soule? Bill Baine?

William Baine: Here.

Jeff Hageman: Jeannie Miller?

Jeannie Miller: Here, no conflicts.

Jeff Hageman: Sheila Murphey?

Sheila Murphey: Here, no conflicts.

Jeff Hageman: Paul Moore?

Paul Moore: Here.

Jeff Hageman: David Henderson?

Woman: Dr. Henderson had to step away from his desk but he will be back on the call and he does not have any conflicts.

Jeff Hageman: All right, Dr. Roselle?

Dr. Gary Roselle: I am here.

Jeff Hageman: Rachel Stricof? Mark Russi? Sandra Fitzler? Roslyne Schulman?

Roslyne Schulman: I'm here.

Jeff Hageman: Joan Blanchard?

Joan Blanchard: I'm here.

Jeff Hageman: Barbara DeBaun? Marion Kainer? Lisa McGiffert? Charlie Huskins?

Charles Huskins: Present.

Jeff Hageman: Shirley Paton? Lisa Maragakis?

Lisa Maragakis: I'm here.

Jeff Hageman: (Bill Blickenbach)? Sanjay Saint? Bob Wise? All right, that is the roll and we do have quorum so we can proceed (PJ).

Dr. Patrick Brennan: Okay.

Jeff Hageman: So as PJ mentioned this is a review of the Norovirus Guideline. I just wanted to - because we just completed the BSI Guideline recently, I wanted to review the way the recommendations are categorized, and so it's the same scheme.

Category IA, Category IB, Category IC are all considered strong recommendations. Category IA are strong recommendations supported by high to moderate quality evidence suggesting net clinical benefits or harms.

Category IB are strong recommendations supported by low quality evidence suggesting net clinical benefits or harms, or an accepted practice such as aseptic technique that may be supported by low or very low quality evidence.

Category IC are strong recommendations required by state or federal regulations. Category II recommendations are weak recommendations supported by any quality evidence suggesting a tradeoff between clinical benefits and harms, and then finally there are recommendations for further research.

These are unresolved issues for which there is low to very low quality evidence with uncertain tradeoffs between benefits and harms. This is the categorization scheme that was used for the Guideline and it will - and it can refer back to that if needed during the call. It appears on the Federal Register Version of the Guideline on Page 10.

Issues that will be discussed as PJ mentioned are in the table found on the HICPAC Web site. There are a total of 40 different issues covering both new recommendations as well as recommendations - essentially changing of the wording of specific recommendations to improve the clarity of the recommendations, as well as making sure that the language that's used for each recommendation is consistent across that gray category so that weak recommendations are worded similarly and strong recommendations are worded similarly.

And so we'll go through this document and probably the best approach because there are many of them is we'll cover it by section of the document, going with the flow of the document.

So the first section is Patient Cohorting and Isolation Precautions. The table is set up with the following columns, reading from left to right. The first column is the Issue Number.

The next column is the Issue/Brief Description Action so it will indicate whether or not this is a major or a minor change, or whether it's just a minor edit to the text.

The next column is the Federal Register Version of the text as it reads. The next column is the Summary of the Comments either received through the public comment period or during HICPAC meetings.

The next column is the response or Clarification in response to the public comment, a brief description, and I have Dr. Tara MacCannell here with me if there needs further clarification.

She was part of the writing group for this guideline. And then the final column are - is the suggested or proposed Revised Text for HICPAC to consider.

So I'll start with Number 1, which is in the section Patient Cohort and Isolation Precautions. And PJ probably it'd be most efficient since we do have a number of items is to after each section, have a provisional vote for those items in that section pending any public comments or changes needed based on public comments.

And then following the public comment period the Committee can then vote on the entire document as a whole to either additional changes in public comment as well as the provisional votes.

Dr. Patrick Brennan: Okay, I think that sounds fine. Sounds fine Jeff. I'll just also mention for those who haven't had a chance to look through the Issue/Action item document yet, of the 40 items more than half really represent minor revisions to language for clarity or - and a few others represent splits in paragraphs that were previously in the Federal Register Version.

So there are a relatively small number of major revisions in this Issues document.

Jeff Hageman: All right, so starting with Number 1, this is reviewing proposed revised recommendation. The original recommendation was to, "Avoid exposure to vomitus or diarrhea. For a recognized outbreak, use contact precautions for

patients with symptoms consistent with norovirus gastroenteritis. Sporadic cases of norovirus can be managed under standard precautions with provision to reduce staff, visitor, and patient exposures to vomitus or diarrhea. “

There were several comments for this issue, specifically concerns over handling sporadic cases under standard precautions, noting delays in receiving confirmation of norovirus.

Also some comments about may put healthcare personnel at risk when it hasn't been confirmed yet. There was - the proposed revised language is to change to - so that all norovirus cases are handled under contact precautions.

This is a slight deviation from 2007 Isolation Guideline, however that's fine if there are differences. The revised proposed text is to, “Avoid exposure to vomitus or diarrhea.

Place patients on contact precautions if they present with symptoms consistent with norovirus gastroenteritis.” So the major change for this were - is to remove the mention of sporadic cases being treated under standard precautions and apply contact precautions for all cases. Any comments or...?

Dr. Patrick Brennan: Okay, no comments.

Jeff Hageman: The second issue is adding a minor change to the language to include young children. The original Federal Register Version of the recommendation states, “Consider extending the duration of isolation or cohorting precautions for outbreaks among infants, even after resolution of symptoms, as there is a potential for prolonged viral shedding and environmental contamination.

Among infants, extending contact precautions for up to 5 days after the resolution of symptoms is suggested.” This is a Category II, a weak recommendation.

The summary of comments suggested changing infant to pediatrics or at least defining the age of the infants, and it also suggested and noted that there were other age ranges where there might be prolonged shedding.

The response to the comments, definition - use the standard definition for infants but reconsidered after looking at two studies and to revise the recommendations to reflect a slightly higher age range to include young children, because these individuals based on those studies have also demonstrated prolonged shedding.

So the proposed revised text for this one is, “Consider extending the duration of isolation or cohorting precautions for outbreaks among infants and young children (for example under two years), even after resolution of symptoms, as there is a potential for prolonged viral shedding and environmental contamination.” But the remainder is the same language as the original. Any comments on that minor change?

Dr. Patrick Brennan: Okay, let’s go to Number 3 Jeff.

Jeff Hageman: Issue Number 3 is another minor change to clarify the recommendation. The recommendation was, “During outbreaks, patients with norovirus gastroenteritis should be cohorted or placed on contact precautions for a minimum of 48 hours after resolution of symptoms to prevent further exposure of susceptible patients.” This was a Category IB.

The comment was that establishing a cohort does not obviate the need for contact precautions for symptomatic individuals. Therefore the response was to remove the cohorting text from this recommendation because it was covered under a subsequent recommendation 3.C.4.b.

So the revised text would be, “During outbreaks, place patients with norovirus gastroenteritis on contact precautions for a minimum of 48 hours after the resolution of symptoms to prevent further transmission,” so a removal of the cohorting language from this recommendation. Any comment?

Dr. Patrick Brennan: It makes sense.

Jeff Hageman: Issue Number 4 - there was some reorganization to the recommendation. The original recommendation is, “During suspected or confirmed outbreaks, preferentially place patients with norovirus gastroenteritis on contact precautions and into private rooms equipped with at least one dedicated handwashing sink and/or - and toilet or commode.

If these provisions are not available, patients may be cohorted into groups of those who are symptomatic, exposed but asymptomatic, and unexposed with access to separate toilets or commodes for each group.

Alternatively, all patients within a hospital unit or section may be placed under contact precautions,” a Category IB. And there was comments about additional guidance is needed for monitoring symptom development of the group, exposed but asymptomatic, or consider the option of cohorting only infected versus noninfected groups.

The response clarification was this suggestion addresses the need to continually assess the evolution and incidence of new cases or exposure

status; however, there were no studies that directly addressed the process of monitoring cases outside of general case finding.

