NATIONAL QUALITY FORUM

Moderator: Sheila Crawford
July 30, 2015
1:00 p.m. ET

OPERATOR: This is conference #: 25710693.

(Shawnn Bittorie): Good day everyone. Welcome to the Renal Post Comment Meeting. Please note, the call is being recorded to day and all public lines will be muted during this call. Committee members, please be aware that your lines are open for the duration of the call today, so please be sure to use your mute button when you're not speaking or presenting, and please, do not place the call on hold at any time. You will also need to keep you computer speakers turned down or off because you are joining by an open phone line.

I'd also like to draw your attention to the links area to the side of the slide window. You'll find resources relative to today's meeting located there.

Today's meeting does also include polling and live voting for our committee members only. Additional instructions will be given shortly for that.

During the screen sharing portion of today's meeting, you can also enlarge your view by clicking the enlarge button above the screen share window.

And now, it is my pleasure to welcome you to today's meeting. Let's get started.

Poonam Bal: Thank you so much, (Shawnn). This is Poonam Bal, the project manager on the Renal project. I don't know if you recognize my voice anymore after all these months apart, but we're very excited to continue this great work.

Just a brief agenda items, you know, we'll start with the welcome and introductions. We'll do a roll call in a second to see who's on the line. We'll also – We will be reviewing and discussing comments. I said in the e-mail that we are only doing some of the major themes that appear from the comments and not going over all comments. If any time, a committee member would like to discuss a comment that was not put into the memo, you can definitely feel free to let us know.

We are asking that just as we did in the follow up call to the in-person meeting that if you would like to speak, please raise our hand in the webinar system. And if you – does everyone remember how to do that? If you don't, speak now and I can go ahead and go over it real quick.

Joshua Zaritsky: I can't seem to reach the webinar. I just got a blank page. Is that normal?

(Off-Mike)

Poonam Bal: I'm sorry, who is that speaking?

Joshua Zaritsky: It's Joshua Zaritsky.

Poonam Bal: Hi, Joshua. (Shawnn), do you mind …

(Shawnn Bittorie): Yes.

Poonam Bal: … would you get that fixed?

(Shawnn Bittorie): Sure. Joshua, we're going to access you out for just a minute and I'm going to give you …

Joshua Zaritsky: OK.

(Shawnn Bittorie): … some help and we'll be right back to the call …

Joshua Zaritsky: Sure …

(Shawnn Bittorie): … shortly.

Joshua Zaritsky: … sure.

Poonam Bal: Thank you so much.

Male: How do you vote again?

Poonam Bal: Voting will go over in a little bit, and (Shawnn) will give better instructions once we actually start voting.

Male: OK, thanks.

Poonam Bal: But for the hand raising, that's just for when you want to speak, not for voting purposes.

Male: I see. So, all right. How do you a hand writing or the hand raising?

Poonam Bal: So if you look to the left of your screen, there will be a little raise hand option underneath where it says attendees.

Male: Got you.

Poonam Bal: All right. So, moving forward, after we review and discuss the comments, we will – there are two measures where we did not reach consensus which we do need to vote on and hopefully come to consensus. There we had – both developers have given new information for you and we'll go over that with you and then see – and then we will revote. We'll start with an overall vote and if we're able to get consensus there, we'll move forward. If the committee feels that in order to do that overall vote, they need to go a little – they need to go back to some other categories, we can, but, you know, we usually prefer that you vote on the overall vote.

Moving on from there, we'll go into – several developers have requested that you reconsider their measures for endorsement. We did have seven measures that were not recommended for endorsement. Six of the seven measures have reconsideration request in. We'll go over those requests with you, what, you know, what the – why the developers feel that you should reconsider their measure and then you'll decide if you want to vote or not. So unlike the consensus not reached measured, you do not have to revote on those measures. It is only if you feel that the new information provided through

comments and the developer responses if you want to vote on those or not. And then as general, we will do a public member commenting and we'll update you on next steps.

We do have another call next Monday from 3 to 5. We're hoping we can get through a good chunk of this and get to that call. If we don't need that call, we'll cancel it as necessary. But we do have a lot to cover, so let's be very conscious of time and try to move things through – things quickly as possible.

So with that said, I'll ask Severa to move it over to the memo. Also, Alexandra, our project analyst, for – she's going to be out for a couple of months. So we do have a new project analyst, Severa, just so you guys can get familiar with her as well.

So, as I said, the purpose of this call is to really review and discuss those comments that we received during the post-evaluation public member comments to review measures where consensus is not reached, determine whether we consider fruition for any measures or any course of action is warranted, and then also to discuss a new related and competing measure. We were not able to discuss this during the post-follow up call because there were a lot of decisions that were not really determined by then. And so based off of this call, we hope to have final decisions on those consensus not reached measures and also those reconsideration measures so we can see what needs to be discussed for related and competing.

We don't expect to be able to get to that today, but we're always prepared to do what is needed. So, you know, if we go through everything very quickly and we need to discuss it during this call, we definitely can. But right now, the plan is not to discuss it during this call.

Moving down, you hopefully have had a chance to read the commenting memo and have had a chance to read the draft report that we posted for comments a while ago. And so, moving forward, where is that?

So for comments received, you know, the table that we send out to you did contain pre-validation comments. So these were comments that we received before you met and it – we just put that there for your information. Those

were all given to you before your in-person meeting for your consideration. But the committee does not respond to those comments. We do have the post-evaluation comments which we received in this last comment period after your recommendations are made, and that's where really our focus is. Anything that was in the table, we do have responses already in there for you for consideration. Both of them were supported of your decisions and thus (inaudible).

I'm sorry. Please make sure that your phone is on mute and your computer is on mute as well, otherwise we will get an echo.

Thank you.

So with that said, we are going to go ahead and start with actually discussing the comments, some of the major themes and comments we received. And I'll …

(Sarah): Actually, Poonam, we need to do a roll call just to get …

Poonam Bal: Oh, yes.

(Sarah): … on the record that we have a quorum.

Poonam Bal: Sorry about that, (Sarah). Good point.

All right, so I'll ask Severa to go ahead and start doing a roll call.

Severa Chavez: Good afternoon, everyone. This is Severa and I'm glad to be joining this team. So I'll start with the co-chairs. Constance Anderson?

Constance Anderson: I'm here.

Severa Chavez: Peter Crooks?

Peter Crooks: I'm here and I just like to let the committee know that this meeting will be run by Poonam and (Sarah). Connie's job is to lay the hammer down and my job is to support her if we're not behaving ourselves. Thanks.

Male: So you're the muscle?

Peter Crooks: Connie is the muscle. I'm standing behind her.

(Crosstalk)

Constance Anderson: Yes, and thanks a lot.

Severa Chavez: OK. Ishir Bhan? Lorien Dalrym?

Poonam Bal: Rymple.

Severa Chavez: Rymple?

Lorien Dalrymple: I'm here.

Severa Chavez: Thank you. Elizabeth Evans?

Elizabeth Evans: I'm here.

Severa Chavez: Michael Fischer?

Michael Fischer: I'm here.

Severa Chavez: Stuart Greenstein? Debra Hain?

Debra Hain: Yes, I'm here.

Severa Chavez: Lori Hartwell?

Lori Hartwell: I'm here.

Severa Chavez: Thank you. Frederick Kaskel? Myra Kleinpeter? Alan Kliger?

Alan Kliger: Here.

Severa Chavez: Mahesh Krishnan?

Mahesh Krishnan: Here.

Severa Chavez: Lisa Latts? Karilynne Lenning?

Karilynne Lenning: Good afternoon, I'm here.

Severa Chavez: Good afternoon. Franklin Maddux?

Franklin Maddux: Here.

Severa Chavez: Andrew Narva?

Andrew Narva: Here.

Severa Chavez: Jessie Pavlinac? Michael Somers?

Michael Somers: I'm here.

Severa Chavez: Dodie Stein?

Dodie Stein: I'm here.

Severa Chavez: Bobbi Wager? John Wagner?

John Wagner: Here.

Severa Chavez: Joshua Zaritsky?

Joshua Zaritsky: Here.

(Shawnn Bittorie): And Severa, just to let you know, we do also have a couple of folks that were accessed out for help. Frederick Kaskel is one of them. You do have him on the call now.

Poonam Bal: OK …

Severa Chavez: Thank you, (Shawnn). And anyone else who just joined us?

Poonam Bal: OK. All right.

Severa Chavez: OK.

Poonam Bal: Thank you so much and that's how we (page) our P.A. to make them do the roll call. So, thank you everyone.

Male: So we have a quorum, right?

Poonam Bal: Yes, we do have a quorum.

Male: OK, thank you.

Poonam Bal: And before each vote, we'll make sure we do have a quorum. I just want to remind everyone that conflict of interest still apply. So if there was a measure that you had a conflict with during the in-person meeting, you still cannot be part of the discussion or the voting process for that measure. And before we discuss each measure, I will announce who those people are. So with – and then we'll let you know if the voting quorum is there.

So with that said, I'll pass it over to (Sarah).

(Sarah): Thank you, Poonam, and thank you all for joining us on I think no matter where you are in the country (inaudible) hot afternoon. And, you know, as Poonam indicated, there – our process for overboard assessing comments is that we provide and over – a general overview of the comments and any themes that we picked up as staff.

And in the Excel table that you had as one of your attachments, we proposed some responses to any of the comments. A lot of the comments were supportive of your decisions at the in-person meeting or at that subsequent conference call. And those, you know, we really don't feel the need to discuss.

But we do pick up the – We did pick up a couple themes which we wanted to briefly go over and then you also have the opportunity for any of the comments that we didn't pick up in the themes, if any of the committee members wanted to talk about those further, we would just need you to raise your hand and tell us which comment you wanted to discuss and we could certainly do that.

The process here as well is once we go over into these public comments and specifically the themes, you'll notice starting on page – as you get through the themes, so starting on page three of your memo, there are some measure specific comments. And what we would ask for any of the measure specific – what we would ask for any of the measure specific comments is that you would – if there's something that you want to decide in on and use those measures just to comment again, you would need to let us know. You'll notice for a lot of those, it says that the committee has the option to revote on any of those measures. It is not a requirement. It's more of a did something come out of public comments, therefore you think you need to reconsider your original vote or the original recommendation.

I will tell you the vast majority of committees don't reopen their votes, but we are also not asking you to, you know, there's no peer pressure involved here. It's just a matter of if you feel that – if something came up in the public comments that you didn't consider during your vote that you feel warrant to revote, we're happy to do that.

So with that, we felt that there were a couple of overall themes to this. So – And let me back up for a minute. We received a total of 97 comments which of course we expected the renal group to be very active in commenting. However, out of these 97 comments, there were only really four organizations or people who commented. So it really wasn't a significant amount of public comments and, you know, we don't use it as a theme, but in reality, the overall – an overarching theme was that some of these comments, there was a lot of support for the decisions made by the committee during the in-person meeting and the current disposition of a lot of the votes as well as comments from folks understanding that you would have the opportunity to discuss some of these measures that were not considered or not recommended during the first wave of voting.

So in looking at the other themes, so these are the overall support for your decisions to date, we're – a lot of folks I would almost say commended the committee and also CMS, University of Michigan and all of the developers in recognizing when you guys as a committee that there maybe some

adjustments that should've been made for the measures whether they were oversights in the submission or – OK, somebody's phone is not on mute.

But anyway, so – but there were – I would say, overall, you know, we had a lot of comments that really just kind of said, you know, we approve the recommendation of the committee as long as those upper boundaries are removed on specific measures. And so those measures were 0249, 0318, 2704, and clarification as well on those measures and we delineated there at the bottom of page two that the upper spKt/V requirement be removed and then that the developers look closely at frequency of dialysis visits to ensure clarification and consistency but also clarifications internally with the measures but then with the guidelines and standard care.

And both in their responses to public comments and then in subsequent conference calls we've had with the developers, we can confirm as staff that these changes have been made in the measure submission.

So I'll stop there and see if anybody had any additional comments or questions about that overview.

OK, I don't see any little hands.

And then the next area that – and, gosh. The next area that was – that we identified as a theme was the – dialysis access considerations. And really it's reviewing the comments as well as going back and looking at the transcript and being involved in the meeting, there was considerable discussion with the measure that are promoting A.V. fistula and A.V. graft over catheters minimizing the use of catheters, and the overall consideration of sort of elderly and other special populations where catheters might be appropriate, as well as comments about specifically between A.V. graft and A.V. fistula and ensuring those were counted as well and considered by the developers.

And, you know, as staff when we went through the comments, we've really felt that you all had talked about this quite substantially during the meeting, and so we acknowledged that, you know, the committee has discussed those and they – those issues were considered in the overall voting of the measures,

but we didn't feel that there was really any additional new information brought forward that would justify reconsideration of any of the measures.

So, you know, our proposed committee response there is that there was significant discussion and when you evaluated the measures, you did consider these situations. I also feel that there were some, you know, I feel that the developers heard loud and clear these were areas in consideration that they should consider in future iterations of these measures.

It looks like Alan has a comment on that?

Alan Kliger: So I was on what you had mentioned previously, you talked about the elimination of the upper limit which it looks like they did. But there's still language as I see it that says three or more treatments a week. So I just want to clarify that that variable frequency is still there because if that's so, then I think we still have a flaw.

