NATIONAL QUALITY FORUM

Moderator: Renal Project
April 28, 2015
1:00 p.m. ET

Operator: This is Conference # 25705164.

Poonam Bal: Hi. Welcome to the fourth and final work group call for the Renal Standing Committee.

I'm Poonam Bal, the Project Manager on this project and I am joined by the other staff members. So we will – the way that this call is structured is that we'll – on one part, be teaching you the process that we'll be using in the in-person meeting, and then on the other part also, (inaudible) the committee an opportunity to review these measures and discuss them before the in-person meeting.

So to start, I would like to see who of the workgroup members are on the call and I'll give it to Alexandra to do the roll call.

Alexandra Ogungbemi: Good afternoon and good morning to some of you. Is Constance Anderson on the line?

Constance Anderson: Yes, I'm here.

Alexandra Ogungbemi: Is Elizabeth Evans is here?

Elizabeth Evans: Yes, I am.

Alexandra Ogungbemi: Thank you. Lori Hartwell?

Lori Hartwell: Yes, I'm here.

Alexandra Ogungbemi: Thank you. Alan Kliger?

Alan Kliger: Yes.

Alexandra Ogungbemi: And Franklin Maddux?

Franklin Maddux: Yes, I'm here.

Alexandra Ogungbemi: Thank you.

Poonam Bal: All right. Thank you so much. And then I'd also like to see if there's any other committee members on the line that are not part of the workgroup and just ask them to call out their name now?

Peter Crooks: Peter Crooks.

Poonam Bal: OK, Peter was there anyone else?

Michael Somers: Michael Somers.

Poonam Bal: Hi, Michael. Is there anybody else from the committee?

Karilynne Lenning: Karilynne Lenning.

Poonam Bal: Hi, Karilynne. Anyone else?

Karilynne Lenning: Hello.

Poonam Bal: OK. So I also want to confirm that we do have the developers on. Is anyone from CDC on?

Priti Patel: Yes, this is Priti Patel.

Poonam Bal: OK, perfect. And then do we have anyone from the University of Michigan or CMS?

Female: Yes, University of Michigan is on.

Poonam Bal: Perfect. And then one thing before I call our next developer is – as many may be aware, Peter Crooks is doing a dual responsibility. He is acting as our coacher but he will also be the developer for measure 2594. During this time, he cannot participate in any manner as a committee member, so he cannot be part of the discussion or add anything to the discussion unless he's acting as the developer. So we do want everyone to keep that in mind.

If you hear Peter's voice, and of course, we will ask him to add input as necessary but he is acting as a developer not a committee member. So with that said, I would like to see if there's anyone else from Kaiser that has joined the line?

Andy Amster: Yes, this is Andy Amster.

(Dexter John): This is (Dexter John).

Poonam Bal: OK, anyone else? OK, perfect. So we're ready to start the meeting. So we have changed the order slightly. We all go with 2594 first to get that done and so you can get news to Peter being the developer instead of a committee member and then we'll go into 1460 and then do all the CMS measures together. So, starting at the same order but starting with 1423 and going through with 2703, 2704 and 2705.

The first measure will go into more procedural knowledge. So we'll try to make it as similar to the in-person meeting, so I'll ask the discussants to introduce the measure, then pause for a minute to see if there's any committee discussion, then only discuss evidence. Have the committee discuss evidence and then move forward to gap and so on. So we'll go through each criteria or sub-criteria as we would in the in-person meeting and try to focus the discussion in that criteria we're in.

Once that's done, we will go a little more into details. So, I wanted first to see if there's question about that structure, OK? So in that case, I think we're ready to start and obviously the staff will be here to (list) any questions that you may have.

So I want to see if Franklin and Alan are on the – I'm sorry – I want to see if Beth Evans and Lori Hartwell are on the line?

Elizabeth Evans: Yes, I am. This is Beth.

Lori Hartwell: Yes, I'm here.

Poonam Bal: OK. So, are you prepared to just introduce the measure and you can decided among yourselves who would like to start.

Elizabeth Evans: Lori, may I ask you to start, I'm having a little bit of a problem pulling it up right now, so…

Lori Hartwell: I'm sorry, I'm on mute. I'm trying to pull up something on the measure and my computer seem (lengthy) right this second. One more second.

Elizabeth Evans: So as mine. I'm trying to go in through – I've had issues with mine.

Lori Hartwell: What was the number again? Let me just…

Poonam Bal: 2594. And we also do have it on the webinar if your logged in.

Lori Hartwell: OK I got it.

All right so I've never done this before. So what would you – would you like me to just present the measure of how I've seen it and what are some of the benefits and then potential obstacles, it's that I've never done this before so this is my first time.

Poonam Bal: No problem…

Lori Hartwell: Is that – that works?

Poonam Bal: Actually, we try to make it a little more structured. So for this first measure, we would like you to start with just a quick introduction so the title, the number, the steward, and then the brief description of the measure. And then anything else you want to pull from the brief measure information and then start with any high point or concerns you have about the evidence. And then

proceed through with high points and concerns you have about each criteria, so that…

Lori Hartwell: OK. I'll do my best here.

Poonam Bal: And I'm here to guide you…

Lori Hartwell: And this is my first time at this, so I'm not very familiar with – I don't have any examples to follow. So as I understand this, the optimal end-stage renal disease measure is basically a measure to help patients with ESRD have an optimal start to the ability of either having preemptive transplant or starting an optimal home dialysis start but starting with an arterial fistula or graft.

From the patient's perspective, I mean – I mean, this is an ideal measure for patients because if we can fit within this realm, it's going to be – we're going to have the best outcomes, I feel. I think some of the – and I cannot find the comments from all the members, I've sent over an e-mail earlier so I don't know if that's table to present some of that. I think the rationale is because it's shown to save money, patients have better outcomes and the fact that if they have an optimal start.

Am I going along the structure you like?

Poonam Bal: That's perfect.

Lori Hartwell: OK you know some of the obstacles I see is that it maybe hard for – if this was a dialysis facility measure, it might be difficult because they don't obviously have the ability to be able to reach patients before they start, but in like…

Poonam Bal: Sorry about that. So now you are going into a little more detail than we need at this point.

Lori Hartwell: OK. OK.

Elizabeth Evans: Lori go ahead and pause here. And you know and this where – so as Poonam said in the very beginning, what we wanted to do on this particular discussion

is – for this very first measure on this call, walk through the measure as we would during the in-person meeting.

And so what you just did was great, the brief measure information of doing the over – and this is for all the committee members, providing the brief overview of the measure. And at this point, we would want to pause and see if there is other committee members, or in this case workgroup members, have any other overall statements on the brief measure information or have questions specifically related to the information provided in that brief information.

So – what you might you know what question you might see here would be you know if there's a question about the measure type or the level of analysis or something like that. There's typically not a whole lot of discussion but if there are any questions about the actual measure at this point.

Franklin Maddux: This is Frank Maddux. I would just want to clarify, this is a – not a facility measure but a clinician measure or a system of care measure that a group taking risk might be measured upon as opposed to a dialysis provider. Is that correct?

Elizabeth Evans: Peter, you may answer that?

Constance Anderson: Beth, this is Connie. And that's I how I read it as well. It's a process measure at the clinician level in an integrated to delivery system.

Peter Crooks: Yes. This is Peter Crooks. Yes, Frank, that's – the idea is that it's really for integrated health care delivery system. It could be at the level of clinician, nephrology practice, and you know dialysis companies might want to look at to see how their patients are coming in and whether they can influence, but that's not the primary level of analysis that's intended.

Franklin Maddux: Yes. And I would just – I have comment in general on the rationale is it's a great concept to have a measure around the health of the – the healthy start of a dialysis patient. And I do think from a dialysis provider standpoint, there's interest because we're all moving towards that period of risk-taking as well.

Elizabeth Evans: Great.

And I do want to point out something in that developer rationale that there is a significant performance gap even within Kaiser initially and how it had – every year that it was in place, had an improvement in the optimal start and they compared to U.S. data and there was a significant difference between that. The U.S. at 35.5 and the Kaiser Permanente in June, 2014 is 57.7 percent.

Franklin Maddux: So I have one question about the numerator for developers. And it had to do with the issue of how the granular details being counted. For example, if you have an AV fistula or graft, basically saying you have permanent access versus nonpermanent access.