And there is some redundancy with the recommendation in 3.C.4.a, and so they proposed to retain the definitions of cohorting but removed the rest of the language, which was covered in the previous recommendation we just discussed.

So this recommendation would be changed to, “When symptomatic patients cannot be accommodated in single occupancy rooms, cohort patients in multi-occupancy rooms under contact precautions (e.g., those grouped among those who are symptomatic, exposed but asymptomatic, and unexposed).

Symptomatic patients within an entire hospital unit or section can be placed on contact precautions (e.g., unit-level isolation),” a Category IB. Any comments on those changes?

Dr. Gary Roselle: This is Gary Roselle - just a brief clarification issue. When you say contact precautions then you put e.g. and the three groups, I worry a little bit that someone may read that to say that you’re going to put all three groups together as a cohort in contact precautions.

And maybe the e.g. should go after where it says cohort patients, because you really have I assume three different cohorts there.

Dr. Taranisia MacCannell: That’s correct Gary, so I think - oh, this is Tara MacCannell. So it would - so then we would retool that to say - we would leave that statement to end at contact precautions and then...?

Dr. Gary Roselle: No, you’d put the e.g. - move the e.g. statement.

Dr. Taranisia MacCannell: Oh, under - okay. All right, so you move it up to - after cohorting patients.

Dr. Gary Roselle: Right, particularly since like the unexposed wouldn't be in contact precautions.

Dr. Taranisia MacCannell: Right, okay.

William Baine: This is Bill Baine. If I could suggest, I don't think these are really eg(s). They're not *exempli gratia*. They're not examples of what you just cited. I'd throw out the e.g. and just say whatever you want grouped among those who are asymptomatic exposed, preferably group them alone or something like that.

And the same thing for e.g. - even though there's isolation I don't think that's an example. Maybe you mean i.e., that is, you know, total isolation or you can throw out the language altogether. So I don't think these are examples of what you just said.

Dr. Taranisia MacCannell: Well, you know, they were basically citations from individual studies, so they weren't sort of - they were just examples used in the - in specifically - specific pieces of evidence that we evaluated but certainly isn't a standard, you know, for the control of these types of outbreaks.

So I wouldn't want people to interpret that as this is the only way to do it. I, you know, if you go i.e. as opposed to just an example of how to do it.

Susan Huang: What if we agree that it is wise not to put the symptomatic with the exposed?

Dr. Taranisia MacCannell: Oh, absolutely. Certainly, but it may be more of a function of the facility arrangement, for example, you know, this may work well in a hospital environment and, you know, there are studies to address that.

But there are also studies for example that were done in circumstances like long-term care where the facilities are not as well equipped to have those delineations sort of perfectly outlined and managed.

So I think that's where we sort of step into a little bit of the gray area in terms of making this, you know, inflexible I suppose for how people should interpret them.

Susan Huang: Maybe you can say, you know, "When symptomatic patients cannot be accommodated in single occupancy rooms, effort should be made to cohort patients by, you know, separately in the following groups."

And that way there's a point to be made without saying it's absolutely mandatory, but it highlights the appropriate desire for us to keep those folks distinct if possible.

Dr. Taranisia MacCannell: Okay, all right.

Dr. Patrick Brennan: Did you get that language Tara?

Dr. Taranisia MacCannell: I did. So, "When symptomatic patients cannot be accommodated in single occupancy rooms, effort should be made to cohort patients into separate groups," and then go on to sort of doing a- the particular subgroups that we were thinking about based on the literature.

Dr. Patrick Brennan: Okay.

Jeff Hageman: Any additional comments? All right, so moving to Number 5 in the table. So this was one of the instances where the recommendation was split. The original recommendation was, “Minimize patient movements within a ward or unit.

Symptomatic and recovering patients should not leave the patient-care area unless it is essential - unless it is for essential care or treatment to reduce the likelihood of environmental contamination and transmission of norovirus in unaffected clinical areas.”

So there were some clarifications made. So essentially this one was split. I’ll read the final - the proposed language to be, “Minimize patient movements within a ward or unit during norovirus gastroenteritis outbreaks,” a Category II.

A new recommendation would be, “It is not recommended that symptomatic and recovering patients leave the patient-care area unless it is for essential care or treatment to reduce the likelihood of environmental contamination and transmission of norovirus in unaffected clinical areas,” a Category II.

Sheila Murphey: This is Sheila. I’d comment - the wording’s just a little awkward, although I know what you’re trying to go for. Would it not be better to say, “It is recommended that patients not leave,” and start it as a positive rather than it is not recommended?

Dr. Taranisia MacCannell: This is Tara. This is in line with the CAUTI Guidelines, so when there’s a Category II framework for a recommendation - so if we went with “it is recommended” then that would change the strength of the language.

So that would be more of a Category I so we would have to say something like, “Consider I guess restricting patient movements outside of the patient-care area unless it’s for a special care or treatment,” in order to stay in line with Category II.

Sheila Murphey: Right, well I think consider would be just as acceptable. It’s just that it’s a little awkward to say it’s not recommended.

Jeff Hageman: Right.

Dr. Taranisia MacCannell: Right.

Dr. Patrick Brennan: You know, just a general comment. There are several places in the last column in this document where we use the word consider and, you know, I just find that to be sort of a weak - and it does fall into the Category II area.

But I’m not sure that, you know, consider will get much of any attention at all. So I’d prefer to limit the use of that if at all possible. Go ahead Tara.

Dr. Taranisia MacCannell: Okay, so...

Dr. Patrick Brennan: Okay so - I’m sorry. Are you done with that part?

Dr. Taranisia MacCannell: If there are no other comments, and so we would change it to say, “Consider restricting symptomatic and recovering patients from leaving the patient care area unless for essential care treatment,” et cetera.

Sheila Murphey: Well, I think you can decide whether you want consider or not recommended. It’s just that do you want to start with a positive or do you want to start with a negative, that’s all.

Susan Huang: If you don't have it in the - like what - could you say, "Symptomatic and recovering patients should not leave?" I mean, do you have to couch it in the recommended, I mean, if it's not necessarily tied to a litany of evidence-based stuff but it's just a reasonable recommendation, are we allowed to use that language?

Dr. Taranisia MacCannell: The word should actually is not used in either of the Category I or Category II recommendations as per again that - by the CAUTI Guidelines. And so if we say should again that's implying more of a must do, so a Category I.

Sheila Murphey: It's impossible to say that it is recommended since you're saying it is not recommended here?

Dr. Taranisia MacCannell: Actually the flip side makes it a Category I.

Sheila Murphey: I see.

Dr. Taranisia MacCannell: Yes.

Sheila Murphey: Because consider does sound kind of weak. It really does.

Dr. Taranisia MacCannell: Yes, because it is a weak recommendation and just to kind of bring forth a few of the, you know, documents that supported that. A lot of that information is very low-grade evidence because it was descriptive work.

It was interventions that were implemented during outbreaks so, you know, certainly not a pre-post evaluation. It was just things that people had implemented but there was a number of studies that had done so, which made

it a reasonable recommendation but certainly not based on a whole lot of interventional evidence, which left it at a Category II.

Sheila Murphey: So basically it comes down to it is not recommended or consider.

Dr. Taranisia MacCannell: Or you could say suggest. It's suggest.

Sheila Murphey: I think it would be - would not be interpreted very well by the people using the document if you say suggest.

Dr. Taranisia MacCannell: Right. Yes, there's a sort of - certainly a limited vocabulary for the Category II particularly.

Michael Bell: This is Mike. I'm thinking this might be a place to allow a consider, just given that this is a Category II and in consistency with the UTI Guidelines. This might be where we can allow that. I don't know, PJ do you feel strongly?

Dr. Patrick Brennan: No Mike, I don't feel strongly. I think we, you know, to the extent possible we should have some consistency in language that really, you know, sort of signals what our intention is here. But I'm okay with consider.

Lillian Burns: This is Lillian. I kind - I prefer it the way it is versus the consider. I know there was a lot of discussion about the use of this document during some major outbreaks of norovirus, even though it was a draft. And I think that consider, people may misinterpret what that means.