(Sarah): And I'm going to ask – And I think, Joel, you're on the phone. If you can – Or somebody from the University of Michigan, I'm not sure which, maybe updates to those measures and – because those were some of the other considerations where those changes made.

(Off-Mike)

Joel Anders: Hello, this is Joel. So I can confirm with it with regard to the Kt/V measures, we removed the upper limit. With regard to the P.D. effort, the hemodialysis Kt/V measure, we had addressed the issue of – the measure then previously included patients who are dialyzed four times in a week, by limiting the measure solely to patients who are dialyzed three times a week. And KECC can respond necessarily to the details. Can you clarify where in the specifications you're seeing this?

Alan Kliger: It just flashed eye in what you're showing on the screen when you were looking at the repairs that you just discussed. It's not there right now.

(Sarah): Poonam, have you moved the screen down a little bit or …

Female: Actually, it's on page three at the top where it says the frequency of dialysis visits been clarified and consistent across measures. And they were lowered from four visits a week to three visits or greater a week which is …

Alan Kliger: Right.

Female: … conflicting them.

Alan Kliger: Right. It still says three or greater, so it's still a variable frequency.

Claudia Dahlerus: Hello, this is University of Michigan KECC. We apologize for jumping in but we just want to clarify that we believe that this is a transposition problem, this is a typo. We did not include this in our measure specification from the revised specifications that we submitted to NQF. So we did not write the statement that is at the top of page three.

Female: OK. And so – and you are clarifying that and I think Joel said this that that is in the actual measure specification which should be those things that are – those have been changed to three times a week and this error of three or more is no longer there.

Claudia Dahlerus: Correct. We removed that from the measure specifications that were submitted.

Female: OK. And, I mean, I think that we just didn't – we didn't catch that in the memo and that was our error. So, apologies.

Male: So is that – Just to clarify though, that was a pediatric measure or – I don't remember now. Were there other adult measures versus three or more or is it only the pediatric measure?

Claudia Dahlerus: This is specific to the pediatric measure as well as the combined measures that included the pediatric population. We removed that three or more times a week specification.

Male: OK, so all adequacy measures are now only three, right, nothing more than three?

Claudia Dahlerus: For the hemodialysis measures, yes, correct, three times a week …

Male: OK.

Claudia Dahlerus: … twice weekly.

Male: That includes the adult and the pediatric, correct?

Claudia Dahlerus: Yes, correct, adult and pediatric population.

Alan Kliger: OK, that's very helpful. Thank you.

(Sarah): OK, any questions about theme two in the dialysis access considerations and, you know, does anybody feel the need to revisit any of the discussions about potential future exclusions or changes to measures related to, you know, special populations where A.V. graft, A.V. fistula may not be appropriate, catheters might be, et cetera?

OK, great.

So, the next part of this measure starting with 2594 in the next page and a half, you know, we're really about the Kaiser optimal start and optimal end stage renal disease starts measure, 2594. And you'll see – you've just seen in the public comments that there were a number of public comments received that, again, were in some of the same veins and similarities to the in-person meeting discussion. Some of the comments received were, you know, were some confusion about level of analysis, the inclusion and exclusion population, the issue of being managed by a nephrologists previously, et cetera.

And Peter and team put together a very substantial response to that public comment. And we wanted to provide you an option had you had the opportunity to read this to determine if you feel that you need to discuss this more and is there a need to revote or are you comfortable with where you are, is there additional information you'd like from Peter. And just as a reminder in this role, Peter is acting as the developer and not as a committee member. So if folks do have a comment or a question, if you could just let us know.

Otherwise, what would happen in this case if you choose not to further discuss, if you choose that there is no need to revote on this, the measure continues to move forward as recommended.

Great.

Peter Crooks: Yes, I would just say that I looked this over carefully and recalled rather intensive discussion that we had regarding this measure and feel that beginning to develop measures around incident care and the optimal start is important, and I would not want to reconsider our original vote at this time.

(Sarah): OK, anybody else?

Lori Hartwell: Yes, this is Lori Hartwell. I'm trying to raise my hands at my computer. I would just echo that I think that it's a very important measure. So, now I got my hand raised. So, yes, I think that it is – I would like to not – I would agree with Dr. Maddux.

(Sarah): Great. OK. So, at this point, you know, our plan would to start going to the 10 consensus outreach measures. However, we will pause to see if anybody – when you read through any of the additional comments, either to the Excel table or through the overall memo, if there were any other specific comments for the measures that are not on the agenda that you wanted to talk about.

OK. So we have a couple of measures where during the in-person meeting consensus was not reached. And Poonam had indicated to you what we'll do here is have discussions about the measures and specifically anytime consensus was not reached as well as when measures were not recommended after the in-person meeting, NQF staff is going to follow up with each of the measure developers and provided snapshots. They have access to the full transcript from the meeting, but we also had provided some bullets of information regarding the votes as well as what seemed to be the outstanding or additional information the committee wanted for reconsideration of the measure or as the rationale for why the measure did not make it through the vote.

When we get to voting, again, we – (Shawnn) will give a brief overview of the voting mechanism and you'll first vote on overall feasibility of endorsement and then have the option to go back and vote on any of the individual criterion. But really, it is through NQF process that just following and voting on overall feasibility and revoting on overall feasibility for endorsement would give us the indication on if you recommend these measures for endorsement or not.

So the first measure is the 1423, minimum spKt/V for pediatric hemodialysis patients. This is University of Michigan/CMS measure. We received two comments that supported the endorsement of the measure with the conditions that we already talked about on theme one. And then CMS has provided additional information based on the discussion that took place at the meeting. And that information is in your memo and there are a couple of bullets starting under the consensus not reached standard. The first bullet indicating the – how to measure has been revised and then bullets on confirming removal of the upper threshold and then some additional specification edits.

So at this point, what we'll do is we'll open up to see if there are any additional questions from the committee to the developers to assist in your voting. Manesh?

Mahesh Krishnan: Just a question. So when we revise this definition, did we also redo the validity? I'm assuming we did, I'm just checking.

(Sarah): And I'll let …

Female: Yes.

(Sarah): … Joel …

Male: Yes.

Female: Oh, sorry.

Claudia Dahlerus: This is University of Michigan. Yes, we did – we updated the validity analysis and the reliability …

Mahesh Krishnan: OK, so …

Claudia Dahlerus: … analysis.

Mahesh Krishnan: And can – And having not reviewed that in detail, I'm assuming there was no change?

Claudia Dahlerus: Very minimal changes, nominal changes at best.

Male: Wasn't the validity the TEP face validity?

Claudia Dahlerus: Yes, yes.

Male: I don't remember there being any other validity, just to make sure.

Mahesh Krishnan: OK.

Claudia Dahlerus: That is correct.

Male: Yes, yes. But you went back to the TEP and most of them responded to you.

Claudia Dahlerus: Yes, they did. Well over a majority.

Mahesh Krishnan: Perfect. Thank you.

(Sarah): OK, I don't see any other hand. So (Shawnn), I think this is up to you to give an overview of the voting and we can go to vote on this measure.

(Shawnn Bittorie): Excellent, thank you. So, in a few minutes, you'll see a voting slide appear on the screen. When the voting slide appears on the screen, you'll see some boxes next to the choices. You'll simply click on the box next to the answer of your choice and it's going to populate your vote in real-time.

Now, as we've discussed, we do have a few folks that are joining us by tablet. You cannot vote on a tablet, you have to vote either on a P.C. or a Mac.

So, if you have any questions or you have any issues while you're trying to vote, you can let us know. You can also – if you have an issue where you do not see your vote register in real-time, you'll see a check box on your screen to

let you know that your vote has registered. If there is an issue, please let us know or you may also send it via the chat box.

Poonam Bal: Thank you so much for that, (Shawnn). And no one has any conflict with this measure, so everyone should be voting. (Shawnn), could you just let us – give us a heads up on how many people are voting on the system?

(Shawnn Bittorie): It looks like we have 17 right now.

Poonam Bal: OK. And then I'll be expecting too in my e-mail. So please send those as quickly as possible. And your vote right now is for the overall feasibility for endorsement for 1423. And this basically means that you – yes indicates that you are recommending the measure for endorsement and no indicates that you're not recommending the measure for endorsement. And we do need 15 votes to hit quorum. But obviously we'll wait to get everyone who's able to on the system.

Female: OK.

Poonam Bal: So we are 18, 19. OK. We do have an overwhelming vote for yes. 19 vote yes, 0 votes no. So, we will change the status of this measure consensus not reached to recommended for endorsement. And we can move forward to next measure, 2702.

(Sarah): Great. Thank you, Poonam.

So, the next measure is 2702. And for this measure, this is the post-dialysis weight above or below target weight developed and stewarded by KCQA. Three comments were received for the measure. One was supportive and two were not supportive of endorsing the measure. The measure that did not support the measure noted that while the measure could have positive effects on the care of patients, the potentially adverse unintended consequences seemed to outweigh the benefits.

KCQA did provide a couple of paragraphs of a response to support their measure. And again, we'll turn it back to the committee to determine are there additional questions that you have for the developer before we vote?

OK. We don't seem to have any questions.

Poonam Bal: OK, perfect. And for 2702, we do have some conflicts. So I ask that Connie and Lori and Mahesh refrain from voting. So, we – that should be down to 15 people that should be able to vote and then two more e-mailing their results.

All right, so voting is now open. Again, this is for 2702. And yes indicates that you would like to recommend the measure for endorsement, no indicates that you would not prefer to recommend it for endorsement.

(Off-Mike)

Poonam Bal: Just one more second. And just to confirm, (Shawnn), we should be getting 15 on the system, not including the three that I listed as not able to vote. Is that correct or is it down to 14 now?

(Shawnn Bittorie): It does appear to still be 15.

Poonam Bal: OK. So if you've not put your vote in, please, please put your vote in now. OK. What we do – do have, do quorum, we did get a vote through the e-mail so we have three yes and 12 no and so that does mean that this measure is not recommended for endorsement and we can move forward, (put it there).

(Sarah): Sure. Before – so the next portion of the agenda are – would be for reconsideration request and before we start I need to check to see if the folks from CMS are on the line and have them the open line. I'm sorry, not CMS, CDC so I think Dan Pollock, (Priti), (Priti)?

(Priti): Hi, this is (Priti), I'm on the line but my colleagues are not available until 2:30.

(Sarah): OK, so then (Priti) just you know, we're going to go ahead and skip and we'll move forward and we'll come back to you.

(Priti): That sounds great, thanks.

(Sarah): OK. So then we will go to measure 16-60 which is ESRD patients receiving dialysis, hemoglobin level, less than 10. This is a renal position associate measure. Two commenters supported the measure's recommendation to not endorse this measure noting hemoglobin less than minus 2 of the threshold while two commenters supported the measure for endorsement as an important safety measure. RPA did provide a memo to provide more information and that's based on the comments received, the information provided by the developer and any additional questions, the committee may have, you really have two consideration.

One is do you want to reconsider this measure and then you know, are there any questions that you would like answer to help you make that decision on reconsideration? Peter?

Peter Crooks: Yes, can you help remind us which criteria, was it evidence, was it feasibility, you know, at which point did this fail to be recommended?

(Sarah): Sure.

Poonam Bal: Did you want to take that on for you?

(Sarah): Yes, if you'd like to do it.

Poonam Bal: So, (1615), (fail) on gap, this is not previously endorsed measure so it was not in measure that could qualify for reserve status but this measure did go down on gap. I see Michael has a question so I'll go ahead and pass it over to him.

Michael Fischer: I just had a question. When I read the – what the RPA provided about this, they gave us some more support for the measure but they seem to have given us with the results of the pre-trial and I thought that the measure pertain to patients on dialysis and I though the pre-trial didn't pertain to patients on dialysis and I just don't know if anyone else on the committee is more knowledgeable about the pre-trial than I maybe.

Peter Crooks: Yes, the pre trial was pre-dialysis.

Michael Fischer: OK.

(Sarah): And so just, you know, I believe Amy and (Dale), are you on the phone that – if there are any questions, you'd like to ask of our P.A., they are on the phone and would be able to answer any questions if you want to address them to allocate as well.

(Amy): I believe we actually had Dr. (Garrett) on the phone. This is (Amy) …

(Off-mike)

(Dr. Garrett): I'm here, (Amy).

(Sarah): Peter your hand still up, do you have additional questions?

Peter Crooks: I just wanted to point out that if it failed on gap, for measures that are considered safety measure, I think we in person we talked about that a safety measure is not necessarily going to meet the performance gap criteria. And I think in their response, they made a pretty good case that this is – should be viewed as a safety measure and I think it makes a lot of sense that way so that's my comment.

(Sarah): And I see Lorien has a comment too but before – let me comment on that. We've been having a number of discussions internally at NQF regarding measures like that, they're not existing measures so we can't vote on them for reserve status when they're tapped out.

But we found is that different committees have considered and voted differently on the measures that can be construed as a safety issue and that they relaxed to some degree their, I guess, was not realize in the criteria but reelecting their view and it's a measure is tapped out or the single that's going to be made if you do not recommend the measure for endorsement when it's also safety issue, the issue.

