National Quality Forum

Moderator: Renal Project
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OPERATOR: This is Conference #: 58733019

Operator: Welcome everyone. The webcast is about to begin.

Please note, today's call is being recorded, please stand by.

Welcome to the Renal Post Comment meeting. Please note that today's call is being recorded and all public lines will be muted during this broadcast.

Committee members, please note your lines will be open for the duration of today's call. Please be sure to use your mute button when not speaking or presenting. And please do not place the call on hold.

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I'd like to draw your attention to the links area located to the left of the slide window. The links area contains links to the presentation slides and resource information relative to today's program. Clicking on the links listed will open them in a separate web browser window and will not disrupt the presentation.

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

Poonam Bal: Perfect, thank you so much. This is Poonam Bal.

I want to welcome the committee members, the developers and the general public to our second post comment call.

As you'll see from our updated agenda, we will be reconsidering four measures.

One, which we did not get to in the last call.

Two, which we – the committee requested be delayed until this call.

And one was the committee did, we discuss last week but there has been updates since then. So we would like to give the committee another opportunity that we consider this an – if they would like.

Along with that, we'll also be going over some other developer updates, these measures were recommended and does not have significant comments. But updates are requested by the committee. And we did want to update the committee, to let them know if any updates were made. We'll have – once all the divisions on the member – measures are finalized, we'll go ahead and have a related in competing this question. And then we'll end the day with public and member comment.

So with that said, as a reminder, last week we discussed our two consensus in out reached measure. We had – we recommended 14 – we recommended that

1423 be recommended for endorsement. Then 2702, not be recommended for endorsement.

We decided not to move forward – change the decision on 2700 or 2703. And so that's the current status of the measures for market.

With that said, it will be – the meeting will be run similar to last week on Thursday. And I just wanted to see if there were any questions before we do the roll call.

OK, then I'll ask (Mary), go ahead and do a quick roll call to see if who is on the line.

(Mary): Thank you, Poonam. Good afternoon everyone.

I'll start with the co-chair, Constance Anderson?

Constance Anderson: I'm here.

(Mary): Peter Crooks?

Peter Crooks: I'm here as well.

(Mary): Ishir Bhan?

Ishir Bhan: I'm here.

(Mary): Lorien Dalrymple?

Lorien Dalrymple: Present.

(Mary): Elizabeth Evans?

Elizabeth Evans: I'm here.

(Mary): Michael Fischer? Stuart Greenstein?

Stuart Greenstein: I'm here.

(Mary): Debra Hain?

Debra Hain: I'm here.

(Mary): Lori Hartwell?

Lori Hartwell: I'm here.

(Mary): Frederick Kaskel?

Frederick Kaskel: I'm here.

(Mary): Myra Kleinpeter? Alan Kliger?

Alan Kliger: Here.

(Mary): Mahesh Krishnan?

Mahesh Krishnan: Here.

(Mary): Lisa Latts? Karilynne Lenning?

Karilynne Lenning: I'm here.

(Mary): Franklin Maddux?

Franklin Maddux: I'm here.

(Mary): Andrew Narva?

Andrew Narva: Hello.

(Mary): Jessie Pavlinac?

Jessie Pavlinac: Hi, I'm sorry I have on mute, present.

(Mary): Thank you. Michael Somers?

Michael Somers: I'm here.

(Mary): Dodie Stein?

Dodie Stein: I'm here.

(Mary): Bobbi Wager?

Bobbi Wager: Present.

(Mary): John Wagner?

John Wagner: Present.

(Mary): And Joshua Zaritsky? Anyone else who just joined us?

Myra Kleinpeter: Myra Kleinpeter.

(Mary): Thank you.

Poonam Bal: Anyone else? I think perfect, thank you so much.

And I just want to check for the developer's role (inaudible), if there anyone from CMS and University Michigan on?

Male: Ms. (Joan), (inaudible) on the line.

Female: And the University of Michigan is here.