Susan Huang: This is Susan. I would agree. Between the two I would prefer it is not recommended.

Dr. Patrick Brennan: All right.

Stephen Ostroff: This is Steve. I feel the same way.

Dr. Patrick Brennan: Other members chime in. That's three that prefer it is not recommended.

Yvette McCarter: This is Yvette. I agree with not recommended.

Alexis Elward: And this is Alexis. I agree with not recommended.

Dr. Patrick Brennan: That's five.

David Pegues: This is David. Make it unanimous.

Dr. Patrick Brennan: Okay.

Dale Bratzler: This is David - Dale also.

Dr. Patrick Brennan: Okay, so I think we have a majority of the members on the phone preferring it is not recommended Jeff.

Russell Olmsted: PJ, this is Russ. I'm also on there.

Dr. Patrick Brennan: Okay.

Jeff Hageman: All right, just to remind everybody since we're on the phone and this is being recorded and transcribed, please state your name before you make a comment so that that can be recorded. Thanks.

So we'll move on to the next one, Number 6. Essentially this is the same - similar issue. This is a Category II recommendation and trying to get it in line with the - it would be consistent with the wording within Category.

So the original recommendation was, "Suspend group activities, dining events, during an uncontrolled outbreak of norovirus gastroenteritis," Category II. So it was modified to add that consider.

"Consider suspending group activities, for example dining events, for the duration of the norovirus outbreak," a Category II. Any comments?

Dr. Patrick Brennan: Jeff does this - there's nothing in the box in the column of Summary of Comments. Does that indicate that this was an internal pickup during clearance or...?

Jeff Hageman: Yes, so this is one upon further review where we spotted some of the recommendations didn't have consistent language within the category, so this is an attempt to ensure that all the Category I recommendations use the same strong language.

And the Category II recommendations that are weak recommendations use consistent language as well.

Dr. Patrick Brennan: Okay. Any comments on Issue 6? Okay, go ahead Jeff.

Jeff Hageman: Number 7 is, "Staff who have recovered from recent suspected norovirus infection associated with this outbreak may be best suited to care for exposed or symptomatic patients."

Comments to add until the outbreak is resolved, and so this was done to that recommendation. So at the end of that one it was added, “suited to care for exposed or symptomatic patients until the outbreak resolves.” Any comments?

All right, so that - PJ, that’s the end of the Patient Cohort and Isolation Precautions section.

Stephen Ostroff: This is Steve Ostroff. Can I just quickly go back to the second - Number 2?

Jeff Hageman: Sure.

Stephen Ostroff: The minor change about the young children. It seems inconsistent to mention them in the first sentence and then not in the second. So I’m wondering if it should be added in the second sentence where it says among infants, add among infants and young children.

Dr. Taranisia MacCannell: Hi, this is Tara. The reason we didn’t put young children in the follow up sentence is because the studies that evaluated duration of isolation and prolonged shedding didn’t actually include those same recommendations for adding on five days for isolation precautions.

Stephen Ostroff: Yes, but you say above that, “outbreaks in young children even after resolution of symptoms, as there is the potential for prolonged viral shedding and environmental contamination.”

So that, I mean, the reader would presume that there is information to say that young children also have prolonged viral shedding. So why would you specifically make the recommendations for infants and then be silent about the young children? What do you want people to do?

Dr. Taranisia MacCannell: Right, it was just basically a reflection of the evidence that basically stated that there was - like a defined period of time to extend the isolation period, but that didn't extend in those evidence pieces that we reviewed that - anything in terms of a duration.

And it would only - and for the studies that we reviewed it only pertained to infants, but not to young children. So it was a hard, I mean, we can make that extension but - and because it is a Category II and, you know, in terms of providing that benefit we could include it.

But in terms of the evidence to support it, it's not there. The only evidence to support the five days or up to five days of additional isolation precautions is only really the data exists only for infants.

Stephen Ostroff: You could state it that way, too. You could state that evidence in infants suggests considering extending contact precautions up to five days.

Dr. Taranisia MacCannell: We could.

Alexis Elward: This is Alexis. I would support that because I think it's a clearer recommendation.

Lillian Burns: This is Lillian. I agree. I was just going to say that. I agree with that statement the way it was just stated.

Dr. Taranisia MacCannell: Okay, great. This is Tara. So I could just say, "Extend or - extend contact precautions without the among infants for up to five days after the resolution of symptoms and - right, or consider extending the..."

Dr. Patrick Brennan: Evidence suggests or two studies suggest that extending contact precautions for up to five days among infants after the resolution of symptoms is suggested.

Michael Bell: Getting back to what Alexis said, were we trying to include young children with the infants now?

Alexis Elward: I think we're - it's Alexis again. I think we were trying to make the distinction about where the evidence exists.

Michael Bell: So a particular focus only on infants indicates that the evidence is for that.

Dr. Patrick Brennan: Yes.

Dr. Taranisia MacCannell: Okay. So then it would read something more along the lines of, "Evidence just would suggest or evidence suggests that extending - that among infants extending contact precautions for up to five days after the resolution of symptoms is suggested."

Stephen Ostroff: I might word it this way. This is Steve - that among infants there is evidence to consider extending contact precautions for up to five days after the resolution of symptoms.

Michael Bell: Sounds good.

Stephen Ostroff: Yes, it's good.

Lillian Burns: That sounds good.

Dr. Patrick Brennan: That's good. Okay, I think we have consensus on Item 2. There were no questions or comments on Issue 1 or 3 or 5. Actually 5, yes there was. No comments on 6 or 7.

So Tara or Jeff, could you just reread one more time the final recommendation on Issue 4 and then on Issue 5?

Dr. Taranisia MacCannell: Okay.

Dr. Patrick Brennan: Where it's missing, right.

Dr. Taranisia MacCannell: Okay, for Issue 4 then - this is Tara, 3.C.4.b., "When symptomatic patients cannot be accommodated in single occupancy rooms, effort should be made to cohort patients into separate groups in a multi - okay, in separate groups under contact precautions."

And then we were going to outline the e.g. among groups who were - among - groups among those who are symptomatic, exposed but asymptomatic and unexposed.

And then continue with, "symptomatic patients within an entire hospital unit or section can be placed on contact precautions."

Dr. Patrick Brennan: Okay.

Dr. Gary Roselle: This is Gary Roselle. Just remember we want to make sure that the e.g.'s, whether it's an e.g. or an i.e., aren't put after contact precautions since probably two of that group will not be in contact precautions.

Dr. Taranisia MacCannell: Great, okay.

Dr. Patrick Brennan: I'm sorry Gary, you want it after cohort, right, cohort patients?

Dr. Gary Roselle: Yes.

Dr. Patrick Brennan: Okay.

Dr. Taranisia MacCannell: All right.

Jeff Hageman: So reread it.

Dr. Taranisia MacCannell: All right, so, "When symptomatic patients cannot be accommodated in single occupancy rooms, cohort patients (e.g., groups among those who are symptomatic, exposed but asymptomatic, and unexposed) into - and then it says into separate groups."

So actually the e.g. should go - come after that, not after cohort patients. So let me try again. So, "When symptomatic patients cannot be accommodated in single occupancy rooms, effort should be made to cohort patients into separate groups (e.g., groups among those who are symptomatic, exposed but asymptomatic, and unexposed)." And then...

Dr. Patrick Brennan: And so on.

Dr. Taranisia MacCannell: Yes.

Dr. Patrick Brennan: Okay. All right.

Jeff Hageman: And then the Number 5 language we...

Dr. Gary Roselle: Let me go back to Number 4. This is Gary Roselle again. But you weren't going to put all these in contact precautions, right, all the cohorts?

Dr. Patrick Brennan: Right.

Dr. Gary Roselle: Okay, just - it's a - like I said it's a matter of clarity and people actually will be doing exactly what you say, so it has to be clear.

Dr. Patrick Brennan: Who was that?

