NATIONAL QUALITY FORUM

Moderator: Renal Project
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OPERATOR: This is Conference #: 26637093.

Poonam Bal: All right. Welcome to everyone to the Renal Post-Meeting Call. We have about 17 people logged in right now. If you're on the phone and have not logged in to the Webinar in our committee number, please do so now. You know, we would like people to get everyone's vote in on these two measures.

So, to start I'm going to have Alexandra do a roll call to see who's on the line.

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

Constance Anderson: I am here.

Alexandra Ogungbemi: Peter Crooks?

Peter Crooks: Present.

Alexandra Ogungbemi: Ishir Bhan?

Ishir Bhan: I'm here.

Alexandra Ogungbemi: Lorien Dalrymple?

Lorien Dalrymple: Present.

Alexandra Ogungbemi: Elizabeth Evans?

Elizabeth Evans: I'm here.

Alexandra Ogungbemi: Michael Fisher?

Michael Fisher: Here.

Alexandra Ogungbemi: Stuart Greenstein?

Stuart Greenstein: I'm here.

Alexandra Ogungbemi: Debra Hain?

Debra Hain: I'm here.

Alexandra Ogungbemi: Lori Hartwell?

Lori Hartwell: I'm here.

Alexandra Ogungbemi: Frederick Kaskel?

(Off-mike)

Alexandra Ogungbemi: Myra Kleinpeter? Alan Kliger?

Alan Kliger: Here.

Alexandra Ogungbemi: Mahesh Krishnan?

Mahesh Krishnan: Here.

Alexandra Ogungbemi: Lisa Latts?

Lisa Latts: I'm here.

Alexandra Ogungbemi: Karilynne Lenning?

Karilynne Lenning: I'm here.

Alexandra Ogungbemi: Franklin Maddux?

Franklin Maddux: Here.

Alexandra Ogungbemi: Andrew Narva?

Andrew Narva: Here.

Alexandra Ogungbemi: Jessie Pavlinac?

Jessie Pavlinac: Present.

Alexandra Ogungbemi: Michael Somers?

Michael Somers: I'm here.

Alexandra Ogungbemi: Jodie Stein?

Jodie Stein: Here.

Alexandra Ogungbemi: Bobbie Wager?

Bobbie Wager: I'm here.

Alexandra Ogungbemi: John Wagner?

John Wagner: Here.

Alexandra Ogungbemi: Joshua Zaritsky? Thank you.

Sarah Sampsel: Alexandra, this is Sarah. Just a reminder, Michael Fisher had let us know that he'll be late, but he does intend to be on the call.

Poonam Bal: Thank you for that, Sarah. Is there anyone that we called and didn't have a chance to say they were here and would like to announce themselves now?

OK. So, then I would want to check to see if we have our developers on the line. Is anyone from CDC on?

Priti Patel: Hi. This is Priti Patel.

Poonam Bal: Hi Priti. And then I know that clinicians from RTA can't join us too, but I did want to see in your (Inaudible)?

(Dale Singer): (Dale Singer) is on the line.

(Amy): And so is (Amy).

Poonam Bal: OK. OK, thank you so much. So, kind of detail (inaudible).

One, any thoughts on the agenda? We won't be discussing related and competing today. There were a lot of measures that originally were notified – identified as related or competing that no longer apply or there were certain completions made and we want to be able to go through those measures and make sure we give you the best related and competing for those.

The ones related to the measure that are going today, we weren't sure if we would be able to hit quorum. And right now we're at quorum, so that's great, and to be able to get that final decision. So, we decided it'd be best to hold off the related and competing discussion until the post-comment call.

So, we are slated to have that in July and we are going to be surveying you to see your availability to, one, extending the call that we already have scheduled at least an hour if we can and then also to see if you have availability for a secondary call.

As you may remember from the in-person meeting, there were a lot of changes we wanted from developers and a lot of measures that we wanted to consider again. So, we do want to give the committee ample time to do so. So that's something we'll be doing at post-meeting call and you'll be getting a survey to your availability very soon after this call.

So, that's the main kind of next step. I also want to let you know that Sarah will be doing the presentation of the call to get it going. We ask that the committee members raise their hands. So there is a feature on software where if you go look to your left hand side there should be an option that says "Raise Hand". And so, if you want to test it out now, you can. But basically, that

notifies us that you would like to speak and we see some people have raised their hand. Thank you so much.

And so, we'll be able to see who's raised their hand and we'll call on them on that fashion just to keep the conversation. Obviously, it's hard to tell if someone else is about to speak or not, so that way we call on you and have a good discussion.

So, at that point, I do not believe there's any other tidbits we want to share with you. Sarah will be going over a recap of the decisions made in the in-person meeting and some – and referring to some next steps for some of the measures. And so with that, I'll pass it on to Sarah.

(Coney): Poonam, this is (Coney), are you going to talk about how we go about voting?

Poonam Bal: Oh, I'm sorry about that. So, we'll go over that once we get to our first vote.

(Coney): OK, thank you.

Poonam Bal: Same to you. Right. Again …

Female: OK, great.

Poonam Bal: … please make sure that you've logged in with your special Webinar link that was sent out to you by Shawnn. I also posted it to the invite. So, please make sure that you're logged in with your correct voting log in.

Were there any questions at this time before I pass it on to Sarah?

Lori Hartwell: Yes, this is Lori Hartwell. So, to vote, is there like a link on the SurveyMonkey to the left there just to make sure I'm signed in to the right place?

Poonam Bal: So, the SurveyMonkey is actually a back-up plan in case we didn't get quorum. If you – Alexandra, could you go to one of the voting sites, actually?

So …

Lori Hartwell: I used the link that I got this morning that had my – from Shawnn. I just wanted to make sure I was in the right place.

Poonam Bal: Shawnn, could you just confirm that Lori is in the right link?

Shawnn Bittorie: Yes, you are Lori. We have you all taken care of. And just to sum up for everyone that's concerned about the voting and we'll expand on this when you get to the site. Right now, you should see a site that does not have voting boxes on it. When it is time to go to a live vote, they will advance to the next slide, you will see small boxes. Next to each option you'll be able to click in the box next to the answer of your choice and that will record your vote.

Lori Hartwell: Thank you.

Male: Thank you.

Female: Thanks.

Poonam Bal: Is there any other questions before we move forward? OK, perfect. So, Sarah, I'll give it to you to do the recap then.

Sarah Sampsel: Great. Thanks everybody for joining today and I hope everybody who is traveling, drive safely. Obviously, if you're on the call, you did.

As Poonam mentioned, you know, we have two primary goals or a couple of primary goals today.

One would be to just give you a recap of the outcomes of the meeting on – from last week and the next step for each of the groupings of the measures, which I will do. We'll then discuss the two measures that we did not get to at the in-person meeting, that's 1460: Bloodstream Infection in Hemodialysis Outpatients and then 1662 is ACE/ARB therapy measure.

And then the last thing we want to make sure that we get to – I say if you can back up the slides too who's ever playing the slides, the other thing that we will – we're hoping to get to today is the discussion about gaps in the renal measurement area since that's an additional area that we recapped in the report that goes out for public comment.

So, for the recap, you all recommended a total of 12 measures. These measures will all appear in the draft report, which is what the staff will be working on to prepare for public comment. And that report will indicate, basically, summarize the strengths that you all found with these measures as well as any other comments that you had. And your vote would stand here as suitable or recommended for endorsement on each of these 12 measures.

Next slide.

So, for these slides are these measures and there's a total of six that are not current withstanding and not recommended for endorsement. And basically with these it means that for one of the most – past criteria of gap evidence, validity and reliability the measures failed at that point.

What we do during these next few weeks as well as during public comment is work with each of the developers to see if there's any additional information based on the information that you all mentioned in your discussions that was either lacking or just not transparent to you and so that the developers do have an opportunity to bring information back to you. And we also want to gather information during public comment on these measures that could also help with your consideration during the post-comment calls.

We have received some e-mail communications regarding the committee decision on measure number 2700 which is the ultrafiltration rate greater than 13 and there had been a recommendation that that measure be reconsidered on this call. Unfortunately, this is really kind of an issue of the developer not being available for participation in the call today, as well as the need to give them a little bit more time as they have with their other measure so that they do have until late June or early July to provide more information.

So, with each of these measures they move forward in the report as not recommended for endorsement. However, in the background we're gathering additional information, as well as we'll look at the public comment information. And then when we have all that information together before you post-comment, you'll have an option to revote on each of these measures.

If we can move on.

The next set of measure is on slide number four. Three measures were recommended for endorsement for – with reserve status, two measures, consensus was not reached and then we have the two measures that we'll discuss here today.

Again, these will be the classifications that each will receive during the public comment period. And during the public comment period, especially with the consensus not reached the measures the developers will have an opportunity to provide additional information for those areas of concern that you all raised during the in-person meeting. We will also gather public comment and put that all together for you in a package for you to review post-public comment.