I'm assuming that the optimal start definition you have is the first outpatient dialysis with that particular vascular access type, not one month later, or three months later, but the first as by some ongoing CKD activity that's preparing these patients. Is that correct?

Poonam Bal: Before we get to that answer, that's actually is going to far more into the sophistication section…

Franklin Maddux: OK.

Poonam Bal: And we do try to keep the discussion by criteria. So if you could just hold onto that question for a little bit until we get the scientific (stability)?

Franklin Maddux: OK.

Poonam Bal: All right, thank you so much.

And at this point, I'd like to proceed us forward with discussing the evidence and then, Lori or Beth, if you have – basically do a summary of the evidence provided and then any concerns or highlights you wanted to bring up and then we'll open it up to the committee.

Elizabeth Evans: Lori, I can go ahead and – I have it open now, I can talk on the evidence.

There really was very good evidence that using education and appropriate preparation that we can improve outcomes. And it was really looking at KDOQI which we all know is from 2006, it's a grade A and B and then the U.K. Renal Association 2008, 2011. It was a grade 1B which is strong opinion and moderate evidence. Also from the Vascular Access Society which did not have the date listed, level 3, which was not defined. And the Canadian Society of Nephrology which was from 2006, grade C and D, C meaning not defined, and D is opinion.

They did have a systematic review of 62 studies which was a large patient population of 586,000 plus patients. It wasn't graded but was a retrospective study and moderate evidence per the NQF algorithm.

They also looked at preemptive kidney transplants and there was one guideline from the U.K. Renal Association with strong opinion and high evidence. And a systematic review in meta-analysis was also retrospective studies with low-moderate quality, and we also graded moderate evidence per NQF algorithm. They also new recent studies, all with positive outcomes with transplant which was a cohort respect – retrospective study in an 2007 article evaluate lifelong cause for transplants.

So, this care is been directly related to improve health care outcomes and improved cost effectiveness. And since it's a process measure, we all know patient education leads to all of this, improved care, decreased mortality, decreased hospitalization.

Fistula first evidence supports patients who start dialysis with a permanent access of less complication. So I think the evidence was very significant that starting with access and preemptive transplant, rather than a catheter would have all positive outcomes.

Poonam Bal: That was a great summary, Beth. Lori, did you have anything to add to that before we open up to the committee?

Lori Hartwell: No, I think she did an excellent job.

Elizabeth Evans: Thank you, Lori.

Lori Hartwell: And just say that is – no. I'm going to stop there.

Poonam Bal: Thank you. So now, I'll open up to the committee to have – to see if there is any comment on evidence.

Alan Kliger: So this is Alan, I have two questions. The first is that if this does ask to focus on adequate patient-centered preparation and patient choice? And when there – there is lots of evidence that when patients get adequate education and choice, that many fewer choose hemodialysis and many more choose peritoneal dialysis and transplant. Is there a way of capturing that adequate patient-centered preparation in choice in this measure?

Poonam Bal: Are you asking the reviewers or the developer?

Alan Kliger: Well at first, I asked the reviewers because I went through this but I perhaps did not do it in adequate details.

Elizabeth Evans: I did not see that when I reviewed this measure. I didn't feel that that was captured in at a more the preparation of the process of access or transplant. And of course the delivery either, hemodialysis, home or peritoneal dialysis but no, I did not captured that in this.

Alan Kliger: OK. So, Peter, may I ask you that question, did you consider you know because you've stated well that adequate patient-centered preparation and choices are among the things that you were aiming at. It would come to capture that and other than the type of vascular access?

Peter Crooks: Not directly. It's – the measure tells us what percentage of patients get to that optimal start. I didn't go into in or we didn't go in the submission in any detail, but it's easy to breakout sub-metrics and within Kaiser, we focus not only on the total optimal starts with them, we can look at the home starts and compare that between regions and in fact to have initiatives in place to prove PD starts as appropriate to make sure patients are getting the education and our empowered to make the best choices. So we feel that that – all that feeds into improving the top level outcome which is the optimal starts.

Is that addressing your question?

Alan Kliger: Well, sort of, but I – would you be talking about an addition measure to capture that piece of it? Because this captures how many people get fistulas or grafts before the first start.

Peter Crooks: As well as those who start – no, home dialysis is a part of it, too.

Alan Kliger: No, I understand that but it doesn't address the specific issue of patient-centered preparation and patient choice.

Peter Crooks: Right. To the extent of – I'm trying to read your mind here but you're saying that a metric that would say 60 percent of patients have appropriate education and made an informed choice or something like that?

Alan Kliger: Right. I'm not – I know – if you want to restrict – if this is measure-restricted – in other words if you're saying basically you want to restrict this to know that the right vascular access was constructed, and then exclude from the numbers, those people going on peritoneal or transplantation, then that would be a measure looking specifically at vascular access preparation. If you want to position this as appropriate best start, then I think you'll leaving out a piece that's really important, I guess that was I'm saying.

Peter Crooks: Well, to the extent that it treats vascular – you know I'll start with the functioning fistula or graft equal to starting home dialysis or peritoneal dialysis, that's true that it is treated equally on the measure.

Alan Kliger: The other comment, just a question also, which is you know it reminds me of what we learned as physicians, of surgeons making a decision to operate on an appendectomy, that is if the appendix was 100 percent of the time inflamed when the surgeon takes out appendices, then it means that the surgeon is operating too infrequently.

Peter Crooks: Right

Alan Kliger: I mean there – in the preparation of patients with a vascular access, there is always a percentage of people who have an access constructed but is never

used. So when we're looking for best start, if we're all – if we're looking at a measure that basically drives for everybody to have a AV graft or fistula, it suggests that there will be lot more grafts and fistulas created in people in Stage 4 or early 5 that are never used. I wonder if you've thought of that and thought of how, again, what you're calling sort of optimal or best start, if that's something worth thinking about.

Elizabeth Evans: I want to answer a little bit of that actually as a reviewer of this measure. And that was actually stated as an unintended consequence that that could be a possibility that as preparation for dialysis and for whatever reason. It access is never used.

Frank Maddux: So, yes. This is Frank Maddux. I would ask Helen and Peter and the reviewers, I interpreted this measure so much differently than I think Alan did. And it was the word optimal that I interpreted differently. I interpreted this essentially as a measure of avoiding catheters by either modality decision or vascular access decision. And I'm interested in was the intent to define that there is a optimal modality or an optimal way to avoid catheters at start, that's really the question for the three of you that I be interested in.

Alan Kliger: Well just quickly, actually that's my question too, Frank. So I was saying is that if it's restricted to asking about the best vascular access, then I think it would be easier for a user to – or a clinician to understand how to use in the intent of the measure.

Constance Anderson: This is Connie, and I guess I interpreted it entirely different. I interpreted it as patient education is the core. And so if those patients that start without the patient education of access and modality, et cetera, versus those that do start with patient education is there the optimal start more frequent with those that have had the patient education versus those that didn't.

And so I looked at it from – when I read it, I was looking at it from the standpoint of the patient education and optimal starts based on the education. So, I would be comparing those that didn't have the pre-dialysis education versus those that did. And how many selected permanent access – came with the permanent access or have a preemptive transplant or chose home as their

modality of choice. And I apologize if you go there during – (drawing) and staff render construction (herein) so, I really apologize for the noise.

But I read it from an education standpoint.

Lori Hartwell: Connie, this is Lori. I would agree with you. You're (saying) these are the reoptimal ways to start dialysis or avoid dialysis like preemptive transplant.

Constance Anderson: And I think the gaps in performance is those patients who don't have that education versus that those do, and the difference in those optimal starts. And so, I interpreted the measure entirely differently, I guess.

Alan Kliger: Well, no, really. I mean again, with the question I was asking, as a matter of interpretation from my standpoint. The question I was asking is if the point is optimal start, then – and patient education informing that, then we have no measure of optimal start as it relates to patient choice of modality, for example. We have no measure of whether or not patients are given an opportunity to choose and what those choices are. It's restricted only to look at education as it informs vascular access.

Franklin Maddux: Well, I don't think it goes – I think it goes beyond that, Alan, because I think it also informs was adequate preparation to begin the modality that was chosen, one that lead to the ability to avoid the catheter. That's the way I look at it. And so…

Alan Kliger: No, I agree with that…

Franklin Maddux: … with combination of education choice and action, the action being this people didn't just decide they will have to be prepared, they actually got prepared.