Poonam Bal: Perfect, thank you. Is there anyone from RPA on?

(Jonega): Yes, this is (Jonega).

(Paul Phillips): And (Paul Phillips).

Poonam Bal: All right, perfect, thank you. And KCQA? And then has CDC joined us yet?

(Silka): Hello this is (Silka) from CDC. I think (Freddie) would join later.

Poonam Bal: OK, perfect. Thank you so much. OK, then I'll pass it over to Sarah to start our discussion, on the first measure which will be 2000 – I'm sorry, 2705.

Sarah Samspel: Great, thank you and thanks everybody for making it back today on Monday.

As Poonam indicated, the one measure we did not get to last week is measure 2705 which is delivered dose of dialysis above minimum which is CMS, University of Michigan measure. Three commoner supported the committee's recommendation to not endorse the measure.

However, CMS did request the committee's reconsideration of the measure based on the discussion that took place after the Steering committee.

Post Steering Committee and during public comments, CMS made a number of revisions to the measure submission to support the reconsideration. One had to do with changing the specifications to measure – pertaining to measuring the Kt/V in the hemodialysis pediatric population in response to the concerns that we're raised. And the appropriateness of single poll measurement for those patients who are dialyzing three or four times a week.

And they did provide some additional notes that are in – that were in your pocket.

As with the other measures that fall – that so in the series of measures, they did remove the upper threshold. And they also (edited) specifications to provide clear descriptions of the numerator, denominator, exclusions and calculation algorithm and made sure that everything was consistent and clarified these submissions after you spoke about them.

And then finally, the – and they revise or evidenced form to include abstracts for the evidence listed in 1882 which was something that was raised by one of the committee members that they have listed a number of references but not those – but did not summarize with the abstracts.

So with that, we'd open the floor up to additional questions the committee may have or comments the committee may have.

As a reminder, this measure at the in-person meeting was not recommended. It failed on evidence. So we stopped voting at importance last time.

Peter Crooks: So Sarah at this point, we're first going to raise hands or take a vote on whether to reconsider before we go into more detail.

Sarah Samspel: You know, I think what we should do and I think what we did last week, we've had some conversations and if there were additional questions that the committee needed to have answered before considering reconsideration?

Peter Crooks: All right, well, for one, as long as I have an open line. I appreciate all the changes that made in – after the committee suggestions and I want – would like to reevaluate this measure.

Sarah Samspel: And Alan I see your handout?

Alan Kliger: Right. Well, I was primary reviewer so let me just make a couple of comments if I can.

The two major objections that we had have been addressed that is there's no longer an upper limit. And that this is now restricted to only patients dialyzing three times a week and not any other frequency.

The developer requested that this be considered for research status since its underlying measure 0249 has shifted to reserve status because of the lack of performance gap. This is a measure if everybody remembers that sort of the granddaddy of measures because it combines pediatric and adult and it combines P.D. and hemodialysis.

And so, my own take is that it should be reconsidered for reserve status. I think they have addressed the appropriate – the underlying issues.

We still have to talk – I suggest after we vote on this one on why we have scores of adequacy measures that this developer has given us. But I would suggest that that's a discussion we can have after we voted on this one and then we'll consider this with all the others.

Sarah Samspel: I think that one concern we have that, Alan, is that this is a new measure so it cannot be considered reserve status. Reserve status is reserved for those measures – those existing measures that would be considered to opt out and

they are could be, you know, considered some harm if the measure was dropped whether it's patient safety or, you know, kind of lack of attention to following that measure and assume drop in quality if the measure was dropped for some reason.

Unfortunately, we cannot consider this one for reserve status.

Alan Kliger: Well, I mean, if that's the case then we'll have an issue because there's at least to my eye very small performance gap and this would fail on performance gap .

Sarah Samspel: OK. All right, so (Casie), I don't know if you or (Joe) had something to say?

(Casie): Yes, a little head after we (wait) for him.