Now, what I will tell you with, you know, any of these measures, you have the option, if you want to revote or not, you know, to vote or not revote on any of the measures. So, if developers bring forth additional information it doesn't change their mind, we don't force you to revote but we'll ascertain that at the post-comment period.

But again, you know, as Poonam mentioned, your recommendations at this point are – the initial recommendations after the in-person meeting and we still have the public comment period and almost kind of a peer period where the developers have an opportunity to provide more information.

Any questions before we move on about that process with these measures?

Great. So, then what I'll do at this point is ask, you know, as we did in the in-person meeting to developers for these two outstanding measures starting with 1460 are on the call and they still have that opportunity to provide an introduction on their measure before we turn it over to the lead discusser.

So, I heard that Priti was on the phone. Priti, if you want to introduce yourself and then if you are providing the introduction on 1460: Bloodstream Infection in Hemodialysis Outpatients.

Priti Patel: Sure. I'm Priti Patel. I'm a medical officer in the Division of Healthcare Quality Promotion at the Centers for Disease Control.

1460: Bloodstream Infection in Hemodialysis Outpatients, the measures is the adjusted ranking metric in standard infection ratio that's based on bloodstream infection rate among hemodialysis outpatients.

The bloodstream infection or BSI rate numerator is number of new positive blood cultures collected as an outpatient or within one calendar day after a hospital admission in patients of a hemodialysis clinic. And the denominator is the number of hemodialysis outpatients treated in that clinic on the first two days of each month, you know, the first two working days of each month.

So, the rationale supporting this measure is that infections are known to cause substantial morbidity and mortality in this patient population. And improvements in practice can influence the bloodstream infection rate.

The data for 1460 are collected through NHSN, the National Healthcare Safety Network. There are currently more than 6,000 dialysis centers that are reporting data to NHSN dialysis event surveillance. The surveillance includes other non-NQF endorsed measures (inaudible) microbial starts among hemodialysis outpatients. So, while empiric antibiotic use is not part of the 1460 measure. It is captured in NHSN and can be (assessed).

CDC performs routine data quality checks and data quality improvement and outreach activities. These activities are informed by the results of data quality assessments and validation studies that have been performed to-date. We have a validation toolkit that's consistent on our website. We promote a piece among all NHSN users. Parts of that toolkit are being used by all ESRD network to assess surveillance practices and facilities with very high or very low BSI rates.

We have templated reports and the NHSN application that users can run to assess data quality and completeness and we encourage them to use these. We also encourage group users such as ESRD network to run these reports to identify outlier facilities and follow-up with them to ensure data (inaudible).

We see, it's also funding a state health department (inaudible) validation study of the data and that study is currently in progress.

Sarah Sampsel: Great, thank you. So, Lori and (Alan), you were the lead discussants on this measure. Are you ready to make, you know, to talk about the overall measure and start introducing evidence?

Lori Hartwell: Yes. This is Lori. Sorry, I was on mute. This is an outcome health care measure and the evidence is bloodstream infection in hemodialysis patients are linked to practices (and as well the) clinics and other locations where these patients are treated. Procedures related to the dialysis treatment contribute to bloodstream infection. You can see that through our access care injectable medication preparation handling an administration, handling – bloodline handling and disinfection of primary equipment – priming equipment and dialyze every use and reprocessing. Plus, improvements in these practices and procedures and elimination of lapses and aseptic technique can positively influence (them).

Interventions that include improvements in catheter care and other vascular access care practice have shown to reduce bloodstream infection in hemodialysis outpatient. The rationale is reduction of intraluminum and extraluminal pathways of catheter vascular access contamination with pathogenic organisms that can result bloodstream infection.

Specific improvements in quality that had been observed are envisioned include enhanced practices in the following areas. One, use of proper aseptic technique during catheter care, use of optimal skin antiseptic solutions that catheter exit site and for hub cleansing, skin antiseptic agents that have been recommended in evidence-based guidelines from the CDC and Health Care Infection Control Practice Advisory Committee, as well as the Kidney Disease Outcome Quality Initiative Vascular Practice Advisory Committee, as well as the – it's another kidney disease outcome quality initiative.

Implementation of other CDC KDOQI recommended evidence-based practices such as use of antimicrobial ointment at hemodialysis catheter exit site, increased hand hygiene, adherence and proper glove use particularly prior

to vascular access care and other invasive procedures, staff education and training on infection prevention.

And I'll turn it over (Alan).

Alan Kliger: Just a couple of quick things to note. First of all, it is an outcome measure, right? So, that – we would be following the algorithm for outcome measures.

The second is that it is an – a currently endorsed measure, originally endorsed in 2011. The evidence to support the measure is as compelling today as it was in 2011. When we get to the specifications or the specifics of the measure itself later, we do need to have some comments about the adjusted ranking metric and sort of what that really is in addition to the SIR. But we'll wait until we get to the validity section for that.

Sarah Sampsel: Great, thank you.

Alan Kliger: But …

Sarah Sampsel: Any other comments? And feel free to raise your hand. If there are any comments or questions about the evidence for this measure.

Hearing none, Poonam, do – how do we do? Do we vote individually here? Or how do – I guess I don't know that part.

Poonam Bal: So, Alexandra is moving back to the voting slide.

Sarah Sampsel: OK.

Poonam Bal: And as Shawnn said earlier, box – basically, boxes (next) options will show up and the committee will pick – click on it on their screen and which it'll show us the results. So, let's go to the first page.

OK. So, you'll see on your screen right now there's a little box next to yes and no. So, what – go ahead and click on the box that you agree with. Again, we're voting for evidence health outcome for 1460.

And we do have 20 people online that have the ability to vote. So, we're just waiting to get those couple of votes.

Male: Once we click the box, you see it? Or do we have to do anything else?

Poonam Bal: We …

Female: It'll populate real time.

Male: OK, thank you.

Female: Yes.

Jodie Stein: This is Jodie. I don't have a box.

Poonam Bal: OK, Shawnn, how about – do you mind working with Jodie on the side. And is Jodie one of the 20?

Shawnn Bittorie: She – I did have her in the count. Jodie, if you just try to refresh your session by pressing F5 on your keyboard?

Jodie Stein: What do I press?

Shawnn Bittorie: F5 on your keyboard.

Poonam Bal: So, while Jodie is trying to get access, we are a quorum so we'll go ahead and move forward with this vote. And so the results are 19 yes, zero no. So, we could move forward on evidence 1460. And we can move on to gap.

Alan Kliger: OK. So, this is (Alan). The performance gap analysis was done nine years ago which clearly showed a substantial variation rates of bloodstream infection and we've all had a chance to sort of look at those data. I really don't want to repeat everything that was here already. But the two important things are that I do think that there was and is still a performance gap. And that maybe that there would – is in a disproportionate impact of bloodstream infections in some subgroups. And so, I believe that the – there is a high evidence or high likelihood of a gap in care.

Sarah Sampsel: Any other committee members have questions or comments about gaps in care? And performance gap?

(Coney)? Your hand is up.

(Coney): Sorry. I forgot to take my phone off mute. The other thing I just like to add is as you look at the bloodstream infections that are noted on the (DFR), I would echo what (Alan) said. There is still seems to be a significant performance gap. And the real community has not done a good job of decreasing bloodstream infection like the hospitals have. And so, I think this is a – there is still a significant gap in performance.

Sarah Sampsel: Thank you. Frank?

Franklin Maddux: Oh, I just a question for Priti and that is – whether – because most of the gap data is somewhat older now, have you seen any changes that have occurred since 2011, when this measure as originally endorsed?

Priti Patel: We do have more recent data. We just haven't really had an obvious place to submit that to NQF, but we can and that would be helpful.

Right now, we're in the process of looking at the, you know, the first year of complete data from all facilities that we're reporting under the ESRD QIP rule. So, I think we'll have – we expect to have more information shortly, it's just that things have been sort of evolving between 20 – the end of 2012 when we had a rapid increase in the number of facilities that we're reporting to getting them up to speed, on using the system and reporting and now like the first full year of data from those facilities.

Franklin Maddux: Yes. And so, I wouldn't contend that I think there isn't still a gap. I just would love to see if we have the opportunity to see some more current data on where we stand once that's available.

Sarah Sampsel: Thank you. Any other questions or comments?

OK. Seeing no hands, we'll go to vote.

Poonam Bal: OK. Voting for performance gap for 1460 is now open. Your options are A high, B moderate, C low, D insufficient.

And I believe we were able to get everyone connected, is that correct Shawnn? OK. Oh, there we go.

Shawnn Bittorie: I believe so.

Female: Twenty-one.

Poonam Bal: Twenty-one. Shawnn, do we have 21 people being able to vote?