Alan Kliger: Sure. But it ignores the choice around peritoneal dialysis, that's what I meant.

Peter Crooks: Alan, I'm not sure that I understand why you're saying that. The – if you look at the process diagram, it says, "Identified patients at risk." And if you (fill up) that, they're going to not have an optimal start.

And if you identified patients at risk, then you educate them about all their options including preemptive kidney transplant, home dialysis PD, home HD, and then – (instead) of hemo. And then they make their choice, and then the team is a multidisciplinary team function with the physician to get that patient from the point of making a choice to being prepared. So that when the day of ESRD comes, they are ready to go.

Alan Kliger: Sure. You know what, that's great. And I, again, I endorse this. I think it's great but where is the measure of how many people are informed? Where is the monitoring of that information, and how many make choices other than hemodialysis?

Peter Crooks: Well the one – well, let me just – can I offer one…

Alan Kliger: And it's not worth – I mean, I will cease in this. This is no reason to spend more time on this.

Peter Crooks: I just like to make one more comment, and that is, I think if we step back a little bit from our roles as nephrologists and nephrology providers to say you know our intention by submitting this to the NQF is to really get the U.S. health care industries' eye on a very important aspect of renal care, and that is that 70 percent of patients, roughly, 65 – 70 percent of patients come into ESRD uninformed with a catheter in their neck.

And this has – this is hopefully, if endorsed, will be a message to the health care industries, CMS and so on, that we really need to start paying more attention identifying patients at high risk, educating them and getting them ready. And that, in fact, it can be done.

So that's stepping back a little bit. That was the intent. Now, when you get down inside how do we accomplish these things, every system is going to require a different you know…

Elizabeth Evans: Processes…

Peter Crooks: … processes, right.

Elizabeth Evans: Right. I think you really stated the primary foci of this measure is preemptive transplant, initial dialysis therapy at home by PD or HD or initial hemodialysis via fistula or graft. How we get to that is different.

And if we're assuming because it's not captured here, that we have done adequate patient education, but we do know we have done some significant planning with obviously patient buy in and awareness to accomplish this right here. And we're not capturing that right now anywhere else nor are we capturing how much that we're doing on patient education nationally. Within each practice, we should be capturing that but not with this measure in how I reviewed this.

Poonam Bal: And with that said and we'll have to cut the discussion short. We'll have more time during the in-person meeting to discuss these topics. But I do want to you know be mindful of the time and move forward.

So, if we could start the discussion on gaps, I think we did a little bit already. But we begin with another synapses of your review of it, Lori or Beth, who would ever would like to go first?

Elizabeth Evans: I'll go ahead and start. So, the Kaiser data definitely demonstrated a performance gap. There was a need for a national performance measure. When they evaluated just from their beginning data just with Kaiser in California, the process was – I can't find that exactly right now. But every year, it grew like about 10 percent. And then they initiated it for three past years nationally. And their data for achieving optimal starts with 57.7.

They extract the data from U.S.RDS as the 2012 – and I'm just capturing this as AV fistula rate because we don't have preemptive transplant rate as 35.5. So, obviously there's a significant performance gap between U.S. and Kaiser Permanente performance.

Disparities in care was very limited evidence regarding that. There was one article about vein differences in African-Americans. One article discussing a disparity with preemptive kidney transplants, concluding that transplants occur more often in Caucasians with private insurance.

No recent article is found comparing PD to hemodialysis disparities except that there's a high utilization of PD in other countries. One article that suggested zip codes with the higher African-American population was associated with lower nephrology care but it really is unclear of disparities with this particular measure.

The U.S.RDS' Fistula First that shows a significant gap in performance of predialysis education and opportunity from improvement. Lori, do you have more to add with that?

Lori Hartwell: I think you did a great job.

Elizabeth Evans: OK.

Poonam Bal: OK. So then I just want to open it to the committee to see if there are any additional comments? OK. I'll take that silence as no. So we can move forward to scientific (specific ability) and start with specifications. Franklin, the question that you asked earlier would fall into this category. So once the introduction is done, we can definitely open up the developers, and see if they want to respond or if you want to summarize your question again I a different way.

So, I'll ask for the introduction from Lori and Beth first so.

Elizabeth Evans: OK. Go ahead, Lori.

Lori Hartwell: Now which section in am I doing, the validity testing?

Poonam Bal: Before the validity testing, there is classification section.

Lori Hartwell: Oh, I'm sorry, yes. I just missed it. OK.

So the specification (part) of the measure, the consistent and credible results as a quality of care was implemented. The target population is (new) or ESRD patients as described in the denominator details. There are no exclusion to develop or provide full measures specification and definition and identification of that element (for ethel).

The measure is not risk adjusted. So when you look at this, the reliability testing demonstrates the measure data element are repeatable, producing the same results, a high proportion of the time one assess in the same population, in the same time period, and or that measure score is precise and that's to distinguish differences in performance across providers.

Accuracy, correctness of data element is empirical tested. This section – I'm going to pass that over – so that's pretty much what it has. The only couple of questions that I had and I don't have the time to do that or…

Poonam Bal: You can start with your questions first as a main discussant.

Lori Hartwell: I just had a quick question if you know if the measure needs to be risk adjusted for you know people who are un-eligible for transplant or has you know an emergency PD year or an emergency start, I mean obviously was a patients that weren't illegible for a preemptive transplant or transplant was a – just kind of understanding how that works.

Poonam Bal: We'll, I would say I'll ask Sarah to confirm this but that would more of a possible exclusion then that would be risk-adjusted for. So, would you agree with that?

Elizabeth Evans: I have to admit, I stepped away from it.

Poonam Bal: All right we'll let's open it up to the committee and see what they're thoughts are on that and then will get back to Franklin's question.

Constance Anderson: Hi (Corette), this is Connie. I think that instead to being risk adjusted, I think it would be something that would be in the exclusion criteria.

Poonam Bal: So then I'll ask to see if there's anyone from Kaiser that would like to respond why that was not created as the exclusion? Or if there's any – if there was any thought put into that category.

Peter Crooks: This is Peter. I'm not sure that I understand what the question is, and so, patient can have a kidney transplant. They are still – but if a patient reaches the ESRD, that is the need renal replacement therapy be it by transplantation

or dialysis, they're in the denominator and they are included. So many patients are not able to have a kidney transplant but they can still have a home dialysis or an optimum start with the fistula or graft. Is that getting at the question?

Lori Hartwell: Yes. I guess, one of my questions, I'm just trying to understand the process of so a patient enters there, not eligible for transplant but if they have the right access or they have a catheter placed in them, put on home dialysis. I mean I'm just trying to understand, you just have to meet one of these three or all of the ones that they're not available. I mean two of the three because they're not eligible for preemptive transplant. And I think it's a great way to look at patient care, just trying to understand a little bit.

Peter Crooks: We'll yes so if a patient reaches end-stage renal disease and if you read through the details and there's a very detailed section provided on inclusion in the enumerator, first of, there is the ESRD there on the denominator, OK. Then the questions, did they have optimal start and it's very specific and we did to chose that if a patient started home hemodialysis with a catheter, that would be a nonoptimal start because it is a catheter start for that specifically.

I think we've cover just about every potential way to start renal placement therapy in our definitions and their specifications.

Did that help clarify, Lori?

Lori Hartwell: Yes. Thank you.

Poonam Bal: OK. And before opening up for the committee, I do want to see if Kaiser had a response to Franklin or if they needed him to repeat the question?

Franklin Maddux: I'm happy to repeat it. So…

Poonam Bal: Yes. Could you please repeat your questions?

Franklin Maddux: Sure.

Poonam Bal: Thank you.

Franklin Maddux: So there are really two part of this question. One is, in the details of your numerator (S6), I want to make sure I understand a couple of pieces to it. Is the concept that patients will start their first product dialysis and the definition of optimal as an outpatient, or simply that we're measuring the first time that they are an outpatient, that they in fact have a catheter (avoided) vascular access.

Peter Crooks: Yes, the definition is what was there access on the data, the first outpatient dialysis.