So, I did want to tell you that NQF has done some research on that and we have found that other committee have recommended measures in a similar to this where, perhaps, there isn't significant room for improvement therefore, would not meet the gap criteria. However, the committee as clinical experts in the area felt that it was an important enough measure that they could

recommend endorsement even though there's no significant room for improvement.

So, Lorien.

Lorien Dalrymple: And I just want to concur with Peter. I reviewed the response and I would like us to reconsider this measures the committee in the context of thinking of it as a safety measure.

(Sarah): Lori?

Lori Hartwell: Yes, as a patient, I echo both comments.

(Sarah): OK, so, what we're going to do – oh, Alan?

Alan Kliger: Yes, so I have a concern about the evidence that nine is the safety level. I understand that it the safety measure, we surely can vote even if there's not a performance gap but in terms of the data to support that there is clear danger at that level, I guess, I have not seen that evidence.

(Sarah): Lorien?

Lorien Dalrymple: Oh, I'm sorry. I meant to lower my hand but I guess in response to Alan's comment, I agree this special of has been difficult for this measure. My recollection was, a few years, it was 10 and we said there was not sufficient evidence to make it 10. So, I think the challenge would this safety measure is coming up with what's that cut point should be. And I don't know if there are others on the committee can kind of give us guidance. Is it reasonable to say, "Well, this makes sense from a clinical perspective and the trials we have in CKD and with safety measures." Is common sense sometimes good enough or do we need the strong evidence?

(Sarah): Any committee members have a – so Mahesh do you want to address that or do you have additional comments?

Mahesh Krishnan: Yes, I was just going to actually say the same thing, right? I think lower – having a lower bound of hemoglobin is a good thing from a safety

perspective. It's just the number and then there's other – I think there another NQF measures maybe it's for pediatric anemia that is less 10. So, I'm just – I think I was struggling with the same thing (inaudible). If we think it's reasonable, it should have been 9 or should be 10. I don't think there is a definitive way to answer that question, though.

Male: I think the difference at the pediatric measure was that they provided data, showing adverse consequences, specifically, life and death but again, we only voted this down because of gap. Originally, we didn't vote it down because of evidence.

(Sarah): Correct.

Female: Actually, evidence was gray zone so you were in, we did not achieved greater than 60 percent threshold on evidence and failed on gap.

Female: And then I see Alan's hand up.

Alan Kliger: Yes. I mean, just quickly. I'm not sure it is between 9 and 10 because in the absence of data, if that was 7, I could vote for it. With no – because of, you know, common sense, or you know, sort of already clinical experience. But, if 9, I must say, as a safety measure, not as an optimal measure but as a safety measure, I just haven't been convinced that somebody would with hemoglobin of 8.6 to 8.8 is at any greater danger of anything than anyone else.

(Sarah): I'm not raising a hand.

Lori Hartwell: OK, so …

(Sarah): Hold on, a minute, Lori. There's a number of hand up here. Frank?

Frank Maddux: The only comment I would make is I think, depending upon details of the patient really determines whether the level is 10, 9, 8. I would agree with Alan, when you get down in the seven range, it's pretty universal, I think the people would be very concerned about that but I know transfusion policies and cardiac surgery are quite different now that they were just a few years ago. Allowing people to get substantial and more anemic. In the ESRD

population, I don't know the answer to the question and that just have nine range which is what gives me a little bit of heartache about thing and minoring now.

(Sarah): OK, Lori.

Lori Hartwell: Well, you know, I know this is evident based but in the majority of the patients I cost to. I mean for myself I begged for blood at an eight, 8.2 hemoglobin. You know nine should be a minimum as a safety measure and so you know to think this as – that this is you know to go to a seven or an eight. I mean I can't emphasize that this is a safety measure and I hope that we consider putting something up there to protect patient.

(Sarah): And (Andy).

(Andy): Yes, I concur with Alan and just in light of that. sorts of measure that we've been – that have been endorsed in – to epo dosing in the past that turned out not to be strongly evidence based. I think if we especially cautious to endorse something, it doesn't have strong evidence behind it.

(Sarah): OK. Dr. (Garrett) you wanted to respond?

(Dr. Garrett): So this is just half of the RPA and we certainly agree that this concept here is not an easy one and we don't think that there's a clear infliction point to Alan's comment. And it's as a safety measure it was the goal was to find the reasonable floor, the concerns that were raised is that if we chooses lone value like seven. There's not a lot of safety net behind them. The patient has any bleeding dialysis, this was certainly increased risk in the dialysis patient. A seven would really not protect the patient and there's no room there because there's no margin of error.

The difference between nine and eight, I think is debatable but nine was chosen based on the earlier work of the KDIGO workgroup which suggested that consideration should be given to keeping the hemoglobin from falling below nine. And we recognize that the prior floor have been ten so choosing a number that seems to be a reasonable for a measure, we arrived at nine.

And I agree with group, there is not hard sign around this because they're in the clear infliction point of using the variable. But we felt strongly that the need to have some floor measure for safety was an important edition to our measurement. OK.

(Sarah): Lori, did you have an additional comment?

Lori Hartwell: I'm just trying to understand some of the speakers basically, it feel a great debt. There needs to be a measure to help patients be safe in having their hemoglobin drop but when here, it's basically we can't free on a number and what – how low is too low?

And you know as a patient, I mean I noticed there's been a lot of studies generated for higher numbers and it just seems to be that we all agree this is important but we can't agree on the number for the evidence and without the committee to consider that we need to have a number to support patients and it seems like (R.P.) has done a good job of presenting evidence for this case then I've just would ask everybody to consider that.

(Sarah): OK. Dr. (Garrett), did you have something else briefly?

(Dr. Garrett): No I think that that is fearsome information. We struggled with the absolute number because it did can seem variable. Seven seems as if there was really no room for error and the patients could be potentially harmed if they did have a bleeding problem and their initial hemoglobin and hematocrit were in the range of seven and what may translate to a hematocrit of 21 that's seem very low to us given the rest of the cardiovascular risk of this population.

Ten had been previously removed in the endorsement maintenance project in 2011. And so we had to choose between eight and nine and based on the KDIGO group and also the data from (TREAT) which was – has pointed out was a pre ESRD group which is a group that's probably at less risk than the dialysis population. Certainly we wouldn't expect them to be at greater risk and in the (TREAT) trial, nine was chosen, but nine was the level that was noted to the level of increased risk. So we felt that it's that was the level in the pre ESRD population that's certainly seems reasonable in the higher risk ESRD population.

(Sarah): OK. Thank you. So Stuart up first and then (Beth)?

(Beth): Yes. He was first.

(Sarah): Stuart? You might on mute?

Stuart Greenstein: Hello.

(Sarah): Yes. Hi. We can hear you.

Stuart Greenstein: OK. I just like to add a word of caution that any number you put here you have to be careful that as a transplant surgeon, I would worry that patients would then have to go and get transfused this if we say that you can't be below this number and then they're going to sensitize them so be very, very careful with any number you put in here because …

(Sarah): OK and (Beth) – I'm sorry, go ahead.

Stuart Greenstein: That's all I want to say. Sorry.

Female: OK.

(Beth): My only concern for nine is tremendous amount of patients leaving the hospital, hemoglobins are below nine. And to have the dialysis clinic have that as a safety measure when they're coming out it put too much. Safety of course is important but that happens too frequently to use that if the number nine.

(Sarah): OK. Mahesh, did you have anything additional to add to what is already been said or can we move to vote?

Mahesh Krishnan: Yes. I think in addition – I think we got to be clear, right? This is what physician measure not the dialysis clinic measure. So I just think we got to be clear in terms of what we're – how the measure will actually be used. I mean we've sort of batted it around just as I listen to multiple definitions work of the dialysis unit or from absolute threshold by which we won't have to grade

ourselves, but it's been used as a physician measure, right? So it's – I'm just want to make sure we put in the right context.

(Sarah): OK. Great. Thank you. Poonam, back to you then.

Myra Kleinpeter: Wait. Before we go, this is Myra Kleinpeter. I'm kind of late joining.

(Sarah): That's OK.

Myra Kleinpeter: Your AAB guideline's a little bit different for level for transfusion and we're going to be totally against that if we have that lower level as a physician goal. Most places won't transfusion less than nine unless they have some cardiovascular active issues or actively bleeding.

(Dr. Garrett): Can I make quick – this is Dr. (Garrett) and just a quick comments about that issue? We certainly are very (inaudible) important meeting not using blood and blood products in irresponsible way and I endorse what was just said. Many of these patients actually are not on erythropoietin agent because remember right now, there is no floor so the current erythropoietin is the target agent.

So what we're concern about is there may be members not letting the hematocrit go higher than the number. So the concern is that there are individuals who may have hemoglobins that are low and they are not on erythropoietin agent because there is no floor. This is not meant to be a rush to transfusion. It's not the purpose of this measure at all. It's rather of appeal to have a floor level for safety.

(Sarah): OK. OK. Thank you all for your comments. I'm going to go ahead and turn it back over to Poonam. Poonam, are you there?

Poonam Bal: Yes. Sorry. Did the same, you know, put myself on mute. Thank you so much. OK. It seems overwhelming that the committee would like to revote on this measure. It did fall on gaps, so we will start with gap. I just want to remind everyone please when we go to discussion points let's please discuss what we're voting on so at this point I will ask if there is any additional comments about gap.

Male: We don't have to vote on evidence because it was gray.

Poonam Bal: Yes. So we did past through evidence that we don't need to revote on even though it was gray.

Male: OK.

Poonam Bal: Yes, unless the committee feel strongly that they would like to revote on evidence.

Joshua Zaritsky: This is Joshua, are we revoting to reconsider or we've already move past that point?

Poonam Bal: Look, reconsideration is more of a verbal discussion and we didn't hear anyone say that they did want to reconsider it, so we're moving forward with the voting. Is the committee OK with moving forward with voting on the measure?

(Sarah): Yes. I'm thinking, so we would automatically and I think just because what Poonam said in the very beginning is that since there was fairly significant discussion on that we are taking that as a queue that you might want to revote on it just to even for practice wise to clearly say that you reconsidered the measure however, if you don't feel that, you know, if you want your not recommended status to stand we are – we could do that.

So I guess what I would ask is Peter and Connie has shares, you know, do you want to move to a vote or do you want to look for a motion and second motions et cetera or how would you like to proceed?

Constance Anderson: This is Connie. I think there's been enough discussion and we need to reconsider and revote because there's pros and cons on both sides of the measure and so I would make a motion to go ahead and revote.

Poonam Bal: Can we get a second on that motion?

Peter Crooks: This is Peter. I agree with Connie.

(Sarah): OK. OK. So, Poonam to you, and let's start with important measure in the report 1B performance gap.

Poonam Bal: Yes. Perfect. So we are ready to vote on gap. This is where the measure fell last time. As a reminder your four options are high, moderate, low, or insufficient.

In order for this measure to move forward, we do need to get a majority only 60 percent within the high, moderate range so please go ahead and put your votes in now. Michael Fischer did let us know he has a conflict with this measure so he will not be voting for accepting 17 measure votes on the software and two votes to be e-mailed to me.

Female: Poonam, do you have the two votes that were e-mailed to you?

Poonam Bal: Yes. That's what I'm waiting on. We have one vote, so we can give a couple more seconds.

OK. I think so let's move forward because we do have quorum and it’s consensus. So we have four votes high, three moderate, 11 no, and one insufficient. So this measure again failed on gap and we will not forward with reconsidering this measure.

Alan Kliger: Can I just raise my hand? I'm sorry, I just asked the question. I thought that we had said that for unless you can't change the rules now but that for safety measures that I wouldn't be on gap that was the whole premise about discussion just now. I thought that if this is a safety measure that we should make the consideration besides the fact that we'd never found the significant gap here.

(Sarah): Yes. So I mean – so Alan, I guess what you're saying just so I understand that even though the measure fails on performance gap that we – because of the safety issue you want to move forward with the vote.

Alan Kliger: Yes. That's …

(Sarah): To the rest of the criteria.

Alan Kliger: Yes. I think.

(Sarah): OK. And Poonam, I think we can do that and this was a discussion that was during the senior director meeting, and so, you know, I don't think the voting software reflects it very well but, you know, in the transcript, in the report this would be something that we just want to move forward through voting on.

Male: We never went forward with the discussion after gap …

(Sarah): Correct.

Male: … at the meeting though, right?

(Sarah): That's correct as well.

Male: I'm a little concern that we would then be going forward without there being the same degree of discussion that we usually have.

(Sarah): Well, and that's where, you know, we could pause at this point and talk about the sciences of susceptibility so therefore reliability and validity of the measure based on the information that you have provided. And I frankly don't have in front of me who the original lead discussants are but that is certainly something we can do as well if have the rest of the discussion. Peter?

Peter Crooks: As a suggestion, perhaps, you know, I agree with (Michael) that we can't move right to voting overall and perhaps, this should be an item that could be voted on Monday so people would have a chance to go back and open the measure an look at the information regarding specs validity, you know, usability and feasibility.

Poonam Bal: Peter, I think that's – we can't just get to the overall voting section. We do have to vote through all the criteria but I think at this point, we as NQF staff need to look at this a little more thoroughly and I think that we want to give the committee a little more time to think about the safety issue so I think I'm in favor of pushing this until our Monday call.

Is there anyone that would disagree with that?