Shawnn Bittorie: Yes, we do.

Poonam Bal: OK, perfect. OK. So, the results for performance gap is seven high, 14 moderate, zero low, zero insufficient and we can move forward on 1460 to reliability.

Alan Kliger: OK. So, the first thing is about the specifications themselves. We're all familiar with standardized ratios. And so, we've talked about those in the past. And so, how you'd go about calculating them and how you describe that in this application looks relatively straightforward.

However, Priti, you can help us because many of us are not familiar with an adjusted ranking metric. And specifically, you talk about using a Bayesian posterior distribution. But you don't – using, you know, the (Monte Carlo) – Markov Chain sampling but you don't give specifications here of what posteriors you choose or how that model actually works. And so, I wonder if we could have some more understanding or information about this particular calculation.

Priti Patel: So, I don't know if my colleague (Duke) is on but I – what I will say is that in the short-term we're focusing on producing the SIR as the primary measure since that is what is in the QIP rule. So, we will continue to produce BSI rates, which is part of what's reported in NHSN in the application. And we'll be producing the SIR for CMS performance measurement purposes. The

adjusted ranking metric is something that we also plan to calculate but that's not something that we've done yet.

Alan Kliger: So, I guess my trouble with this is that as we rate reliability, I'm clear in my mind about the reliability of the SIR. But without understanding what priors you're choosing for a Bayesian analysis, it's hard for me to endorse the adjusted ranking metric as the calculation for this particular measure.

Priti Patel: (Duke), are you on?

(Duke): Hello.

Priti Patel: Hi, (Duke). Is that something that you can speak to?

(Duke): I think that we are planning to use the diffuse prior for the Monte Carlo Bayesian method.

Alan Kliger: Well, I mean the prior really means that you have some numeric understanding, right? I mean, as I understand it, I'm surely not. You're the expert, I'm not. But in the times that we've done Bayesian analysis, you have an opportunity to choose different priors, different likelihoods of the outcome and that's, you know, that's what helps look at the Bayesian analysis. So, I don't know what the specifications of the priors are that you're using in this method.

(Duke): So, we are planning to use a diffuse prior for it's got the correct terminology for it.

Alan Kliger: And so, how do you use a diffuse? I'm sorry I don't understand what a diffuse prior mean. How do you use that to calculate this in the chains?

(Duke): In the open, some of our …

Female: Is that something that we could collect some information on and provide it to the committee?

Alan Kliger: Yes. I guess I would – I wonder if – we're not going to have, you know, we don't have enough time to go through the details. But I just say from my

standpoint, it's hard to endorse this particular measure with the degree of specificity that we have right now. And I wonder if it's possible to move forward. As Priti suggest, talking about the standardized infection ratio which is clear, rather than the ARM.

Sarah Sampsel: I mean I – I guess my interpretation, Alan, is the same as yours is that, and I guess, Priti, what I'd want to know is, you know, kind of why put the ARM in here at this point if it's not functionable? And if it's really not in use right now, are you really seeking just for continued endorsement of the SIR?

Priti Patel: Well, I think we have – so, you know, the reason for the – this ranking metric is we have concerns about – between facilities that have the same rate. So, let's say we have a large number of facilities that have a zero rate, but they all have very different exposure volume. Providing some way to differentiate between those and say that there is a difference between a facility that has a zero numerator and had a thousand patient months of observation versus a facility that had a zero numerator and had, you know, 50 patient months of observation.

So, you know, I think we're hoping to have both endorsed, you know. But I realized that we don't have a lot of detailed information on the adjusted ranking metric right now.

Sarah Sampsel: Mahesh?

Mahesh Krishnan: I just had a question to Priti that this may help or not. I know you're trying to differentiate and it's a question I just had in general.

We've looked at other standardized adjustments that are used through classical standardized adjustment from the claims data. Is it part of the issue you're trying to fix because we're only utilizing – I mean it's a general question. Would it make sense to use a more broader standardization methodology than just access, would that help with the distribution?

Priti Patel: When you say a broader standardization method, I'm not sure what you mean.

Mahesh Krishnan: So, we reviewed, you know, standardized transfusion ratio, standardized mortality ratio, all of those different things that's really – the usual, you know, 27, 28 co-morbidities, all those different things. It's a broader set. If I understand this method, you're only adjusting for access in the standardization, is that right?

Priti Patel: That's correct.

Mahesh Krishnan: And you're not adjusting for any other comorbidities like vintage or phrase or anything like that, is that correct?

Priti Patel: Yes, that's correct.

Mahesh Krishnan: And I just wonder whether or not things were – I'm just thinking to myself, if you're trying to get – if you can't get separation because you're only addressing access, you know, the question I had is would we be using a more standard definition with claims for adjustment as we are with other standardized measures?

Priti Patel: So, I don't think that, you know, I don't think that, I guess, was the issue because I don't think that those other case-mix factors or other comorbidities have anything to do with exposure volume, which is really what we're talking about here.

So, you know, this is something that is a relatively uncommon event, you know. So, you're going to have a lot of facilities that have a zero rate. And the question is, should they be treated equally?

You know, from my standpoint we feel like the facility that has a larger patient volume that, you know, that value has more reliability to it than a facility that is very small and doesn't have the same amount of patient volume or exposure volume and opportunities to have bloodstream infection rates.

We're also very, you know, I think that our approach to adjusting is a very conservative one. We don't want to adjust for anything that – we don't want to adjust for something that is potentially a modifiable risk factor and we don't want to adjust to things that aren't really risk factor. So, you know, our

approach is one of, you know, adjusting for the least amount of variables necessary to explain differences in facility performance.

Sarah Sampsel: Frank?

Franklin Maddux: So, in response to Priti's comment, I would say just a couple of things. One is, it appears you do want to limit the number of adjusting factors and yet there are some adjusting factors probably that do play a role. And it might be the comorbidity like diabetes or it might be vintage as an example of too that I think might make sense but not the full broad set.

It strikes me that we are in a position to try to answer the question of, is the measure as proposed the measure that sort of makes the most sense for this? And I would suggest that if your distribution is so narrow that you have to use the adjusted ranking metric to create the dispersion based on size and volume of exposure. If you're willing to adjust to add to that I'm wondering why not be wiling to adjust for some of these other factors that are clearly related in some fashion.

And so, I'm just …

Priti Patel: So …

Franklin Maddux: … struggling a little bit with that answer right now.

Priti Patel: Yes. So, I'm not aware of a data to suggest that does a vintage associated with infection risk? You know, unrelated to vascular access type, if that, you know, again I think the – if there – if either obvious risk factors they're not obvious to me based on what's in the published literature.

Franklin Maddux: Yes. So, I would suggest that I think on a facility population basis, the vintage mix that the facility has is going to be fundamentally related to access type and the types of patients that are received in those facilities whether they have had, you know, whether it's a facility that has a proportion of people with reasonable preparation of end-stage renal disease versus no preparation for end-stage renal disease which many of the latter would come to, you know,

have a substantial higher number of risk factors, including risk factors for infection by being more malnourished and other such things.

So, it just strikes me that it's a more complex story than what's described right now.

(Off-mike)

Sarah Sampsel: Peter?

Peter Crooks: I just like to say I share the concerned voice by (Alan) that they're basically asking for NQF endorsement of a component of their measure that hasn't really been tested yet, hasn't been calculated and tested. We can't vouch for its reliability or validity. And that I'm very concerned about that.

Sarah Sampsel: OK. If no other comments then I think we're ready to …

Alan Kliger: No, no. I mean – we just talked about specifications. We didn't …

Sarah Sampsel: Yes, I'm sorry, (Alan).

Alan Kliger: … reliability.

Sarah Sampsel: (Alan), I'm just going to back and say, you know, that the specifications. Any additional comments on reliability?

Alan Kliger: Sorry. So, are you ready to hear about the rest of reliability?

Sarah Sampsel: Yes, please.

Alan Kliger: OK. All right, so the developers do very nicely outline several of the parts of reliability that are clear. Number one is – that the measure is electronically reported and available, that there is stratification by vascular access type. But as Frank pointed out, no other characteristics of the population. And that it excludes – the denominator excludes inpatients and home dialysis. So, it's only in center patients.

In terms of the reliability testing that's been done, there was a validation study done. And as I understand this, it was before the current data selection devices, NHSN, was used and it was a classic validation study done in 2002, I think. Priti, is that right? And in that study, the results did clearly show accuracy and completeness of the measure to be high.

Sarah Sampsel: Any other comments or questions on reliability and reliability testing?

Peter?

Peter Crooks: So, (Alan), when you're saying it was high, that was particularly the SIR that was tested, right? It was the ARM involved in that as well?

