NATIONAL QUALITY FORUM

Moderator: Renal Project
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OPERATOR: This is Conference #: 25700065

Poonam Bal: Thank you. Welcome to the third workgroup call. This is Poonam Bal, the project manager on the call.

For those of you who have not attended before, the structure of the call, basically would be half of the committee discussing but half also learning the process we'll take in the in-person meeting.

So, before I start explaining a little bit more about how the meeting will be run, I just wanted to see if we have all our workgroup members on. And I'll give it over to our project analyst, Alexandra, to do the roll call.

Alexandra Ogungbemi: Hello. Is Lorien Dalrymple on the line?

Lorien Dalrymple: Present.

Alexandra Ogungbemi: Stuart Greenstein?

Stuart Greenstein: Present.

Alexandra Ogungbemi: (Debra Hain)?

(Debra Hain): Present.

Alexandra Ogungbemi: (Karilynne Lenning)?

(Karilynne Lenning): Present.

Alexandra Ogungbemi: Andrew Narva?

Andrew Narva: I'm here.

Alexandra Ogungbemi: And Andrew – or Jessie Pavlinac, pardon me.

Jessie Pavlinac: Yes, present.

Alexandra Ogungbemi: Thank you.

Poonam Bal: OK, perfect. And I also want to take this time to see if there's any other committee members on the line that would like to introduce themselves?

Frank Maddux: This is Frank Maddux.

Poonam Bal: Thank you.

Peter Crooks: Yes, Peter Crooks, I'm on the call.

Poonam Bal: OK.

Michael Somers: And this is Michael Somers, I'm also on the call.

Poonam Bal: Any other committee members?

OK. So now, I also want to confirm that we have our developers on the call, is anyone from KCQA on the line?

(Lisa McGonigal): Yes, (Lisa McGonigal) for (Inaudible), we're expecting Dr. (Robyn Mancini) as well.

Poonam Bal: OK, perfect. Is anyone from the University of Michigan or CMS on?

(Claudia Delores): Yes, this is (Claudia Delores) from the University of Michigan. And I just – I want to let you know, I had stepped out from another meeting, so I will may not be available the whole time, but we have someone else from our team also on.

Poonam Bal: If you could just speak up a little bit, it was very difficult to hear you.

(Claudia Delores): Oh, I'm sorry about that. So, I am actually in a hotel lobby at another off-site meeting. This is (Claudia Delores) from the University of Michigan.

(Tampi Sharon): And also, (Tampi Sharon), (Kang Zu) and (Shu Tan) from the University of Michigan.

Poonam Bal: OK, perfect. And also, do we have anyone from RPA?

Amy Beckrich: Hi, this is Amy Beckrich and I believe we'll have (Paul Pilopski) joining us.

Poonam Bal: OK, perfect. Thank you so much.

So, the structure of the meeting, we'll do the first measure and we will be shifting over the measures a little bit. So, we will now be going in a different order, so the order will be 0256, 0257, 0251, 1662, 1425, and 2706.

So, we did change the order up a little bit for how we'll be going through the measures.

The process will be that we will start it with having the lead discussants introduce the measure, and then start off with their analysis of evidence. And we'll open it up to the committee, they'll discuss their – ask any questions, or, you know, disagree with the analysis that was made of the evidence. We'll move forward into gap analysis, and again, do the same thing, the lead discussant would introduce their analysis and the committee would have an opportunity to comment. And we'll just proceed through in that manner.

For the sake of time, we'll only do that for the first measure. And then moving forward, we'll do kind of a fast-forward version where we'll ask the lead discussant to introduce the measure and then only list any concerns or anything they want to highlight about the measure before moving forward.

Again, still will be allowed for committee to discuss it and, you know, provide their reflections to their fellow committee members and the developers who are on line.

But, since we only have about two hours, we do want to do that. Again, we will follow the process (inaudible) in the in-person meeting, but just for the sake of time, we'll be doing the other one.

So, we'll start off …

Stuart Greenstein: Poonam, I have a question before you start, because I know you're going to be doing 256. Do you want us to discuss some of the server response that we did have – I mean, trying to figure out what – how do you want to work this, because I want to open up my e-mails, I mean, my websites.

Poonam Bal: Yes, so we do want the lead discussants to bring forward their own reflections and then if they had an opportunity to review the committee's reflections as well to note any of those.

Stuart Greenstein: Oh, I don't see any of the committee reflections, I'm not sure if I'm opening up the wrong form. Maybe that's not (comm). I was not …

Poonam Bal: Are you going through the SharePoint site and opening up the measure worksheet?

Stuart Greenstein: I am on your SharePoint site, and I'm just looking at the surveys. And …

Poonam Bal: Not the surveys.

Stuart Greenstein: … the preliminary levels and then – oh, I see, show all responses, is that what we're supposed to be looking at?

Poonam Bal: Well, actually, instead of going to the survey, you need to go to the measure worksheet, which if you – Alexandra, if you just want to bring up the SharePoint site real quick.

Stuart Greenstein: Yes, I'm in the SharePoint site right now.

Peter Crooks: Yes, go to committee home and then you can see all of the measures there.

Stuart Greenstein: Right, I have that. And I have the measure open 256.

Peter Crooks: Yes, then there's one called measure worksheet 256 and then you open that.

Stuart Greenstein: But I don't see that, I don't see measure worksheet. I'm looking at all the measures. Oh, below that, is that where …

Poonam Bal: Yes, so if you just – if you go to the SharePoint site and you'll see on the screen that we have up on the webinar, (Alexandra's) gone down on the measure if – OK, Alexandra, can you go up for a second. You'll see the second category is measure documents, and now, if you go down to the measure that we're looking for, which is 0256 …

Stuart Greenstein: Right.

Poonam Bal: … you'll see that there's a highlighted title, you click on that.

Stuart Greenstein: I did that.

Poonam Bal: There will be a measure worksheet.

Stuart Greenstein: Right, I did that. I have the worksheet open.

Poonam Bal: OK. And then, once the worksheet is open, you go down, keep going down until you get to this little orange peach, depending on your computer, and that will have the pre-meeting – I'm sorry, the pre-meeting evaluations.

Stuart Greenstein: The pre-meeting evaluation?

Poonam Bal: Yes.

Stuart Greenstein: And – oh, I see. So there will be responses.

Poonam Bal: Yes, that is comments from the …

Stuart Greenstein: OK.

Poonam Bal: … committee.

Yes, was there another question?

Jessie Pavlinac: Yes, this is Jessie. I am also troubling in having a heck of a time with my internet up and in and out, so. I don't know if I can get in the end of the quality forum stuff yet. I'll try, but.

Poonam Bal: And that's not a problem, if you can remember your Insight from before, it's fine. There is a …

Jessie Pavlinac: In general.

Poonam Bal: Yes.

Jessie Pavlinac: Because you made me very nervous when we were the first one (up), so.

Poonam Bal: Well, I could say we could switch, but then the next one is up.

Jessie Pavlinac: My colleague, since he's got this up, start and then I'll – yes, I had really good situation on memory.

Sarah Sampsel: And this is – hi, this is Sarah. And just to add, to what we're looking for here for those of you who haven't been on any of the other workgroup calls, we're looking for you to first just a statement of this is a – you know, the measures, the following, the number, the description of the measure, numerator and denominator. And if it's a process measure intermediate outcome, outcome, whatever type of measure it is.

And then going into the evidence and as Poonam indicated, your own reflections as well as the other comments that you would find relevant that your co-workgroup members have provided in that orange section.

And then, you'll also find – you know, these are also the forms that do have some of the staff analysis in them. But, really, kind of just looking for your summary of what you saw and what you, you know, kind of how you would be thinking about evidence when we get to the in-person meeting when we eventually vote.

Poonam Bal: And also just for support, on the other workgroup calls, other committee members even if they were not assigned to that specific measure, you know, brought up topics and we're able to support any committee members out. You

know, that we're able to access their notes or what may be. So, don't feel nervous, we found that all the committee members have been very supportive.

So, obviously, the staff is here to support you as well.

So with that said, I will ask Jessie and Stuart to start us off with 0256. And you know, since Jessie is troubling, maybe Stuart, you want to start with just a brief introduction and then, your reflections on evidence.

Stuart Greenstein: OK. So, this is a measure, centers or patients who are on hemodialysis during the last hemodialysis treatment and using catheter usually for 90 days or longer. And essentially, the measure as we all know that hemo catheter usage has an increased mortality and morbidity related to it. So this is the measure to look at those patients who have been dialyzed with just more than 90 days and that don't have a different access.

So, the numerator is the number of patients who are consistently using a chronic catheter, access for 90 days or longer (inaudible) hemodialysis session during the month. And the denominator is all those patients who have had ESRD for greater than 90 days has over the last reporting month.

The exclusion are pediatric patients because pediatric patients are always much more difficult in terms of how to – what kind of access is due for them. Many of them are actually PD patients. So, and besides that there are no other exclusions, it's an outcome measure, I believe it's an intermediate because it's correlating from the catheter using morbidity and mortality to this.

OK. Now, let's see, where do you want to go from there?

Sarah Sampsel: So, what we would want to know here is do you feel from what was provided in the – you know, so the developer provided some evidence and do you feel that they supported the rationale for this clinical …

Stuart Greenstein: Right. So there are clearly numerous articles that support the concept that decreasing the use of these catheters will lead to increased survival rate for patients.