OK. I'm not hearing any disagreements so Severa, how about we just move on to a next measure. Did you want to see if actually I'm reminded only two of five so I think we'll need to move forward to the CMS measures and then come back with CDC at later point.

(Sarah): Sure. So the next measure is 14-54 for portion of patients with hypercalcemia. CMS has officially, formally asked us to reconsider this measure. There were two commenters that agreed with the committee's recommendation and not endorse the measure so I think that is a poor measure that would be more harmful than no measure.

The developer rationale for reconsideration, CMS has provided a more detailed rationale and that is attached to your memo and so the question goes back to the committee that based on the comments received as well as the additional information provided by CMS. Do you have additional questions to CMS and do you want to reconsider this measure?

Mahesh?

Mahesh Krishnan: I just had a question actually on the data that was provided I just didn't understand so was the data – what was the year that the data came from in the response and I assume that that data that was provided was the percentage of patients whose average yearly calcium was clearer than 10.2 consistent with the measure and it was albumin adjusted but I didn't know so I was – I just have two technical questions.

(Sarah): OK. I would ask if CMS if Joel or someone from your team would like to respond?

Joel Anders: This is Joel, yes and I'd like for a tech to go ahead and respond to the question.

Claudia Dahlerus: OK this is Claudia Dahlerus from the University of Michigan KECC so the data that we provided in their request fro reconsideration was calendar year 2014 data and then to – yes, and the second part of your question Dr. (Christian)?

(Dr. Christian): Was the definition the same? Is it the percentage of patients whose average yearly calcium was greater than 10.2 and was that albumin adjusted or not? Or was it a different crisis. That's (inaudible), I think you're saying.

Claudia Dahlerus: Right, right. It's not albumin adjusted so it's the same definition as specified in the measure specification and it's the three month rolling average of calcium calculated over the year.

(Dr. Christian): OK. And then the other question I had was there's the discussion around the oral only drugs for monitoring argument. We've used this for calcium contained binders I assume. I'm not sure it addresses the issue for non-calcium contained binders or calcium medics so I just didn't understand that policy piece that was part of the rationale.

Claudia Dahlerus: We would defer to CMS on the policy piece.

Male: Right. So I think there are actually two issues here. The (inaudible) as a policy piece and the other is the clinical definition of what falls into the requirements as listed under the statutory mandate for (PAMA). And so, I'll address the policy side of it and then I'll ask tech to direct to the rationale for why we believe that hyper calcium meets their requirement – meets the definition of VNAA condition treated with (inaudible) medications.

On the policy side there was – there's a requirement implemented in panel that requires the implementation, the (quip) of a quality measure that addresses a conditions of – conditions that are treated with oral medications and requires that that measure would be NQF endorsed.

Now, as (Mahesh), I think you're well aware there are relatively few measures in this – in this area that are NFQ endorsed and of those the only measure that has gone before the MAP and has been reviewed there, it is also the only non-reporting measure in this area.

There have been efforts to develop a measure for hyperphosphatemia that's been before NFQ previously and has been rejected due to a lack of evidence. There's a phosphorous reporting measure which is currently endorsed and then

there is or was – or I should was a calcium reporting measure that was subsumed essentially by this one.

The issue here is primarily that as I understand that is that of those – of the universal conditions, there are three of the oral medications. Hypercalcemia is the only for which we have – had in the past sufficient evidence to develop a quality measure that was endorsed by NQF.

The issue of its implementation is somewhat separate I think from the issue of its relevance as a quality measure, I think – I'm sorry, relevance for the policy it's the – I think the main issue here is that the measure itself is well supported by the existing buddy of evidence but it is a measure of patients safety is recognized by two separate clinical TEPs that have reviewed the measure to prevent – (inaudible) on place to prevent hypercalcemia which is it self associated with our patient survival and can influence providers bone and mineral disease management practices.

In terms of the precise clinical definition for how hypercalcemia fits in as a measure four calcium medics, I'll leave that to KECC to provide the clinical expertise.

John Segal: So this is John Segal at UM KECC. And I think the issue that we were just addressing was that if calcium based phosphate binders were included in the bundle payment and there was a migration towards increased use of those binders but that would have an impact then on calcium levels balanced by rising use of (inaudible) that which would lower calcium level so those are these indications from based on clinical grounds.

Male: OK, great. Thank you.

(Sarah): Michael, did you have a question?

Michael Fischer: I guess I just had a comment since this is one of the ones that I think Mahesh and I think (Josh) and (Liz) and others were assigned to in a group that went back to our notes in our phone calls we had in small groups in May.

I think the response from CMS is quite elegant and I think just I think to inform what we're going to vote on you know what it happened last time is this a patient safety measure and I think in the CMS memo they reiterated why that is and their poor evidence is waved. Then it failed on performance gap which they address I think quite nice. And I think the histogram so oftentimes pictures can convey things that words cannot. And I think that histogram really underscores that there's a performance gap at a facility level, not patient level but as facility level but this is a facility level measure.

And I think they nice illustrate that in accompanying tech but the histogram I think in many ways just does that. What it happened before and Severa you can correct me, they're kind of summarized in your memo is that we didn't feel there was a performance gap then there was a conversation reserved status and for reason I don't recall. That probably reveals my vote. It was voted down as a reserved measure.

So to me I think the vote for the committee is one, do we want to, to re-examine whether or not there's a performance gap, yes or no and whichever way we vote on that then, do we want to – can vote either it's a reserved status. We don't think the performance gap or if we do and I think there is then voting as it's a traditional measure, yes or no. And now, I just want to summarize and I guess my thoughts because I just want to put everything together so we have an informed vote.

(Sarah): OK, yes and, you know, and I don't and Poonam you'd have to pull up the table that I think for this one that certainly is a measure that was not recommended for gap and that, you know, I think Michael is correct. It was not. It was not voted for reserve status so that could be part of the reconsideration is if you – the first question would be, would you want to – at this point, you know, proceed this the first we'd probably needed your hand vote on would you want to vote on this measure as reserved status as we did consistently in the in-person meeting for any other measure that you wanted to move forward with reserved status?

Poonam Bal: Yes, I just want to confirm that this was a measure that the committee considered and then eventually decided not move forward wit the reserve status but that is definitely something that we can consider at this point.

(Sarah): And do we want, Poonam do we want folks – do you have slide to that or did you want to just do it by raising of hands online?

Poonam Bal: We would be doing with the raising of hands.

(Sarah): So the question to the committee, if you raise your hands right now is an indication to us that you want to continue through the evaluation of this measure and vote on it at the end for reserved status.

Peter are you voting or did you have another comment or question? OK. It looks like folks are voting. So if you are voting online then you need to raise your hands in that box on your screen. And if you're sending Poonam messages with your vote, if you could just let her know via message.

And Poonam, I don't have the count so I'll leave it up to you to determine if we have consensus.

Poonam Bal: Yes, I would give everyone, just one second if you want to put your hand up please put it up now and I'll start counting.

Male: Yes, I counted of 13 up already and kind of hard with this to – it's keeps flipping back to the beginning but …

Poonam Bal: OK. We have 14 that technically would like to consider this measure for reserved status and that is enough for us to move forward for that vote. So we'll start with reliability and we will go ahead and would the lead discussant …

Peter Crooks: This is Peter. I'm sorry to interrupt but I don't know if we are voting for reserved status or we're just voting to reconsider the measure? The reserve …

Poonam Bal: Sorry, go ahead.

Peter Crooks: Are you saying that if a measure is a safety measure which may not have a performance gap that makes it reserve or how would define a reserve measure again?

Poonam Bal: So this – the safety measure issue are completely separate issue from the reserved status issue or there's status only indicates that the measure – the committee feel that the measure is a very useful efficient measure.

But if, you know, covers all other criteria, however, there's not that much room for improvement and that they also feel that if the measure is removed that there is a risk our performance is going down.

That is all that reserved status indicates. It's right now the vote that we just did was not a vote to make it reserved status, we do have to go through our formal vote where we go through all other criteria before we can get to that vote. This vote was simple saying that, yes he want to considerate for reserved status.

Peter Crooks: OK, so we voted to reopen it and that we will consider as reserve – going to the process we'll also consider whether to meet criteria for reserved status.

Poonam Bal: Yes, at the end we'll – after we review all our criteria, we'll go – we'll have another vote for it to see if we want to endorse it for reserved status. Unlike other measures where we went to all the criteria and then you would see overall feasibility, we won't do that vote. We'll substitute that vote with the suitability for reserved status.

Do your final vote changes essentially? But we treat it like every other measure. Does that make sense Peter?

Peter Crooks: I believe so, thanks.

Poonam Bal: OK. Were there any other questions from the committee, I want to make sure that everyone's clear on what we're voting and how we're proceeding?

Male: So …

Poonam Bal: Was that a question?

Michael Fischer: Yes, sorry, this is Michael. Everyone's hands up so I didn't know what to do on the computer.

Poonam Bal: I want to just see all your hands.

Michael Fischer: Sorry, it was a little bit (inaudible). But when voting on reliability, I'm just, again, that we're having informed vote. If someone going to make comments about the reliability and summarize what the group's comments had been – I mean I have mine. I'm just trying to understand the process.

Poonam Bal: Yes.

Michael Fischer: At least we're getting ready to vote on reliability.

Poonam Bal: Of course. So we want to give the same process we did in the in-person meeting and in the follow-up call. Where we'll ask the lead discussion if they feel comfortable we know it's been a while so not everyone may feel comfortable doing it now.

But basically to take that on role on starting the discussion and giving an overview of their thoughts on the measure, if the lead discussion aren't comfortable, we can ask if anybody in the committee would like to lead the discussion, no the discussion, start the discussion with their thoughts on the specific aspect of the measure.

But then we'll proceed forward. So we will allow open dialogue and discussion amongst the committee, if there's questions to committee has with developer we'll call in the developer on their behalf and so on.

Michael Fischer: OK.

Poonam Bal: So very similar to the post comment call.

Michael Fischer: Well, thank you for the clarification.

Poonam Bal: No problem. So …

Male: Michael is your question though like the one we did before, has everyone reviewed the revised data other than what's presented here?

Michael Fischer: So there's the original application which covers reliability. The two points that were addressed in the memo and maybe I'm not understanding your question – was really around performance gap and around evidence woven into, you know, the importance of a patient safety measure.

When I read the memo, it didn't address or it may have made one sentence comment but since reliability in other things – I don't believe it have been raised this concerns before CMS did not extent so they comment on those in their response memo which focused chiefly on performance gap, patient safety and evidence

Male: Yes. So that was my question. Is what's on here, we think it's sufficient? We always go back and w review everything which sounds like the answer is yes.

Michael Fischer: Yes.

Poonam Bal: Yes. That's correct.

Male: OK..

Poonam Bal: Perfect. Would there any additional questions before we move forward? I want to make sure I went comfortable before we move.

OK. I'm not hearing anything, so I'll ask …

Peter Crooks: Progress that I'm still – this is Peter. I'm still a little confused so – did we just say that if we already voted scientific evidence reliabilities that's the case, and the validity et cetera.

Do we need – do we open those areas again?

Poonam Bal: No, we would not. If we previously voted on something, so we …

Peter Crooks: And it passed.

(Crosstalk)

Poonam Bal: It passed and then we would not review it, it fell on something. We would review it but in this case, since it fall on gap but now the committee is determined that they would like to move forward and considers whether for reserve status, we do not need to revote on gap. We can just move to reliability but in other situation, we would start the vote on the criteria that is fell on and just keep the old vote. However, if the committee felt strongly about changes made by developer, alters their decisions made previously, we can go back even though – even if measure passes a certain criteria before hand.

Male: OK, so, it fell on gap so we didn't yet discuss reliability and validity, et cetera?

Poonam Bal: Yes.

Male: Correct? OK, thank you.

Michael Fischer: Right. Sorry, this is Michael and not to muddy the waters but again, one of the things they heavily addressed in their manual was the issue of performance gap and I know, Mahesh, I know you've looked at this. I'm just trying to remember who else is on our small group. So, the reason – I mean, I guess we're not going to revisit performance gap and vote on that, Poonam, because why again?

Poonam Bal: Well, we had the committee responded. They want to consider it for reserved status and because of that, we made the assumption that everyone was still content with their decision on gap. However, if the committee feels that with this new information provided, they may want to change their vote, we can also start with gap as well and just hold the reserved status decision so we can start with gap if the committee would like and then that can determine if we go through the regular endorsement route and then we can move forward. Either way, we are going to move forward.

Michael Fischer: I understand and I'm not trying to make this too laborious, tedious, or complicated. I just want to be fair and evenhanded about everything and

have, you know, a nice review process with the developer. That's why I was saying I know Josh and Lisa were the lead discussants. I went back to the notes and I know Mahesh and I apologize, I think there were other people on our small group. I don't know. Mahesh, I know you're on the call and Josh maybe and Lisa as well. I don't know if you were swayed in terms of thinking of the performance gap when you looked at their response?

Mahesh Krishnan: Yes. I guess when I was thinking about the performance gap, Mike, I was thinking about it more from the QIP perspective in terms of the percentage of patients or facilities that receive as penalty as opposed to the actual distribution because this metric is set on a threshold so this is slightly different.