Alan Kliger: Yes, of course. That's exactly the right question. And it really was not either of those metrics but was the reliability, an accuracy of the reporting. So, they did a validation study to assure that that was the case. But as I understand it and, Priti, please help me if that's the case. I didn't see it expressed as an SIR or an ARM. Priti, is that correct?

Priti Patel: That's correct. So, both the validation study that Dr. (Claiger) was just talking about and then the subsequent one that was done in 2012 both looked at the validity of the data elements that were reported that are components of the rate and also the components of what would be an SIR. So, those are the data elements that they looked at to try to determine whether positive blood cultures, for example, that should have been reported were missed or were over reported.

Alan Kliger: So, I guess in summary for – if I might for this piece of it, I am troubled as Peter said. I think that the testing that was done was excellent. Unfortunately, it didn't specifically test for the measure that were being asked to endorse as calculated. And, again, personally I'm not concerned about the SIR. I think that understanding how that is calculated is clear.

But I – from my standpoint, I'm afraid that I have insufficient evidence on the reliability of the ARM because I don't understand what priors are being selected in the – in that analysis. And I'm afraid we'd need or I'd need more

understanding or information before I could say that I have insufficient evidence for that part of reliability.

Sarah Sampsel: Mahesh?

Mahesh Krishnan: Yes, I just wondered, if a developer has any information. I think it was mentioned that the networks did do some reliability testing on the NHSN system itself. Is there a data that could be shared with us, because – other than the chart review that provided?

Priti Patel: So, they are not doing reliability testing and they're not doing chart reviews. What they are doing, as what I would describe, is a data quality improvement activity. So, they have done – they have administered surveys – surveillance practices to the facilities with those high BSI rates and low BSI rates and in to the network.

And they also do monthly data quality checks. So they run four different reports and they identify outliers with respect to their BSI rates, with respect to numerator values, denominator value facilities that have inconsistently reported no events for a certain number of consecutive months. And they follow-up with those facilities to try to determine if the data were accurately reported or if a correction needs to be made. So, that's really more of an example, I think, of, you know, ongoing data quality improvement activity.

Mahesh Krishnan: So, Priti, are you saying that – with the NHSN system, is there any reliability testing for that, for this measure in dialysis, or just the chart review that was done in 2002?

Priti Patel: So, two validation studies were mentioned in the NQF documents 2002, 2012 done by Colorado that mandates – that have mandated reporting statewide and also mandates validation. We're also funding an additional state to do a validation study currently and that's ongoing.

You know, the other thing I will say in terms of data, so the ESRD networks that are administering this survey (inaudible) practices have collected what I would describe as a lot of qualitative data. So I think we've learned through that process what some of the challenges are to, you know, collecting data,

reporting it completely and accurately. And so those are things that help inform our ongoing data activity and training of users.

Alan Kliger: Priti, I guess I hadn't mentioned the 2012 because that, as I understood, it was validity testing not reliability testing.

Priti Patel: OK. I apologize if I'm using the terms incorrectly. I'm not 100 percent certain which one we're calling validity versus reliability.

Alan Kliger: I'm just using it in a way that, you know, you put it in to the application. You talked about the 2012 in your validity section.

Sarah Sampsel: OK. I don't see any additional hands. So, I think we're ready to vote on reliability.

Poonam Bal: OK.

Sarah Sampsel: Poonam?

Poonam Bal: So, we're going to go ahead and vote on reliability for 1460. Your options are A high, B moderate, C low, D insufficient.

(Inaudible) to change your mind if you want to. OK. So, the results are zero high, four moderate, three low, 14 insufficient and we do not move forward on this measure.

Sarah Sampsel: And so, as we did in the in-person meeting, you know, I think it would be helpful to summarize for, Priti, you know, kind of what additional information you all would like to see as we move, you know, through public comment. CDC does have an opportunity to bring information back to you.

Overall, what I heard in the very beginning was, you know, even though you passed on evidence in gap, you'd love to see more current data on how the measure has evolved over time especially with performance but then, you know, what we heard was more definition regarding reliability's best for the (AR) specifications for the ARM portion of the measure and then just more clarity on reliability and validity testing for both portions of the measure.

Although, overall it seems like there are very few concerns about the SIR portion.

(Alan), did you have anything you wanted to add to that?

Alan Kliger: No, that's an excellent summary.

Sarah Sampsel: Great. Peter, your hand is up.

Peter Crooks: Yes. So, I can understand, you know, because this is an outcome measure it's different than a lot of the measures that we look at and I'm struggling a little bit.

I can understand being able to show critical data element accuracy. And for this, that's critical because you're going to take these numbers and you're going to make sure the data elements you're collecting are correct. But then you go to a process of punching numbers that either the SIR or the ARM and then that's the measure.

And often in validity we try to link a measure to improve health outcomes because this is an outcome itself. Maybe validity doesn't mean the same for this, for an outcome measure than it does for a process or an intermediate outcome.

So, I guess I'm kind of asking the staff too to help us as a community understand for an outcome measure what should be the bar for validity testing. Reliability, I can pass this because I think they do show that they're collecting accurate data elements. The validity, I'm having some trouble with.

Alan Kliger: Peter, I'm sorry. We didn't talk about the validity testing yet, right? Because …

Peter Crooks: Well …

Alan Kliger: … we've been talking about reliability and it was my concern how to do with the definition and utility of one of the metrics.

Peter Crooks: Right. And my concept of reliability is that the data elements that whoever goes and gets the data element they're going to get the same data elements. And that would be a positive blood culture, not a positive blood culture. So, that's before you do any other computations in my mind.

But validity is, what you're saying now, we had this measure and it actually means that there's more infections in unit A than in unit B, you know. Because of the differences that it's valid, that it's actually showing a little difference. So to me, the concept of validity is where the computations come in.

Sarah Sampsel: And, Peter, you asked – there's really not a difference – I mean while critical data level element testing can suffice for reliability testing under NQF criteria, there's not a difference between – whether it's an outcome measure or a process measure, et cetera, you know, it's just across the board.

(Off-mike)

Peter Crooks: What's clear to me that for a process measure or an intermediate outcome the validity testing, one type anyway is empirical testing where you test your results against standardized mortality ratio or hospitalization ratio or some other health outcome. In this case, this is the outcome, so that type of logic doesn't work. So, that wouldn't apply for this type of a measure, right?

(Off-mike)

Sarah Sampsel: I mean, when we, you know, (inaudible) went through this, basically it's the data that was provided. And frankly, we felt the level of testing that was provided was, you know, applicable of course or acceptable. You know, we didn't discern between outcome and process measures.

(Off-mike)

Sarah Sampsel: So, Lorien, did you have something?

Lorien Dalrymple: I just had one questions since we didn't get to validity that I'm wondering if we can discuss if we are going to ask for the CDC to bring us back more

information during the public comment part. And at least in my notes, I took a statement out that validity is evolving, it needs to be reassessed now that a large number of centers are reporting for purpose of performance measurement. And as these facilities include their understanding of the NHSN reporting protocol and developed systems reliably capture all the reportable events. We expect more information regarding the validity and reliability of the data to become available in the next one to two years.

So, at least in my initial review, this raised questions for me regarding the validity, we didn't get to validity because we didn't pass on reliability. But I'm wondering if (Alan), Lori or other of the primary workgroup members had thoughts on the validity issues in particular if we need to get recommendations to the CDC for more information. That would be helpful.

Alan Kliger: Yes. So, you're right, we didn't get there, Lorien. I was going to say just almost exactly what you did. The staff wrote that paragraph, which I think is absolutely accurate. In their – In the measure validity testing, now that they do have NHSN available, you see that the data itself showed an evolving picture of validity but not yet sort of the gold standard that we're often have seen in other measures which show a high correlation of what's being reported and what actually happens. That's the kind of validity testing that's being done, so that it would be very helpful where we – when we review this again to have perhaps some updated or more information on what is reported through the NHSN compared to what actually is found in some objective measure.

Lorien Dalrymple: Great.

Sarah Sampsel: Any other comments for the developer?

OK. So, basically we'll take these comments and recommendations and, Priti, we – a staff will work with you to help identify how additional information will help in the reconsideration period and reach out to discuss the timelines, et cetera.

Priti Patel: OK. That sounds great, thank you.

Sarah Sampsel: Great. OK. So, the next measure up 1662 and Dale and (Amy), you were waiting for a clinician, correct?

(Paul Alexey): This is (Paul Alexey). I'm on the phone.

Sarah Sampsel: OK. Hi, (Paul).

(Paul Alexey): Hi.

Sarah Sampsel: So, Dale, (Amy), (Paul) whoever's going to speak and introduce the measure. It is 1662, the ACE/ARB therapy measure.

(Paul Alexey): So, thank you.

Female: … yes, take it away.