And so, I think that the evidence that they provided clearly shows that there's stuff in the literature to show that. So, I thought that it was high evidence. And it looks like the comments also support that from others.

Peter Crooks: There are …

(Crosstalk)

Jessie Pavlinac: I apologize. I do have a question, do we talk about 251 independent as 256, or – since they're kind of …

Stuart Greenstein: 251 is the official one. I know we have two …

Jessie Pavlinac: Yes.

Stuart Greenstein: Yes.

Jessie Pavlinac: And then we have the reduction of – or increased in AV fistula.

Stuart Greenstein: Right, that was a different one.

Jessie Pavlinac: For 251, yes. Exactly.

Female: So …

Jessie Pavlinac: So I'm – I was just – I just needed some clarification, we do them independently and then if they happen to be, whatever the right word as I always forget, then we talk about it after we talk about them independently.

Sarah Sampsel: Right, so what we would suggest on the workgroup calls is that you – we talk them about them independently and …

Jessie Pavlinac: OK.

Sarah Sampsel: … this will also give us an indication in the in-person meeting how we might want to group them together.

It is really up to the committee to determine when you want to group measures for discussion or if, you know, you have a discussion about this measure

which is minimizing use of catheters, where the other measure is increasing the use of AV fistulas. If you – you know, you could then say, you know, our conversation is pretty much the same for both measures, but you would vote separately. But on this call, it's really helpful for us to have the discussions independently.

Jessie Pavlinac: Thank you. Well then, I agree with Stuart that there is quite a few supporting evidence and – for this particular measure.

But I also probably rated it oddly because I was looking at two at one, so I apologize for that, if you look at my rating.

Sarah Sampsel: We won't hold you to the ratings at this point. And so …

Jessie Pavlinac: Thank you.

Poonam Bal: All right, so could we open it up to (inaudible) if there's any comments on evidence.

OK. If not, we can …

Peter Crooks: Well, this is Peter Crooks. I was waiting for the other workgroup members if they wanted to jump in, I'm not in the workgroup per se. I was just going to plant the evidence is based on KDOQI 2006 updates. And that, you know, the grading of the evidence, I guess, was grade A and B depending on exactly which guideline you're looking at.

I think the – in terms of filling out the boxes and so on, they really didn't report on the evidence review in 1a.7 where they're required to, you know, assuming the KDOQI was a systematic review of the literature, they're supposed to go into that in some detail in 1a.7 and they did not do that.

In 18.a, which is where they have a chance to bring another new evidence, they cite 50 papers, eight of them new since they were last endorsed in 2012. It's requested that they provide a summary of each new study and they didn't do that.

So, you know, to me, as a reviewer, I'm sort of left saying why (inaudible) the form, why don't they report them on the systematic evidence review. They're basically saying, "Here is the KDOQI guidelines, you know, take them." And so, that's my comment on evidence review.

Poonam Bal: OK. And then we can discuss that further in the in-person meeting.

How about we move forward to gap at this time?

Lorien Dalrymple: Can I ask one question? This is Lorien. Is there an opportunity for us to give this feedback and be revised prior to the in-person meeting, or is that not possible?

Poonam Bal: Unfortunately, no, we don't take the comments after the meeting, and put them into worksheet. However, you can bring them up in the in-person meeting and be able to discuss them at that time.

Lorien Dalrymple: OK.

Peter Crooks: Yes. And for some of you who've been on before, just to kind of restate that our job is to review the metrics as they're submitted off and this is in – in our very first versions, we were very tempted to be offering suggestions to rewrite the measure.

But that's not an option, we're not really going to make suggestions directly, you know, we may have opinions about how a metric might be improved or changed, but we really have to deal with what we have in front of us now, there's not going to be any opportunities for them to change their submissions.

Lorien Dalrymple: OK, so we are not going to allow for supplemental data for each specification, for example. I know last time around, there was some flexibility on that. But, for this meeting, if there are concerns about specifications or if clarity is needed, that will not be provided prior to the meeting, we will vote as is.

Peter Crooks: You know, the only chance for the developers to really – unless you have some – a direct question today or at the meeting, they do have a brief presentation without PowerPoint, I understand, before we consider each

measure. And so if you let them know that you have a question, they have a chance to maybe address your question at that – in that time slot.

Lorien Dalrymple: OK, thank you.

Poonam Bal: Yes, that's exactly right. But, developer does have an opportunity to bring additional information based on what the committee has said. So, if, you know, the committee would like more information of certain aspect or they listed something that the developer wasn't aware, they can bring that forward.

And again, we do want the committee to, you know, if you're aware something that hasn't been submitted, obviously, you can discuss that during the workgroup call in the in-person meeting. And take that – the committee can take that to consideration as well.

Were there any other questions before we continue?

OK, I will take that as a no. And we can move forward to performance gap.

Stuart Greenstein: Is that me again?

Poonam Bal: Yes …

Stuart Greenstein: Yes, OK.

So, there were clearly the strategies in care performance gap when they stratify based on race, sex, age, so this clearly has to be, you know, a measure that has to be based, you know, disparities, that's the exact term you want me to use it as – I felt there were disparities noted.

And makes sense actually in my own mind because I think that as an access specialist or access surgeon, depending upon where the patients are, they may not get permanent access developed, they would be on – with catheter.

And that's the multiple reasons.

Poonam Bal: Jessie, did you want to …

Lorien Dalrymple: This is Lorien. In terms of the disparities, I was hoping to get other committee members' thoughts on the data that was presented, for me, on the new worksheet that's on page 16 going through 17 with the updated comments.

Although the P value was significant, I was wondering what other people thought about the absolute effect though, or the clinically absorbed difference, if people thought this difference warranted there's being a disparity sensitive measure.

Peter Crooks: This is Peter Crooks, and I'd like to comment on that. I think – we've seen this actually in multiple measures that CMS is providing this sort of a disparities analysis. And in this case, I would agree with your impression, this is statistically significant but the differences are probably not clinically meaningful in this particular measure.

Age, sometimes you see there is a little tendency among the age groups from 9.1 percent to 10.7 percent going from the youngest to the oldest quintile. But the others, I don't really think you can see a pattern. So I would agree with your observation.

Stuart Greenstein: How would you explain those – such a loss, physical significance then?

Peter Crooks: We can have …

(Crosstalk)

Lorien Dalrymple: … are large because the large number allows it to detect a very, very small effect size.

Peter Crooks: Right.

So, it's not the same as distribution, it's not by chance alone so there is differences by these characteristics, but the – you know, in any group, the differences are so small that I don't know that it's actionable or that you can conclude that there's a significant difference in care by these categories, the gender, White-Hispanic diabetics, maybe an age, but even that is very small.

Stuart Greenstein: So how do we get better clarification then?

Poonam Bal: So, at this time, I do want to see if the developers on the line to see if they want to respond to your comments.

Is anyone from the University of Michigan or CMS on?

Female: Yes, we're here.

Poonam Bal: Please speak a little bit louder.

Female: We're here.

Poonam Bal: Right. Would you like to respond?

Female: I don't think we have anything to respond with at the moment.

Poonam Bal: OK. So then, I'll bring it back to the committee. We can have the developer bring something for the in-person meeting or, you know, you can just go with the data that you have. Were there any other comments not related to this topic but around gap?

OK. Then let's move forward to …

Peter Crooks: I just wanted to say – this is Peter Crooks. I just – I muted myself by accident.

The gap is 9 percent with the standard deviation of 7 percent.

So, the – you know, this isn't a – it is a significant problem though even if 9 percent of patients have chronic catheters. What is the floor? I don't know, if we can get below 5 percent, 4 percent, 3 percent.

One could make the case that maybe this is close to the floor and that there really isn't much of a gap. I'm not going to try to make that case, but I'm just pointing out to the committee that the gap is probably not real large.

Andrew Narva: This is Andy Narva. It's hard to know, I mean, if you look just five or six years ago, the percentage of people with catheters was still quite – was high as well. And I think this performance measure has actually had an impact.

And one of the things we've heard along is, you know, we can't reduce – we can't include (reduce) anymore, we can't reduce catheters more and that I don't know that we have any evidence that we reached that limit.

Lorien Dalrymple: And this is Lorien. This came out from me on this measure and another measure, even if the gap is narrowing, is there a role for maintaining the measure to ensure we don't lose ground where we've made progress? And I'm not – I was curious how other committee members evaluated that issue especially if they're related to catheters or perhaps fistulas that big improvements have been made, but if the measure were to go away, would we lose the improvement even if we've narrowed the gap.

Stuart Greenstein: I think the way you do that is actually by one of the other measures where you want to increase the AV fistula rate.

And that's really – you know, you can either have a catheter or you can have a fistula graft so if you can increase the other rates, then these rates have to go down. I mean, they really go hand in hand.

Peter Crooks: Yes, and in terms of what we can do as a committee with a measure, this came up in a previous workgroup call when we were looking at Kt/V, which may be getting topped out in terms of the measure being – getting closer and closer to 100 percent.

The NQF has a status called reserve where a measure can be – if it meets all of the criteria evidence, feasibility, usability, and so on but the gap is just small, it's probably considered topped out, it can be put on reserve status. So it's still a NQF-endorsed measure, it's still a standard of care that everybody should strive for. But it isn't as active as others.

I don't know if the staff wants to explain any further what's the difference between a reserve measure and a regular measure. But that status is available for some of these measures that are getting topped out.

Lorien Dalrymple: Thank you.

Frank Maddux: This is …

Female: Yes.