Franklin Maddux: OK. So that's fine. I just want to make sure that was clear. So the term optimal doesn't actually extend to the condition in which an optimal start for hemodialysis, so for example, maybe an outpatient first dialysis as opposed to inpatient first dialysis?

Peter Crooks: That's correct.

Franklin Maddux: OK. And then the second was one that I believe Lori was asking, I just wanted to confirm the answer again. If you – if your outpatient hemodialysis is home hemo, are you also excluding catheter as a vascular access for home hemodialysis?

Peter Crooks: We went back and forth on that a lot. It's been – and you know we came down with that's a nonoptimal start. I know you can say it's optimal in the sense that they're at home doing their own dialysis and that's a good thing. But having to had to make that decision, with we decide that's nonoptimal.

Franklin Maddux: Great. No, that's fine. I'm comfortable with that. Personally, just want to make sure it was clear to everybody.

Male: Just a quick question in relation to that Frank here. Is there evidence that home hemo patients using catheters have a higher rate of complications or problem than those who don't use intravenous catheters at home?

Peter Crooks: Anecdotal only. I wasn't able to find any published data on that.

Male: The only reason I mentioned it is that if you speak to people doing relatively large outpatient treatments like Lockridge, for example, in Virginia. There's anecdotal evidence is that they handle their catheters very differently in you know individual patients handling – get thought in handling themselves. And don't have the complication and sequelae that inpatient experience?

Peter Crooks: Yes, I appreciate that. And it's a small number, I guess in terms of the total population but I argued the other way but we came down on this decision. We had to make a decision and either one could be criticized I guess.

Franklin Maddux: One last question, Peter, on numerator methods. You're centering the population of patients to those who start dialysis and last 90 days, is that correct?

Peter Crooks: Correct. In order to exclude those who have kidney failure and recover…

Franklin Maddux: So how are managing incidents deaths?

Peter Crooks: Incidents death after 90 days?

Franklin Maddux: Prior to 90 days, which is about…

Peter Crooks: They're – they stay in. They had a non – if they start with a catheter, it was nonoptimal.

Franklin Maddux: So they stay in in both numerator and denominator?

Peter Crooks: Right.

Poonam Bal: Before we continue, I do want to make sure that this process-wise, we do generally try to encourage that the committee talk to each other and have kind of go through each other's theories together and discuss it before going to the developer. Just to encourage us more, the reviewer having the chance to give their thoughts to each other. And then the developer just mainly more for answering questions, that's the processing.

And then we do need to keep moving forward so I do want to see if there anymore questions about the specifications before we move forward to reliability testing.

Franklin Maddux: I have one question for the group. Does the group believe there's no more than 10 percent of all patients with the correct is, realistic outside of with developers world.

Female: You're just asking for our experience?

Franklin Maddux: I'm asking you whether from this measure standpoint, where the measure as a national measure is being held standard that's being derived by a single provider system that is you know very well this. Nationally when I look at graft rates and graft propensity, it's quite variable around the country. And so the question really is about should a measure be targeted towards a particular location or systems identified best practice.

Lori Hartwell: And this is Lori. I have a question o will we will be going that system in the future, where more people will be more managed care or health care plans. So not being on this committee before, do we look at measures that can have an impact in the future as we go into more integrated care?

Male: Frank, can I respond to your – I mean you're right, Lori. As we move to a population management, there's going to be a lot more attention, I think, paid to these kinds of measures and use in large outpatient systems to try to understand what we're doing to prepare people for dialysis. So I love the idea of this kind of a measure and I think you're right that that you know it is one that is particularly well poised for the future.

But Frank, unless I misunderstand this, the measure doesn't set a floor or a requirement, does it – unless…

Franklin Maddux: Just limited to no more than 10 percent of all patients, starting in-center hemodialysis on the numerator details with a graft.

Male: I see. OK.

Franklin Maddux: And that will – what struck me about that is, I think that that's a great target. But I can't convince myself with saying national benchmark as opposed to a system benchmark.

Elizabeth Evans: I don't remember reading any evidence to really support that number. Maybe Peter could comment just on the evidence for that.

Poonam Bal: Yes. And we can open up to Kaiser now to see if they would like to respond.

Is any one from Kaiser still on the line?

Peter Crooks: I'm on, I'm sorry. I was muted, this is Peter.

The 10 percent is an acknowledgment and that the Fistula First effort that has been ongoing and everybody on the call is familiar with. And I think that, yes, if – it's defensible in that, if there is a certain area of the country or certain health care entity where that isn't being achieved, that's something we should strive for.

Is 10 percent the correct number, we used to have 5 percent, we've increase it to 10 percent within Kaiser. And I think going forward you know as things evolve and things are renewed every three years. I think that's going to be a point that could be looked. Elderly patients maybe appropriate for grafts in some cases or even fistulas – I mean catheters if they're on trials.

So, but that's where the 10 percent comes from and I would say it's defensible that – even if a certain entity isn't hitting that, that's a reasonable target.

And knowing Fistula First, our fistulas are on the increase, I think catheters are coming down into that range, end of (comment).

Male: Well Frank, I think you raised an important question.

Franklin Maddux: Yes, I like the measure. I just worry about that one piece of it creating an unintended consequence much as Fistula First did with elderly you know Michael and staff, and other work that's been done on the elderly patient and the you know just constant trying to get a fistula on and to mature.

Poonam Bal: And we can speak tomorrow about in the in-person meeting that would actually fall more into the use and usability criteria, then into the reliability and validity testing. But it's something definitely to keep in mind for all sections. And we do need to keep going. So I want to see, if there's any of their comments about reliability before we move to validity testing.

OK, so then Lori and Beth, if you want to give a quick introduction to the validity testing before we open up to the group.

Elizabeth Evans: OK. I'll do the validity. So there was no risk adjustments for it. There was meaningful differences between the regional rates compared to the national rates. Missing data rate was low. It was the data that was missing was among the numerator data which was the method of renal replacement therapy. It happened with dialysis clinics outside the Kaiser Permanente network which was in 3 percent. Had no statistically significant effect upon the observed results.

There's significant variation in national optimal ESRD starts in the U.S. So they felt that was no – that missing data of 3 percent post no statistically significant effect.

So in their particular close system, the data was much more able to be obtained and accurately followed. So chest sample is well-defined and adequate for generalization. Accuracy and correctness of the data element is empirically tested. The section for missing – for minimizing bias was not required and was skipped by the developer.

And test sample size is adequate and results are reliable. The only concern I had was this was a close system for obtaining data and they missed even though it was very small amount just from clinics that were outside their network.

Poonam Bal: OK. Did we have neither comments on validity testing? OK, I'm going to assume that everybody is fine with that analysis and we can move forward to feasibility.

Elizabeth Evans: And I'll take feasibility. So its been tracked with the regional coordinator from Kaiser Permanente that uses part of a connected Kaiser system with the national measure. There will be hundreds of different electronic sources that would require a definite coding system or some sort of tracking program across – pulling data from the (LLS) centers, transplant centers, and nephrology offices. These measures are important, it could definitely promote better health outcomes but unclear the data collections strategy.

Preemptive transplant and predialysis patient education are not routinely generated, so would require new data collection tools. It would be a significant burden on staff to collect this data. And the information on supporting the10 percent AV graft placement would also be a potential problem with that, maintaining that on the patient population.

Poonam Bal: OK, where there any other comments on feasibility? OK we can move forward to usability and use. And this is a lot of the comments about unintended consequences would fall into this category.

So I'll ask for Lori or Beth to go ahead and introduce usability and use.

Elizabeth Evans: Lori, you can go ahead and do this one.

Lori Hartwell: I'll do my best. And basically I can read the statement. There are three related measures and now competing measures and I think we've said that on the call, the (yes, no) ESRD start focuses on patients who need to start. Renal replacement therapy including hemodialysis. The other measures that are presented address improvement if vascular access for patients ready for hemodialysis.

And so, I think – I'm just trying to summarize this but I think this measure would – I'm trying to not put my own opinion and I am trying to read the facts. And as oppose to an optimal (effecet) which is an (incident) rate for new ESRD patients measure, 0256 is a prevalent measures of the existing hemodialysis population …

Poonam Bal: Lori, I'm – sorry, I'm going to interrupt you real quick. I think you're actually talking about the related and competing and we won't be discussing that quite yet. We're on the usability …

Lori Hartwell: I'm always ahead in myself, that's the problem.