(Joel): Yes, thank you. So, I think the issue here, of course, is that we're – we eventually submitted this as a new measure.

And we have the (many each) overview measures because we didn't want to lose the existing measures and the event of that, you know, and then the events that we could not obtain endorsement for the new set of combined measures.

I think the – I think the only other point I would make is that the comment that was made by NQF. And I want to confirm if this is true that had we submitted this as a modification of 0249? There would be no particular issue of it going forward as a reserve status measure. If that's the case, then what I would foresee happening if this fails on performance gaps and does not move forward because it can't be considered for reserve status is that we're going to be back here at some point in the near future and having the exact the same conversation but it will simply be a modified measure.

And so, I put forward because I think that there's some sense to considering that under this with the providers that we will be addressing the current and apparent glut of K-2 overview measures in the near future.

You know, we can certainly bring this back to NQF. I think the question is, are we wisely spending everyone's time and resources in doing so? And I will simply leave it at that.

Peter Crooks: Perhaps we would want to open it and then we'll move right to the voting on the performance gap. Would that be acceptable Sarah, Poonam?

Sarah Samspel: Well, what we would need to do because a measure failed on evidence is we need to – we actually do need to revote on evidence before we would move on. But, you know – so I guess – you know, Peter you made the motion to reconsider this measure. And – as we did last week. Then, what I would ask is that the committee members go ahead and raise their hands if they are amenable to, you know, reconsidering this measure. And then we will go through the full vote and discussion as we did with the other measures that we did last Thursday.

Alan, did you have a question or you – OK, you already started voting. I got you.

So, committee members if you please raise your hand if you are in agreement with reconsidering this measure. And raise your hand virtually please.

And Poonam you're counting, correct?

Poonam Bal: Yes, I am. If you have done already, please put your hand up. And I'm about to do the final count.

Lori Hartwell: You know – this is Lori Harwell. I don't see my name on there. Maybe I'm in. Let me resign in through the link. So I'm raising my hand.

Poonam Bal: Thank you, Lori. And before you sign out, I will just ask the CommPartners representative to assist you in doing so they will be able to do it quickly.

Female: Yes. Thank you so much Poonam. Actually, Lori, we do see your name on there. It's just a little further down on the list.

So if you hit the plus sign in the upper corner of the meeting info area, you'll see your name a little further down.

But you can hit raise hand in the upper left corner of the screen.

Lori Hartwell: Thank you.

Poonam Bal: OK, we have 15 vote to move forward with reconsideration of this measure. We got so more but either we needed 12, so we can start with evidence. You know, I'll be the one who's going to take the call from here.

Sarah Samspel: Yes. So, this is just – again, you know, I want to make sure that we're following some consistently and with some consistency in what we did last week.

And when we did have this reconsideration, there seem to be some committee members that wanted to make sure that any additional conversation that may not have come out during the in-person meeting. There was an opportunity to do that.

So Alan, as one of the original lead discussants, did you have anything else you want to add on evidence for this measure before we start voting on evidence?

Alan Kliger: Yes. Just briefly that I believe that the additional changes that would made satisfy the adequacy of evidence.

And so for evidence, I – my own assessment is that they do pass on evidence.

Sarah Samspel: OK. And if everybody could put their hands down or Poonam I think if you know how to clear them just so.

Poonam Bal: Yes.

Sarah Samspel: If anybody else had any questions or comments on evidence? Beth?

Elizabeth Evans: I have a question and it's not really about the evidence. Is it possible to do what (Joel) had suggested, looking at if this can be a modification of the other or do we need to go through everything and then vote and then look at it or is that not possible at this time?

Sarah Samspel: So, you know, I think here is an example of where – I would suggest we go through everything and vote. And well I understand, you know, maybe the simpler answer to this could have been what if CMS had just submitted a modification of 0249 that added the additional population. That's not what we have. So now, we have this open measure that was voted on from the first report.