Frank Maddux: … Frank Maddux. I would say, I don't think the catheter measure is topped out, I agree with you at that. But I do think the interplay between measures, a fistula measure and a catheter measure can sometimes impact one or the other if we are looking at permanent versus non-permanent access.

And so to some degree, some of the lack of this particular measure being optimized may be influenced by the other fistula measure, so. And I think we just need to be aware of the interplay between measures that are on the same topic but not necessarily the exact same perspective on that topic.

Peter Crooks: Good point.

Poonam Bal: OK, were there any additional comments before we move forward?

OK, so let's move forward to scientific acceptability and start with reliability, specifications and testing.

And that, Stuart …

Stuart Greenstein: Yes, I'm here, I'm just scrolling down.

So, in terms of reliability, the measure is clearly well defined. So, that I didn't see any problem in terms of from a reliability point of view, because we know what they're looking at, either have it or don't have a catheter and then you're looking at who else is – you know, however it goes being dialyzed so that the numerator now is clearly well defined and they're getting the information from claim forms in CROWNWeb.

That was for specification. Do you want me to go to reliability also?

Poonam Bal: Yes, please.

Stuart Greenstein: Oh, I'm sorry.

So this is talking about how reliability is, all the factor, if you have a hemo catheter related to measure of mortality and morbidity related. So, the test that they provided, (literally) show that there was a correlation between having a catheter and increased morbidity and mortality.

And therefore, it's truly an indicator of quality. If you have a catheter, you can have at the end of the day poor quality of care.

Hello?

Peter Crooks: Right.

Poonam Bal: OK, was there any other comments?

Peter Crooks: I looked at the reliability and validity pretty closely and I inspect – I'm OK with them, they used the entry unit reliability 0.78. They also did that critical data element testing which they didn't claim as reliability and validity check, because what they're doing was trying to – they're showing that they – there's comparability between their data sources which was well done, too.

So, I think from my perspective, the only problem I had under trying to show meaningful differences, there are – if I recall, I think the results came out worse than expected, oh, no, I know what that is. Yes, they showed 11.7 percent of units that worse than expected so they do claim that you can show a meaningful difference between facilities as well.

So I felt that the section was OK.

Lorien Dalrymple: The only section I had a question on was when the data was compared between using claims versus CROWNWeb that there was high correlation, but it appeared that when you use claims data, it was 11.4 versus CROWNWeb, 8.5 percent. And I was curious what other people thought about that absolute difference and whether that brought up any questions for people.

That's for me on our newest worksheet at page 30, table two.

Peter Crooks: Right, right.

Lorien Dalrymple: Although they correlate, the absolute difference is almost 3 percent on a measure where the overall is 9 percent which actually seems like a relatively big difference to me.

Peter Crooks: Yes, I know one thing that they may point out and we could ask them about that is, that they're not totally overlapping, there are some claims where there's no CROWNWeb and there are some CROWNWeb which may not match up with claims. Maybe more of the former than the latter. I don't know if that could account for that difference or not.

Stuart Greenstein: Is there a delay in terms of when forms are filled out, for that claim forms versus CROWNWeb, I mean, could that be part of the reason?

Lorien Dalrymple: I didn't see an explanation of this difference, I could have missed it, and I didn't know if others understood that – what underlined this. I know …

Peter Crooks: Can we ask the developers, Poonam?

Poonam Bal: Yes, so is anyone on the – from the University of Michigan or CMS on that would like to respond?

(Claudia Delores): Yes, this is (Claudia Delores) from the University of Michigan.

So, we're going to – we don't have our full team present so we're going to need to look at the original analysis that was done and then this is something that we can address at the in-person meeting.

(Tampi Sharon): Although – this is (Tampi), I can say for part of your question about the difference – whether the claims data would be lagged, we did do the analysis going far in not using data foreign effect to avoid a problem with that. But you are right that it would be the patients are not completely overlapped.

Peter Crooks: So I think it would acceptable and appreciated if you can give us a brief explanation of why the claims data results are different in the CROWNWeb even though they kind of meet the statistical test for being comparable. But, it is a persistent difference of 3 percent. Thank you.

Poonam Bal: OK, and then, was there any other topics that we want to talk about reliability before moving forward?

And obviously, we'll have more time in the in-person meeting to discuss.

OK. So then, Stuart and Jessie, want to start on data analysis of validity testing?

Stuart Greenstein: Let me just look at my notes.

So they don't include pediatrics and there was clearly valid reasons for that because pediatric patients have totally different set of animal so to speak. I know that they didn't have any other exclusions, and I felt that at the end of the day, the validity testing was appropriate.

Peter Crooks: I agree, it look good.

They correlated with mortality, both mortality and hospital or standardized mortality and standardized hospital rate and both had a few value, very low P value suggesting that if the measure changes, the outcome is changed.

Jessie Pavlinac: Yes, I agree.

Poonam Bal: OK. Were there any other comments before we move forward?

OK, so then, let's move forward to feasibility.

Stuart Greenstein: OK. Not a problem, I mean, it's clearly using claim forms at CROWNWeb and so therefore, the data is there for them to take and get the numerators and denominators. So I have no concerns related to feasibility.

Poonam Bal: Anyone from the committee that would like to comment?

Lorien Dalrymple: I think it's feasible.

Poonam Bal: Thank you for that, let's …

Peter Crooks: I agree as well.

Poonam Bal: All right, then let's move forward to (usability and use).

Stuart Greenstein: Where we at now, sorry.

Poonam Bal: Usability and use.

Stuart Greenstein: So, there's accountability because they already report this and actually, there is ESRD, (QRP) does reduce payment facilities that don't meet the standards of catheter usage. So, it's right now being used as part of the payment process and quality improvement process.

Peter Crooks: And it's reported, they say a dialysis is facility compare.

Stuart Greenstein: Right.

Peter Crooks: So that's also a public reporting. In the improvement section under usability, they were unable to show improvement in 2013. That doesn't bother me a lot in that. I think that there has been improvement in this metric over. I mean, we know that catheter use has gone down in the last six or 10 years. But, for some reason, they won't able to show any improvement during the – in their 2013 year.

Stuart Greenstein: Well, there will reach a point where you can't get it down by much.

Peter Crooks: Right, if it is topped out or close to topped out or because it's competing with fistulas, you know, it's kind of consequence of trying to get a lot of fistulas that may not be that much more improvement.

Stuart Greenstein: And also as the patient population keeps getting older and older, your accessibilities may go down.

And then, there's the other point to that when patients are started on dialysis, many of them was started on – via catheters. And they get used to the catheter because they don't have to get stuck so they – there are patients who actually refuse other access options.

Peter Crooks: Right, but we don't accept that.

Stuart Greenstein: That's right, I know. But that's doesn't – if that's not taken …

Peter Crooks: That means that there's a systems problem that they, you know, they get to that point in their minds and we weren't correct, I mean, you can always go back up stream and say, you know, something could have been different or – so, you know, that's a truth, but it's – you know, I don't think that justifies.

Stuart Greenstein: No, agree with you. Agree with you. I'm just saying that there is clearly that element that goes on.

Male: And by the same token, it's possible that this is a measure which drives improved late CKD care. And that's an area that's hard to affect because those patients aren't cared foreign dialysis units and may not even be on Medicare, if they're under 65.

Peter Crooks: Right. The ultimate solution that they never started to ask is with the catheter, you know …

Male: Right.

Peter Crooks: … when possible.

Stuart Greenstein: Right, right.

So, that's only if you really can get to the – get a fistula in them first and, you know, to figure and referred early enough. I mean, as a practicing vascular access surgeon, I can tell you, my under-thought is it's just fairly convincing. But, there are those patients who, you know, on denial and then they don't come and then, you know, they got to get that catheter and then they get used to it.

So, my only point is that you never can see – I think 9 percent, 10 percent is not bad rate for catheter usage, personally.

Peter Crooks: OK, any other comments on usability?

I think this group is going to get the time award for getting through the first metric in less than 45 minutes, congratulations.

Poonam Bal: Thank you for that, Peter.

So, just as a reminder that we will be discussing related and competing measures in the in-person, we don't discuss them right now.

I believe Sarah said earlier, we review all the measures separately and then discuss related and competing, just so we know if there are still something that we need to look at, if the measure did not get recommended for endorsement, there's no point of discussing related and competing to another measure, so.

Peter Crooks: Do we want to acknowledge public comments in the workgroup sessions or just – there was one public comment from (phase).

(Off-mike)

Poonam Bal: Yes, so we do actually wait for the – we ask the committee does review the public commenting, Alexandra, if you could just go down to that section real quick.

So, there is public – pre-meeting public comment that is available for the committee's use. We do ask that you review it before the in-person meeting so that you know the public is saying. But we don't discuss it during the workgroup call.

And you are – if the committee would like to bring up a topic during the in-person meeting that a committee member – a comment are made, they can definitely do that as well. OK.

Peter Cooks: OK, thank you.

Poonam Bal: If I – and then that's how we'll be doing the in-person meeting to the role that I was taking on would have been. With the coach, I would be doing – leading the call and basically, you know, opening it up for feedback and moving us along.

So, for – moving forward, we're going to do the fast way of reviewing the measure even though this committee, as Peter said, the fast – did the first measure the fastest we've done in most workgroup calls, we do want to give each measure enough time to be discussed early.

So, we'll ask the next presenters, who are Stuart and Lorien, and we'll just ask that you do 2657. Start by doing a brief introduction and then only bring up topics that you feel either you have concerns about or you want to, you know, say this is a really good part of this measure, so really only highlights.