(Paul Alexey): This measure is described that the percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease not receiving renal replacement therapy. And proteinuria who will prescribe ACE inhibitor or Angiotensin Receptor Blocker Therapy within a 12-month period, this is obviously a process measure and it's a physician level measure.

The measure is aimed at increasing the number of patients with CKD and albuminuria who are appropriately prescribed ACE inhibitor or ARB therapy. As per the KDIGO clinical practice guideline for the evaluation and management of chronic kidney disease therapy within ARB or an ACE inhibitor, but not both, should be used in diabetic and non-diabetic adults with chronic kidney disease and with overt albuminuria defined as an album excretion greater than 300 milligrams for 24 hours or the equivalent which is how we have defined it in this measure.

(Off-mike)

Sarah Sampsel: Great, thank you. And then the lead discussants on this measure are, let's say, (Deborah) and Lorien.

Lorien Dalrymple: Yes. And this is Lorien. I'll present on behalf of (Deb) and I. And she'll interject if I miss anything.

So, this is measure 1662 and I'm just going to briefly describe it, again, to kind of remind everyone as we go to the levels of evidence. So, this is percentage of patients 18 or older with CKD who are not receiving renal replacement therapy but have proteinuria defined, basically, as macroalbuminuria who were prescribed in ACE or ARB within a 12-month period. The level of analysis is clinician or group practice. This is submitted as a process of care.

And in terms of linking the process of care to outcomes, the stewards for the following forth which – this is a process measure aimed at increasing the number of patients with CKD and albuminuria who are prescribed to ACE inhibitor or ARB. These are recommended as preferred agents as already pointed out for diabetic kidney disease and non-diabetic kidney disease with proteinuria even in the absence of hypertension.

I think for the point to – because we're a little short on time, I'm just going to select the guidelines that (Deb) and I felt were relevant to this. The challenge in selecting which evidence to present to the group is impart as many of you probably also feel, this is a fairly broad population, so depending on whether someone does or does not have hypertension, does or does not have diabetes, certain guidelines will or will not apply to them. So, we've done our best to try and summarize the guidelines that could potentially apply to this population.

And there was updated information submitted immediately prior to the meeting which we'll include. So, the guidelines we thought were relevant included the KDOQI 2012 update, the workgroup recommends that in ARB or ACE be used in non-diabetic adults with CKD-ND and urine albumin excretion greater than 300 milligrams for 24 hours or the equivalent and then treatment with a B.P. lowering drug is indicated. That was graded 1B.

In terms of KDIGO, the workgroup recommended that an ARB or ACE be used in adults with diabetes and CKD-ND with urine albumin excretion greater than 300, and that was a 1B.

A JNC8 recommendation was included. And we can go over that if you all would like. But there was also that KDIGO CKD guidelines that recommended an ARB or ACE be used in both diabetic and non-diabetic adults with CKD and urine albumin excretion greater than 300. And that was graded a 1B.

I think when our group – workgroup initially discussed this measure, the most discussion came up about what is the evidence or recommendations around those patients who do not have diabetes and do not have hypertension that have albuminuria in terms of ACE or ARB. So, I think this guideline most directly addresses that concern.

There were a number of other studies listed and cited but I think for the sake of brevity, we hopefully highlighted the major applicable guidelines and at least given you a sense of the grading of the evidence.

Poonam Bal: All right, thank you so much for that. This is Poonam. I'll be taking over for a little bit.

So, I wanted to open up the committee. I see a hand on (Alan). Go ahead.

Alan Kliger: Lorien, you just quoted the evidence for 300 milligrams or higher. The measure – it doesn't specify the degree of albuminuria, although some – you've mentioned the, you know …

(Paul Alexey): (Alan), it does in the definition.

Lorien Dalrymple: (Alan), and that's probably something I should have been more specific about. I read the part as described on the front page, but once we get to the numerator and denominator it does specify the degree of proteinuria. And we may want to discuss whether albumin and UPCs are equivalent and other things along those lines that this measure, and please anyone in the workgroup correct me if I'm wrong, really is focused on those with macroalbuminuria or that's the intended population.

Alan Kliger: So, I apologize that I didn't have a look at that before, (Paul), but you're talking that the only people with 300 milligrams or higher are the proteinuria.

(Paul Alexey): No, we define it as greater than 300 milligrams of albumin in the urine for 24 hours, or an albumin creatinine ratio of greater than 300 micrograms per milligram creatinine or a protein to creatinine ratio greater than 0.3.

Alan Kliger: Oh, great. Thank you. Sorry for the interruption.

Sarah Sampsel: Any other – sorry, this is Sarah, I'm back, any other comments or questions about evidence?

And I think we can go to the voting slide.

Poonam Bal: All right. Give us one second to pull that up for you.

OK. OK, so we are voting for evidence for 1662. The options are A high, B, moderate, C low, D insufficient evidence.

OK. So, the results for evidence for 1662 is one high, 20 moderate, zero low, zero insufficient and we'll move forward to gap.

Sarah Sampsel: Lorien?

Lorien Dalrymple: So, in terms of gap, the following information is included which is the measure was used in the CMS Physician Quality Reporting initiative, the claims option in 2008. And for the stewards 44.9 percent of patients reported on did not receive the optimal care, the 50th percentile with 62.5 percent. I don't think it was entirely clear to the workgroup if this quality reporting initiative was directly applicable to the exact same population specified in this measure or perhaps these were patients who had to have hypertension to get in to this measure. So, I don't know if other committee members have comments or this would be a good opportunity to maybe get further clarity from the developers with regard to the performance gap information.

Sarah Sampsel: (Paul), did you have any information you want to provide to the committee?

(Paul Alexey): I actually have to admit, I cannot recall whether the population that was used only included hypertensive patients. But if it did and the performance gap –

one would anticipate that in a broader population without hypertensive patients that the gap would even be greater.

And, you know, just – I suggest the nephrologist and the – on the committee from experiential data also, we see large gaps in treatment in both diabetic and non-diabetic patients.

Sarah Sampsel: Peter?

Peter Crooks: Yes. I'll just point out that the majority of patients that would be covered in the denominator would not be under the care of nephrologists. Therefore, I posit that the gap is probably high even though, you know, not specifically stated that way.

Lorien Dalrymple: And this Lorien. I think it's reasonable to assume there's a gap in care and this slide will be, I presume, at least moderate but I don't have specific statistics that relate to it.

Male: It was dated from the VA and Indian Health Service and I think I've seen some from Kaiser that shows that these diabetics with hypertension, the use of ACEs or ARBs approaches 80 percent.

Sarah Sampsel: OK. I don't see any other hand. So, we can go to vote.

Poonam Bal: So, the vote is now open for performance gap for 1662. You options are A high, B moderate, C low, D insufficient.

OK. The results are one high, 20 moderate, zero low, zero insufficient and we move forward to reliability.

Sarah Sampsel: OK. Lorien, (Deb).

Lorien Dalrymple: And I'm sorry, were we supposed to do disparities first or just move forward? We didn't get to address that, I apologize.

Sarah Sampsel: I mean if you have additional – certainly, it would be great to have a transcript if you have additional comments on disparities.

Lorien Dalrymple: Disparities information was not presented that related directly to ACE and ARB use and specified in this but more specifically to incidents of the ESRD and in blood pressure control. So, I don't think we necessarily would consider this disparity sensitive based on the information in front of us.

So, in terms of reliability, I'll first go over the specifications. So, the numerator is prescribed or taking an ACE or ARB within a 12-month period. The denominator is 18 or older with stage one through five CKD, not on renal replacement therapy which does include transplant with proteinuria defined as greater than 300 milligrams of albumin for 24 hours, and ACR of greater than 300 micrograms per milligram or a UPC greater than 0.3. Denominator exclusions include documentation of medical reason for not prescribing therapy such as pregnancy, angioedema, allergy or other or a documentation of not prescribing due to patient declining.

In terms of the data sources, the specifications include CPT codes and e-spec, so I think we should go through the CPT code first. There is a specific listing of the CPT codes to capture the numerator an exception. However, one of the questions that came up on our initial call with how is the denominator being captured especially if it's relying on EHR where the actual measure of the urinary albumin level can be difficult to capture in the number of the EHRs being used broadly in the U.S.

So, we did want further information on how the denominator is captured when using the CPT code, CPT II codes and perhaps there's a code for the denominator. That was part was unclear to us.

Sarah Sampsel: So, we'll ask the developers to comment on that.

Lorien Dalrymple: Yes, if the developers could clarify that piece of us.

Male: I actually though that there was a CPT II code for the albuminuria.

Lorien Dalrymple: And there may be in the – we did not see it in the measure or missed it, but we could find the numerator and the exception CPT II codes. So, if there is a CPT II code that captures this denominator that's helpful.

Male: I'm looking at the specifications file.

Poona Bal: We do see have another hand up. Andy, if you want to go ahead and make your point.