Poonam Bal: No problem.

Lori Hartwell: So you want the criterion. I'm sorry, I'm looking at…

Poonam Bal: Yes.

Lori Hartwell: So, the usability and use evaluate the extent in which the audiences, the consumer (participants), providers, policy makers user could use this performance result for both accountability and performance improvement activities.

So the measure is planned for use in public reporting and for quality improvement with benchmarking measure could be used for public reporting and other accountability purposes and situations where there are significant members of new ESRD patient, at least 50 a year. A health plan, a large provider group or – my (staple) is on the plan – or CMS could utilize this metric and compensation formula.

Currently use for quality improvement internal to specific organizations, metric accountable to the regional medical director at Kaiser, optimal ESRD (starts) is currently utilized by permanent federations sponsor of the NQF submission to track the performance of six Kaiser Permanente region.

Poonam Bal: All right. Perfect. Thank you for that. Do we have any comments that we've not already made about usability and use at this point that the committee's willing to share? OK, I'll take that as a no.

So we have completed our first measure. As Lori started discussing, the related and competing, we actually don't discuss that until all the measures that we have deemed as related and competing have been discussed. We do want to give each measures opportunity to be endorsed or not – recommended

for endorsement or not recommended for endorsement individually before we discuss them for related and competing. And those measures – the committee decide they don't want to recommend the measure for endorsement, there's no point in discussing it on how many (days) because the other ones are already deemed the more appropriate measure.

So we actually don't – we won't discuss that right now but there will be time to an in-person to discuss it. As I said earlier, this is the process we'll go through where we're in the in-person for each measure. The role that I would taking (be more approachable) and they'll be doing that in in-person. So for the rest of measures, as you guys can see, it's already be an hour and we've got through – through one measure. We have to get through a good chunk of more. So we're going to actually go off the process just for efficiency of time.

So just everyone know, we do have a public comment time at 2:50. And so we do want to try to pause at 2:50 for that but otherwise, the new procedure we're going to use just for this call is that we will have the discussants introduce the measure and then just provide any highlight or concerns they had for any of the criteria. So, it 'd be more but Lori and Beth were talking about at the beginning, we're just (highlighting).

And we'll proceed – so that we would quickly be able to proceed to the measures and get any concerns out there now. But in the in-person you know each measure will get a thorough discussion just like we had for that first measure. So, I do want to move to 1460. And so, let's see here …

Peter Crooks: And this is Peter Crooks again, I just like to reintroduce myself as a committee member. I am no longer a developer.

Poonam Bal: Yes, that is correct. So Peter can now participate as a regular committee member. And he – should we do (treat) as everyone else now. So I want to see if Franklin and Alan – if you want to start – I'm sorry, again. It's actually Lori again and Alan. If you want to start with 1460 and give a brief introduction and then any concern or highlights you may have, and then I'll let you decide who wants to go first.

Alan Kliger: Lori, do you want to go or do you want me to go first?

Lori Hartwell: Please go first.

Alan Kliger: OK. So, I'm hoping we can do this one relatively quickly. It's a measure of bloodstream infections and it's using two metrics, either the adjusted ranking metric or the standardized infection ratio. And define so that it is able to pick up infections that happened in dialysis facilities or within 24 hours of admission to the hospital.

The evidence – if I'm going out of bounds guys by this new rule, let me know, but if I can just hit the high point. The evidence of the importance of capturing new bloodstream infections because of the downstream morbidity and mortality is very high. And thus, the rational for having an effective measure like this is compelling, I believe.

The performance gap has been identified back in 2006. I didn't see from the developers any current evidence beyond that, but I suspect that the evidence would be very similar now to what it was in 2006.

It's really only been relatively recently that we started paying a lot more attention to ways of reducing infections. And so, my – the evidence that was clear in 2006 is likely to be current as well now.

The developers speculated that older adults and Blacks might be disproportionately impacted by bloodstream infections but they really provide no evidence for that. Nonetheless there is clearly evidence of a performance gap, I think we need to pay attention to.

The specifications of the measure are clear and I believe can be consistently implemented now. I'll just throw in the whole thing. So when we talk about reliability, we know that back in 2002 that the accuracy of measurement and the completeness of reporting was high when it was tested. We haven't had any testing since then but likewise, I suspect that it would be similar now.

Validity testing was done in 2012. The measures that were entered in to the NHSN dialysis event module turns out to be accurate but with a wide range of results.

And so, if we're talking about the validity because of that wide range of entered results, I think we still don't know for sure how valid those data are.

I – overall, I guess my overall sense looking at the measure was that – oh, I'm sorry you know the feasibility is not clear to me. New data that was being collected in NHSN is the current way and we no longer have a track record for their – this tool's feasibility. So, it's likely that the feasibility will be high but it's not yet clear.

And the usability is probably high. Lots of facilities, 6,000 of them now reporting to NHSN, and so I think overall it was a well constructed tool and I didn't see any major problems with the measure.

Poonam Bal: OK. Then I'll give it to Lori now to see if she has any additional comments, concerns or highlights that you feel Alan didn't present.

Lori Hartwell: I think he did an excellent job. I had nothing to add.

Female: Perfect. So then we'll open up to the committee to see if they have any – if they have a response to Alan's analysis or if they would like to anything additional.

Constance Anderson: This is Connie. The only concern I have is we found out over the last couple of years if we've been meeting in the collaborative effort with the CMO and the operations people, is many people aren't doing blood cultures prior to giving empirical antibiotics. And so, the reportability of bloodstream infections in the NHSN data is contingent upon positive blood culture plus fever yada, yada, yada.

So, I'm just concerned about the reliability of the reporting through NHSN as indeed in practice. It's giving the empirical antibiotics before you're giving – before you're drawing blood cultures. Just a concern.

Poonam Bal: Would any of the committee members like to respond to that?

Franklin Maddux: I mean I don't want to say I agree with that, having been through those same conversations, but also question, the degree, or that questions which is –

would ask those that reviewed the details of this one whether they found that NHSN is adequately segregating out false positives from you know staff or other…

Female: Contaminants.

Franklin Maddux: … types of infection and whether that's been statistically validated that you are able to clearly segregate a true (VSCI not count) false positive.

Male: Yes. So Frank, I think those are both really good questions, of course to that empiric use of antibiotics. What I would say looking at the measure is that that's an issue but the measure – measures you know infections that had adequate you know accounts to pop up as an infection.

So, the measure itself works. There is a question about empirical antibiotics and whether or not the people are adequately getting cultures done, which will impact how you're thinking about it but you know not those which are actually capturing at the measure – the measure looks at.

In terms of the you know the question about false – so called false positive, that's always and I did not see (evidence). I'd be interested in the developer's response. I can tell you though that in all of the work that this – here and in hospitals that had gone with looking at central line infection rates. That's always been the bugaboo. When you talk about (det ethy) it's never clear in fact if it's a contaminant or if it's a real infection or I shouldn't say never but frequently not clear and I think that sort of goes with the territory here.

(Crosstalk)

Male: I like to just comment and sort of underline what Alan said. I would have like to have seen more up-to-date reliability and more of validity testing. I do – I do worry about that, particularly if this is used for you know accountability and perhaps for accountability or payment. And I would encourage the developer to go back and reassess validity and see how that looks.

Franklin Maddux: So I would like to just make two other comments. One is the capture of the blood stream infection certainly within an organization is a piece of it. We

find at least in a larger organization about 9 percent to 11 percent of blood cultures are not done in systems that we have direct access to. And so, that creates one of the complications of getting the accurate data for timely manner.

And then my other comment is I am concerned about Connie's comment on empiric antibiotics prior to blood cultures being a potential unintended consequence of a measure like this. Putting people under microscope that, unfortunately, could be a way people might work around the system of measurement and that would not be a good thing I think in general.

Male: Yes, yes. I never thought of it that way Frank, but you're right on with that. You're right.

Female: OK. Were there any other discussions about 1460 before we move forward? All right, great. This is exactly what we needed to get to unless there's anything. Thank you so much for your analysis. And so, we'll move forward and we'll go back to our original order. So, 1423 and that's Franklin and Alan. And this time I did do it right.

Franklin Maddux: Great. So Alan and I talked about this. Alan, do you want to just do the quick review?