Does that make sense to everyone?

Stuart Greenstein: Yes. I try to get to the measure, my computer is really being slow on me. So, I apologize.

Poonam Bal: Lorien, would you like to take it on …

Lorien Dalrymple: Oh, sure.

Poonam Bal: … since Stuart …

Lorien Dalrymple: Yes, I can introduce it.

So this is measure 257, maximizing placement of the arterial venous fistula. This is – the measure steward is CMS.

And the brief description is, this is the percentage of patient months or patients on maintenance hemodialysis during the last (inaudible) month using an AVF with two needles. The numerator is the number of patient months and the denominator who are using (antagonist) AV fistula with two needles.

Again, during the treatment month and the denominator will include all hemodialysis patients who are 18 and older who have had ESRD for greater than 90 days at the time of the reporting month.

The exclusions are essentially pediatric patients. Acute hemodialysis which here in is defined as less than 91 days in the extent of the exclusions.

So, should we move onto the evidence?

Poonam Bal: Yes, please go ahead.

Lorien Dalrymple: So, when I reviewed the evidence, I felt like it did support AV fistulas as the first choice. However, I do not feel it addressed the complexity of access decision-making that we (haven't) make and whether at times grafts are actually clinically indicated and more feasible and perhaps the evidence also didn't discuss unintended consequences such as prolonged use of catheters while failing to see fistulas mature or achieve the goals.

So, I felt the evidence did support AVF, but perhaps, did not address all the issues that are clinically relevant to this topic.

Let me see if can get to other committee members' comments, which I think you have up as well so that I have several fields up.

So, do other committee members have thoughts on the evidence?

Stuart Greenstein: I agree with you, (Jessie). I think that in terms what you just said, the measure, you know, talks about increasing fistula rate. But, you know, that should not be the only thing we're looking at. I mean, if you have to put a fistula in and it takes nine months before it can be used because you have to go through multiple balloonings, whereas if you put a graft in somebody, they could use it within two weeks and four weeks.

That's going to be a big difference so that patient were probably for morbidity. And also from a cross point of view, because, you know, given fistula first and the still call the push to do fistulas all the time, there is this downside to it and that we're really losing track of, you know, that we should do the operation with what is right for the patient not, you know, individualize it.

Peter Cooks: This is Peter. I would just call out as I did in the last metric that CMS developers didn't go through the systematic review which was done for the 2006 update and that they left that blank.

So – and also, in the other sources of evident, they have 50 articles, six editorials, number 42, they actually reference again KDOQI 2006 which – so, you know, I mean, if you really look at it, I think, you know, the quality of the evidence review in terms of giving it to us could have been better.

However,, you know, KDOQI 2006 update is strong and, you know, I felt I'll give them a pass, but again, if we said – if the grade was on following the directions and filling in the form, it would make it in my (inaudible).

Lorien Dalrymple: And Peter, you bring up an important point that also reminds me of the steering committee a few years ago, which is, when we're deciding on pass or fail either at the committee or in the in-person meeting, are we relying only on what is presented or also what we all made personally know or are able to present to the group.

This time around, is it purely what's in the measure or can we present additional information if we think it's applicable?

Peter Cooks: That's a great point. And clearly – yes, the physicians, if you know something, if you have – if you know of evidence that they didn't cite, the committee is certainly free to consider that in the important section.

Poonam Bal: OK, were there any additional comments on evidence?

OK. And then, again, I was asked that you only bring up highlights, so if there's anything else that you want to highlight about this measure, let us know now, either Stuart or Lorien, and we can also open it up to the group to see if there's anything they want to highlight.

Lorien Dalrymple: And I'm sorry, do you mean for all the topics or just moving onto performance gap, are we going to go through each section or just anything else about this measure period?

Peter Cooks: I think we like you just to kind of run down all your comments on the measure, especially things that you think are needed to be called out. And then we'll open it to the committee for their input on any part of the metric. Is that the way we want to do it?

Poonam Bal: I see we were hoping to just do major highlights through the whole measure just so we can make sure that we're hitting all the major topics.

I mean, you can go through each of the criteria and just say no major concerns and then we move forward or – and then we can go through that way.

Does that make sense?

Peter Crooks: Yes. So you're saying that we don't need to read the comments or go over the information that we all should know and just go to your concerns on a particular area.

Poonam Bal: Correct. So we would go to gap now and basically say no concerns or, yes, I have these concerns about gap and then move forward that way.

Lorien Dalrymple: OK. So, for performance gap, I think we've already addressed this in our prior discussion about when we think a measure is starting to be topped out. I don't think we need to address that at length.

The current facility mean reported was 67 percent and the first quartile was 60 percent.

Did others have concerns?

OK. So we'll move onto high priority. I had no concerns with this field, others?

Male: No.

Lorien Dalrymple: OK. So specifications, in my review, I did come up with one question or point I was hoping for clarification.

In my reading of the numerator in the specifications, it includes AV fistula and catheter. In addition to AV fistula was two needles, and I thought that was somewhat inconsistent with how the measure is specified or at least described on the very first front page.

So, I didn't know how others felt about the numerator including the CROWNWeb field that's AVF and catheter in addition to AVF with two needles given the measure name.

Peter Crooks: Yes, I agree. I think (Annie's) clarification from the developer might be that this catheter is present but there's – that it just hasn't been removed yet, and they are going dialysis with two needles. But I supposed it's possible it could be one needle in the fistula and then the catheter is being used.

Stuart Greenstein: Right. And that does happen. I mean, from a clinical side, I – sometimes when I do fistulas, I don't know if (inaudible) can really get two needles and I'm prompt to do one on one, so the catheter will stay in for sometimes longer. And it should be still considered the catheter case rather than a fistula.

Lorien Dalrymple: And to be honest, my bigger concern was, our people marketing this field with a catheter is completely being used and the fistula is still maturing.

Stuart Greenstein: Right, and that gets …

Lorien Dalrymple: And I think – my question because then we've, I think, really be off topic on this measure if that field was included in the numerator.

Peter Crooks: Yes, because sometimes people have a new fistula and it's in there for six to eight weeks before it's used.

Stuart Greenstein: Right.

Peter Crooks: So, can we ask the developers now, do you think or should we – I think this is important enough to ask them to comment if they would.

Poonam Bal: Yes.

Lorien Dalrymple: Can answer, I think that would be helpful.

Poonam Bal: Yes. So let's open it up to the developer to see if they have a response.

(Tampi Sharon): Hi. This is (Tampi Sharon). Unfortunately, I don't know enough about the details of this to answer that question, but it's possible that (Claudia), if she's still on might have something to add.

(Claudia Delores): Yes. This is (Claudia). I'm still on. So, actually, the timing of this question is quite apropos. We have been meeting the past few days with a vascular access TEP who is addressing this very issue with the measure. Some of this is a function of the data elements in CROWNWeb and what can be selected, and that does include an option of presence of the catheter while a fistula, for example, is measuring for the scoring of the measure, that means that the facility would get credit for fistula even if the catheter is present.

However, this very issue in the construction of the measure has been discussed in the past two days. And so, we will have more information at the in-person meeting about any potential revisions.

Stuart Greenstein: I would think that …

(Claudia Delores): Yes?

(Off-mike)

Stuart Greenstein: You could take the nine months with the catheter in before fistula could be used, you know, by the time, and that means they would get credit for fistula when it's time – when it's later – I mean, they've chosen the wrong access for that patient.

Peter Crooks: Well, plus the measure says with two needles in the fistula.

(Claudia Delores): Correct. Correct. And this is the very issue with the measure that the vascular access TEP has been discussed in the past few days. So we will be able to provide sort of more comprehensive responses to these questions and any potential revisions that are recommended by the TEP. They also had this very same concern.

Peter Crooks: Yes, I don't know that they're allowed to revise it at this point that I would have to defer to the NQF staff on that, but, yes, I think that's a really important thing to clarify.

(Claudia Delores): Yes.

Peter Crooks: OK.

Lorien Dalrymple: If there are no other comments, I can move onto reliability.

The only note I made with reliability testing is I was hoping either other committee members or the developers weigh in on how the non-normal distribution was influencing the RUR. The statement is made that we should interpret this with some caution. But I was hoping to get more information about how much caution and which way this could be biased by the non-normal distribution since this is the primary presentation for liability there.

Peter Crooks: Well, this pushes beyond my bounds of understanding biometrics or biostats. But the IRU – RUR value of 76 percent seems OK. It's not great. But that would mean that 70 – 24 percent of the variabilities within unit as opposed to 76 percent between units, and this method of reliability checking is apparently been endorsed by NQF as a valid way to check – as a good way to check reliability.

Does the staff or anybody else have other insights on this?

Lorien Dalrymple: And again, what caught my attention was the specific statement by the developer stating this should be interpreted with some caution. So I was hoping they could inform us as to what that caution should be because of the non-normal distribution.

Poonam Bal: OK, so I'll give it to the developer first to see if they have a response and then ask Sarah to see if she would like to say something.

(Tampi Sharon): Hi, this is (Tampi Sharon) again. I think that we can't answer that question at the moment. We don't have someone who knows enough about the details …

(Off-mike)

Poonam Bal: OK, no problem. We do ask that you compared for the in-person meeting to discuss that.

Sarah, did you have any comments?