Jeff Hageman: That was Gary Roselle.

Dr. Gary Roselle: Gary Roselle. Because they're going to call me and ask me, "How do I put all these people in the contact precautions?" So it's just - I just want to make sure that the unexposed and the asymptomatic people don't end up in contact precautions.

Dr. Taranisia MacCannell: Right, okay.

Lillian Burns: Right.

Jeff Hageman: Do we need the e.g.? And it starts out as symptomatic patients, you know, it's cohorting symptomatic patients.

Dr. Patrick Brennan: I don't think so. Others?

Lillian Burns: No that's - this is Lillian. I don't think so.

Dr. Patrick Brennan: Okay, are there any other comments on the Item 4? Okay, do we have agreement on the language then?

Lillian Burns: Yes. This is Lillian. I agree.

Dr. Patrick Brennan: Okay, and then 5.

Jeff Hageman: And 5, that's the one we decided to leave as it is not recommended?

Dr. Patrick Brennan: Yes.

Lillian Burns: Yes.

Dr. Patrick Brennan: Okay. Okay, so that completes the first section on Patient Cohorting and Isolation Precautions. Do you want to take a roll call vote Jeff or just yea and nay?

Jeff Hageman: We can do a yea and nay and then any recusals, too.

Dr. Patrick Brennan: Okay, are there any recusals? Okay, all those in favor of the language that we've discussed in Items 1 through 7 in this first section of the Norovirus Guideline on Patient Cohorting and Isolation Precautions, all those in favor, aye.

Any opposed? Okay, and I heard no recusals. Okay, so the first section is approved pending public comments. All right, Hand Hygiene Jeff.

Jeff Hageman: Sure, so Hand Hygiene, the first one, Number 8, is actually not - there's no action needed. It's just a reordering of - from the original document. This one was currently showing second and it was felt that - just put it first in the section to, "Actively promote adherence to hand hygiene among healthcare

personnel, patients, and visitors in patient care areas affected by outbreaks of norovirus gastroenteritis.”

It used to be within the flow of the document, the second recommendation. So there’s really no action needed for that one. Number 9 is the review of the restricted activities where hand washing with soap and water after contact with symptomatic patients.

So the original language was the 3.C.1.a, “Perform handwashing using soap and water, according to standard precautions prior to contact with patients, medication preparation, preparation or consumption of food, insertion of invasive devices, after touching contaminated equipment, removing personal protective equipment or toileting activities with patients with symptoms of norovirus infections.”

And then there’s a link to that Guideline. It’s Category IB. There were comments about it, hand hygiene, changing the term handwashing to hand hygiene as standard precautions include either technique.

Reinforce the recommendations of CDC’s Hand Hygiene Guideline from 2002 that emphasize handwashing if hands are visibly soiled. And it’s also unclear as stated that this is intended to be directly - directed solely to care of patients with suspected or proven norovirus infection.

The second grouping of comments was, can use alcohol hand sanitizer prior to contact with the patients, medication prep, food prep, insertion of invasive devices as well as some of the other activities.

So the response was that this language has been clarified to promote the use of soap and water after contact with patients experiencing symptoms of norovirus.

Add “after contact with norovirus patients” and removed the statement “on the use of soap and water,” which was I guess redundant with 3.C.1.a and retained only the statement on alcohol hand sanitizer for the new - there’s a new recommendation that we’ll come to next.

So that the recommendation was redone to - and it might be helpful - I’ll read this one and then maybe we’ll just go through all of the related ones together.

So this one, 3.C.1.b, “During outbreaks prioritize hand hygiene with soap and water after providing care or having contact with patients suspected or confirmed with norovirus gastroenteritis based on the possible benefits of mechanical removal of infectious material.” This was a IB.

And I guess we can stop and see if there’s comments on that one, or unless we need to go and review all of them.

Dr. Patrick Brennan: Okay.

Jeff Hageman: So then Number 10 was a minor change to the language to include “FDA-compliant” terminology. And so the original recommendation 3.C.1.b.1, “During outbreaks, use of soap and water is the preferred method of hand hygiene. Consider FDA-approved alcohol-based hand sanitizer as supplemental method of hand hygiene during outbreaks of norovirus gastroenteritis when hands are not visibly soiled and have not been in contact with diarrheal patients, contaminated surfaces, or blood or other body fluids.”

There was suggestions that use the FDA-compliant language. There were some changes made to this recommendation to read, “For other hand hygiene indications, use standard precautions to guide practice, including the use of FDA-compliant alcohol-based hand sanitizers when hands are not visibly soiled or have not been in contact with diarrheal patients, contaminated surfaces, or other body fluids,” a Category IB, and then referring to the 2002 Guideline, HICPAC Hand Hygiene Guideline.

Susan Huang: This is Susan. I just want to make sure that we don't make it confusing for people where in one section you're saying now you should use contact precautions, and then here you're saying that for very specific things you can use standard.

And it might be interpreted that in the room they can do something different. So I want to make sure that we don't confuse the issue. I know what you're saying about distinguishing between how you wash your hands for different high-risk actions, but the language of standard precautions may be confusing.

Russell Olmsted: This is Russ. That - I agree with you Susan on that one, and perhaps it could be just for other hand hygiene indications, follow CDC 2002 HICPAC Guidelines.

Dr. Taranisia MacCannell: This is Tara. I just - that sounds probably a little more clear than to complicate it with the use of the standard precautions language.

Dr. Patrick Brennan: Any other thoughts?

Russell Olmsted: Just one other comment on this. The - I don't know what the literature - when it was published but some suggestion that it, you know, in a outbreak setting

perhaps hand washing, dry hands and then apply alcohol-based hand rub was one of the studies as I recall.

But I like the way it's worded here so I don't want to muddy the water. I think this study may have been published after the literature search time span. So I'll withdraw that comment.

Jeff Hageman: All right. So this one would then change, "For other hand hygiene indications see CDC 2002, you know, HICPAC Guideline." Is that - did I hear that correctly?

Russell Olmsted: Yes, that would - I think that's - the other possibility would be CDC 2002 HICPAC Guideline or 2009 WHO, but I'm happy to stay with 2002.

Susan Huang: Sounds good. This is Susan. If your intent was to highlight the e.g. portion of this, you could leave it as, "for other hand hygiene indications," and then keep that parenthetical phrase, and then refer to the Guideline. Otherwise I'm not sure it'll be taken out of context.

Jeff Hageman: That's a good point Susan.

Dr. Taranisia MacCannell: That actually reads probably a little better actually, so if we say, "For other hand hygiene indications, e.g.," and then the stuff that's in that parentheses, "refer to the 2002 HICPAC Guideline and include the use of FDA-compliant alcohol-based hand sanitizer."

Dr. Patrick Brennan: Any further comments on that one?

David Pegues: This is David. Is FDA-compliant Sheila appropriate terminology?

Sheila Murphey: Yes, because otherwise you get into an awkward, “complies with FDA monograph or OTC drug review or FDA. It’s easier to say compliant.

David Pegues: Great, thank you.

Lillian Burns: This is Lillian. I think it will read well with the changes that were suggested, and now having the explanation of the FDA-compliant then the whole issue about that I think it’s, you know, I think that will work well for the Guideline.

Jeff Hageman: All right, so moving on to the next one of those changes. This was another situation of consistency of language within the category recommendations. The original one read, “Ethanol-based hand hygiene - hand sanitizers (60-95%) are preferred as a supplemental method of hand hygiene compared to other alcohol or non-alcohol-based hand sanitizer products during outbreaks of norovirus gastroenteritis.”

Again, changed the wording to be, “Consider ethanol-based hand sanitizers (60-95%),” and then it’s the same. Any comments on that one?

Susan Huang: Am I not mistaken that I thought the rule for ethanol-based hand sanitizers has to be greater than 60%?

Dr. Patrick Brennan: I think we can verify that. So that just needs a greater than, Susan?

Susan Huang: Yes, somehow - I may be remembering it wrong but...with anybody else.