Joshua Zaritsky: This is Josh here. I mean, I was – you know, since I was a junior member and I think I was – it was pretty early on, you know, it's just, it seem to be that, you know, when we are voting by the rules at the time which now have kind of slightly changed, I'll put it that way, mildly, that it just didn't need gap based on the data that was presented.

Male: Right, but, to Josh, but based on their response, is your opinion changed or not?

Joshua Zaritsky: I have to – honestly, I have to think a little bit about it because, initially, my response was, "Well, this is a no-brainer." And then when I saw the actual patient data, not the dialysis center data, then I had changed my mind. I have to sort of process it and look a little bit more carefully to the histogram, I guess.

Poonam Bal: And before we move the discussing forward, there're couple people that have been very patiently waiting to speak so I do want to call on them. Connie, you've had your hand up for a while. Did you want to make any additional comment?

Constance Anderson: Well, I did and this is a facility level measure and I think Mahesh, you started with something that is was the path I was going down. With the QIP measures, hypercalcemia greater than 10.2, 90 percent of the nation is that 0 percent. So I think in our discussion, if I remember rightly back at the in-

person meeting of the standing committee, they're really looking at this as a, if you want to call it, topped out measure when you look at 90 percent of the nation.

And I understand that the histogram that was presented here, I wonder when this histogram, what year this data was collected from because if you look at the 2014 data, it may look different than the distribution of hypercalcemia as presented in the histogram. So, I think if this is truly a facility level measure and 90 percent of the nation is at 0 percent, it's going to be very difficult to show that there is a performance gap.

Poonam Bal: And then I just want to let Ishir have a chance as well.

You may be on mute. We're not …

Ishir Bhan: Sorry, that was an accident.

Poonam Bal: Your hand raising is an accident or the mute was accident?

Ishir Bhan: That hand raise.

Poonam Bal: OK. Peter, did you have a comment?

Peter Crooks: Yes, I agree that in fact the histogram shows us that there is a performance gap. It's a small number of facilities but it – but those facilities have a high percentage of patients that are being mismanage presumably because they're at such a high proportion of patients with hypercalcemia.

So I believe that there is a performance gap. I think we should open this up as a regular measure with the performance gap and not necessarily – I don't view it as a reserved measure, as being topped out, or at least that's – I would want to reopen that discussion.

Poonam Bal: OK, I'm going to ask Mahesh to make a final comment and then I think based on what everyone said, it really seems that we need just reconsider gaps just so we can make sure that everyone is on the same page. And then, either way, since you've already voted on the reserve, if we want to consider the measure for reserved status, we'll be moving forward. But I want to make sure that we

really get – we make sure we catch everyone's thoughts on the gap. So, Mahesh, final word please.

Mahesh Krishnan: Yes, that was my questions for well, I think, Poonam, is how do we reconcile these two things, right? What we hold and read and see around the QIP gap, as Connie mentioned or what was mentioned and what we see here. And maybe if CMS or even KECC could help us think through that, that'll be hopeful. I agree this does show something slightly different, but I'm struggling with how to hold both those things – two things in my head at the same time.

Poonam Bal: OK, that's a very good point. I'll ask if anyone from CMS or University of Michigan to make a quick – do a quick explanation of what they've done with the gap analysis and any changes or updates.

Claudia Dahlerus: So this is the University of Michigan, Claudia Dahlerus again. And so the – so what we're showing on the histogram is 2014 data. So we just – we redid the facility level analysis but using 2014 data. And as we explained in the rationale, you could see that about 23 percent of the total reported facilities had 4 percent or more of their patients with hypercalcemia. And so we believe that this dose demonstrate an important gap in terms – certainly from the perspective of safety.

Mahesh Krishnan: Yes, Claudia, I guess my question is slightly different which is we've previously described the – in the QIP that this measure is nearly topped out, right, less than X percent of facilities. And now you're saying that – which was all of our data. So now you're saying that more recent data shows that the gap is widening, is that the way to interpret this?

Claudia Dahlerus: So this is DMC data. So we cannot comment on the measure that is implemented in the QIP. We would differ to CMS for that as well as the definition that they have developed and applied for topped out measures.

Mahesh Krishnan: Sorry, I'm not following. Are you saying that this definition is different than the measure definition?

Claudia Dahlerus: So CMS …

Mahesh Krishnan: For the histogram?

Claudia Dahlerus: … implements measures in its respective programs that may differ slightly base on policy decisions from the NQF endorsed measure. As the measure developer, we are not formally part of implementation decisions. So we would differ to CMS to address your question.

Mahesh Krishnan: OK. I'm just confused. So should I not be thinking about the small gap that Connie outlined that I usually see in all the CMS stuff and I should think about that differently for this, is that what you're saying or somebody is saying?

Joel Anders: So this is Joel. So I think there are a couple of things here. We have the CMS for purposes of policy, creating a definition they can supply it across programs. For when a measure they consider – you consider to be topped out, and there are two criteria for that. I believe – So I won't try to hit on both of those. I can tell you that one is where the – depending on which direction the measure is, either the 75th and the 100th percentile or statistically indistinguishable or the 25th or 0 percentile are – or the 1st percentile are statistically indistinguishable.

The other is a as a statistical test that I don't have in mind precisely. I think the issue here is that when you're looking at a quality measure for endorsement, you essentially have two questions. Is there a gap? Technically, I think the answer to that is always yes, but the more important question is, is there a gap that is – one that is meaningful for the use a quality measure to capture that particular (entry).

And I think what we've tried to do here with regard to the – with regard to this measure is to say, you know, there was some question with the information we provided in the original submission about whether or not there was a meaningful gap available. We've provided this additional information to show you a different way of approaching looking at how this operates as a patient safety measure. I think the argument this has actually performed is that for the vast majority of facilities, I should say, for about 3,000 facilities, you have

a performance rate of 1 percent or lower. That is 1 percent or fewer patients have hypercalcemia as defined by this measure.

However, you see a substantial portion of facilities in the amount of some 6,000 facilities are looking, you know, at about 1,400 or so where – or a quarter of all facilities with 4 percent or greater – or a greater proportion of patients with hypercalcemia.

So, the argument we're making here is that, you know, taken by, you know, taken as our analyses had provided before, there was some question in the steering committee's mind as to whether or not there was sufficient gap and I think to (merit) the measure's endorsement. I think our, you know, (provision) here was to say, you know, we recognize why that discussion we've had and why we don't necessarily agree with the steering – all the steering committee's thoughts on the matter, we think that there was another way to look at it. When we were looking at this portion of facilities where, you know, performance is substantially worse than most – than it is in most facilities, that argues for the utility of this measure.

And I think – I just got – I'm sorry, I just got a text message from Tamyra Garcia who's the policy lead for the QIP and I think she might be able to clarify on the – on how to define when a measure is topped out. And I think what you'll find is that the definition, while it was useful from policy point, it's not necessarily – that doesn't necessarily speak to the analysis that we provided today for your consideration. But I'll, you know, let her speak to that. I guess the question to NQF is to let her have an open line so that she can speak.

Poonam Bal: I'll ask (Shawnn) to double check on that, but again, I ask the response to be very brief. We do have many – a lot of measures to go through, so I do want to be conscious of time.

So, (Shawnn), could you please make sure she has an open line and she'd give us a brief update of the policy, unless the committee feels that they received enough response where they feel comfortable moving forward.

Male: Yes, could I suggest, as we did for the other one, to think about this on Monday as well? I got to process all that because what we said in the committee meeting and what we said on the data now is I just recollect this, this is different. So I'm with Josh of thinking I need a little more time to think through this.

Poonam Bal: I'll just ask, is there a second from the committee members that feel we should wait to discuss this measure until on Monday?

Michael Fischer: Aye.

(Off-Mike)

Poonam Bal: OK. I've heard someone's voice.

Michael Fischer: It's mine, Michael.

Constance Anderson: And this is Connie. I agree. I think to get my head around this, I need a little more time to think about the data that they presented.

(Off-Mike)

Poonam Bal: … I'm sorry, (did you say it was Tamyra)?

Male: Could we get the date on that data for the percentage of facility patients with hypercalcemia, where that data came from for the histogram?

(Sarah): It's 2014 data, it's CROWNWeb data.

Male: OK.

Male: Yes.

Alan Kliger: This is Alan. Can I just make two quick comments if I may? First, just that I know we're going to – we may consider this on Monday, but as we think about it, just first the clarifying question, hypercalcemia here is the rolling three-month average or is it a single value of high calcium, just remind me of that please.

(Sarah): It's a three-month rolling average, Dr. Kliger.

Alan Kliger: OK, thank you. The second is when we're talking about the percentage of patients in a facility with hypercalcemia, I think we have to remember that since most dialysis facilities are on a small side, that it's pretty easy to have one patient than have a, you know, a 10 percent or a 5 percent incidence of hypercalcemia.

So, I think as we look at the data, some of the differences in interpretation between looking a t the numbers of people overall with hyper calcemia and then looking at percent by dialysis facility, we have to be really careful in that interpretation because of its various sizes of a dialysis facilities.

Mahesh Krishnan: And I won't even bring up the CROWNWeb thing.

(Sarah): Thank you, Mahesh. Thank you, Alan.

Constance Anderson: That's OK, Mahesh. This is Connie. I was going to bring it up, but that's OK.

Peter Crooks: This is …

Female: But I think Alan's comments are well taken. Very small facilities, low volume of facilities can really skew the data.

Peter Crooks: This is Peter. I just also like to ask the staff to – when we reopen this on Monday that we kind of review what – if we're considering this as a safety measure, then performance gap isn't really relevant. As I'm, you know, I know this is sort of a work in progress for NQF, but I think we need some clarity. Are we considering this as a safety measure? And if so, do we even need to look at performance information or not, the gap?

Poonam Bal: Peter, I just want to provide a clarification. I think there was a misunderstanding earlier. We're working on considering – not considering gap during – when considering a safety measure, but we have not – it's not an official decision yet. So at this time, unless the measure is being reviewed for

reserved status, we do need to come to at least the gray zone on gap. If not, coming in full consensus to move forward on gap.

What we were saying earlier that many committee members have chosen to vote higher up on gap such as high or moderate instead of saying, "Well, we're insufficient," due to the fact that it is a safety measure and they would like to see it in forward. But we cannot skip that criteria unless the measure is being reviewed for reserved status regardless if it is a safety measure or not. I know that we weren't very clear about that earlier in the call but I just want to make that clear now.

Peter Crooks: So to make sure this is clear then, at this point, NQF doesn't have a policy quote for how to review a safety measure versus a regular measure. And so we're going to have to sort of blend that in in our assessment of the performance gap.

Poonam Bal: Exactly.

Peter Crooks: OK.

Poonam Bal: We, you know, you can definitely take that in consideration when you're reviewing the measure. However, we do still need to review gap in order to move forward and be – get at least a gray zone if not full consensus that we can move forward.

Peter Crooks: OK, thank you.

Poonam Bal: No problem. Were there any other questions at this point, policy or about this measure? You know, we have a limited time on Monday as well. We do want to get the related and competing and make sure we're putting the best measures out there. So I just want to be conscious of everyone's time and I know that there – one more representative from CMS wanted to make a statement about how they determine topped out measures. Was she able to get an open line?

(Shawnn Bittorie): Yes, I believe she does have an open line. Ma'am, can you confirm that as well please?

Tamyra Garcia: Hello, this is Tamyra Garcia. Can you all hear me?

Poonam Bal: Yes, barely. Could you speak up a little bit please?

Tamyra Garcia: Yes, I'm sorry. I'll try to speak up a little more.

So in terms of speaking to the topped out analysis piece with respect to – we typically do with – in terms of programs, the ESRD programs specifically. Let me just sort of pull up a bit of language that I could speak to. I apologize. Here we go.

Poonam Bal: OK. Well, thank you …

Tamyra Garcia: So in determining if a measure is topped out, there are few criteria. So, if the – of course the measure performance is extremely high and it's unvarying, then, you know, we would look to potentially top out a measure. Additionally, if a performance or improvement on a measure does not result in better intended patient outcomes, we'd look to consider a measure topped out. If a measure no longer aligns with current clinical guidelines or practice, if they are more broadly applicable across settings or another measure topics that's sort of better becomes available, if a measure that is more proximal in time to decide patient outcomes for a particular topic becomes available, if a measure that is more strongly associated with desired patient outcomes for a particular topic becomes available, or if the collection or public reporting of a measure leads to negative on intended consequences, we would removed the measure.

So those are sort some general criteria that we use across the board when it comes to quality reporting programs and value based purchasing programs that would sort of lead to us determining when a measure is topped out.

Poonam Bal: OK. Thank you so much for that. With that said, we would like to move forward on to 2700. (Sarah), did you want go over the changes real quick and the request for reconsideration?

(Sarah): Sure. So this next measure is measure 2700. Ultrafiltration rate greater than 13 milliliters. And so there were three comments that supported the committee's recommendation to not endorse this measure. However, not only this we received very consideration from CMS but there we're a number of committee member of close the in person meeting alerted NQF staff that there is a feeling that more information or more discussion and further evaluation could have happened that may have made folks reconsider the measure or vote a little bit differently. And I think this was mostly around validity testing and the fact that I think a one point there's a statement made that basically it was not provided on this measure when in fact that it was.

And then I know there were some additional considerations regarding the evidence for this measure and how it differed from the other measure that's similar to this measure that was brought forward by another developer.