I think after the fact, you know, NQF staff and CMS can sit down and kind of make some decisions on what we do as (Joel) called as the glut of measures that kind of fit into this. It balances adequacy category but, you know, Poonam and (Katie), unless you feel differently.

Poonam Bal: I think we'll need to have talks about what next steps are. But unfortunately, we won't be able to revert this measure or anything at this point. But we can definitely speak to CMS and have to look forward with this new conversion.

Elizabeth Evans: Thank you.

Sarah Samspel: Frank?

Franklin Maddux: Yes. I just had a question for Alan and maybe some others that, I don't the answer to myself. And it has to do when you begin to aggregate individual measures and performance, especially when we're aggregating, for example, hemodialysis single pulled K-2 review with the weekly K-2 review for P.D. and others. Are there any unintended to just call consequences that we need to be considering here as we look at the evidence or is all of this simply additive. I'm just – I'm not sure I can get my head completely around how this might play from a standpoint of unintended consequences.

Alan Kliger: It's Alan. It's a good question. It's one we've had to ask a statistician. I don't know the answer to that, Frank.

Poonam Bal: OK. Does the CMS have a quick – could probably want to answer that? Or does someone on the committee feel comfortable answering Franklin's question?

(Nash): It can't work, right, because of the time period is being different, to your point Frank.

Alan Kliger: Well – No, I mean there are ways statistically that you can aggregate data that have different characteristics if it's a yes, no – you know, it's a – if it's a binary answers …

(Nash): Sure.

Alan Kliger: … so that is possible. I just don't know as this is constructed if a statistician would say this (passes master) that. That's all, (Nash).

(Nash): Yes. I think Alan you're right, but this isn't that, right? This is – I just – this is where I understand to this. We're aggregating. As individual metrics they make sense to me, but when you combined them as a (polled) analysis across the population for what appears to be a recklessly issue around trying to get to the number 11, it just – it seems – I don't think that will work statistically.

And as it is pointed out in the document, there is no evidence literature that doing this makes any sense.

Alan Kliger: At least my interpretation was that the – was that we're not aggregating the clearances for the different methods, but we're aggregating the binary pass or fail for the different methods.

(Nash): If that's the case, can the developer comment if that's the case or not?

Poonam Bal: Yes, we can be going to the developer now. Anyone from CMS or in with Michigan would like to speak up?

(Claudia Miller): Yes. This (Claudia Miller) of the University of Michigan and yes, that's correct. We're just aggregating the binary outcome.

(Crosstalk)

Franklin Maddux: I'm sorry. This is Frank. I have a holler for (Claudia).

So (Claudia), when you – if you pass or you fail, do we have clear enough understanding of – what the drivers of that are. And what the – specifically, what the intended – that the intended consequence that you want for those failures is going to be able to be remediated and I guess that's the question. Have you all done any analysis looking in how this would actually play with various scenarios?

(Claudia Miller): Hi Dr. Maddux. This is (Claudia). I'm not sure I completely follow the question what you're trying to get at in terms of any potential unintended consequences. I mean again, it's just the aggregation of different proportion.

And we did, you know, reliability testing on the measure and that results of that were also quite consistent with the individual components on the measure.

And then I think (Joel) also wanted to respond.

Franklin Maddux: Yes. So let me just ask her quick and then (Joel) maybe able answer this. If, for example, you have – you've got a group of hemodialysis patients from which you have pass but on smaller group a weekly K-2 review patients where you haven't pass. And the driver the aggregate result is not passed because of the mixed of P.D. in Hemo patients that are in the cohort being assessed.

Its strikes me that there could be a lot of ways to try to change that mix that's independent from just the clinical care that you would be providing to each individual patient one by one.

It could you'll be either a positive or negative result for example if my P.D. programs, if I made sure that P.D. was an issue to try to pass thing in this frequently then I would want make sure that they'd never represented more than a certain amount in a population of patients being tested.