Lillian Burns: No, this is Lillian Burns. I thought at least 60%. Yes.

Susan Huang: It may be at least but I...

Lillian Burns: Sixty percent or greater.

Michael Bell: Are you asking about the 95% cutoff?

Lillian Burns: No, the 60%.

Susan Huang: Okay, is it greater than 60 or does it include 60? Sorry, small issue but...

Michael Bell: I see what you're saying. Yes, we should confirm that. We shouldn't say just greater than. We can say - so we need to confirm that it includes 60. The point here is that 100% alcohol doesn't work as well in terms of an activated organism. That's something that contains some water. The 95 is actually an important cutoff.

Dr. Taranisia MacCannell: Tara. The studies that we evaluated did go as low as 60%, so that's where the 60% comes in. I know that commercially available products start at 62%, but for the purposes of the basic science studies showing efficacy the minimum that was used was 60%.

Susan Huang: I think you're right. I'm confirming on the CDC Web site so it's at least 60%.

Russell Olmsted: Yes.

Jeff Hageman: All right, so we'll say that language here. So PJ, that finishes the Hand Hygiene section.

Dr. Patrick Brennan: Okay, do we need to review the language again then? There were one, two, three, four, five, six recommendation - there's six issues in that area. No, I'm sorry, four. I skipped four issues.

Okay, let's go ahead and vote then. All those in favor of approval of the recommendations as stated in the Hand Hygiene section, say aye. Any opposed? Any recusals? Okay, so let's go to Patient Transfer and Ward Closure.

Jeff Hageman: Can you go through this one? I'm going to ask Tara to go through this one.

Dr. Patrick Brennan: Okay.

Dr. Taranisia MacCannell: Okay, great.

Jeff Hageman: This is Number 12.

Dr. Taranisia MacCannell: All right, so we're on Number 12 and this was actually a major change to the wording. And basically we maintained using a Category II, so the original recommendation for 3.C.11 was, "During outbreaks, patients on contact precautions for norovirus can be transport - transferred or discharged to skilled nursing facilities as needed.

If receiving facilities are unable to provide adequate cohorting or isolation provisions, it may be prudent to postpone transfer until arrangements are made for appropriate isolation or cohorting.

Expedite the discharge of symptomatic or recovering patients who are medically suitable for discharge to their place of residence," and that was a Cat II.

And so there was a few comments that came into the Federal Register and we had also if you recall we discussed this a bit at the HICPAC meeting. But there was concerns about transfer and inter-facility spread and just sort of

practical concerns that even applying for provisions for movement, even if people were medically suitable but recovering may actually become the, you know, a new site for a new outbreak.

So we went back to the literature again and also cited several studies delaying - demonstrating the benefits of delaying that transfer until - unless it was medically urgent.

So the change to the recommendation to reflect that, the evidence we reviewed, plus a change to the words so that the last sentence on 3.C.11 was to expedite the discharge, which is more indicative of a Category I recommendation.

So the way we reworded it was to, “Consider urgent transfers only if receiving facilities are able to maintain contact precautions; otherwise it may be prudent to postpone transfers until patients no longer require contact precautions.

During outbreaks, medically suitable individuals recovering from norovirus gastroenteritis can be discharged to their place of residence.” So basically, you know, the only way that patients can move safely out of the place where they were originally recovering from norovirus is to their place of residence.

And - otherwise to try and hold transfers until they are able to maintain contact precautions in the receiving area or wait until actually they’re done with being on isolation. Are there any comments?

Russell Olmsted: This is Russ. I like the wording that you got - the new wording.

Dr. Taranisia MacCannell: Okay, great.

Dr. Patrick Brennan: And I agree.

Dr. Taranisia MacCannell: All right, then...

Susan Huang: Sorry, this is Susan. Just wanted to check - so when I read, "consider urgent transfers," I automatically think of acute care facility, so acute to acute care. Did you mean - based upon the original language, did you mean to have a specific sentence about transfers to long-term care, because the way it's worded it seems to exclude - it seems to refer to just acute care?

Dr. Taranisia MacCannell: I see what you're saying in terms of like the urgency would only probably be in a medical, you know, medically urgent cases. And, you know, we did see some comments on pushback from particularly long-term care facilities who wouldn't want to take on patients who require contact precautions.

But, you know, our messaging is about if they can accommodate that then they should take those individuals. But also if they are not urgently required to move then they should probably stay where they are regardless of whether they're start or end in acute care.

Susan Huang: So are we saying - I just want to make sure. I'm not disagreeing but just wanted to understand that. Are we saying that even if they're able to maintain contact precautions on the transferring side, the recommendation is not to do so until they're recovered?

So again thinking of the long-term care facility, I was just wondering, you know, if we removed urgent then it seems to apply to both settings but you're saying the recommendation is that even if the long-term care facility says,

“Yes, we can maintain single room contact precaution,” the recommendation here is not to transfer?

Dr. Taranisia MacCannell: Only - unless you go based on how it’s originally worded, only if they’re medically urgent. So yes, so I agree that we can take out the word urgent.

It still preserves a lot of the meaning and like you said maybe extends out to different kind of healthcare facilities and the reasonings for their transfer. But - so the main message should be that receiving facilities must be able to uphold the standard of contact precautions in order for that to go through.

Lillian Burns: Hi, this is Lillian. I agree. By taking out the word urgent I think the statement could work very well and it would be - people would be able to understand what the intent was.

Dr. Taranisia MacCannell: Thank you. Great comment.

Susan Huang: Thank you.

Dr. Taranisia MacCannell: So I - should I read it with the new wording then Jeff? Okay, so it would read for 3.C.11, “Consider transfers only if receiving facilities are able to maintain contact precautions; otherwise it may be prudent to postpone transfers until patients no longer require contact precautions.

During outbreaks, medically suitable individuals recovering from norovirus gastroenteritis can be discharged to their place of residence.”

Lillian Burns: That works.

Dr. Taranisia MacCannell: All right, great. Jeff?

Jeff Hageman: That's fine.

Dr. Taranisia MacCannell: Okay, if I may I'll go on to Number 13. So these are again minor changes and this was actually not related to a key question, but we wanted to make sure that the language was reflective of the strength of the recommendation as a Category II.

So it originally started out reading, "Implement systems to designate patients with symptomatic norovirus and to notify receiving healthcare facilities or personnel prior to transfer of such patients within or between facilities."

And now it reads, "Consider implementing systems to designate patients with symptomatic norovirus and to notify receiving healthcare facilities or personnel prior to transfer of such patients within or between facilities."

Dr. Gary Roselle: This is Gary Roselle.

Dr. Patrick Brennan: This is one of those where I had a problem with the word consider. You know, this just seems so, you know, the transfer of information here just seems so fundamental to the delivery of care here that to say consider it just doesn't seem to make sense.

Dr. Taranisia MacCannell: Agreed. I mean, there was no evidence, so for example a reader that wanted to identify the evidence that supported it would not be able to determine where this information came from because it was sort of brought in from other guidelines.

So yes, it totally made a lot of sense to keep it as a, you know, more of an instructional recommendation as opposed to something that's a little less strong.

But unfortunately without having the evidence to support it there's nothing we have to basically say, "Here are your references to say that this has worked in previous cases."

Dr. Gary Roselle: This is Gary Roselle. I think that there's a difference between having evidence, I mean, you're right. Who's going to do the study about hiding someone with infectious diarrhea going to the next place?

I think actually it comes closer to a moral imperative. It's hard to imagine not telling for instance a long-term care facility that you're sending them someone with symptomatic norovirus disease, which is what it says here, and you didn't tell them.

It's - I don't think that's very optional. And the fact that there's no data is correct which is like, you have to tell them it's a Category II. But I just don't - I think this would set the wrong stage for taking care of people.

Craig Umscheid: This is Craig Umscheid. If I could make a comment about the categories and quality of evidence it might help a bit.

Dr. Patrick Brennan: Craig, go ahead.