Alan Kliger: So may I start – let me just sort of whiz through this if I can and then Frank will have some comments to make as well. So, this is – the name of measure was the minimum single-pool Kt/V for pediatric hemodialysis patients. That was its name.

Interestingly enough, that's not in fact the way the measure is defined because while the measure is defined as having a minimum, that a single-pool Kt/V of 1.2, it also gives a, apparently, a maximum of less than 5.0. There is, in adults, lots of good evidence that a minimum single-pool Kt/V of 1.2 for patients dialyzed three times a weeks, adults dialyzed three times a week, that that is a minimum below which the rates of morbidity and mortality rise.

And so with that piece of it, the evidence is good. I see no evidence that was presented nor, to my knowledge, in the literature that would support an upper

limit of urea kinetic measurements. And so I was very confused about why that was here and not in the title and also not defended by clear evidence. So that was one issue, a problem that I had.

The second dealing with this measure was that there are very little data among children, and this is a pediatric measure. And the developers of course know that because with the relatively small numbers of patients, pediatric patients on hemodialysis, it's hard to pull together sufficient numbers to have evidence such as we have in adults.

And so, they're really suggesting to us that we use similar numbers and measures to what we have in adults and apply them to children as sort of you know face validity evidence that if it's good enough for the adults, it should be good enough for the kids as well. I think we need to recognize that there are no data to help with that and that that would be a bit of a stretch. It may turn out to be correct but we don't know that that's correct.

Third problem which actually I believe is a very substantial one for this measure and for several of the other measures that University of Michigan and CMS has presented is in their description of the measure because they specifically say that this should apply to all pediatric in-center hemodialysis patients on dialysis more than 90 days, and dialyzing three or four times weekly, who's average delivered dose of hemodialysis is between limits I mentioned before.

Now the systematic problem here is that when Kt/V was first developed by Frank Gotch, and later when it was applied by other kineticists like John Daugirdas, they were using Kt/V as a – really a surrogate for some measure of continuous treatment. Now, regular kidneys operate continuously, we're dialyzing only intermittently. And so the measure was designed with in mind the fact that if you're doing it only intermittently, that the number is not additive. You can't simply take a Kt/V of one treatment and then multiply it by the number of treatments per week. That does not work.

And there have been better measures when you – and that's is a fine – it is a fine measure if you're looking only at three times a week. Only as a single

frequency dialysis because then the numbers are comparable, it does translate to a continuous function such a standard Kt/V but you can use single-pool Kt/V for a group of patients, all of whom are dialyzing with the same frequency.

But if you're looking at patients dialyzing with different frequencies, then that formula no longer is applicable. You can't use a Kt/V for that. What you need to use is a measure of some continuous function such as standard Kt/V. And because the developers here in fact quoted John Daugirdas and his Daugirdas 2 formula, I took the liberty of speaking to John Daugirdas about this very problem. And John pointed me towards 2006 NKF KDOQI documents, in which he and the other people, the kineticists and the other experts in the group, did in fact clearly recommend two things.

Number one is that you derive a minimum Kt/V for three times a week which they did, which was 1.2. Because that equated to a standard Kt/V – the standard weekly Kt/V of 2.0. If you look at what would be required for patients dialyzing four times a week, the equivalent to a standard Kt/V of 2.0 was not 1.2 but actually was 0.77.

So my point is that we have real problem I believe in the way this measure is constructed because it asks us to use a tool, the single-pool Kt/V, for measuring different frequencies of dialysis during the week. And the tool can't be used for that, it's like – really, it's like trying to use a tape measure in order to get somebody's weight. It's just the wrong tool because you can't have a valid answer that comes from it.

So, I believe we have a real problem here, that is that the developers either need to restrict it to three times a week and exclude people dialyzing with different frequencies. Or they need to use a measure of something like the standard Kt/V rather the single-pool Kt/V.

The second issue with this, again, as Daugirdas and his group pointed out in the KDOQI guidelines, is that the measure for hemodialysis excludes endogenous kidney function. Interestingly enough, that's not the case for peritoneal dialysis where the convention is always been to measure Kt/V, but

include endogenous kidney function, or residual kidney function. And in the NKF KDOQI guideline documents, they have a table in which they show the different Kt/Vs at zero endogenous kidney function or at 2 milliliters per minute of endogenous urea clearance, just as an example. And show the differences in those.

So, my problem with this measure is that it's using tool that can't apply to multiple frequencies of dialysis. And also that, like it did years ago when it was first developed, it's not including endogenous kidney function and I raise the question about whether it would be wise or if it did.

So, I mean, I can talk – I just talked about the other aspects of the testing but as I remember right in the past, the first thing was whether the evidence and the tools were appropriate. And if they were, you'd then go into the testing, et cetera, but I would stop at that first stoplight for this and several of the other measures because of that concern.

Male: Alan, so…

Alan Kliger: I'm sorry, can I just ask Frank because Frank was the other primary reviewer if he has…

Franklin Maddux: So, I had a couple of other issues that I want to (grab) related to this and it actually translates over to a couple of the other adequacy-related measures. There were a couple of things that have bothered me about these measures in general, and this one in particular. And one is the definition of using either urea kinetic modeling or the Daugirdas 2 formula for fundamentally based on similar things, but they're actually performed quite differently as you know.

And the U.K.M model and the Daugirdas formulas actually have concordance with, but there is no clear description that in this pediatric population, for example, we even know whether the full kinetic modeling actually functions the same in very small children as it would in adults when it was originally developed. That's one piece.

The other is like, I think there is the opportunity for not only interunit reliability at the facility level to be looked at. But because an organization

would pick either using Daugirdas 2 or U.K.M, you may well have interorganizational variability that's completely untested at this point with regard to whether this measure work – perform as expected or create unintended consequences.

And then at the more granular level for all of these adequacy measures, and this one included, I would say there are subtle distinctions on how the urea levels are timed and drawn, and days, week, and other things, but are not in the detail specifications to the point where, again, you're going to get dramatic differences based on subtle procedural differences that are done, whether the timing of the post-urea, whether it's the day of the week in which it's chosen to be done that can heavily influence the outcomes here and sort of distort reality because some measures don't get down to that level of distinct detail on how the primary measure are actually captured.

So I would just add those into the mix of things that concern me about this measure and same comment for some of the others.

Alan Kliger: And one last comment quickly which was the performance gap. Performance gap at most here now for adult is 14 percent with 90 you know with 86 percent of people above that minimum. And I do wonder whether we should be paying our precious attention to things other a minimum Kt/V.

Poonam Bal: OK, so those are great point. Where there any additional comment or response from the committee members?

Michael Somers: Alan, this is Michael Somers. I didn't disagree with your comment but in terms of the you know number – if this measure were to restricted to children who are only being dialyzed three times a week and that there are only relatively small proportion, around 5 percent or so of kids who were dialyzed four times a week. And they tend to do (with) really with all kids who knew that in term of their volume elements. So you know restricting it to three times a week would really not exclude majority of pediatric patients.

Alan Kliger: Right.

Lori Hartwell: This is Lori. I'll just take and – I was on PD most of my pediatric life and I never fell within the measure of what was defined as adequacy but I performed, I (live) alone, I worked, it felt good. So, when I talk to their patients, I don't know if this measure actually describe when a patient is doing well. And this is the patient's perspective.

Male: Michael, do you know whether urea kinetic modeling in very small body mass individuals like young children actually has been evaluated, I just wasn't able to find that.

Michael Somers: Well, I mean, it's been evaluated in you know very small group. There aren't large groups that there's any sort of (validity) …

Male: And does it operate identically as it does in adults?

(Crosstalk)

Michael Somers: Yes. Pretty much, pretty much, so…

Male: So, OK.

Michael Somers: Yes, yes. You know and it is also true that there is you know no data in terms of what that best you know Kt/V should be for children? I mean it's just been this thought that obviously, if you're growing and developing, you probably need at least what an adult needs. And obviously, there can be individual variation in terms of what you need to achieve to still be doing well, but overall that being a major concept.

Alan Kliger: So, Michael, I mean I guess if the developer would want to exclude patients dialyzing other than three times a week, and that wouldn't be an objection to the tool. But I would raise the in larger question of isn't it wiser instead to pick the better tool to accommodate all of the kids and adults that these days are dialyzing at very different frequencies.