Andrew Narva: Sure. You know, because the data on treating people with lower levels of albuminuria is not strong. It's important to distinguish these patients who have 300 milligrams or more per day. And it's extremely hard to do that in EHRs and the accuracy of providers entering of codes related to proteinuria, I think, is pretty poor.

So, you know, I think is a measure – this is a kind of measure. Actually, we were thinking about trying to promote, in order to leverage EHR is to make albuminuria results searchable. But they unfortunately aren't. And as a result, it's very hard to create registries of CKD patients in many EHRs, even good ones like Epic because the – in the basic Epic package you can't do that. So, that's – I think it's significant obstacle in implementing this measure effectively. Unfortunately, true.

Male: I am trying to search the specs here for the CPT II code. Unfortunately, it's written in such small type that I'm having trouble finding it. Albuminuria. And there is – it does state – I think it does stated here that there is one.

Female: And we were just trying to get clarity if the CPT II codes for the denominator directly apply to the measures now specified. So, macroalbuminuria independent of blood pressure was …

Male: They said that there was a CPT code for albumin – CPT II code for, if I'm reading this correctly, for albumin greater than 300 milligrams for 24 hours.

Female: OK. Thank you.

Sarah Sampsel: So, then in terms of e-specification, we did notice some slight differences, or at least we believe differences between some of the e-specification requirements in the CPT code such as – the e-specification, the requirement of at least two visit with the MD/PA and P probably of relatively minor difference to reconcile.

But then the denominator specifications in the e-specs appear to include diagnoses and lab tests that weren't relevant to this measure. So, for those of you who have that opportunity to review the e-specs, you can weigh in on whether you agree with our interpretation. But if you go the attachment, it looks like a three, four, five – probably page six or so. Let me see. It's page two of when you actually start seeing all the PCPI e-specification.

Under topic indicator, these are two of the measure component, it's the – as you'll notice to the far right, there's a lot of code descriptors that do not appear applicable including albumin, phosphatidylcholine albumin, prealbumin, surfactants, bilirubin, I can't even pronounce that, sorry, bilirubin, and a number of other tests that to be honest really don't appear relevant to this measure. They appear to be lab test with the word albumin in them.

So, because of this, we thought it was worth discussing the e-specifications as these probably need to be reconciled in some ways.

And then the other question was, can all the denominator captured electronically such as patient decline? There's a CPT II code it appears, it's unclear to us if that can be captured electronically. And then as Andy already mentioned this issue of if you use e-specifications, can you actually get the value of the urinary albumin? So, I'll open it up to the broader committee for discussion.

Sarah Sampsel: OK. Peter, I think your hand was in first.

Peter Crooks: This was a case of where, I think, when this measure is first used it's, you know, it's not going to capture everybody first time around. There are specification issues. But I would point out that this is an important measure and it's something that health plans should be measuring and expecting from their providers and – that once it's in use then health plans will incentivize their doctors to code correctly if it's going to depend on a code versus a lab measurement and that these things should work out. And in my mind the important sort of overruled the difficulties and will hopefully help solve the problem with the difficulties as things move forward as it recognizes an important thing to measure.

Sarah Sampsel: OK. And Frank?

Franklin Maddux: I just had a question for (Paul), because when I was reading through reliability testing details there were a number of references to patients with ESRD. Is that just a typo or was there reliability testing done on different population?

(Paul Alexey): I think that's a typo. It should – because this was non-ESRD.

Franklin Maddux: Right, because in a couple of places there are P.D. patients, H.D. patients and others reference them, so I just couldn't quite get my arms around …

Lorien Dalrymple: And the committee had a similar – this is Lorien, I'm sorry we didn't get to reliability testing yet. But we agreed four sites were listed, all with ESRD patients, but subsequently there was a comment about CKD and ESRD sampling. So, we were hoping after we discuss specifications to also get clarification about the CKD sampling procedures and so much data on ESRD sampling was presented.

Female: Yes. There were 30 records for CKD and 30 records for ESRD patient sample to each of the four practice sites.

Lorien Dalrymple: But for the focus of this measure, only CKD patients were examined.

Female: That would be correct. Yes.

Franklin Maddux: The ESRD patients would have been excluded.

Female: Correct.

Sarah Sampsel: OK. Frank, any – your hand is still up. I didn't know if you had anything else.

Franklin Maddux: I'll put it back down. Sorry.

Sarah Sampsel: OK. Any other committee comments or questions on, I think, specifications?

OK. So, what I've heard so far in specifications is there may be some typos and it need to look a little bit closer as to what was submitted for the committee's consideration.

Lorien, did you want to move on to testing?

Lorien Dalrymple: So, the reliability testing, yes. It's already mentioned it sounds like the sample was from a CKD population. The reliability testing is – on page 27 and 28, at least at the earlier measures and inter-rater reliability was reported with a kappa of 93 percent. And this is for the ACE inhibitor or ARB therapy measure, which we are presuming is the same measure that's specified in this application that if that's not correct we thought the developers could correct us at this time.

Male: It is the same measure.

Sarah Sampsel: OK. If no other comments or questions to the developer, I think we can go to vote on reliability.

Poonam Bal: Give us one second. We're pulling it up. OK. So, the voting is now open for reliability for 1662. The options are A high, B moderate, C low, D insufficient, and we apologize for the extra T next to high but it is high.

OK. So, the final results are zero high, 16 moderate, four low, one insufficient and we can move forward to validity.

Sarah Sampsel: Lorien?

Lorien Dalrymple: So, validity information is presented on an expert panel with phase validity and the expert panel rated the measure had a mean rating of 4.7 with 10 rating it as a four and nine rating it as a five.

In terms of other issues under validity exclusions within the measures to begin at four sites with CKD patients and found an exception rate of 18 percent. However, when they reviewed it in more detail, they felt the exclusions were necessary and important for the measure.

And then in terms of meaningful differences, again data is presented from the CMS Physician Quality Reporting initiative claims option 2008 and in this 45 percent of patients did not receive optimal care and there were significant variation in performance in the PQRI program.

Sarah Sampsel: OK. Any other questions, concerns, strengths from the committee regarding validity testing?

Poonam Bal: OK. We're bringing up the voting slides right now.

OK. Voting is now open for 1662 for validity. The options are A high, B moderate, C low, D insufficient.

Shawnn, do we still have 21 people on for voting?

Shawnn Bittorie: It does look like it.

Poonam Bal: OK. There we go. All right. So, the results are zero high, 20 moderate, one low and zero insufficient and we all move past validity for 1662 to feasibility.

Lorien Dalrymple: So, in terms of feasibility, I think we've already addressed the major questions and I think the major issue raised in the workgroup was, can actual urine albumin values be captured when using Electronic Health Record?

And can the developers give us their feedback on that issue as Andy outlined it earlier?

Male: I can tell you that within the VA's HER, we can do it.

Lorien Dalrymple: OK.

Male: I can't speak specifically from personal experience with other EHRs but we can go into our national data warehouse and identify the data. The big problem is different specifications with any – even within the V.A. from site to site within the EHR but it can be done.

Sarah Sampsel: Peter?

Peter Crooks: We use Epic and Kaiser Permanente and we certainly do it and have no trouble pulling it out within Epic, at least Kaiser uses it.

Lorien Dalrymple: OK.

Andrew Narva: So this is – I have one other – this is Andy. You know, the one – for all of us who would like to be able to create registries of patients, having this measure, I realized this isn't really a criteria that we look at, but having this measure would potentially help advance the agenda of making albumin urea results searchable and make it easier to create registries of people with CKD and do population management.

Poonam Bal: Sarah, are you still on the line?

Sarah Sampsel: Oh, I am. I'm sorry. I think we can go to vote.

Poonam Bal: OK. So, the voting for feasibility for 1662 is now open. Your options are A high, B moderate, C low, D insufficient.

OK. The results are zero high, 17 moderate, three low, zero insufficient on feasibility for 1662 and we can move forward – actually (never mind). The results are zero high, 18 moderate, three low, 0 insufficient for feasibility for 1662 and we can move forward to usability and use.

Sarah Sampsel: So, Lorien, before you start – Peter, you've mentioned a little bit ago about health plan implementation of this measure. And I just want to make sure that there's clarity on this that this was – this is what's submitted, the physician level measure. I believe it's collected or could be collected via PQRS. I don't think this is a health plan model measure but I would like the developers to clarify.

Peter Crooks: It is intended as a physician level measure PQRS and we're using it in the RPA registry.

Sarah Sampsel: Great, thank you. So, Lorien?

Lorien Dalrymple: So, in terms of usability as already mentioned is currently being used in the RPA Kidney Quality Improvement Registry and also Q.I. for internal to

specific organizations. Planned uses include public reporting or professional certification or recognition program.