Craig Umscheid: I worked with Tara in a writing group on the methods and the writing of the Guideline, and one thing to keep in mind is that the category of recommendation is the strength of a recommendation and it has nothing to do with the evidence.

If there are net benefits or net harms then it's a Category I. So if we see only benefits in informing people and we can't think of any harms that are possible, it sounds like there should be a Category I. And if there's not good evidence to back it up then it would probably be a IB.

Sheila Murphey: This is Sheila. I certainly can't put my finger on a regulation, but I would wonder if this doesn't fit under IC. Don't institutions transferring patients have some obligations under the third party payers like Medicare and so on to provide the necessary information to the receiving facility? Maybe we can find a way to make this a IC?

Russell Olmsted: Yes Sheila, this is Russ. There is a Joint Commission, you know, requirement that speaks to inter-facility communication so...

Jeannie Miller: And this is Jeannie from CMS and I completely agree, and I would recommend the language say, "Implement a system or systems."

Dr. Patrick Brennan: Yes.

Lillian Burns: This is Lillian Burns. I totally agree with the implement.

Dr. Patrick Brennan: Okay, I think we'll try to make this IC and wordsmith it accordingly. We are about 2/3 of the way through the call and about 1/3 of the way through the issues.

So we'll try to move as quickly as we can through the rest and we may be faced with having to schedule another call to get this, unless we can get all the way through and field public comments as well.

So that completes the section on Patient Transfer and Ward Closure. Are there any further comments or objections to the recommendations as they stand now?

All those in favor of approving Items 12 and 13, aye. Any opposed? Any recusals? Okay, thank you. Jeff, want to go to 14?

Jeff Hageman: I'll let Tara continue.

Dr. Taranisia MacCannell: Okay, so this was a change from basically language that was supportive of Category IB that - in consideration of the existing FDA Food Code.

This language was changed to reflect the IC particularly with food handlers, so that covers those who are performing food preparation in healthcare. So the original recommendation read, "To prevent food-related outbreak of norovirus gastroenteritis in healthcare settings, food handlers should perform hand hygiene prior to contact with or the preparation of food items and beverages."

And then to reflect the Food Code by FDA, it is now reading, "To prevent food-related outbreaks of norovirus gastroenteritis in healthcare settings, food handlers must perform hand hygiene prior to the - prior to contact with or the preparation of food items and beverages."

And that's now a Category IC to be in line with the regulations under the Food Code.

Dr. Patrick Brennan: Okay, so there's only a one-word change in that, right?

Jeff Hageman: A should to a must.

Dr. Patrick Brennan: A should to a must, okay. All right, next item.

Dr. Taranisia MacCannell: All right, so again minor changes. This is basically moving from another Category IB to a Category IC. And so personnel - again this is following the FDA Food Code and there's a link under the column of Clarification.

So, "Personnel who prepare or distribute food or work in the vicinity of food should be excused from work if they develop symptoms of acute gastroenteritis consistent with norovirus infection.

Personnel should not return to these activities until a minimum of 48 hours after the resolution of symptoms or longer as required by local health regulations."

And so our evidence has suggested IB but I specified here that there is actual language by FDA. So now it reads, "Personnel who distribute - who prepare or distribute food or work in the vicinity of food must be excluded from duty if they develop symptoms of acute gastroenteritis.

Personnel should not return to these activities until a minimum of 48 hours after the resolution of symptoms or longer as required by local health regs."

Dr. Patrick Brennan: Okay.

Dr. Taranisia MacCannell: Yes. And so yes, as Jeff said, one word change.

Dr. Patrick Brennan: Okay.

Dr. Taranisia MacCannell: All right, so again - so then Issue 16 is just a minor change to - for clarity and consistency with the recommendations or the category. So 3.B.2 says, "All shared food items for patients or staff should be removed from clinical areas for the duration of the outbreak."

There was some comments on providing examples that, you know, if you - as we saw in the evidence and sort of in clinical practice, the reservoir for norovirus can be multiple things and there really isn't a discreet bunch of, you know, groups of food that really contribute more or less to norovirus.

It's, you know, a lot of things. So the new recommendation states, "Remove all shared or communal food items for patients or staff from clinical areas for the duration of the outbreak."

Dr. Patrick Brennan: Okay, so communal is the big change. Any comments? Okay, 17.

Dr. Taranisia MacCannell: So that's the end of that section PJ.

Dr. Patrick Brennan: Okay, right. Any further comments? Okay, all those in favor of the minor changes to Items 14, 15 and 16, say aye. Any opposed? Any recusals? Okay, let's go on to Diagnostics then.

Dr. Taranisia MacCannell: Okay, great. So Issue 17 again is a wording change for clarity and consistency of the wording for the recommendations. So 1.C.1 said, "Develop and institute facility policies to enable rapid clinical and virological confirmation of suspected cases of symptomatic norovirus infection and promptly implement control measures to reduce the magnitude of outbreaks in a healthcare facility."

And that was a Category II based on our evidence. And so change to the wording is, “Consider the development and adoption of facility policies to enable rapid clinical and virological confirmation of suspected cases of symptomatic norovirus infection while implementing control measures to reduce the magnitude of a potential norovirus outbreak.”

Dr. Patrick Brennan: Comments? Okay, Number 18.

Dr. Taranisia MacCannell: Okay, so again here - and so Jeff has advised me to, you know, go with more of the changes rather than read all of the text. So that'll probably save a little - us a little time.

Again - so to be consistent with the wording in the Category of evidence that was assigned to this recommendation, we have a change to 2.C. And so that is, “Use effective protocols for laboratory testing suspected - suspecting - laboratory testing of suspected cases of viral gastroenteritis (e.g., refer to the Centers for Disease Control and Prevention’s most current recommendations for norovirus diagnostic testing).”

So we changed it because we don’t use the word should in any of our guidance that follows the new grade methodology, so that was basically the only change.

Dr. Patrick Brennan: Okay, any comments?

Dr. Taranisia MacCannell: And that concludes that section.

Dr. Patrick Brennan: All those in favor of adopting the recommendations in Items 17 and 18, say aye. Any opposed? Any recusals? Okay, thank you. Personal Protective Equipment, Item 19.

Dr. Taranisia MacCannell: Okay, so this one was basically - there is some comments that had come through, through the Federal Register to - as to whether visitors are excluded from the provisions of using PPE under contact precautions.

So the original recommendation read, "If norovirus infection is suspected, healthcare personnel and visitors should wear PPE to reduce the likelihood of exposure to contamination by - or contamination by vomitus or fecal material when caring for patients with symptoms of norovirus infection.

Glove and - gloves and gowns are recommended for the care of patients on contact precautions and according to standard precautions for any contact with body fluids, non-intact skin, or contaminated surfaces."

So we decided in order to be consistent and the fact that the 2007 Isolation Guidance do not have anything really explicit in terms of using PPE in the same way as healthcare personnel, we changed it to still include visitors but just not explicitly sort of identify them in the recommendations.

But - so now it reads 1.C.4, "If norovirus infection is suspected, individuals entering the patient care area are recommended to wear PPE according to contact and standard precautions (i.e., gowns and gloves, and among vomiting patients, face masks) to reduce the likelihood of exposure to infectious vomitus or fecal material." The category is the same at IB.

Dr. Patrick Brennan: Comments? Okay, Item 20. Jeff and Tara, I didn't see any difference between the Federal Register Version and the Revised Text.

Dr. Taranisia MacCannell: Oh, you mean on 1.C.4?

Dr. Patrick Brennan: No, 20.

Dr. Taranisia MacCannell: Oh, 20. Actually yes, you're right.

Dr. Patrick Brennan: Was something cut and pasted erroneously?

Dr. Taranisia MacCannell: Let me just...

Jeff Hageman: I'll verify.

Dr. Patrick Brennan: Okay, why don't you verify Jeff, and Tara why don't you go on to 21.

Dr. Taranisia MacCannell: Okay.

Jeff Hageman: Yes, I found it PJ. You can stay on that one. So the original text did not have the term - so in the second column anticipated wasn't in the actual Federal Register Version.