So, I'll leave it at that and hopefully committee members had read the memo and CMS's comments and clear request for reconsideration and open the floor for discussion.

Peter?

Peter Crooks: So, I move that we open this measure for consideration and pick it up where we left off.

(Sarah): Alan?

Alan Kliger: Yes, I agree with Peter. Just quickly, I haven't gone back. I think I may have been one of the culprits who misinterpreted the data. And I went back and carefully examined the data that was presented to us. And it is clear that both mortality and hospitalization for all of the quintiles of ultrafiltration above 9.5 mls per minutes did show increased risk. I think that I and perhaps others misinterpreted some of those data when we spoke. So I believe we should reopen it as well.

(Sarah): OK. Is there anybody opposed? OK. So are there additional questions to the developers on this measure that will help you in your reconsideration and the revote, any additional qualification you all wanted before you vote?

Michael Somers: This is Michael Somers. I just – Quintile 05, was there a difference – I though there was no significant difference with mortality but almost with hospitalization. I'm just saying that because of what was just said I think by Alan that there was no difference with any of the quintiles.

Alan Kliger: I don't have it in front of me, Michael, but what I – when I reviewed it, it was – there was a significant difference for all quintiles. It may have been at one hand it was in the right direction but was not significantly different …

Michael Somers: Yes.

Alan Kliger: … in the …

Michael Somers: Yes, that's – I think it almost meant significant.

Alan Kliger: Right. But I'm looking at all, I think that we had or I had misinterpreted the data.

Michael Somers: Yes, OK.

(Sarah): OK. Connie?

Constance Anderson: Sorry, I had my phone on mute. I guess I'm a little confused. I need a little bit more clarification. We had two measures that were almost exactly the same, the 2700 and 2701. And the only difference between the two was that 2701 had time on dialysis, the greater than 240 minutes per session.

And so I'm confused as to we had two measures that were almost exactly the same. We set one forward and now we're reopening a measure that doesn't have time on dialysis as a part of the criteria. And so I'm confused as to why we're opening it if we determine 2701 in the in-person meeting. And even if I remember rightly from my notes from the in-person meeting, the developer at that time said the measures were almost exactly the same except for that time on treatment.

So, if we're voting to reopen this, does this mean this then would – and let's say it passes though, does that mean then that this goes on for harmonization between these two measures?

(Sarah): Yes, you have to vote – so both of these measures; this measure was put forward by CMS. The other measure was put forward by another developer. So you consider the measures on their own merits and you vote on the measures on their own merits to get to a recommendation status. And then if both measures are recommended for endorsement is when there'll be a discussion on related and competing including harmonization recommendations.

Constance Anderson: For the clarification, I appreciate that.

(Sarah): Sure. Lorien?

Lorien Dalrymple: So, I just to want to follow up on a couple of the earlier comments also to try and perhaps remind ourselves of the discussion and I hope others committee to weigh in as well. My recollection about some of the issues that were raised on measure 2700 as compared to the other measure that did make it through that this only required one day of data and there was some concern about whether that changed the reliability.

And then with regards to the validity testing, I don't know that the concern was statistically significant as much as there wasn't a graded association. So, for example, quintile five had one of the lower relative risk compared to quintile two, three or four, so the question became why aren't we seeing a graded association with higher quintiles of U.F. and then quintile five was not statically significant, I believe from mortality, but stewards can correct me if we're misinterpreting that.

So, I think it wasn't – And the discussion around validity I think was also can we explain why there isn't a graded association because the stewards had mentioned that there may be selection bias around healthier patients with higher U.F. rates and they – and we had asked, well, can there be further analyses done to clarify that point. I didn't see in the memo that we got follow

up to that, but if others remember this conversation better, that's what I recall about this measure from the in-person meeting.

(Sarah): OK. Any additional comments, Peter?

Peter Crooks: I agree with Alan that we – that there was a misreading by some of us of the validity data, and in my mind, it did in fact show validity. The fact that it didn't get progressively worse with each quintile doesn't particularly bother me, what – I think the bottom line is that patients who did not meet the criteria for low ultrafiltration rate had bad outcomes.

And also, I think in the memo, do they address this question about one measurement versus multiple measurements? One point for the measures versus several dialysis sessions?

(Sarah): (Casey), did you want to respond to those questions?

(Casey): We want to let Joel Anders at CMS respond to that.

(Sarah): OK. Joel?

Joel Anders: Sorry. So, I apologize. I don't have access to a computer right now so KECC is kind enough to raise their hand for me. The first point that we want – we won't ask for additional analyses. Of course, we were all just going to provide additional analysis.

I think that the one thing that you want to make sure gets recognized as well as the food analyses were not our sole basis of validity. We also presented the (inaudible) voted on and supported by a majority of the TEP that helped us develop the ultra filtration rate measure so I just wanted to make sure that that was also another because I think that was not mentioned in the discussion at the last meeting. I just want to make sure that that's something the committee is aware already.

(Sarah): OK, Peter, your hand is still up. Did you have anything else?

Peter Crooks: I forgot to lower it. Thanks.

(Sarah): OK. And Poonam?

Poonam Bal: Sure. So, as a remember this measure did go down in validity. I think we've had a good chunk of discussion on some of those parts by doing it and letting it – opening it up to the committee one more time. The lead discussants originally on this measure were (Frederick Castle) and Dodie Stein. I just wanted to see if they feel comfortable doing a discussion on this. I know that Allen, you had found some new information. You can also join as well. I guess, of course, I want to let (Frederick) and Dodie have a chance. Did you want to make any comments about validity?

I'm not hearing anything, so, I know …

Male: Can I just ask about the TEP, the validity testing for the TEP because I thought what we had been shown originally was that it was a voting of the TEP after the conference about the idea of having a measure? Was it actually voting on a measure of greater than 13 mils per kilo per hour? I just can't tell from my notes that I have here.

Poonam Bal: Does anybody in the committee feel comfortable responding to that before we go to the developers?

(Sarah): I have a note that says 5 out of 8 TEP members recommended UFR measure greater than 13 mils for k per hour but these are just my hand typed notes.

(Crosstalk)

(Sarah): If the stewards can weigh in, it would probably be the most helpful.

Poonam Bal: OK, if we can get a quick response from CMS or University of Michigan on what that covered. Thank you.

(Off-Mike)

Female: Yes, this is University of Michigan here. We have the moderator, Dr. Rajiv Saran.

Rajiv Saran: Hi, Rajiv Saran and we had a vote back in business for some time right now.

(Crosstalk)

Rajiv Saran: Thirteen?

Female: Yes.

Rajiv Saran: Thirteen. And there was a vote on UFR measure for all patients, more than 13 members of the TEP voted to recommend the development of a facility level measure for percent of patients at facilities with UFR greater than 13 ml per kilo per hour based on observational data. Yes.

Poonam Bal: Terrific. Thank you. So moving forward, were there any other comments? Anyone wants to make about validity and I do ask again that we go back to the hand raising procedure.

I don't know, Alan, if you want to make additional comment since we did receive e-mail from you stating that you have found some new information since our initial review?

Alan Kliger: I've already shared it. Thank you.

Poonam Bal: OK. I'm not seeing hands so I think we're ready to vote on validity. Give us one second and we'll have that pulled up for you.

Male: Just a clarification actually from the NQF, from the staff perspective, so we're talking now about both. We just talked about face validity from the TEP and we also talked about statistical validity from the numbers. Can you just tell us, does one trump the other? How do you have both? How do you reconcile those two?

Poonam Bal: Severa, I'll let you take that one.

Severa Chavez: Yes, I mean we don't differentiate between that on the vote. And I wouldn't say that one necessarily trumps the other. I think this comes down to your clinical expertise and your belief on do – I mean, what I would personally be looking for that both, both concepts support the measure whether it's the face validity or, you know, and the statistical testing and validity that they both

support the measure. But it's not, you know, you wouldn't see measures come through NQF at times that just have face validity versus other types of validity.

So, you know, this is one of those areas that you would walk through your algorithm to determine where you felt it's all between high, medium and low based on each of the validity criteria but they're not separated out.

Male: OK.

Poonam Bal: OK. Were there any …

Male: And I'm still …

Poonam Bal: Sorry, go ahead.

Male: Well, and maybe just back to the discussants who discussed this. I'm just so unclear when we said, do we – we heard last, face validity, did we come to a consensus on statistical validity? I know Alan, you had had some reconsiderations. Lori, you've summarize it as well. Just – did we come up with an answer across all of us or no?

Alan Kliger: Well, we're going to vote on that now I guess to see how – where people come down. I personally felt that it doesn't meet both stats in the tab show validity.

Poonam Bal: OK. So, I'll just ask one last time, is there any additional comment? Is there a response or any to that sort? I do not hear anything or see any hands raised so, I'll – we'll go ahead and move forward and vote.

So, we are voting on the validity for 2700. The options are high, moderate, low and insufficient. And we do have one conflict, I think. Actually, no, we do not have a conflict on this one. So, we can go ahead and move forward and vote on this one.

So, (Shawnn), could you confirm how many voting lines we have? I know some people had to step away or get off the line.

And please vote while we're getting that number and especially, if you're going to be e-mailing it.

(Shawnn), are you still on the line or (Nan)?

(Shawnn Bittorie): Yes, one moment.

Poonam Bal: All right.

(Shawnn Bittorie): Sorry about that. My mute button was stuck.

Poonam Bal: No problem. Can you let me know how many people are voting – are able to vote? I know ...

(Crosstalk)

(Shawnn Bittorie): Looks like 15 because I know you have a couple that you're receiving by e-mail. So, no, I'm sorry. I'm double checking, 17.

Poonam Bal: OK. Perfect.

Male: Has it been posted yet to vote? I don't see anything on my computer.

Poonam Bal: Yes. We – you should be able to see a slide that says scientific susceptibility of measured property to be validity and then (have four) voting option.

Male: I don't see anything.

(Shawnn Bittorie): OK. If you fail to see the options on your screen, you can refresh your session by pressing F5 on your keyboard or refreshing your browser line. And it should reload for you.

Male: Yes, coming up now.

(Shawnn Bittorie): Excellent.

Poonam Bal: OK. So the final results are three high, seven moderate, six low – sorry, seven low, zero insufficient. And that does put us in the gray zone but we can move

forward. And then the next discussion would be on feasibility. Were there any comments on feasibility?

OK, I'm not seeing any hands raised or anyone speaking up, so we can go ahead and vote on feasibility for 2700. The options are high, moderate, low or insufficient. Again, if you for whatever reason cannot see the feasibility slide, please refresh your screen so we can make sure you're getting your vote and we should still be at 17 on the screen and I'm receiving one vote. I believe one person had to step away on my phone. Thank you.

Severa Chavez: Poonam, you did have a hand raised just a second ago.

Poonam Bal: Oh, I'm sorry. I missed it. Did someone want to make a comment?

Peter Crooks: This is Peter. I was just going to say that just remind people this is CROWNWeb data for what it's worth in terms of considering feasibility.

Poonam Bal: Thank you for that note, Peter. Does anyone have any additional comment? OK, I'm not seeing anything. So, please proceed to vote. Thank you.

(Shawnn Bittorie): Poonam, we're 16 online right now, so your account is correct.

Poonam Bal: OK. Perfect. All right, so we have six high, nine moderate, two low and this measure does pass on feasibility and we can move forward to usability and use. Were there any comments on that section?

OK. I'm not seeing anything. So we'll go ahead and start voting on usability and use. The options are high, moderate, low, insufficient, and voting is open. And we are looking for 16 votes on the software and one through e-mail. Thank you.

If you've not voted yet, please put your vote in.

I've not received the e-mail vote yet. Just hit the number here.

Female: There were go.

Poonam Bal: We actually do need that last vote through e-mail because we're very close to the decision here. And I want to make sure we catch everyone that's one the line. Never mind, I forgot there's not much time. We can move forward.

The usability and use it is one high, five moderate, 10 low and zero insufficient. And we move forward to the overall suitability for endorsement decisions. Were there any last minute comments that someone wanted to make before we make the overall decision for endorsement?

Sorry for the flipping of the slides. We are having some software difficulty there but this is for endorsement and nothings else.

OK. I'm not seeing any hands or comments made. So we're going to go ahead vote on overall suitability. Your options are yes, I recommend this measure for endorsement or no, I do not recommend this for – measure for endorsement. And we are still looking for 16 on the software and one on the phone. Thank you.

OK, we have received all the responses, the results for overall suitability for endorsement is five yes and 12 no. So, this measure has not been recommended for endorsement and we will move on to our next measure for consideration. (Sarah), we'll pass it back to you.

(Sarah): Sure, thank you. OK. So I think the next two measures are fairly similar both in where they ended up in voting as well as the additional information provided but the first is 2703 minimum delivered hemodialysis dose, again, it's CMS measure. One comment of support is the committee's recommendation to not endorse the measure. Another commenter supported the endorsement of this measure with the condition that the upper limit be removed.

CMS did provide response regarding their request for reconsideration on this measure which are the bullets noted in your memo. And just as a reminder in the in-person meeting, this measure was not recommended. Evidence was gray zone and the measure failed in gap.

So, any additional comments or considerations from the committee in determining interest in reconsidering this measure or any additional information you would like from the developers to help you make that decision? Alan?