Sarah Sampsel: I don't have any comments. I mean, I really think that's up to the developer because I do know that was through a number of the measure information form to be able to answer that because they would be the only ones who can answer it based on the data.

Peter Crooks: Yes, I would say, this is Peter again, that they'd also did critical data element testing, which is a second test of reliability. And I guess it was by comparing claims and CROWNWeb again.

And here, I'm looking at the comparability data and you don't need to go through because down on page 29, it looks pretty comparable there, too. So that's the second way of demonstrating reliability. So that even if this one may be – I think what they mean is, you know, the model is developed assuming a normal distribution.

So when you apply it to a situation where there isn't a non-normal distribution, it's questionable whether it's valid because that's not the way the statistic was developed. So I think that's why they're saying you have to be cautious.

But the fact that they also did data element – critical data element reliability is also – this further evidence that's probably a reliable measure.

Poonam Bal: OK. And we can discuss this more in the in-person meeting. Was – were there any other topics we want to discuss before moving forward?

Stuart Greenstein: I had one question on – not as much as a reliability, but still we know that this measure is a measure of quality, but no place do we take into account the true cause of creating fistulas and, you know, because you can create a fistula and you can take, you know, 10 treatments that the (inaudible) to balloon them up. And is that – and isn't cost going to be an important factor for us to consider?

Peter Crooks: The rule of cost in our process is under importance, you know, in other words, if improving a measure reduces health care cost, that's something that can be – I believe – and the staff can certainly jump in and correct me if I'm wrong. But, that – you know, that could be an element of saying this is importance although …

Stuart Greenstein: And what if it increases the cost? In other words, you make a measure, you want more of this, but by doing that, you're going to really increase cost dramatically. And where there is an alternative.

Peter Crooks: Well, I – you know, I would argue that getting fistula is overall saves money. We know that the number of encounters needed after a fistula is successful is about one-seventh (at per) graft and probably – and sepsis is much less than a catheter so that, you know, and maybe that's – in terms of establishing the fistula, the cost are higher but the overall cost, I believe, the data would show that it's actually lower and lower mortality and so on once you have the fistula established.

Male: This is pragmatic. It seems to me though that that's probably can be stratified by age and some other things that might not be true at all.

Stuart Greenstein: Right. I agree with you about that. I think that, you know, when you stratify for age, if you try to do a fistula on a 75-year-old or 80-year-old, that could be the same rate as you – and I don't think much longer for it to mature, things will all be destroyed for some degree also.

Peter Crooks: Yes, I'm in agreement that fistula first strategy is not appropriate for patients in their 80s and that a new strategy, you know, needs to be developed for those patients on several levels, or should they, you know, I mean, more appropriate for palliative care for, you know, are they candidates for grafts even sometimes if they're on a with brief trial maybe a catheter.

Catheter infections seem to be less frequent in (older) patients. So, I think that's kind of an emerging area in vascular access. But we're going to, you know, deal with what we have before us here.

Lorien Dalrymple: Well, in line with that, do members have comments with regards to unintended consequences of this measure? That was the only other major point I had written in my initial review, was the potential unintended consequences of a measure that only looks at fistula rate and has no exclusions other than pediatrics. And for …

Poonam Bal: Well, before – I think before we get to that, that really is more of a use and usability concern …

Lorien Dalrymple: Oh, sorry. I'm skipping to my only other major comment. My apologies.

Poonam Bal: OK. No problem. OK. Then if that's the case, we can move forward. Where there any other comments on the committee on validity or feasibility before we go to usability and use?

Peter Crooks: I thought the validity was good, they linked it to add something on HSR again. And they also, as I mentioned, have the critical data element analysis, too. So, I'm fine with the validity testing.

And also that there's a meaningful difference – meaningful differences statistical and meaningful differences can be demonstrated. So – and so I'm fine to move on. Anybody else?

Poonam Bal: OK. Not hearing anything, I think we can move forward with the independent consequences question.

Did you want to elaborate more on it or were you ready to open it up to the committee?

Lorien Dalrymple: Oh, I think it's in line with the discussion of, are there certain population or fistulas actually are not the first choice, and when you have measures that emphasize simply fistula rate, are there unintended consequences such as inappropriate attempts of fistula that prolong catheter use or ignore potentially more appropriate access types like graft?

Because I think that's specifically in question number four, do we think this measure could have unintended consequences? And I think there has been a

lot of debate around what the unintended consequences of fistula first were, and although this and of itself is not fistula at first, it's a measure that relies only on fistula rate to determine quality of care being delivered.

Male: This is pragmatic. I think if you begin to think about some of the newer ways we're looking at catheter contact time and exposure days and other things, this particular measure could have substantial influences on how we look at time based – other time-based measures or performance time, degradation time, the maturation time, the cannulation and those types of measures.

So, part of the unintended consequence could be a derivative that other measures will actually have much poor performance because of this one.

Peter Crooks: Yes, I think these are really valid things for the committee to consider when it comes time to do our ultimate voting.

Any measures, a three-year – it's a three-year measure and it's not in perpetuity. And things change and evidence changes and practices change, so another point to keep in mind, I guess.

Poonam Bal: OK. Were there any additional points before we move forward?

Sarah Sampsel: Yes, actually, Poonam, this is Sarah. And I just want to back up because I actually was in a position, I could speak immediately earlier.

But, regarding – I think (Claudia) had mentioned that they are looking at – here in the University of Michigan/CMS are looking at this measure right now and there may be some potential recommendations through divisions of the specifications and it may happen right around the time of the committee. We will have to be opened-minded about that. It might be what happened at the committee that the committee considered the measure as it was submitted on its form but during public comment, if CMS and University of Michigan actually have testing data that would support the recommendation to a change, it may be saying that we revote on.

I just wanted to make sure that that wasn't a slam door on University of Michigan and CMS and may understand that they definitely should proceed

with working on what they're working in relation to this measure and it may need to be considered at the in-person meeting.

Peter Crooks: Yes, I agree. Thank you for that. You know just another question, in other words, standing committees instead of like a temporary committee, and let's say we endorsed or endorsed, you know, or didn't, you know, and then a year from now, they've got it all worked out and they've got their testing data together. And they come back and say, "We're ready to reapply." Because we're standing committee, can we take it up in the year or do we have to wait for, you know, a particular time period?

Sarah Sampsel: No. So that would be, you know, that would come under its annual evaluation and if it is a significant change to the measure, we would reconvene the committee whether on the phone or in-person depending on the number of measures that might fall under this in an ad hoc review.

Peter Crooks: OK. Cool.

Female: That would only be if the measure was recommended for endorsement? That – it would come to an annual review and we were able to do an ad hoc review otherwise, we would have to – we're still working on the best method for – within standing committees and measures that were not recommended and how to move forward those.

So, this is something new and we're working through it right now. So if it was not endorsed, then we probably would have to wait for certain situations to come through before we could review it. But if it was recommended for endorsement and there are major changes during the annual review or any point, it doesn't have to be next year. It could be two years, three years now. We would get – They would come under the ad hoc portion and review it then.

Peter Crooks: OK. Thank you. So time check we're done 55 minutes so we move to the next measure or anymore comments on this measure?

Not right now. OK.

Poonam Bal: OK. So we're going to forward to 0251 but before we do I just want to ask Lisa, I believe we were – you wanted to wait for one of your representatives to be on the line, are they on now?

Lisa Latts: Yes. Dr. (Jaime) is on the line. She is available.

Poonam Bal: OK. Perfect. So before we go to 0251, I just want to remind everyone that we did send a conflict of interest list of all the members, committee members with the first workgroup of assignment. With that said, (Debra) does have a conflict with 0251. So as part of our policy we ask the she not comment during this time on this measure and basically will not be able to vote in-person either and that will be the same situation for anyone that has a conflict also for this call. Stuart has a conflict with 1662. So again, he will not be able to comment and during the in-person will not be able to vote on the measure.

So I just want to let everybody know about that before we start. But other than that, let me ask if anyone had any questions about that policy?

Female: Nope.

Poonam Bal: OK. So let's start with 05 – I'm sorry, 0251 and Jessie and (Karilynne), are you on?

(Karilynne Lenning): Yes. I'm on. This is (Karilynne).

Poonam Bal: OK. We do …

Jessie Pavlinac: And then it is Jessie and I still can't get access so (Karilynne) I didn't bring any handwritten note, so I'm sorry. If I have anything to contribute I'll say something.

(Karilynne Lenning): That will be great. I can introduce the measure. I might need some help with some of the comments. This is NQF number 0251, the measure is vascular access, functional AVF or AV graft or evaluation for placement. The measure is towards the kidney care quality alliance and a brief description of the measure, this is percentage of end-stage renal disease patient aged 18

years and older receiving hemodialysis during the 12-month of reporting period and on dialysis greater than 90 days who – this is kind of a long measure, who have a functional AVF defined as two needles used or a single needle device not one needle used and a two needle device or a secondly have a functional AV graft or have a catheter that have been seen, evaluated by vascular surgeon or other surgeon qualified in the area of vascular access or interventional nephrologist trained in the primary placement of vascular access for functional AVF or AV graft at least once during the 12-month reporting period.

The numerator statement is pretty much what I just read the number of patients from the denominator who either have the functional AVF or they have the AV graft or they have the catheter and seen or evaluated by the vascular surgeon or other qualified individuals that are listed in that denominator statement. And the denominator for this measure is all ESRD patients who are aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis for greater than 90 days. This particular measure does not have any denominator exclusions and it is listed as a process measure.