Dr. Patrick Brennan: I see, okay.

Jeff Hageman: So it just said, "protection if there is a risk of splashes."

Dr. Patrick Brennan: Okay.

Jeff Hageman: So anticipated was added.

Dr. Patrick Brennan: Okay. Okay, so that's that. Comments on 20? Okay, go ahead to 21.

Dr. Taranisia MacCannell: Okay, so this is a combination of the previous req that I had read to you which was 1.C.4, which was under Item 19 and the removal of 3.C.2.b which is as follows:

So, “Clinical and environmental services staff, as well as visitors, should wear gloves and gowns when entering areas under contact - under isolation or cohorting.”

And so as you can see some of the comments that came in said to recommend the clarification of this. Is it the use of PPE upon - in use - in discreet patient rooms or what does it mean by areas under isolation or cohorting?

And so actually we - despite having those comments we actually collapsed that recommendation to be included in 1.C.4. So I can just read that again to you just in case so...

Dr. Patrick Brennan: That’s Item 19, right?

Dr. Taranisia MacCannell: Correct, yes. So then this would basically have encompassed - so the previous one to say specifically that, “Clinical and environmental services staff and visitors should wear the appropriate PPE.”

That is now covered under 1.C.4 which is, “If norovirus infection is suspected, individuals which includes environmental services and then, you know, staff as well as visitors are recommended to wear PPE,” and then it goes forward from there.

Dr. Patrick Brennan: Okay, so everybody is included under an individual.

Dr. Taranisia MacCannell: Correct.

Dr. Patrick Brennan: Okay.

Dr. Gary Roselle: This is Gary Roselle. I'm confused again - 1.C.4 in the actual document, is that staying or going or what is that going to turn into?

Dr. Taranisia MacCannell: 1.C.4 basically had a - the difference between the old 1.C.4 and the new 1.C.4 is that we took out the specification that it includes - PPE donning includes only healthcare personnel and visitors to now all individuals, which encompass the recommendation of 3.C.2.b which specified clinical and environmental services staff and visitors.

Dr. Patrick Brennan: So Gary, 1.C.4 stays and 3.C.2.b goes.

Dr. Gary Roselle: But it's the new 1.C.4.

Dr. Patrick Brennan: Correct.

Dr. Gary Roselle: Not the old 1.C.4 that was on - in the original document.

Dr. Patrick Brennan: That's right.

Dr. Taranisia MacCannell: Right.

Dr. Gary Roselle: Okay, because that was the one I didn't like so this looks better. All right.

Dr. Patrick Brennan: Okay.

Dr. Taranisia MacCannell: This now just applies to anyone who's basically on approach to patients on isolation.

Dr. Patrick Brennan: Patient who has visitors, environmental staff are both consumed under the word individual.

Dr. Gary Roselle: No that's good, I just was confused about who was where.

Dr. Patrick Brennan: Yes, okay.

Dr. Taranisia MacCannell: The - Issue Number 22 is new. It was, you know, it was drawn up as the result of, you know, potentially identifying another option for supplemental outbreak control and that was the implementation of universal gloving.

There is no information to support this for norovirus. There are a few select studies particularly with VRE and there was a newer one that has problems that I've seen for C. difficile.

So it's a consider and it's basically a no recommendation but certainly just out there for the consideration of healthcare facilities. So it reads as Issue 22, "Consider the implementation of Universal Gloving (e.g., routine use of gloves for all patient care) during norovirus outbreaks."

And that is not supported by direct evidence but, you know, in consideration it could provide net benefits.

Dr. Patrick Brennan: Okay.

Lillian Burns: Okay.

Dr. Patrick Brennan: That is the end of that section, right?

Dr. Taranisia MacCannell: Yes.

Dr. Patrick Brennan: Okay, any comments or questions? All those in favor of approval of the four items in the Personal Protective Equipment section, say aye. Any opposed? Any recusals? Okay, why don't you go on to Environmental Cleaning then, Item 23?

Jeff Hageman: I just wanted to - so we have 15 minutes left on the call, about 15 minutes. The Environmental section is quite large, the number of comments. There's not as many comments to go over for Staff Leave and Policy and Visitors.

In order to leave enough, you know, I don't - it does not look like we're going to get through all of the issues on this call and leave enough time for public comments.

Dr. Patrick Brennan: So maybe we should stop here Jeff. We're at - and if there are not a significant number of questions we could come back and perhaps go through Education or Communication and Notification. Do you want to take - or Visitors. Should we take questions now?

Jeff Hageman: Yes, I think we can go through - we can probably get through Staff Leave and Policy. That's just two issues, and then we can take comments. And then we'll have to schedule another call to finalize the rest of the items.

Dr. Patrick Brennan: Okay.

Jeff Hageman: So that would be Number 34 is the issue.

Dr. Taranisia MacCannell: Okay, so with 34 under Staff Leave and Policy we reviewed the proposed recommendations by - so this is recommendation 3.C.A and 3.C.3 - sorry, 3.C.3.a and 3.C.3.b.

And we also made changes to the wording for consistency dependent on the category of evidence - recommendations, sorry. So 3.C.3 was, "Facilities should develop and adhere to sick leave policies for healthcare personnel symptomatic with norovirus infection.

Ill staff members should be excluded from work for a minimum of 48 hours after the resolution of symptoms. Once staff return to work, adherence to hand hygiene must be maintained."

Now as - now it reads - just looking to see if there's any other additional things I can add to this for you.

Dr. Patrick Brennan: It's basically minor wordsmithing really.

Dr. Taranisia MacCannell: Correct, just putting it into two things for clarity. And so, "Develop and adhere to sick leave policies for healthcare personnel with symptomatic norovirus infection."

And then the new one is, "Exclude ill personnel from work for a minimum of 48 hours after the resolution of symptoms and continuing to adhere to strict hand hygiene once work has - personnel have returned to work."

Dr. Patrick Brennan: Okay.

Dr. Taranisia MacCannell: And so both of them were Category IB.

Dr. Patrick Brennan: Okay, comments? Okay.

Russell Olmsted: Just - PJ, this is Russ - just a thought on the 3.C.3, Sick Leave Policies for Healthcare Personnel. Just concerned that you'd have to interpret this narrowly, but if I'm not lab confirmed norovirus so that - do we want to add the suspected or confirmed or...? I don't know.

Dr. Taranisia MacCannell: This is for 3.C.3?

Russell Olmsted: Yes, for the symptomatic address.

Dr. Taranisia MacCannell: Or it could say, "with symptoms consistent with norovirus infection."

Lillian Burns: That should work.

Dr. Taranisia MacCannell: Right, because we've used that elsewhere.

Dr. Patrick Brennan: Okay.

Russell Olmsted: That's fine with me.

Dr. Taranisia MacCannell: So, "Develop and adhere to sick leave policies for healthcare personnel who present with symptoms consistent with norovirus infection."

Dr. Patrick Brennan: Right.

Dr. Taranisia MacCannell: Okay. All right, Issue 35 was a clarification based on a Federal Register comment on defining patient cohorts for staff. And so the original recommendation read, "Establish protocols for staff cohorting in the event of

an outbreak of norovirus gastroenteritis, where staff care for one patient cohort on their ward and do not move between patient cohorts.”

There was some question about whether this is for the shift that they work or for the entire length of the outbreak, and we didn't want to really fix the interpretation to one thing.

And - nor did we have anything in the evidence to suggest, you know, whether cohorts were looked after for a very short period of time and then, you know, reshuffled and, you know, basically staff assignments changed to reflect that - the - sort of the dynamic, you know, evolution of a outbreak.

So to be more general we said, “Establish protocols for staff cohorting in the event of an outbreak of norovirus gastroenteritis. Ensure staff care for one patient cohort on their ward and do not move between patient cohorts (e.g., patient cohorts may include symptomatic, asymptomatic exposed, or asymptomatic unexposed patient groups).” And that was a Category IB.