Female:: Other committee members want to comment on this …

Sarah Sampsel: OK, Peter? Peter, your hand is up.

Peter Crooks: I'm sorry. I forgot to unmute. I would just like to, you know, on the issue of usability and level of analysis, I'd suggest the developers that this is exactly the type of measure that a health plan could and should use. They can put their resources to work helping their providers –their provider networks do a good job. It could be linked to even, you know, accountability and payment and so on.

So, I think that – and for instance within Kaiser Permanente we have an expectation. It's not this exact measure but that patients with proteinuria are found and treated. So, I just would suggest that that would be an appropriate level to consider going forward.

Male: Peter, but are you considering it as evaluating providers or group of providers within the health plan or evaluating health plans from health plan to health plan?

Peter Crooks: Right, from health plan to health plan such a HEDIS type of measure. There is a HEDIS measure for testing for proteinuria and diabetics for instance, and that's a health plan level measure.

Poonam Bal: OK. So, I think we are on a vote for the overall recommendations. Now, we're on the vote for use and usability. Sorry.

Female: Yes. Yes.

Female: And can I ask one question before we go to that, Sarah, just for my own clarity?

Sarah Sampsel: Sure.

Female: In terms of its current use, is this all related to CPT II codes or have – has the measure through e-specifications been implemented? Can the developers give us an update on that?

Lorien Dalrymple: It is included in our registry which uses e-specifications.

Female: In this 2014, that first year for the registry?

Lorien Dalrymple: 2015.

Female: 2015?

Lorien Dalrymple: We don't have any data yet for 2015.

Female: OK, thank you.

Poonam Bal: OK. Now, we're ready for a vote, I think.

OK. So, the vote for usability and use for 1662 is now open. Your options are A high, B moderate, C low, D insufficient.

OK. The results for usability and use for 1662 is 10 high, eight moderate, two low, one insufficient. And if there's no other discussion, we can move forward to the overall feasibility.

Sarah Sampsel: OK. Any other committee comments, questions on this measure before voting an overall feasibility? OK.

(Off-mike)

Poonam Bal: All right, the vote for overall feasibility for endorsement is now open. The options are A yes, B no.

(Off-mike)

Poonam Bal: OK. The result of overall feasibility for endorsement is 20 yes, one no and this measure has been recommended for endorsement.

Sarah Sampsel: All right, thank you everybody. And so that changes your numbers from the recap from earlier. We have 13 recommended measures, seven not recommended, three recommended in reserved status, two where consensus was not reached and obviously, you have now reviewed the full portfolio of 25 measures brought before you.

What we wanted to do now for – we have about a half hour left is one of the areas that we include in our report that goes out for public comment and then eventually back to CMS and post it on the NQF website is about gaps and measurement. And, you know, I know in the in-person meeting there were a couple of times that those mentioned where there might be some opportunities to explore different measurement areas whether it's finessing things that we haven't been able to get to so far or, you know, these areas that are openly missing in the area of renal care.

And so this – I guess the way I would say it is in thinking about renal care overall and the delivery of renal care whether that home dialysis, hemodialysis, personal dialysis et cetera as well as, you know, I think with the Kaiser measure of optimal starts is one of the first times we've seen a measure that has anything to do with transplant. But where does that continue to be gaps and measurement that you would like to see developers place some focus? And that's open to the committee.

Andy.

Andrew Narva: Yes, no, I'm sure everyone would agree that we really don't have enough patient related outcomes. They're much harder to measure but clearly they're more of greater and greater importance.

Sarah Sampsel: Great. (Alan)?

Alan Kliger: Yes. I'd echo that and in addition, specifically, measures for patients whose goals of therapy are not curative. That is patient seeking comfort care or patient seeking palliative care. All of our measures are really designed so far for patients who are seeking curative care and we need measures, I believe, for patients choosing different outcomes of care.

Sarah Sampsel: And I know this may not be in the order that people put them up, but they're the order coming up on the screen. So, (Coney)?

(Coney): I also would like to see more in the areas of patient experiences care and maybe relating something to KDQOL or the CAHPS or depression screening or some area there. I think we still don't get a lot of the patient experience measures.

Sarah Sampsel: So, when you say that, you know, there is a (CAHPS) in some Center of Hemodialysis suite of measures that actually went to person and family centered care. There is a process measure use of the KDQOL that I believe is reported to CROWNWeb and frankly, you know, NQF continues to almost test (to run) to find out what they're doing with that measure but then maybe a change of stewardship for that measure. So, (Coney), are you talking beyond those measures?

(Coney): Those in particular but also maybe some of the depression screening measures in terms of looking at depression in the ESRD population. I think the CAHPS survey can get somewhat at the experience in care. But I think it's an area – we did great at measuring the numbers and disease processes but I'd be very interested in hearing more from our patients that are on the committee and where they might see gaps and being able to do anything with the experience in care.

Sarah Sampsel: OK. Jodie.

Jodie Stein: There is a requirement coming up for January 16 that depression will be required to be measured and assessed in addition to KDQOL. And I expect in the future years some other things will come up as well.

Sarah Sampsel: All right. (Beth)?

(Beth): I was on a conference call last night and an interesting thing was brought up to me was staffing ratios as a measure in dialysis clinic, so mainly based on a safety of practice.

Sarah Sampsel: OK. Frank?

Franklin Maddux: So, a couple of thoughts that echo a little bit of (Coney's) comments. I think we need to – I'd be interested in looking at measures that distinguish quality of life measures from experience with care measures and whether that patient engagement or other activities, there's a distinction in my mind with these two areas and yet we don't really distract how we look at those from a measure standpoint.

The second area is, and it came up at our in-person meeting just very, very briefly, but at some point we should think about patients as targets for measures, not just health system by all those facilities and providers. But a worth point to patients become part of the equation with these measures. And then finally, I would be interested in – I think the Kaiser measure on optimal start was a good one, but trying to distract measures for incident patients versus prevalent patients, I think that's an area of focus that needs more attention.

Sarah Sampsel: OK. (Rick).

(Rick): Yes. Can you hear me?

Sarah Sampsel: We can.

(Rick): OK, good. So, I may be opening up a can of worms here but, you know, in the pediatric and adolescent lifespan work, we worry about transition a lot with our colleagues and adult medicine. And this is a big emphasis today to try and develop initiatives that cross the lifespan for adequate preparation for transition, no matter what the chronic disease.

And I just think it's a fertile area for us to think about in collaboration regarding at least developing templates for appropriate transition. And I can just cite the example that worries me the most is the 18-year-old or an older adolescent to transition from pediatric care to adult care and because of a lot of issues may be fall through the cracks.

Sarah Sampsel: Great. (Lisa)?

Lisa Latts: Yes. I have a couple actually. And related to that transition measure, I like that a lot and specifically – and it's may be too small but we see a kind of pregnant patient who has end-stage renal disease and nobody were talking about birth control, so then they go on to loss their kidneys because nobody bothered to tell them the dangers of getting pregnant. So, something in that might be interesting.

As the co-chair of the cost and resource use committee, I would really like to see something around renal disease there. This is obviously an incredibly expensive area, very high acuity, a lot of resources being used and so the measure around cost and resource use either in ESRD or in renal care.

And then thirdly, I would like to see some more measures around transplant, population is getting larger. There are a lot of measures (to) considering in the transplant area.

Sarah Sampsel: Great, thank you. Lori?

Lori Hartwell: Yes. Well, I've been thinking about a measurement, many of you on the call have heard about it. But I'm thinking of patient experience of care a little bit different. I'm a big proponent of quality of life and depression but I know a lot of patients who they're depressed no matter what we do for them. So, I would like to narrow the focus a little bit and develop a patient experience of care measure after each treatment because I feel that if the dialysis providers provide a good treatment and people are able to lit the light that they want to live, it's up to them to improve their quality of life.

And I thought about this a lot but as a patient, the patient has to participate in improving their quality of life. And I think, you know, the biggest role the health care community can do is to give us the – so when we get off dialysis, will it still OK to go have lunch, or go to work or do the things necessary? And I think measures should be focused more on a pretreatment experience as opposed to, you know, just an overall experience.

Sarah Sampsel: Great, thank you. Mahesh?

Mahesh Krishnan: So, just to pick up on the home team that was talked about before (home) for (PD 1) for the CAPHS, there is no P.D. version of CAPHS or non in-center version of CAPHS. So, if a patient satisfaction, that'll be good. And two, and this is a topic that people talk about is peritonitis, which is an infection measure for peritoneal dialysis. All the measure that we've been working out recently is just oral medications, medication list coordination adherence to a medication list reviews, et cetera.

And then lastly for the KDQOL, I think the problem there may be that we as providers hold all the KDQOL data that's not actually currently being streamed anywhere. So, if you want to do a KDQOL measure we'd have to aggregate some of the provider data because (Ran) doesn't have that aggregated data.