Michael Somers: Right. Which – I mean I think that (same is) discussion is something the committee as a whole is going to have to have for adult adequacy measure too.

Alan Kliger: Right. Right.

Michael Somers: Yes.

Peter Crooks: This is Peter. One other comment about gap, Alan, in this and other and several others of the Kt/Vs, the measure sitting on other is actually over 90 percent, 93 percent so one. And you know the question whether measures "topped out" or should receive a lot of attention of there's not much of gap, will be coming up with other measure too. The option for making a metric put on reserve status is something we would be talking about with some on this measures going forward.

Poonam Bal: And that is correct. If you want to give the committee a little more clarification on reserve status, basically NQF does have a policy that you can endorse the measure with reserve status indicating that overall, you feel the measure is a good measure but it topped out, and you feel that there not much more room for improvement, but you do things it's a good measure for us to continue.

So that's the general theory of reserve statues and we'll provide more information during the in-person meeting on that. I just want to make sure everybody is aware of the policy.

So with that said, I do want to see if there's any other – any questions you want to direct to the developer real quick or if you feel that the general comments that you've made and that you just want more clarification during the in-person meeting.

Alan Kliger: Perhaps it's wisest to wait for the in-person meeting.

Poonam Bal: OK, perfect. So where there any other comments before we continue to the next measure? OK. So let's move forward to 2703 and I'll look to Connie and Franklin to determine who wants to start with that measure?

Franklin Maddux: Connie. It's up to you if you want to start that's fine or I can?

Constance Anderson: Sure. I have no problem. This was a measure on that is the minimums of overdose with a patient whose averaged delivered dose hemodialysis is between single-pool Kt/V of 1.2 and a single-pool Kt/V plus (inside). I do have some concerns about this in terms of the performance gap and this is one of the measures that we were talking about that maybe topped out.

If you look at the QIP measure and the national data, the 10th percentile was at 98 percent and so I'm concerned that there is really no gap in performance in this measure when you're looking at a 98 percentile measure.

And again going back to one of the comments Frank made on the earlier measure in terms of the reliability, it certainly can be influenced by the day of the week draw and variations on how you draw the single-pool Kt/V. It certainly is a reliable measure, it's a measure that has been monitored over the last several years and there's a lot of validity in terms of the value of the measure and that higher Kt/V is represented, the quality of life, decrease mortality, and decrease hospitalization rate.

Feasibility, it's easy to measure. It is (a crown) Web measure, it's also through Medicare claims, you're required to put the Kt/V on it. So the only concern I have with this measure it's been a measure that's been in placed along time, is that it's a top out measure and at 98 percent, so I see no performance gap.

Franklin Maddux: So I'm not going to repeat items that I chat about the prior measure, but many of them where comments that applies similarly with this. I think the some – this is clearly one of the measures that as we have our in-person meeting, I hope we will really talk about that reserves status because I think we all believe adequacy is an important feature of an outcomes.

And if I understood that and just where with this measure do we place it today, recognizing that they're maybe ways to breakdown component into pieces of the measure that I actually would have some validity if we were are to look at those in a different format.

So with that, I don't have an other comments.

Alan Kliger: Can I ask the two – this is Alan. Can I just ask the two of you, is this really a measure we've had before? Has there been an upper limit in the other measures of single-pool Kt/V of less than 5 because that's what the specification is here.

(Crosstalk)

Alan Kliger: So, I would submit to the – yes I would submit this is not the same measure, this is a different measure with specification that I don't see the sense for.

Franklin Maddux: So one of the prior workgroup meetings, there was a response regarding the less than or equal to 5 as the upper limit. And I think it was looking at a way to discard these various results were results that were coded in some other manner in with some some codes that were not actual values.

And it strikes me that it is distinguished for both but I think we don't want to – I mean I'm concerned about the president saying that you know there is this range that actually exists.

And so, I think it is different, Alan.

Alan Kliger: Yes, I mean it's the difference between a method of reducing errors and mistakes in data entry and having the specifications of a measure. This – this is the specification of the measure that suggest that patients with a single-pool Kt/V less up greater at five – at five or greater or getting inadequate or inappropriate dialysis. And that's a separate question that you can raise but that is what this raises since that's the definition here.

Peter Crooks: This is Peter and I would just like – I don't want a response from the developers at this point. But as – when we are in-person, I think the one question it also comes up in my mind is we have several different in catheter versions of Kt/V, some combined with (feeds) some combined with CD, and there's several measures including the next two. And I think I just would like to understand why – what the intention is is. Did they need all of these passes to define the best in class. Do they intend to use all of these measures in different settings, why the duplication and overlap.

Poonam Bal: OK. Were there any additional comments or questions before we continue? Not hearing any, we should move forward to 2407 and Beth and Connie are the discussants on this, and I'll let you decide who wants to go first.

Elizabeth Evans: I'll go ahead and go first. With measure 2407, it's titled Minimum Delivered Peritoneal Dialysis Dose, University of Michigan and CMS. This actually is a grouping of results. It's the percentage of all patient months who's delivered peritoneal dialysis dose as a weekly Kt over the urea between 1.7 adult or 1.8 pediatric, and less than or equal to 8.5 of the dialytic with residual.

They evaluated the PD adequacy every four months for adults with that Kt over the urea of 1.7 for adults and 1.8 for pediatric. It's of course been linked to improved outcomes.

Their numerator is the patient months, number of patients months and the denominator who's delivered PD dose with a weekly of 1.7 adult or 1.8 pediatric, and the single-pool Kt will be 8.5 dialytic with residual. Denominator is included. The particular month must have had ESRD for greater 90 days and be assigned to the facility for the entire month.

Exclusions are all people had patient's ESRD for less than 91 days and patients were not assigned to the facility for the entire month. No additional exclusions for this.

The evidence is pretty much based on the clinical practice guidelines of K/DOQI 2006 update at both for adults and pediatrics. It does apply. There is adequate evidence for lower limit out the weekly Kt/V 1.7 for adults, correlates with survival. There was no measure of PD adequacy which identified issues that can have an impact on mortality. It applies directly to quality outcomes. It did support the measure.

There are some controversy about the exact level in which the inflection which this outcome occurs.

For performance gap, they analyzed CrownWeb and medicare claims from January to December 2013, and the mean percentage of patients with PD adequacy that achieved the target at least once in four months and six months

in pediatrics with 78.1 percent with a standard deviation of 17.9 males non-Black, non-White, non-Hispanic aged 18-64 were in the same range of achieving that which demonstrated no disparity in the care but does demonstrate needing national performance measure.

So, approximately 18 percent of patients do not reach this target Kt/V. It's a – does the need for national metric. A modest percent of patients falling below the hemodialysis numbers and no disparity.

As far as the specification reliability, the data elements are clearly defined. The clinics with greater or equal to 11 patients are included and if the Kt/V is not measured, this measure – this data is still included in the denominator. The logic and the algorithm is clear. The main concern is that if they do not have a Kt/V collected every four months, it does skew the results. No data was presented on the amount of non-collected Kt/V and further analysis should be done on how this impacted the results. How many patients are excluded from this analysis due to the clinic size and it's statistically significant.

The validity of achieving a Kt/V of 1.7 is consistent with the evidence resulting in better health outcomes and it has adequate phase validity. The data elements were clearly defined. It seems like the measures can be consistently implemented. No concerns with the implementation of this and the measure is consistent with the evidence.

Reliability, test samples, adequate provides spread implementation from validity testing, the test interpretation, use the experiment correlation. And obviously, the lower standardized lower Kt/V is associated with the lower hospitalization or I should say a higher hospitalization although the magnitude of this is low. A very weak association between facility level percentage of people achieving Kt/V target in a lower standardized mortality was observed although not statistically significant. It is definitely known as indicator equality.

Phase validity is also demonstrated by the KPSC and the K/DOQI clinical practice guidelines. Specifications are consistent with the evidence for lower

limit of Kt/V urea with no evidence for the upper limit. Correlation between this measure and the SMR is excellent, weak evidence with PD adequacy in SMR and a low association with SHR. It does have evidence that more dialysis results in between patient outcome.

Validity testing, there was exclusion of patient clinics with less than one patient. Patients less than 91 days but they did say the first Kt/V is to be done within the first month of starting dialysis of PD. Also, concerns the patients did not have Kt/V but included in the denominator. Risk adjustment was not necessary for this measure since disparities were not found.