Dr. Patrick Brennan: Okay, comments on that? Okay, Jeff should we just take questions on the sections that we reviewed?

Jeff Hageman: That's right.

Dr. Patrick Brennan: So that would be Items 1 to 23 and 34 and 35. Let's approve 34 and 35 first or vote on them at least. So on Staff Leave and Policy, Items 34 and 35, all those in favor of the recommendations as read. Any opposed? Any recusals? Okay, let's go to questions.

Jeff Hageman: So operator we can open up for questions.

Coordinator: Thank you. If you would like to ask your question, please press star then 1 on your phone. You will be announced prior to asking your question. To withdraw your question, press star 2.

Again please press star then 1 at this time to ask your question. Ensure your mute button is turned off to record your name. One moment please. At this time there are no questions.

Dr. Patrick Brennan: Okay, let's go back to the document then and try to do - try to pick up at Item 36.

Dr. Taranisia MacCannell: Okay.

Dr. Patrick Brennan: Actually Jeff, you want to do that or do you want to go to 38?

Jeff Hageman: Given that we have around five minutes, I mean, let's just go ahead and do 38.

Dr. Patrick Brennan: Okay.

Jeff Hageman: And then we can probably cover 39 and 40 also.

Dr. Patrick Brennan: Yes, yes. Okay, so let's do 38.

Dr. Taranisia MacCannell: All right, so this is just a minor wording change. 3.C.8.a under Education is, "Healthcare facilities should provide education to staff, patients, and visitors about symptoms preventing infection, and the modes of transmission of norovirus at the start of and throughout the duration of an outbreak," Category 3 - IB.

Again as you saw this is the word should in there, so we took that out. And so now it states, “Provide education to staff, patients, and visitors about symptoms preventing infection, and modes of transmission of norovirus at the start of and throughout the duration of a norovirus gastroenteritis outbreak.”

Dr. Patrick Brennan: Comments? All those in favor of approving Item 38, say aye. Any opposed? Recusals? Okay, let’s do 39.

Dr. Taranisia MacCannell: All right, again another minor change just to remove the term norovirus gastroenteritis. So anyway - but I think we made a change - we were considering whether this recommendation should just be a statement because all outbreaks of, you know, public health importance should be reported to local and health - local and state health departments.

And so originally it read - originally it reads, “Notify appropriate local and state health departments as required by state and local public health regulations, if an outbreak of norovirus gastroenteritis is suspected.”

And so the way that we accommodated that, you know, so that it basically still includes, you know, a specific guidance for norovirus but then also enforce the idea or, you know, remind people that all outbreaks need to be notified to the state and local, that we said, “As with all outbreaks, notify appropriate local and state health departments as required by state and local public health regulations, if an outbreak of norovirus gastroenteritis is suspected.” And that is a IC.

Dr. Patrick Brennan: Comments? Okay, and Item 40.

Dr. Taranisia MacCannell: Okay, so this one actually is a new recommendation. It’s - well I guess you’d consider it a major change because it wasn’t there before. It’s just

the address - addressing the notification of patients and visitors at the onset of an outbreak.

We felt this was an important thing to - that was potentially an oversight with the original evidence review and so we felt it was useful to include it as a IC. So, "Provide timely communication to personnel and visitors when an outbreak of norovirus gastroenteritis is identified and outline what policies and provisions need to be followed to prevent further transmission."

And as we felt that this was a standard of care and of net benefit that this would be a IB.

Dr. Patrick Brennan: Comments on Item 40?

Stephen Ostroff: Yes, this is Steve Ostroff. Should it be, "when an outbreak of norovirus gastroenteritis is identified," or should it be suspected?

Dr. Taranisia MacCannell: I think that, you know, if you notify or basically identify an outbreak as opposed to cases of norovirus gastroenteritis, you know, the public - sort of public notification to visitors would probably be more useful if you actually knew what, you know, knew that it was definitively a norovirus outbreak.

Stephen Ostroff: Will it be timely if you wait until it's identified as opposed to suspected?

Dr. Taranisia MacCannell: True. Let me think. I mean, we could put in suspected just because it's sort of qualified by the fact that you have an outbreak and normally, you know, an outbreak at some point in time would be confirmed.

Stephen Ostroff: Or it may not be confirmed and then you don't have to do it anymore.

Lillian Burns: I think - this is Lillian. I think suspected would be the better word because sometimes by the time you get back all of the test results, working at a community hospital it takes a little longer sometimes to get the results back even though the clinical symptoms are consistent with...

Dr. Patrick Brennan: If it's suspected does it become a II rather than a IB?

Lillian Burns: That's a good question.

Dr. Taranisia MacCannell: No. No, it wouldn't because it's just the point in which you - it doesn't change what...

Susan Huang: Well I would just say that this crossed my mind earlier but it relates to, you know, the ones that you described above as well. I mean, there are many places then in this Guideline where the intent is for it to be than if it's suspected.

So I just want to be thoughtful about whether it's okay to just leave it as is knowing that we all understand that there are suspected outbreaks versus having to change it throughout the document.

Dr. Taranisia MacCannell: I think, you know, where sort of this is coming from is when you actually sort of put it out there publicly that you have an outbreak within a facility that you, you know, you have an identification.

If you're saying, "We have a norovirus gastroenteritis outbreak," but yet have no evidence to suggest that at this time because, you know, there's a lot of - there's sort of these downstream effects I think of being able to announce a

particular type of outbreak without, you know, really having much evidence to support it at that point.

Lillian Burns: This is Lillian. I think we kind of - I think the intent of this statement is known. I mean, we could say suspected or identified, but I think the intent is if people feel that they have an outbreak of norovirus they're going to notify all the appropriate individuals.

Stephen Ostroff: Yes, I - and this is Steve Ostroff. I think it's a little inconsistent to say that you should provide timely communication and then at the same time say it's okay to wait until you've definitively identified it as being norovirus.

Lillian Burns: Yes.

Dr. Patrick Brennan: How many would like to change the word to suspected?

Stephen Ostroff: I would. I would.

Dr. Patrick Brennan: I would to.

Susan Huang: I would.

Russell Olmsted: I agree.

Sheila Murphey: I think it's a good idea.

Dr. Taranisia MacCannell: I'd agree with that.

Sheila Murphey: Yes.

Dr. Patrick Brennan: Okay, so we have a majority of the members. So we'll change the word to suspected in Item 40. So for Items 39 and 40, all those in favor of the recommendations as read, say aye. Any opposed? Any recusals?

Susan Huang: PJ, I think though that suggestion has ramifications for the other parts of the Guideline.

Dr. Patrick Brennan: To switch to suspected.

Susan Huang: Yes, I think that for example 38 would be affected wouldn't it?

Dr. Patrick Brennan: I think it says suspected doesn't it?

Lillian Burns: Thirty-nine says suspected.

Dr. Patrick Brennan: No, 38 doesn't, 39 says suspected. Yes.

Susan Huang: I would just make sure that we - that it's consistent and if it becomes a gray point where now there are recommendations for things that we may not feel strongly about for suspected, then we'll have to wrestle that.

Dr. Patrick Brennan: Okay.

Lillian Burns: Right.

Dr. Patrick Brennan: Okay, we've covered everything except Items 24 through 33 and I think 36 and 37, is that right Jeff?

Jeff Hageman: Right, the Environmental Cleaning section and the Visitor section.

Dr. Patrick Brennan: Okay, so I apologize to everyone for not getting through this faster. We should have scheduled more time, but we'll have to schedule another public teleconference to cover those items and then make a final vote of approval on the document.

Jeff Hageman: And so we'll be sending out information about that shortly to get that next public call scheduled.

Dr. Patrick Brennan: Okay, and we'll try to do that as soon as possible. Okay.

Stephen Ostroff: Thank you.

Dr. Patrick Brennan: Thanks everyone.

Lillian Burns: Thanks.

Dr. Patrick Brennan: Bye-bye.

Dr. Taranisia MacCannell: Bye.

Sheila Murphey: Bye-bye.

END