So do we move to the evidence?

Poonam Bal: Yes. So, if you have any concerns about evidence list them now. If there not, you can just say that you didn't have any concern (inaudible) and we'll with that process.

(Karilynne Lenning): Well, I personally didn't have any concerns with the evidence. I think a lot of the evidence support some of the other measures that was also discussed and we've already talked about through unless there's other committee members that have anything to bring up.

Lorien Dalrymple: This is Lorien. The only question I had with regard to evidence was, was there strong evidence and evaluation by a vascular surgeon or other in the 12-month reporting period, was there reflection of quality per se and it's not really the same as having the official or graft?

Peter Crooks: Right. This is Peter. I agree with that observation. The evidence is basically saying for sure good catheters, bad and I don't think it can really tie into having than referred, you know, it is – that is associated with good outcomes.

Female: Did you want us to respond or just wait until the in-person?

Poonam Bal: We will have time, so go ahead and respond.

Female: It was used as face validity that either being seen by or at least an evaluation, a nephrologist contacting the surgeon to confirm that the patient was still not an appropriate candidate for permanent access. So it was a face validity assessment that – unless Lisa corrects me, I don't believe that there is (inaudible) the others have indicated it. In fact, it wouldn't be something necessarily that's one with the study.

Female: No, yes, there (inaudible) that we came across. Issues in our (inaudible) with the belief that sometimes the status of these patients were previously deemed inadequate candidates does change. It's very important to make sure that a reassessment is done on routine basis.

Male: I don't understand one thing about the measure. I mean they talk about the graft and then they also know about the catheter. But we're looking to try and create a certain graft but then it looks like the catheter is in part of the numerator though. It shouldn't be then.

Lorien Dalrymple: If you say, for referred for evaluation so it's the numerator is you have a fistula, you have a graft or you were evaluated by a vascular surgeon or other qualified person for vascular access. I think it gets that is everything being done that can be done to optimize your vascular access is the way at least I put this together. It's a fistula a graft or best attempt to improve your vascular access if you have a catheter.

Stuart Greenstein: Then why are they talking about in the measure title function of AV fistula or AV graft.

Lorien Dalrymple: Or evaluation for placement. It's the last one.

Stuart Greenstein: But every patient gets evaluated, I mean, because if they have fistula, they were placed by a surgeon. The graft, I mean, so …

(Crosstalk)

Peter Crooks: So that would be evaluated within the last year. So this is for you know, I have been in the dialysis unit for more than, with a catheter for more than a year and so they have to show that at least once a year, they're being reevaluated for permanent access.

Lorien Dalrymple: That among those with a catheter, they've seen a vascular access surgeon in the last year.

Male: If you have a catheter.

Lorien Dalrymple: I think that flows nicely into that performance gap question.

Male: OK.

(Karilynne Lenning): Is that my cue to bring up performance gap comments?

Poonam Bal: Before we do though, I do want to consider if there were other concerns about evidence before we move forward? OK, I'm not hearing any, yes, let's move forward performance gap.

(Karilynne Lenning): Hi and again, I think most of the comments are recognizing that there is evidence of supporting a gap. And I have to apologize my social work that I'm not sure really, need to be an expert on this. So is there someone that maybe can help me out here with this performance gap data? I greatly appreciate it.

Peter Crooks: I think what they're saying is that there's 14 percent of patients who have catheters who were not seen by a surgeon within the last year. So that would be their negative side. So the 86 percent, OK, and one could argue if you would favor this measure that the 40 percent gap with those patients should be that's an improvement in care that still needs to occur.

Stuart Greenstein: But so, you're saying now once a year, if a person with a catheter, you still have to evaluate it for other permanent access?

Peter Crooks: That's the way the measure is constructed. If you read the numerator description.

Male: The option is other permanent access or other modality.

Stuart Greenstein: Most of those patients are, or many of them are elderly patients who have really used up all their alternative sites. So why would I want to see a patient every year for some other – like it's, put somebody else in when I really said they you know, can't have something else.

Female: You wouldn't necessarily have to see them but you would have to confirm to the physician, this physician level of measure that that's the case.

Peter Crooks: Yes. Things could change. Maybe there's new technology. Maybe the patients had a change of heart. Maybe the surgeon thinks about it. So I think I could try something. You know, so I think it's still not an unreasonable thought that even for the patients has apparently nowhere to go or is absolutely not interested, that you still kind of go back to reevaluate them once in awhile. That's what their measure is suggesting anyway.

Stuart Greenstein: OK.

Female: I think the challenge though is back to the gap which is this, let's say, 14 percent during this era, there were 30 percent with catheter only but let's say now we're recently, we believe them as a data we were reviewing earlier in the call. Let's even go up to 15 percent. But then the gap is 15 percent of 15 percent, correct? Which is like 2 percent?

Peter Crooks: I have to study it more to be able to respond.

Female: Well, and perhaps I don't know if we can ask the developers. I do want to make sure we're interpreting the data correctly and not misunderstanding it but it's the statement. Facilities reported that 291 or 86.4 percent of are 337 patients who did not have a permanent access at the commencement had been

evaluated by a vascular, other qualified surgeon. So in this measure, those 86 percent of the you know, 30 percent or so would get credit because they had seen the surgeons. But then this begs the question of well, what's the residual gaps then in care?

Male: You know, if we have another measure that was being met, 86 percent, we'd say they probably popped out and maybe suggest this measure is not very effective at moving the ball ahead.

(Lisa McGonigal): I'm sorry, this is (Lisa McGonigal), developer. I just wanted to point out that the mean score on this measure take the facilities that met with other DMs, clinicians that met all three numerator criteria but 93.8. There was a very significant range. Some were down as low as 41 percent, as some as high as a hundred. So there was a pretty significant variation in performance (inaudible) peaks to gap.

Female: Thank you. That's helpful.

Peter Crooks: But is that based on the type of facility? I mean, are these nursing home, dialysis units, were they going to have you know, a certain patient population that may be very old and therefore, they're going to be only dialyzed by catheters or facilities that may have younger patients?

(Lisa McGonigal): No, we went into a wide range of different types of facilities and there was not a distinct correlation with – that took care of nursing home patients primarily or anything. So it was pretty much all over the place when we did the testing.

Poonam Bal: OK. Were there any additional comments before we move forward? OK so let's talk something about scientific acceptability with reliability.

Female: So reliability, is that where we're at here? So it's reliability. It appears that there isn't – I'm not saying that there's any concerns that come up. I don't have anything listed if anyone else has concerns with reliability testing.

Peter Crooks: Well, they claim they did clinical data elements. So I send, which I guess I sent in second radars, audits of a sample and you know, I don't – what I don't see is the statistical analysis. They give – here it is, this statistical analysis for

reliability, 96.9 percent inter-rater reliability and that held up pretty much for facilities also did physician offices, 91.5 percent reproducibility. So, it would seem to be OK.

Female: Although it's the intended use for this to be implemented via crown web as opposed to how the early testing was done.

Peter Crooks: Well, when it comes to usability, I think we'll see that there are, there's a lot of – there's issues there. Maybe we can …

Female: And there's a specification …

Peter Crooks: Yes, so …

(Crosstalk)

Female: Committee and I didn't know if others did with specifications with trying to understand how this would be implemented moving forward, and if it was crowned, how would the data collection be achieved regarding word you've seen by a surgeon in the last 12 months?

Peter Crooks: Right. Yes. In fact, you know, when you get down to usability, they admit that they haven't yet been able to implement the surgical evaluation part which I think is a significant problem because this was endorsed several years ago and they're still not able to actually do the – perform the measure. So, I don't know more about how they – what their data sources actually are, but it is concerning that they haven't been able to actually do the measuring yet. Except through their testing.

(Casey Woods): Yes. This is (Casey Woods) with the developers. The G codes that now that permit the electronic evaluation weren't available till late 2014. So they're now available for use. So, the committee is correct that usability use essentially is problematic for this. But as part of the CMS test that's ongoing now. We've been in contact with them and so they are considering that component of the measure.

Female: And I'm sorry, are they considering adding the feel to CROWNWeb?

(Casey Woods): There could be two different pathways. There could be adding the feel to CROWNWeb or there could be purely as a clinician-level measure. Remember, this is endorsed frankly as a clinician-level measure. Not as a facility measure. So there are two conflicts there …

(Off-mike)

Female: I see, thanks.

Peter Crooks: So you're maintaining that, so you're making a case that even though, so far, this hasn't been able to be – this measure hasn't been able to be implemented that because of coding, because of ICD-10 code or there's going to be a code that pick it up. And that …

Female: There are G codes that are used for the PQRS that only became available to the system lag.

Peter Crooks: And you'll find those because they're going to be sending us Medicare claims or how would you find these codes on specific patients?

Female: The G codes are used as part of the physician quality reporting.

Female: So would it only from those physicians participating in specific, these specific quality measures? They could – They have choices about what measures they use. So they could choose to use this measure and there's mechanisms by which they then submit code.

Poonam Bal: And not to cut the discussion short but we are getting closer to the time where we need to conclude the discussion. Do you want to move us forward and we will definitely, you know, be able to discuss this more in person. At the time, I mean, I ask that you just bring up any major topics that you want to bring since we have only about 30 minutes left to discuss the measure, instead of going to carry bacteria, if he's going to bring up any major topics you want, in any of the criteria.

(Karilynne Lenning): I don't have any other further comments that need to be brought up. I think we've touched upon most everything that's been listed for this particular measure.