Alan Kliger: Again, I just want to point out that we heard from the developer unlike what your summary here. This is not dialyzing three or four times per week. I just want to clarify it's only three times a week.

(Sarah): OK, that is actually a developer response so I'll need them to …

Claudia Dahlerus: I'm sorry, this is Claudia Dahlerus at the University of Michigan KECC and what's indicated on the screen, this is just our summary of the committee's concern about the three or four times a week specification which is we explained earlier that was removed, that was revised in the measure so this is just limited to thrice weekly patients, both for children on dialysis as well as adults.

(Sarah): OK so your comment is that it was made more explicit on the specifications that the adult component is also limited patients on three times per week?

Claudia Dahlerus: Yes.

(Sarah): So it's really that last sentence is what you clarified?

Claudia Dahlerus: Correct.

(Sarah): OK. Any other comments or questions?

OK, then the question to the committee is with this additional information then, the revisions made to the measure as well as the information that came in during public comment, do you want to reconsider this measure and vote on it?

And so I guess what the question – I'll ask you to raise your hand if you feel this warrants reconsideration of the measure.

Poonam Bal: So we're at 10 people saying yes, they would like to reconsider this measure and that is consensus for revoting so we will go ahead and start discussing this measure where we dropped off.

I'm sorry. Severa, I forgot you're reading.

(Sarah): Actually, I mean to be consistent with what happened last time is that the committee revoted on where the measure failed so they started that revoting at the performance gap.

Poonam Bal: OK, perfect. That's what I was looking for, performance gap.

All right, so we'll go ahead and open that up. Were there any comments on performance gap before we vote?

Male: And I'm sorry guys what was the S8 or S7 because I don't have that raise hand option anymore, just have option on my screen.

(Shawnn Bittorie): To refresh your screen, you can press F5 on your keyboard.

Male: OK.

Poonam Bal: OK, and I just want to make sure that everybody in the committee still has the ability to vote and feel comfortable moving forward. I've cleared the hand so if someone would like to make a comment, please raise your hand now before we vote on gap.

Male: I can't raise, I'm sorry go ahead. I can't raise my hand but I'd like to say something.

Poonam Bal: Go ahead, no problem.

Male: I think this one, I still struggle with this, right? I mean if I read through the rationale, a lot of this has to do with the number 11 which seems to be internal CMS privacy related member as opposed to the statistical significance. So, and then I have a hard time just understanding the rationale. I think it's important to have pediatric patients in the system but you need to be able to

use them out, I would think, individually if I was picking a center for pediatric patient as opposed to one big measure.

So, I'm just having a hard time still thinking through how we think through the performance gap.

Male: Alan?

Alan Kliger: It just would be useful to me to hear the subcommittee again. Just briefly give us your take on these questions.

Poonam Bal: Is there anyone else who want to make any comments or respond to that?

Peter Crooks: I think I was on that workgroup. This is Peter and my notes say that the gap was – the mean was 93.5 percent plus or minus 7 percent. There were statistical differences and disparities in care but not meaningful differences. So, if 93.5 percent are obtaining the outcome, there's a, I guess, a relatively small gap which I think we discussed at the in-person meeting.

Alan Kliger: Thank you for refreshing our memories.

Poonam Bal: OK, were there any additional comment? Mahesh, if you're not able to vote, please, go ahead and e-mail me your vote so we can make sure we get it. And (Shawnn), I'll just ask you to help us in any way you can making sure – Are we still at – I'm sorry, I see a comment from Connie.

Connie, what was your comment?

Constance Anderson: I guess from my minutes, from the in-person meeting, one of the concerns with this measure, if I remember rightly, is it was pooling pediatric patients and adult patients. And there was concern about that. And excluding pediatric home patients which was fine.

But if I remember the discussion correctly and again, my notes are pretty cryptic on some of this information is, it was the pooling of both the adults and the children into a single pooled measure.

Can anybody refresh my memory about that?

Michael Fischer: I thought the concern had more to do with it, I don't know.

Constance Anderson: Well – And Michael, maybe this might help you. But in my notes, it says that the pediatric population, the discussion was surrounding the single pooled Kt/V of 1.2 but most of these, there's other criteria that are as important as that. And most of the pediatric patients may not dialyze just three times a week.

Michael Fischer: Yes. I thought I remember it was something about the frequency. Well, most of them do dialyze three times a week and it's only somewhere between, you know, four and eight percent who dialyze more than three times a week. I thought, you know, what I remember the discussion had to do with the inclusion of those extra and going back to just thrice weekly may help with that.

Poonam Bal: OK. The developer does want to make a comment before we go to them. I do want to – I see Lorien's hand is up. I wanted to go to her first and then …

(Crosstalk)

Female: I don't know if you're raising your hands ...

(Off-mike)

Poonam Bal: OK. Give us a second. I just want to give Lorien a chance to make her comment and then we'll come to you.

Lorien Dalrymple: And I was just going to say my recollection is actually similar to both of the last statements. I think there were two concerns. One was …

(Off-Mike)

Poonam Bal: I'm sorry. Lorien, continue. I'm not sure what …

Lorien Dalrymple: OK. So, all I was going to say is that my recollections, there were two areas that we talked about at committee. One was this issue of pediatric having three or four times weekly and it sounds like that issue can address by this

measure will now be limited to thrice weekly for both adults and pediatric. But I thought there was a broader discussion around when we put peds and adults together, does this become a meaningful quality metrics for pediatric population.

And what did the committee think was the advantage of grouping them, so that we don't lose facilities with small ends because the cells have to be 11 or larger and kind of the benefits of grouping and maybe having less information as compared to losing facilities that won't otherwise get reported.

So I don't recall if the committee really came to a consensus on which of those we thought was more important that you capture more facilities, and the way you do that is you group pediatrics and adults and maybe drown out the pediatric numbers a little bit or the home numbers depending on which of the composite measures we're looking at.

So, it would be helpful to me before we vote just to get committee members' thoughts on are there any concerns about pulling pediatric and adult population.

Joshua Zaritsky: I'll speak just from – I'm sorry, I can't raise my hand. But I'll just speak from a pediatrics' perspective. I do want to have – the Kt/V in general, in pediatrics is usually pretty easy to obtain and I'm not worried about, you know, the peds' voice being drawn out. But I do want it, I do support that there is something for pediatrics because I believe there is that we voted on before, right?

Poonam Bal: Thank you so much for that, Josh. Peter, I see you raise hand and then after that we'll definitely go to Joel. Give us one more second, Joel.

Peter, do you have a comment?

Peter Crooks: Yes, the – Just as Lorien said, there was discussion about the pediatric patient not being captured if you don't bundle them together this way. And then, it's also an issue of whether you buy in to the CMS logic of ultimately rolling all these Kt/Vs from hemo, peds, adult, you know, into one grand metric which I think is their intention to move towards that and whether you believe that that's a good thing or not.

Poonam Bal: Thank you so much for that, Peter. At this point I would like to give it to Joel or someone else from CMS that would like to make a comment.

Joel Anders: Thank you very much. I think that we've just kind of gotten back on what our intent with this measure is. Just a couple of points that I want to make clear. There is of course some information that's lost when you combine the two populations together. The tradeoff for that is that you simply exclude the quality of care provided for certain populations entirely from consideration of public reporting and the QIP and other similar programs.

So the measure's intent is to get around those limitations to ensure that there is capture of the care being provided for all patients not just primarily adult hemodialysis patients. And that's the primary logic that goes behind this. I think the other thing to touch on has been the high level of performance. And this was something that we ended up hitting on as a question of classification at NQF and that is whether or not a measure is appropriate, for instance, for reserved status if it hasn't – if it is essentially a modification of existing measure but is not itself in its current form presented as its own measure.

I think that was the other issue that we want to continue. You know, I think we feel like the underlying metrics for the combined hemodialysis measure are sound. They are applying appropriate inclusion/exclusion criteria and performance standards as defined by the TEPs who developed those measures as well as the – as reviewed by the National Quality Forum in the past, which is why they're endorsed.

What we have identified essentially is an unintended consequence of an existing policy that we have to follow and we're trying to shape the measure in such a way that exist in that reality and I understand that there's some concern with the, you know, that this doesn't reflect the quality issue but I think it does because if we don't shape the measures in such a way that they address that issue we will be excluding patients who should not be excluded from the measures and who we don't want to exclude from measures. And there are potential consequences for this. They go beyond measure performance because it also affects, for instance, potentially the improvement of care and

modalities where we have found that have been tied with improved patient mortality and mobility and I think that's an important consideration to take into account.

These are things that we want to con – at least promote the consideration off when patients are receiving dialysis treatment. And if we're excluding that from our quality measures I think that we undercut any movement in that direction. And I think this is one way that we can have these measures to ensure that these patients remain front and center in consideration for quality assessment and improvement in dialysis facilities. Thank you.

Male: Joel, the one thing I don't understand though is what was said before. Isn't it the case that if we do this there won't be an individual? You're advocating this in lieu of an individual pediatric measure, is that correct?

Joel Anders: I think the intent that we would – we would certainly be considering this for encouraging this in lieu of pediatric measure. I think the thing to keep in mind, however, is that for an individual dialysis facility, that facility is accountable then for the patients under its care whereas before it may have had both adult patients and a handful of pediatric patients and those pediatric patients simply not had been part of the measure assessment because there were not 11 of them, or there are not sufficient patients to reach a reporting threshold at CMS.

And this measure allows for that to happen, so in the broad population yes, it's true that you are being assessed for all of your patients and most of the patients within the measure will be adult hemodialysis patients but within the facility itself it's – you're looking at performance and the – you're holding the facility accountable for the provision of adequate dialysis for all of its patients regardless of their age or in the case of the file combined measure 2705 regardless of their modality.

Male: But trade off for that is you lose the individual pieces that may be relevant to someone looking for that.

(Crosstalk)

Joel Anders: Well, that gets to a question of what it's relevant for. I mean it's possible to assess a facility on an overall measure but also to report out that measure broken down into the subcomponents. I mean that's the measure but that's an issue of implementation and in reporting and improvement programs, not necessarily an issue of measures classification.

Poonam Bal: OK. I do want to keep going because we're going to a little off topic. We do need to focus on gap at the time. I know this is important discussion to have to really understand the measure but we do need to move forward. I also want to remind everyone that we do need to have public comment in 3:45. We will probably not get to 2705 but I do want to try to at least get to 1460 after this as the measure we skipped earlier and try to go back to that.

Were there any additional comments on the gap before we move forward? I'm not seeing any hands so I do want to go ahead and vote on gap for 2703. The options are high, moderate, low, insufficient and Mahesh, if you're not able to do the vote through the software please e-mail me, this is Poonam, please e-mail your response and I will take that to account in the final vote. Thank you.

OK, based on the votes we have zero high, five moderate, 10 low – I'm sorry, 11 low, one insufficient. And so this measure does not move forward on gap and we will move on to 1460 now. I just want to check with (Priti) if all your representatives are ready on the phone to answer questions as needed.

(Priti): I'm here. Can others identify themselves?

Dan Pollock: Dan Pollock at CDC.

Jonathan Edwards: Jonathan Edwards, CDC.

Poonam Bal: OK, perfect. So I'll give it back to (Sarah) to introduce 1460 and see if the committee would like to reconsider or not.

(Sarah): Yes, so just as a reminder this measure is 1460, the Bloodstream Infection Hemodialysis Outpatient. It is a CDC measure and commenters' themes were that they agree the tracking of bloodstream infection is extremely important.

However, there were concerns raised about the methodology used especially in regards to the inclusion of the adjusted ranking metric and the standardized infection ratio.

There were also three commenters supporting the committee's decision to not endorse the measure and then one commenter felt the measure should be endorsed by methodological concerns. The overall status of the measure after the in-person meeting was that it was not recommended and the developer, CDC, have provided some additional information in their reconsideration of the measure and when we spoke with some of the staff prior to this meeting, getting ready for this meeting, CDC did say that they would welcome the opportunity to make a couple of comments in support of that reconsideration.

And I just think in light of the previous community conversations on this measure, we should give Dan and his team an opportunity to make some very brief comments and then allow the committee to ask additional questions.

Dan Pollock: Thank you very much, this is Dan Pollock at CDC along with (Priti), Dr. Nguyen, Jonathan Edwards. We all work on NHSN together and NHSN is a nationwide surveillance system that serves as a source of data not only on dialysis patient bloodstream infections but also hospital patient infections. We've got of five NQF-endorsed health care associated infection measures and each of those measures either in the initial submission or in updates or measure maintenances have included both the SIR and the ARM.

And the reason why we are including both is that they serve different purposes. The SIR is a risk-adjusted summary measure of the observed to expected infections. The ARM is a reliability adjusted SIR that takes into account differences in volume of exposure and that is a fair way to evaluate facilities be they dialysis facilities or hospitals or other types of facilities if the evaluation purposes is to rank facilities.

And so we have either introduced the ARM or added it to our HAI measure specifications over time because of each of these measures is being used by CMS for initially pay for performance and now more and more – I'm sorry initially pay for reporting and that more and more pay for performance, the

HAC and value-based purchasing programs on the hospital side and the QIP program on the dialysis side.