Sarah Sampsel: Great, thank you. Bobbie?

Bobbie Wager: Yes, thank you. I want to echo Dr. Maddux and Dr. (Claiger) in regards to, I think, a lot of the measures like stated in the center meeting that we've left out the patient and for patient centered care the patient is, in my opinion, the number one person on the health care team. And I have to echo Jodie because I think depression should be more draft. It's not addressed in the CKD population and it's certainly not addressed in the ESRD population. Thank you.

Sarah Sampsel: Great. And (Jessie)?

Jessie Pavlinac: Yes, malnutrition in this population that doesn't include albumin and the marker and thereof. There's actually a group that's proposing the eMeasures in the hospitals that the Academy of Nutrition and Dietetics is trying to work with to try and get some around there and I was thinking about that for our ESRD population.

Sarah Sampsel: Right, OK. Stuart?

Stuart Greenstein: Well, I have – I so many access hat that I always wear. And I think that one area that we have no measures on is patients who have (inaudible) graph and they go for repeat procedures in the year's time and we don't have a sense of

the utility of it, the quality and the cost related to those multiple procedures in a year's time and even beyond to keep and the access working. There are options in terms of how to keep an access working and I think that we don't understand at all and if we could create measures for this that would be great.

And the other measure I think that I'd like to see some somehow brought through is in the transplant world, we took about one-year and three-year year graph survival rates and it should not beyond five years (for) the patients. It should beyond five years and for the patients. I don't think that patients really think of a kidney, you know, to last only one year or three years is being, you know, the right thing. But nobody really falls and beyond that or reflected on them well enough to know what the true survival rates are.

Sarah Sampsel: Agreed. John?

John Wagner: Yes, hi. I think this may do something that is touched upon elsewhere but I think a simple measure for patient engagement might be to look at the actual participation of patients in the plan of care. Obviously, this is a goal that patients do participate. But whether patients are able to do that and have done that, I don't think it's actually measured in metrics, and I think it's probably a very important thing to look at.

Sarah Sampsel: Great. Peter?

Peter Crooks: I'd like to put in – raise my voice or raise my hand for medication reconciliation. I was recently a reactor at a – I think it was a QIP planning meeting and I believe the ARM – there is at least one measure that has been in the works for medication reconciliation. And unfortunately, it didn't make it past the committee to be included in the QIP, but I believe that medication reconciliation can save lives as well as to focus on medication adherence. I'd like to see something in those areas.

Sarah Sampsel: Great. So, Frank, I think you put your hand backup.

Franklin Maddux: Yes. I had two that sort of made me think of – that I think are actually important.

One is the transition from transplant back to renal replacement therapy of the dialysis, and just one that's really risky for the population. And this year, we had probably 75 percent of the number of people that got a transplant – came back from transplant this year in our organization. And I think it's just a lost population in preparation.

The second is, on vascular access is, we're beginning to develop some measures that I think might be of interest from a process standpoint on what I call the time two milestones and they are the time two creation of a permanent access, maturation of a permanent access, cannulation of a permanent access and then removal of the catheter. And shortening the root causes of those timeframes that can be too long are process measures that if evolved could be fairly effective in helping some of the vascular access issues.

Sarah Sampsel: OK. (Deb)?

Debra Hain: Hi. I just had – I wanted to agree with the medication reconciliation, but to add a little bit more to that considering the risk of polypharmacy with older adults, to consider looking at the appropriateness in some of the medications that we're reviewing and not just reconciling those medications.

The other thing that I thought of is having that conversation about palliative care and the life.

Sarah Sampsel: OK, great. So (Rick), did you put your hands backup?

(Rick): No, I did not. No, it's an accident. I don't think I did. I'm sorry.

Sarah Sampsel: OK, sure. I want to focus now on the people who we haven't heard from, (Caroline)?

Karilynne Lenning: Hi. I just wanted to support the mentioning of the depression screening measure as well as the medication reconciliation. Excuse me. I've worked on the measures in those areas, not with the ESRD population but general population. So, I'd like to just give my support for those and also the mentioning of comfort care palliative care type measures as well.

Sarah Sampsel: Great. (Dom), did you have a – you might, anything differently or …

(Dom): No. I'm sorry. I didn't realize I'm still up.

Sarah Sampsel: OK. So, I think one thing we need to do is wrap up here because I think we need to go to public comment before the timelines. But, Jodie, did you have anything additional?

Jodie Stein: Yes. The one other gaps that I've been thinking of and I've been working on a little bit is, in addition to depression screening and dealing with it, and providing the social worker time to do that. We're talking about anxiety issues as well and I'm wondering if those are even more prevalent frankly. But that's another direction or a – a related direction to look at, particularly in the beginning of dialysis, just as another aspect of quality of life and quality of dialysis.

Sarah Sampsel: Great, thank you. And thanks to all of you. Always an overachieving bunch and I'd say, this is the longest list of gaps I've ever written down in one of these calls. So, but also just really important areas and I think, you know, those of you who'd work with me when I was in the previous position, a lot of these same issues came up. So certainly some trends in the (dearth) of some areas of renal measurement that we will put in the report and hopefully people will acknowledge and perhaps pick up some development activities.

So, Poonam, do we need to go to public comment now?

Poonam Bal: Yes, we do.

Sarah Sampsel: OK. So, operator, if we could open the lines for public comment.

Operator: At this time, if you have a comment, please press star then the number one on your telephone keypad.

And there are no public comments at this time.

Sarah Sampsel: OK. Poonam?

Poonam Bal: OK. So this next step, so we do have recommendation for each for the measures that that will be taking time over the next month, so write up the results. We will go out to comments in July – I'm sorry, June 12th, so we have about a month. And then we will have a 30-day comment period ending July 13th. The committee will be currently meeting on July 30th, 1:00 to 3:00.

As I mentioned earlier, we will be sending a SurveyMonkey to see your availability, to see if we extend that meeting and also create a different one – I'm sorry, additional meeting. So, you'll be receiving that soon.

Also, during the next couple of weeks, staff will be working with developers to kind of take your comments and help them alter their measures as necessary. And have that ready for you by the post-comment call.

So once we have the post-comment call, we will discuss the measures that didn't have consensus, any comments that may encourage you to change your decision can – we'll go over those as well. And then if there's any measure that you really feel that we need to discuss again, we can discuss during that time as well.

So after that point, we do feel that that the decisions are final from the committee and we would take those and find back up – we'll update a draft report and post it for NQF member vote. Those votes along with your theme or new decisions will be shared with CSAC September 8th. And then, we will go to the board, October 1st. And at that point, the board will ratify your recommendations as necessary. And it will open up appeal period, if there are no appeals received, the measures will be considered endorsed.

So, that is a long way of saying we still have a lot to work, a lot of work to do and we are not done with these measures, so if you had any second thoughts or, you know, really want to see that information that we request from developers rest assured we will look at those measures again.

At this, I will …

Peter Crooks: This is Peter, can I just interject here? This is relevant to your timeline. How can we be sending an out for a vote that closes by July 26th when we don't have our next phone call until July 30? So, if we reverse course on a metric and endorse one that we didn't endorse initially or a developer provided information that we endorsed, that will be after the member voting, according to this timeline.

Sarah Sampsel: So, sorry about that. This is actually a typo. I guess we're getting known for the typos in this project. So, that – it's supposed to be August 12th to 26th, not July. Apologies for that error.

Peter Crooks: OK, thanks. We forgive you.

Sarah Sampsel: Thank you.

Peter Crooks: You're very busy.

Sarah Sampsel: If there are – and if there are no other questions, we finished a few minutes early but really I wanted to, again, thank everyone for the participation not only on this call but at committee, at the in-person meeting last week. You certainly set the bar for a committee being prepared and ready to discuss and, you know, really being very diligent in your review each of these measures.

As Poonam mentioned, you know, staff now takes us and move it into a report. At the same time, we'll be working with developers to either make the small adjustment to specifications or collect additional information that will help you and your consideration. And then, we're also having some internal discussions at NQF about some of those issues that were raised in the meeting such as the patient, you know, how do you consider the gaps for a patient safety?

I think we have some fairly significant – where we may have some fairly significant issues when talking about related and competing measures coming up and how do we consider those and, you know, how do we look at harmonization, et cetera, and do we need to, or can we have two separate standing measures? As well as just, you know, some of the process issues of

changing submissions after the fact which, you know, made a lot of people uncomfortable.

So, with that, again, I just want to thank you all as well as – we really recognize the staff team who did a lot of work behind the scenes and giving that only the in-person meeting ready but then these calls as well, so thanks to everybody.

Male: Thank you.

Female: Thank you.

Male: Thank you.

Sarah Sampsel: And thanks to the staff, you guys are great.

Female: You're welcome. Thank you so much.

END