Poonam Bal: Perfect. Are there any …

(Crosstalk)

Peter Crooks: I just have a concern that this is something that may not lead to improvement and permanent vascular access and might actually provide a way of you know, passing a performance measure without meeting the intended goal. I think there are a lot of ways to indicate referral or discussion with a surgeon that may or may not address all the barriers to the patient getting permanent vascular access.

Poonam Bal: OK, and we do have the committee keep that comment into consideration during the in-person meeting. Was there anything else, any last comments before we move forward?

OK, so let's move forward to 1162 and who's (Debra) and Loren, OK.

(Debra Hain): Hi, this is Debbie. This is 1662 as you know. And it's angiotensin-converting enzyme inhibitor or angiotensin-receptor blocker ARB therapy. And the measure description is percentage of patients aged 18 years and older with a diagnosis of CKD, stages 1 to 5 not receiving renal replacement therapy and albuminuria alert, prescribed ACE inhibitors, ARB therapy within 12 months.

The management period is 12 consecutive months. The initial patient population is 18 years and older. Starts before the start of the measurement period, the patient, is diagnosed with CKD and albuminuria started before and during the encounter. And it's at least two visits with the physician, physician's assistant nurse practitioner during the period and the denominator, all those 18 years and older for diagnosis of CKD, stage 1 to 5 not receiving you know, replacement therapy and albuminuria. And definition of albuminuria is over 300 milligrams of albumin in urine per 24 hours.

The numerator is patients who prescribe ACE inhibitor, ARB therapy within 12 months. The denominator is the documentation, oh, the exclusions of the denominator or documentation of patient set are not prescribed, ACE or ARB. Patient-declined or other reasons are those that are – other comments that they can't take, ACE or an ARB, with pregnancy, allergy. And if they have allergy, cough due to an ACE inhibitor.

It is a process measure. The evidence is strong. It comes from, the evidences from KDIGO and then prior to that KDOQI guidelines, there are several studies that show the benefit of giving an ACE or an ARB for albuminuria and patients with CKD.

Lorien Dalrymple: And this Loren. In terms of the evidence, my primary concerns were around that I felt most of the evidence related to those with CKD and hypertension which, my understating of this measure is not one of the inclusion criteria, so this is PKD with albuminuria independent of blood pressure. So I felt the majority of evidence being presented, related to CKD and hypertension or perhaps other populations such as those with diabetes.

(Debra Hain): Exactly. This is one of the promises that – the one that concerns about the evidence so I agree with you is that it is not looking at those with hypertension and the guidelines are for people with CKD and hypertension with or without diabetes.

Peter Crooks: Yes this is Peter. I've spent a good time, deal of time this morning. I was going to review this measure. I couldn't get past the evidence. There's a lot of stuff in the evidence section, and I was thinking maybe I missed it but I believe that all the evidence cited is either talking about patients with CKD and hypertension or CKD diabetes. I think CKD diabetes without hypertension, I think the case has been made. But for patients without diabetes, without hypertension, I don't see that there's evidence there. I may be missing it. There's a lot of stuff in there.

I may be missing it. There's a lot of stuff in there.

Lorien Dalrymple: With one statement, patients with non-diabetic kidney disease and UPC greater than or equal to 200 with or do hypertension should be treated with an

ACE or ARB, parenthesis strong, but I couldn't find the source for that, honestly. There is a KDIGO guideline that I think relates to this group. I didn't see it specifically. So I did, and I wonder what others on the committee think. I think the guideline 3.1.7 does relate to non-diabetic CKD with protein excretion for albuminuria greater than 300 milligrams. But again, if we're focusing on evidence presented I did not feel like the evidence was strong for the population that's the target of this measure.

(Debra Hain): This is Debbie, I agree with you. I – This is why I didn't say that right off when I (inaudible) is that the evidence doesn't support, I didn't see it either. It wasn't strong for those without hypertension or what's been previously stated.

Peter Crooks: I think that we might have the developer to address that when they do their presentation. That's going to be a critical issue. Somebody, one of the commenters said that, may have brought this up and I don't know who it was in the comment section, stating that there's other NQF-endorsed metrics that covered these patients already if you, let's see, where was that?

Lorien Dalrymple: I think I read that review as well. I'm not sure if anyone on the phone wrote it but they were saying there's measures that I think address those with diabetes, those who have hypertension, so you know.

Peter Crooks: Also I …

(Crosstalk)

Peter Crooks: … metrics, but …

Stuart Greenstein: Actually, I wasn't thinking of a specific measure. I thought there was a measure in diabetes that people with diabetes and proteinuria – what I was concerned about was they were addressing a population which might not be even that large which is people with greater than 300 milligrams of albuminuria without hypertension and without diabetes. But I assume that NQF had a measure on hypertension and measure hypertension kidney disease and diabetes and kidney disease.

Peter Crooks: Yes. I don't think the CKD and hypertension the proteinuria is within the renal metrics. It might be in another group of metrics. Maybe the staff knows. We may need to look at an overlapping metric.

Female: Yes, we have to look at the whole portfolio and see – that might measure these and the endocrine project or it could be in cardiovascular but we'd have to look to see where it is.

Poonam Bal: Right. Well, and we will get back to you on that for in-person meeting. So …

Peter Crooks: Yes, they claim no competing measures when – at the end of the submission just for the record, OK.

Female: And I wasn't able to access the comments, so I'm sorry that I wasn't able to see that.

Poonam Bal: That's not a problem, we will make sure to have that ready for your – the committee during the in-person meeting. Was there – any other major issue you want to bring up for this measure or, are we ready to move on to another measure?

(Debra Hain): No, a have a couple of things when …

Poonam Bal: OK.

(Debra Hain): … in the gap I just have an issue of some of – we're they – the measurement, where they're talking about – there definitely probably is a gap and concern about people not receiving the therapy which I can understand that. But some of these – the measure was used by CMS physician quality reporting initiative and that's 2008. Is there any more recent data than that or is that the most recent that, that we have?

Lorien Dalrymple: And I have to be honest, the 2008 data, I struggled to understand what the 44.9 percent meant and I do not know if others had a better understanding, because my understanding is, they said 44.9 percent, did not receive optimal care. But again it wasn't clear to me if that meant EKD patients without

hypertension, without diabetes, with albuminuria, not getting an ACE and ARB or – did others understand what that 45 percent measure meant?

(Debra Hain): I don't think that they we're clear on the population, I agree with you.

Peter Crooks: Yes.

(Debra Hain): And then – so that was very confusing – performance gap information.

Lorien Dalrymple: So, it was hard for me to make an assessment of how big of a gap there is and I think as others mentioned, we don't quite understand the size of this population and how many of these patients aren't already getting ACE or ARB.

(Debra Hain): The other is then when you look at reliability testing – and once again, it's – when they're discussing this, the measure was tested in 2007, 2008 using V.M. medical records in nephrology practices. I have one concern there. Is, if they're state 1 to 5, are they all going to in the nephrology practice? What about primary care where we most likely would see those? And are they going to be diagnosed at stages 1 to 5?

The data extracts the patient's records so are used to calculate the inter-rater reliability and their patients are randomly selected for visits for ESRD. So, if we're talking CKD 1 to 5 and not receiving renal replacement therapy, is this an appropriate population?

Peter Crooks: I like to comment on that, the fact that a lot of these patients may not be in nephrology care directly, nephrologist care directly including most patients in three, that doesn't in any way impact my decision to – if I want to endorse it because, what we're really asking is for health care systems to address this, not just the nephrology.

Female: Well I think that should be clear in there. That comes up to not so much. I agree with you. My concern is then, when they go to measure that, is it – I'm not quite sure how the usability – that becomes a question for me. Is how are they going to get this information and how – is it going to be through CMS

data, then the question, does it – it is also in – how else –does it make a difference to someone who has insurance versus Medicare?

Male: You know, another issue is the – most EHR is you can't – you maybe identify the patient have had tests for urine albumin but you generally can't search by quantity. So if you were trying to do look at a population of patients, in most EHRs you wouldn't be able to identify the patients with albuminuria, or proteinuria above 300 milligrams per day.

And in fact, we've thought about this a lot, as a way to leverage getting EHRs to build in tools that would enable the identification of a patient registry with CKD. And the barrier is you can't search for now based – in most EHRs based on quantity. So it would be very problematic to identify patients with – with urine albumin – with urea above a certain …

(Off-mike)

Peter Crooks: Right, I haven't finished my review of this metric, so I don't – I haven't been to the specifications and how they're going to be – how they're going to get that data. But that – it's their obligation, I mean, they have to provide us that and it should be clearer, we hope from the application …

(Debra Hain): Well they said in here, measure currently used for quality improvement and RPA kidney quality improvement registry date of collection is still 2014, thereby a number of percentage are not available at this time and it's open to nephrology professionals.

Peter Crooks: Yes.

(Debra Hain): In the U.S. So then, my concern comes – when they're not being seen by a nephrology professional, are we going to be able to get it from other practices?

Peter Crooks: Right, it only applies to who is being measured and you can't say anything about outside of that. So maybe that the committee's concerned is that, this is of a limited scope if it's only from nephrologist practice and it's only

nephrologist that agree to participate and it's only data that has to be submitted by the nephrologist office.

Female: Yes.

Peter Crooks: You know, how useful is that really?

Andrew Narva: I agree with you, I think that, that's a very big limiting factor for this measure.