(Meaningful) differences used monthly level labs for achieving versus not achieving Kt/V targets, 1285 which is 82.5 percent of the facilities have achieved expected performance and 272, approximately 17 percent have performed worse than expected to in the overall national proportion.

And so, this does demonstrate a difference in this quality. There wasn't a multiple set of measures, missing data, no response. Once again, the 1557 facilities with at least 11 PD patients. Public reporting on this measure would be restricted to facilities with at least 11 patients, so this includes 46,000 plus PD patients with 402,000 patient months were included in the calculation.

So no disparities were found. No risk adjustment needing – needed. Meaningful differences as above stated.

So, the test samples adequate to generalized or wide spread implementation. These claims data was used to calculate the inter unit reliability to test the reliability of this measure.

The (IUR) is 0.914 which (tie and) suggest a 91 percent variation in the measures, and this suggested the measure's reliable, and it's obtained from DFR and CROWNWeb sites. It's influenced by two performance rate and the testing rate.

So, data collection strategy, the biggest challenge is obtaining the (240) urine for patients, the PD nurses initiate a follow-up. Definite patient involvement

with this by patient education, routine scheduling, help the patients understand that.

Data elements already obtained through CROWNWeb, or claims data, No concerns with that. Feasibility is challenged in the – the denominator includes patients that do not meet the protesting standard. Is this is going to distort the actual performance in trying to avoid the potential gaining of the measure.

Unintended consequences, it's a combination of individual adult and pediatric Kt/V measures. The exiting NQF endures the adult PD Kt/V measure on number (0218), it's currently publicly reported. And the pediatric (tape) would be measure is under NQF review and has been finalized for 2018 of the ESRD quip.

CMS will decide if and when these measures publicly reported. Unsure if there's a benefit to group these two measures together or have this individual measures. No potential unintended consequences are known, high usability. So that's kind of the end.

Connie, do you have anything to ask?

Connie Anderson: No, I think you've said it well. I think the only concern that I have about this is the ability to get the residual renal function testing and the variability that that might cause within the measure.

Elizabeth Evans: Me too.

Poonam Bal: Were there any other comments?

Franklin Maddux: I have a question for the other committee members and then I'm exposing my own ignorance in this area. But there are two things that strike me from a nomenclature standpoint on the measure information and the numerator statement.

I don't think of currently all dialysis and adequacy, I think of it as either weekly Kt review or total Kt review. I don't actually know whether it's single-pooled or not. But that is a measure I think of as a hemodialysis mechanism

of measuring clearance. And maybe it is, but when you have dialytic and residual, then the implication as a single-pooled measure is that you're not using residual renal function. So I'm just confused a little about how they use this and what I'm missing with regard to that.

And then the other is, Alan's prior comment, that this – title is Minimum Delivered PD dialysis Dose, and yet there's an upper limit provided which means that if you were above that limit for some reason, you would be deemed inadequate which is probably not were as intended.

Male: Yes, it's an interesting question, Frank, about single-pool. I don't know the answer to that. I do know that we – I'm sure you do as well, we regularly measure endogenous urea clearance and then combine – and translate that into a Kt/V.

Franklin Maddux: Right.

Male: So we do that, but calling it single-pool, we'd have to ask one of the kineticists, I really don't know …

Franklin Maddux: Yes, I mean I think of the kinetics as being when you're having a collaborated KT review, you're adding in residual renal function, you're basing it on interdialytic urea generation rate…

Male: Yes, that's right.

Franklin Maddux: … and other things. And it strikes me that, I just don't know whether this correct or not. I just – I don't know enough of the (Kt) kinetics with (perineal), I always thought of it as either total Kt review or weekly Kt review. And that (embedded in ishkall) what was generated from the peritoneal dialysis and what was generated from the patient's residual function.

Male: Right, Right.

Male: Peter, do you know or Michael?

Peter Crooks: I don't – I can't provide any other clarification. I think it would be all right to ask the developers and if not now for them to be prepared at the in-person

meeting. Depending on our time, Poonam, do we have time to ask the developers about that issue?

Poonam Bal: We still got – time. So let's open it up to the University of Michigan or CMS to see if they would like to respond now or hold off until the in-person meeting. But please brief comments only.

Rajiv Saran: Yes. This is Rajiv Saran. I'm listening in from the University of Michigan. This is typo – and error which should not be referring to PD adequacy in terms of single-pool or collaborated and so on. This is analogous to the standard Kt/V but we don't – we just should've written Kt/V).

Peter Crooks: Yes. Yes. Good. That makes more sense for me too. Thank you. Yes.

Franklin Maddux: Thanks, Rajiv. I thought there was something I was missing.

(Off-Mike)

Poonam Bal: OK. Were there any other questions before we move forward? OK. So we do have five minutes before the public member commenting. Let's start 2705 and then we'll pause around 2:50 to allow public member commenting. And I'll give it to Alan and Beth to determine who wants to start with 2705.

Elizabeth Evans: I'll let Alan. He does a very nice concise job.

Alan Kliger: Well in two minutes, I mean, fortunately, we've really discussed many of these issues before because this is looking at a measure of – percent of all patient months, so patients whose average delivered dose of dialysis, either hemo or peritoneal, met the specified threshold during the reporting period. So it really is kind of a threshold measure seeing how many people came up to that threshold.

And the problem with it is where are those thresholds and how are they defined. So similar to other discussions we've had before, we don't have data specifically for the kids, for pediatric calculation. We do for adults in face validity. We perhaps can say that we can make that translation.

The evidence in adults for a lower limit of Kt/V and its relation to outcomes is clear. But the upper limit still remains an issue for me because I don't see any evidence of defining an upper limit. There also is the same question which we won't repeat again about dialyzing three or four times a week if you're on hemodialysis.

So I guess I'd raise the same question Peter did. There are multiple measures that are sort of overlapping here. They have similar problems but they also have similar utility and I do wonder from the developers why they would propose sort of a threshold measure of all in addition to proposing individual measures as we've just talked about before.

So those are really my only comments.

Elizabeth Evans: I don't have anything to add either.

Poonam Bal: OK. Were there any comments from the committee? Well that, I have to say is a new record. So we finish before public member commenting. I hope the public members won't mind two minutes early, if we can open up for commenting.

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

And there are no questions or comments at this time.

Poonam Bal: Perfect. Thank you so much.

Male: So we'll have it out at the face to face meeting, right?

Poonam Bal: Exactly. So that does conclude our fourth and final workgroup call. As I said, the first measure that we did, that will the structure of the in-person and the fast version was that so we could get through the measure. The in-person meeting is next week and so everyone should have arranged travel and we're looking forward to seeing everybody in person.

I do want to just remind everyone that as discussants, you are introducing the measure but also giving a summary of what was discussed in this workgroup calls during in-person meeting. We'll provide another document during the in-person meeting to kind of guide you through the lead discussant role. I know that many of you didn't get…

(Off-Mike)

Poonam Bal: … So there will be a instructions provided to you that explains it further.

At this time, I just want to see if there is any other questions about next steps before we met in the in-person next week.

Male: Just to thank you for your organizational skills and the fine job you've done in putting this complex set of measures together so that we can review them. And we look forward to the challenge and you guiding us through the challenge next week.

Poonam Bal: No problem. The renal team has been very lucky with getting quick committee members. You have been very good at you know being compared and reviewing the measures and being ready to discuss them. And we really appreciate all the hard work the committee members have been putting in. It made our lives much easier.

With that said, I'll be sending out one more e-mail before the in-person meeting to provide you with the related and competing measures developers have provided the responses to (inaudible) measure.

What they've done to harmonize the measure, and if they haven't harmonized them, why they feel like there's no need to. And so that will be sent out to you along with a request to see if anyone would like to take part in a committee happy hour on the first day that we meet. And so that will be a poll and if you would like to, we can set up – the staff will set it up for you.

Other than that, if there's no additional questions or comments, I'll let everybody go, 10 minutes early.

Male: Nice job guys. Good work.

Male: Thank you very much.

Female: Very nice.

Female: Thank you so much.

Female: Thank you.

Male: OK.

Female: Bye-bye.

Male: Thanks. Bye-bye.

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

END