So in keeping with what we've accomplished in the hospital-oriented measures, we have with the measure proposal before the committee introduced the ARM into the dialysis measure. The ARM itself is based on an extensive amount of prior statistical development and use including in quality measures. It is a metric that relies on the based in the statistical techniques. It's well established. Our vision for is that it would be used to summarize data on an annual basis for purposes of ranking facilities and as I said earlier, it compliments the unadjusted SRI which we see as the metric of choice when data are being summarize on a quarterly basis or used for four rolling quarters as often the case in CMS public reporting.

So, we think both belong in the measures. We think that there's ample evidence of its value. The ARM that is and we're just very appreciative of the committee reconsidering its initial decision and would be glad to comment and questions.

(Sarah): Great, thanks, Dan, and just to remind the committee, your past conversation with one that was on the phone that was suppose to be in person meeting and there were a number of questions regarding the actual specifications of the R-methodology and validity reliability, et cetera. So, if there are additional questions that you have to CDC based on the information and they subsequently provide this, this would be the time to ask this additional questions. Lorien?

Lorien Dalrymple: My recollection of the phone conversation that we had was first in part around our reliability for which we've been provided a lot of additional information but I thought there were also concerns about validity because within the submission in my notes, I had cut and paste the statement that validity is evolving needs to be reassessed. Do we have more information on validity now? I didn't see it in the memo but I may have missed it.

Dan Pollock: So, in terms of the – you're talking about the validity of the bloodstream infection measure itself not the validity of the R-methodology?

Lorien Dalrymple: The validity of the measure.

Dan Pollock: OK, right. So, the measure has been in use of – for couple years by CMS in equip program. We are working with CMS to bring that reporting into their validation efforts. We have also worked with states such as the State of Colorado that has validated the dialysis of that the reporting – reported to NHSN from facilities in Colorado. So, we do have some experience with validation. I think the Colorado data are quite encouraging. We look forward to having a national validation program in collaboration with CMS but that is in a launch phase at this point.

Lorien Dalrymple: Are you able to give us any specifics about the Colorado validation project?

Dan Pollock: I don't have them in front of me and I don't have then off the top of my head. I don't know pretty if you're in a better situation to recall specifically.

Female: So, I don't have them in front of me but I believe that that was included in the measure specifications. We included I think two different studies. One was the initial Colorado data validation and the other one was one that was done I think many years ago back in 2002, I believe.

So there are two that should be …

Lorien Dalrymple: Project 1 and project 2 is one of this the Colorado project.

Female: Yes, that's it.

Lorien Dalrymple: OK.

(Sarah): Lorien, my recollection as well is there and I think you're right. There was a comment made regarding ongoing validity but they had provided both of those studies in their original submission.

Peter, you hand is up.

Peter Crooks: Yes, just further on validity, is the validity testing that's been done so far is that basically testing of validity of the elements that are reported or is it comparing the outcomes to – outcome such as mortality or hospitalization.

Dan Pollock: I think that the Colorado's study was an effort to confirm the determination as to whether or not there was a bloodstream infection. So, that's the outcome that is the focus of the measure and the strategy was to evaluate whether on the basis of culture findings what was or was not reported by the analysis facility that could be confirmed.

Male: And Dan was that validity done with the ARM or without the ARM?

Dan Pollock: That was done basically without regard to the SRI or ARM it's just a matter of case finding. And of course the cases that are found then configure into both the SRI and the arm of calculation but it wasn't designed to validate the statistical summary method.

Male: But so many of this still study aside and turn the validation of DNHS measure with the ARM as presented?

Dan Pollock: No because we're introducing the arm with this measure of proposal. We have done analytic work with the ARM using the blood stream infection data but we have not published that. We intend to use the arm in collaboration with CMS or the quality measurement reporting purposes that I mentioned earlier. And we're also intending to incorporate the ARM in ways that would make a part of our regular reporting at out of CDC on the summary statistics nationwide. But we haven't reported those data yet.

Male: OK. This is a relay question that we've been asking for a while. I think part of this is the explanation it's given for the actual methodology is …

Dan Pollock: Yes.

Male: … continuously vague. I mean I can't – if I gave this one of my people I have because that's why people just to try to replicate. Nobody understands that these are way the CEC can at least provide us some point, more detail on what the calculation is rather than just saying it's based in distribution?

Dan Pollock: Well, I – yes. Yes, we definitely can do that, we have done that. Jonathan Edwards is here, he's our lead statistician and has basically provided that type

of information in other situation. There are series of sophisticated statistical steps that are often better described in article and even book length treatments.

So, you know, as much as we would love to be able to provide a replicable description of each of the steps, our strategy instead is to refer to the processes that are involved in the ARM calculation insight on peered reviewed literature and authoritative text that describe each of those steps.

And, you know, we have included and we provided the NQF in hopes that we would be able to talk with you a list the references that covered that and that are available for those who want to do a drill down on the specifics of the methods.

Jonathan, you want to add anything to that?

Jonathan Edwards: Right. So, one thing that sort of comes into focus is just the whole idea of using Bayesian method and sort of coming in to the knowledge base of what does that entail. It really does as Dan said brings with it of, you know, of fair amount of detail, heft, knowing and understanding of the theory.

But, you know, basically what we're trying to do is used sort of long standing methodologies that really seek to adjust that SIR, so that it is – we take into account that the volume of the denominator which is in this case, patient months.

And so, it's largely about adjusting the SIR and it's just doing it in a way where there Bayesian methods being used to produce that adjusted SIR and so that's the basic idea.

And so, I'm happy to go into more detail now but it's probably not the time of – there have been papers since the late '70s talking about how to adjust various data for reliability. And it's, you know, sort of – it's not easy to document exactly all steps in, you know, some short enumeration of exactly how to produce that. So that's …

(Sarah): OK.

Jonathan Edwards: Go ahead.

(Sarah): Jonathan, can I break in here? And I'm really sorry to have to do this, but we have a time requirement to break the public comment. And so, what we want to do then is have the operator open the call for public comment and then we can come back to this conversation. And I'm sorry if it's a really awkward time to have to do this.

Jonathan Edwards: No problem.

(Shawnn Bittorie): If you wish to make a public comment at this time, please press star one on your telephone keypad.

And there are no public comments.

(Sarah): Perfect. So, Jonathan, did you have anything else to wrap up or did the committee have additional questions for Jonathan or Dan?

Male: I just have a hard time with this. Jonathan, I mean I get what you're saying, but if you can write a paper on it, it just seems where that there's no way of even describing it, right? I know we've been asking for a while, so I just have it – I have a hard time understanding how to vote on the validity of a calculation that only has references and not an actual calculation.

Jonathan Edwards: So, there are calculations but it just – it involves this Bayesian sort of family of methods. And that's not easy to write. I mean I can write at a high level, but you'll still have questions about what this – that mean.

And I'm really regret in a way for it to sound like that there's something in black box because if you knew me at all, you'd know that I abhor either just black box, but it just – it's not easy to just explain other than to say that the methods that we have used Bayesian analysis to come up with an adjusted SIR.

And this is basically about an adjustment that deals with the observed accounts. And anyway, so …

Dan Pollock: I mean, yes. This is an example. I mean, as we said in, you know, our brief that we submitted and also we could be talking with you, one of the steps of Bayesian posterior distribution constructors to Monte Carlo and Markov Chain sampling is used to produce the adjusted numerator for ARM which is reliability adjusted SIR.

So that's make reference to Monte Carlo and Markov Chain sampling which we refer to and would, you know, welcome an opportunity to elaborate on.

Jonathan Edwards: Sure.

Dan Pollock: But this has been done in the peer reviewed literature. So, you know, if Jonathan really is an excellent teacher and we all learned a lot from him methodologically, but Jonathan in turn like this classic references and I think invoke them and can summarize them, but that would take time.

(Off-Mike)

Dan Pollock: And again, we provided the references that are the basis for the work that Jonathan has been leading.

Jonathan Edwards: Right. I can speak to the concept of waiting that really is sort of at play here and what's being carried out in this. You know, what Dan mentioned is a short acronym. We all love acronyms, so we love them in a statistic space as well. But, MCMC is Markov Chain Monte Carlo simulation and it's a way of producing estimates that are – anyway, I really can't go further in that direction.

But it's a way of producing when you don't have an objective function, you can produce estimates and then you can summarize those estimates and then you can use those in producing the reliability adjusted SIR.

But the concept is that a particular facility's data to the extent that they don't have very large denominator or patient month volume relative to others, they just can't allow the SIR to be staying exactly where it's at whether it's a low value of an SIR or a high value of an SIR. And that obviously assumes that you understand what an SIR is.

But the idea is that the facility is going to have lower exposure volume, get weight at more toward the mean than those that have higher volume. So, the idea is as there's greater reliability of a particular facility's SIR, it is allowed to stand more on its own and does not need to be waited toward the grand mean. And that's the basic idea of what's going on. So …

(Sarah): OK. Peter, your hand is up?

Peter Crooks: Yes. I'd like to just kind of step back a little bit and think about, you know, what our job as a committee is a role to this measure. This is an outcome measure. So, the case has made that bloodstream infection is the outcome as opposed to process that leads to reduce mortality or and so on.

So, number one, do we buy that and I think that's a reasonable postulate then the committee is over all deciding is it important to have a measure of bloodstream infections and hemodialysis patients is it – is there a gap? Is it something that's useful that would help improve care and that's meaningful to our practices and should be ultimately, you know, rewarded and acknowledge in public reporting and perhaps in payment systems, so that's a step back a little bit and there is difficulty – it's more complicated than a numerator over denominator but I can see how what it means and how do a interpret that, but I guess it's sort of – for those about expert statistician is sort of a matter of faith and trust.

And so, that was just to try to re – step back and say, you know, how do we move ahead on this?

(Sarah): Thanks, Peter, and, you know, I think that if – I don't see any other hand this is one of the measures that it is up to committee to make a determination that based on the additional information and the request by the CDC as well as review of the public comment and any rereview of materials that have been provided, if you would like to move forward with a reconsideration of this though, meaning that we'd go back to the voting process.

So, if you would like to revote on this measure and reconsider this measure please raise your virtual hand.

Poonam Bal: (Sarah), are you still there?

(Sarah): I am still here.

Poonam Bal: Were we looking if see the committee would like to comment more before moving forward? I'm sorry.

(Sarah): Well, they're raising their hands if they want to reconsider the vote so I'll made you to keep track of counts of that.

Poonam Bal: All right, thank you.

So we're at six right now which is not enough to reconsider this measure, do you want to give a couple more seconds or just go with the six at this time?

Male: Going once, going twice, I guess that's all we're going up to six so …

Poonam Bal: Then we will not reconsider this measure.

(Crosstalk)

Poonam Bal: Sorry. And so, we are at the tipping point. We did push 1660 and 1454 up until on Monday. I guess I'll ask from the committee, I know we've been on line a very long time, so we can attempt to go to the last measure that we need to reconsider today or we can just push it up till Monday. I just wanted to see from the committee if they had any – what their preference would be.

(Andy): It's (Andy). I got to – I have to leave right at 4.

Alan Kliger: This is Alan, I do as well.

Poonam Bal: OK, and I want to give developers, you know, enough time to really have the committee discuss their measure. So, let's not push it and try to get it done today. We do have time on Monday's call. We do have a lot less time. We

only have 2 hours then and we also need to cover related and competing on that call.

So, again I ask everyone, you know, not repeat comments from the in-person or today and not to basically try to keep the discussion going and moving along.

Again, I want to thank everyone on the committee today, you guys have always been wonderful, always so prepared and ready to discuss things and we really appreciate it at NQF.

Peter Crooks: Poonam?

Poonam Bal: Yes. I'm sorry, go ahead.

Peter Crooks: Yes so, please repeat the numbers of the two measures that we delayed so that everybody have a chance to take up another look at them over the weekend or before (the) meeting.

Poonam Bal: The two measures that the committee would like have a little more time with are 1660 and 1454. And there are memos for both of those measures, so we do recommend the committee, read all these memos and also familiarize themselves with the (mix) as well, or the measure worksheet, sorry.

Peter Crooks: Thank you.

Female: Thank you.

(Crosstalk)

Poonam Bal: Were there any question before we move forward?

(Crosstalk)

Poonam Bal: ... one. Maybe not. OK, so for our next step the committee will be meeting again on Monday, August 3 at 3:00. We'll go until 5. I just want to remind everyone that the committee will get a new voting login, so you will not be

using the same one you received for this call. (Shawnn) will be e-mailing you on relatively soon for Monday's call and you should be using that web link to get in.

Also, along with that will be discussing the two measure we moved over, any remaining measures that we've not had a chance to review on this call and also be discussing related and competing. Once we have that call that would take the feedback from the committee and update for that support and we'll go out from member voting and then eventually go to CSAC and the board.

So, that is moving forward, I just wanted make sure before we let everyone go, if there were any remaining questions, please let me know now, and also, always can feel free to e-mail me or anybody on the team with any questions you have if you think of something later.

I'm not hearing anything. With that said, I'll let everyone go with five minutes extra. Thank you so much for being so attentive and we'll speak to you soon. Bye-bye.

Male: Thank you.

Female: Bye-bye.

(Sarah): Bye all, thank you

Male: Thank you.

Female: Thank you.

Male: Bye-bye

(Shawnn Bittorie): This concludes our call. Thank you, and you may now disconnect.

END