Lorien Dalrymple: I would also say – when I initially reviewed the specification, a lot of questions did come up, such as patient refusal, it sounds like there's a CPT 2 code that captures this for those participating in the program. It sounds like there may be but I was wondering if others knew that there is definitely one that captures that?

So I guess we could ask the developers other things where at times, they mentioned dialysis facilities were included and long-term care facility. I wasn't sure if that was a typo in the attachment. They included codes for orthostatic proteinuria, lordotic proteinuria, which I didn't think was consistent with the measure. They also included laboratory measures that we're not relevant in the specification.

So, I thought the specification attachment, it is a lot of clarification. And then – so, I personally had a number of questions about specifications as I read through measure and thought significant more clarity would be needed to understand the measure fully.

Poonam Bal: And normally we would give developers an opportunity to respond but since we are getting a little short in time, I will ask them to take your feedback and be prepared to respond in the in-person meeting. So we do have about a little less than 20 minutes left and we need to do a public member comment in about 10 minutes.

So, we're there any other additional comments that you want to make on 1662?

Lorien Dalrymple: If reliability testing could be presented at the in-person meeting I think that would be helpful, it stated patients were randomly selected from ESRD visits but this is – this measure excludes people with ESRD on renal replacement therapy. So maybe just clarifying the reliability testing.

Poonam Bal: OK, thank you for that. Were there any additional comments?

Anything from the committee that they want to bring to the developer's attention before we move forward?

OK, then we'll move forward to 1425. And is Andy and (Debra) ready to present?

Andrew Narva: I can do this one, so this – 14 25 relates to the measurement of nPCR in Pediatric Hemodialysis patients. It's from CMS, and it basically it looks at the percentage of patient months of pediatric in center hemodialysis patients with documented nPCR, by PCR measurements. The denominators, the number of patient, months – number of patient – sorry, the number of patient months – Patient months and the denominator with monthly normalized PCR measurements, the denominators, the number of – have all pediatric (months) for less then 18-year old patients who are in-center hemodialysis treatment.

It's a process measure, it's supported by clinical guidelines and out of the evidence is – the evidence is based on dissociation between measurement of this nutritional status and improved nutritional status.

(Inaudible) because of the high risk of the pediatric population and high instances of malnutrition in this group. I think there's limited published data on the performance gap and – you want me to stop here or you want me to go on?

(Debra Hain): Unless there are any other concerns, we can move forward.

Andrew Narva: OK. I just – this is established on basis of face validity and it's supported by the pediatric nephrology community as well as the (large dialysis) providers.

Peter Crooks: So this is Pete. Are there others that primary reviewers want to jump in? I have a couple comments but I'll …

Female: Can you …

Male: Yes.

Lorien Dalrymple: … address the validity testing and what your thoughts were. Did we think and I'm sorry if I missed that while I was scrawling but I thought it was explained but that the NPCR, the lower percent associated with higher serum albumin.

Peter Crooks: Yes, that was a concern I had too that the validity test actually backfired and they had a some sort of a – try to explain that but I think they do claim face validity but they are – they're testing a validity, the measure to serum albumin was – came up in the wrong direction.

Andrew Narva: Right. I think their explanation which had all of these numbers are pretty small and their explanation was that in settings where there are larger numbers of malnourished patients, there would be more efforts to assess nutritional status using this tool.

Peter Crooks: Yes, that's believable I guess but the fact is that they didn't establish validity except by experts saying it's important. The other concern I had – I'm sorry.

Lorien Dalrymple: Oh, I'm sorry. I needed to come back to you, you know. It could be confounding by indication but what about other information that measuring NPR improves outcomes in pediatric patients? There could have been other attempts to look at that to support that this is a measure of quality that improves outcomes that are meaningful especially in the face of the albumin not showing the expected association although I agreed, I explained it by confounding by indication.

Peter Crooks: Well you know, you can also go back to your evidence. When you're looking at validity, the medical evidence can be looked at as another source of validity and if there was a systematic review in the evidence that really show that improving the NPCR improved the patient's health in some measurable way,

then that could be decided but I don't think that the evidence itself is based on KDOQI 2006. I don't know that there was a really systematic review. They do call it Grade D evidence.

And another point that – for the committee is that this is, when it comes to usability it's not been in use yet and when it comes to demonstrating improvements since it's been used, they can't do that because it's not in use. So, is this in fact usable at all? That I think that hasn't been demonstrated yet. And for a re-endorsement I think, you know, and it's been since 2011, I guess one that was originally endorsed, you'd hope that in the four-year period, they'd be able to show some – that it's useable and perhaps some improvement or some results over time anyway.

Michael Somers: This is Michael Somers. I just want to – on your last comment in terms of having been able to be used. Because there have been very limited pediatric measures in the clip so far, it would be difficult to think of another sort of national forum that a pediatric measure could have been used to date. So …

Peter Crooks: Right and we – yes. And as a committee, we have been in the past and it could be assessed to the fact that the peds patients are much small in number than the adult patients …

Michael Somers: Right. And that we – in the pediatric community we definitely want to have measures so that has measures that get rolled out to the pediatric community. There'll be measure that can be rolled out.

Peter Crooks: But we, as a committee we'd like to also be able to tell the pediatric community that these measures are likely to actually be meaningful, you know. So …

Michael Somers: No, I agree completely with that. I was just commenting on your statement that it hadn't been used yet.

Peter Crooks: Right, OK.

Poonam Bal: OK. These are all great topics to remember for the in person meeting. Was there anything else you want to discuss that 1425?

OK. Perfect. So I do want to take a small little break and open up commenting for the public members and public. (Nan), if you could open up the line please?

Operator: Thank you. At this time, if you have a question or comments please press star or the number one on your telephone keypad. We'll pause for just a moment to compile the Q&A roster. Thank you.

Male: Are we going to discuss 2706?

Poonam Bal: We will after the public commenting.

Operator: And there are no questions or comments at this time.

Poonam Bal: Perfect. OK. So now we'll move on to 26 – I'm sorry, 2706. And this is Andy and (Karilynne) if you're still on.

(Karilynne Lenning): I'm still on, this is (Karilynne) but I'd defer to Andy if you're on the line?

Andrew Narva: OK., sure.

(Karilynne Lenning): OK. Great.

Andrew Narva: This measure looks at peaked peritoneal dialysis adequacy in pediatric – in the pediatric population. Achievement of the target Kt/V. It's from CMS and it looks at the percent of pediatric peritoneal dialysis patient months who delivered PD those was a weekly Kt/V urea between 1.8 and 8.5.

And the measure is based on studies in adult PD patients because an equivalent base of evidences at the time really exist for children. However there doesn't seem to be any reason to believe that a lower goal would be appropriate for children.

The data suggests that there are significant gaps in care but there's not data to describe disparities. And this is again, a very highly-vulnerable population and the measure would be assessed using CROWNWeb data likely to be

highly reliable and identify especially differences between facilities or significant inter facility differences. It does rely on face validity, though guidelines and expert opinion strongly support assurance of dialysis adequacy. It's not currently used or reported and perhaps Michael want – you know, I'm not a pediatric nephrologist so Michael might have additional comments that are more informed. If he's still there.

Michael Somers: No, I'm here. I don't really have much else to add with this.

Lorien Dalrymple: This is Lorie. I don't know if others had questions about the specifications. I there may have – there were multiple references to single pull Kt/V which I think of may have been accidental and the intent was weekly Kt/V since this was for peritoneal dialysis.

I also had questions with regard to the residual renal function because in one of the statements, it said it would be calculated as a mean of urea and creatinine clearance. But since is Kt/V, I wasn't sure if the intent was actually urea clearance. So I did have questions about the specifications into that now if others also felt maybe there were some pieces to clarify.

Poonam Bal: We do have a little bit of time so if you want to – if the developers are still on the line and they want to respond, we do have time for that.

Anybody from University of Michigan or CMS …

(Tampi Sharon): Hi.

Poonam Bal: Yes, go ahead.

(Tampi Sharon): Hi. Sorry, this is (Tampi Sharon). I'm sorry. I don't think we can address those questions, but we will certainly know for the meeting.

Poonam Bal: OK. Perfect. Was there any other committee member that wanted to make a comment about this measure?

So with that, we have finished all the measures. Thank you for everyone to kind of speeding through the process to make sure we can discuss all the

measures. Again, in the in-person, we will go through a much thorough – more thorough discussion of the measures and there will be plenty of opportunity to go through each criteria.

For the next steps, we have one more workgroup call left which is next Tuesday. Committee members and the public are free to join that workgroup even if you're not assigned to it if you want to hear the discussion on the measures assigned to that workgroup. We have an in-person May 6 and 7th. If you have not either received the information for travel or have not filled out the information for travel, please fill that out as soon as you can and that goes for the public and developers as well.

We do, if you plan on attending in-person, we would like to know in advance so we can (prep for) that. Other than that, we hope to you see soon. Were there any questions before we conclude this meeting?

Peter Crooks: Nope. I just like to thank everyone for your pre-work and your work to come.

Poonam Bal: Yes. I completely agree with that. It's been a great committee so far and we really appreciate how active everyone has been in discussion – discussing the measures.

Male: Thanks.

Poonam Bal: OK. With that, I'll give you back four minutes of your time. Thank you so much and we will look forward to seeing everyone in-person.

Male: Take care.

Male: Thank you.

Female: Thank you.

Male: Bye.

Operator: Ladies and gentlemen, this does conclude today's conference call. You may now disconnect.

END