Those are the kinds of things where I just would wonder how this plays in the real world where you've got a mix of programs with patients being combined on weekly basis, patients being combined on a, you know, per treatment basis. It just – I'm not sure I can answer. I can't quiet sorted out in my own head.

(Joel): So I think that's (our) example.

First of all of course each patient is based upon the criteria for inclusion and exclusion in assessment will you find them each of the core underlying measures. So that hasn't changed. The bases of assessment for each patient have not change.

What is currently done with its measure is implemented all of these measures are implement I should say. Is that we in fact wait performance based upon the number of patients that fit within the individual measures. And the reason for that of course is that if you only have a handful of P.D. patients, then that represents only a relatively small proportion of the care that you are providing. So that is already done.

It is something that is handled through in the example of (equip) and also in the example of the desired ratings as they currently apply. It is done through the scoring mechanism.

And that is how we have done and that was in fact how we explored continuing to move that simply including, you know, a greater number of patients within the body.

And so the reason that we could not and actually that was that statutory as I will explain and so we settled upon the – this modified or combined measure as a way to address that.

I would say that the measure as it stand is accomplishing the same way that these measures as implemented always have so there would be no, I mean, and as a matter of fact (inaudible) be no unintended consequences as a result of that except of that more facilities would be held accountable for their peritoneal dialysis and pediatric patients which I think is appropriate.

When you're assessing Kt/V because the measure essentially says for these patients, what is the appropriate definition of adequate dialysis?

And as – it's defined in the underlying measures that is depended upon the patients age, and the patient's modality of treatment that are handful with other

excluding criteria but then we assign a threshold that they have to reach for exceed in order to helps count towards – toward the numerator.

And for no patient that this measure has that change of the consequence of our combined (inaudible), the only consequence is that instead of relying upon a scoring methodology that we, you know, that's going to apply in the past we are simply incorporating them into a single called quality measure that can be implemented in a more streamline fashion within the – within any given programs.

So I think the (immense) one of the consequences we would've expect would be a minimal demand. And, where there are consequences, there are consequences because we are more effectively measuring populations that have been underrepresented in any measures as they are currently – as they currently exist and are (recorded).

And I think for a – to our mind that is a comparable thing. And something to be encouraged as we – as our quality measures evolve.

Sarah Samspel: Thanks (Joel). Frank, is that answer your questions?

Franklin Maddux: Well, I think it addresses my questions. I still wonder what the benchmark performance would look like given this kind of measure and some other questions which I don't know whether that's been part of it. But I think I understand where they're coming from. Thank you.

Sarah Samspel: Great. Mahesh did you have a question?

Mahesh Krishnan: I think (Joel) answered it. But just so I'm clear so if there, (Joel) or (Casey), if there's one or (Claudia) if there's one in this measure, if there is one pediatric patient and 50 hemodialysis patients, they're proportionally weighted and given to that that may change over the multiple units, I'm just interested how we did the validation right against the nocturnal outcomes. First, I understand the methodology correctly and then secondly, the validation then represents the cross-section of time when you did this. But that validation may change based on how the mix changes at individual units. (That's the point) I think about it.

(Joel): So I think just quickly and I'll kick it over to (Casey). For some of our technical (best). The way it's weighted is that each patient applies to the denominator and to the numerator as appropriate. So, if I have 100 patients, then 99 of them are adult hemodialysis patient and one of them is a pediatric hemodialysis patient. The 99 percent of my performance score is going to be dependent upon my treatments of adult hemodialysis patients.

If that changes to a split of 95 and 5 or 90 and 10, then the scoring will be, you know, based upon the numerator and denominator as they are added to by individual patients. But these patient is adjudicated on that matter by the – they include the same enclosure and exclusion criteria that they have been in the past.

Mahesh Krishnan: OK.

(Joel): I'm sorry, I'm …

Mahesh Krishnan: And then…

(Joel): …that for the validation piece.

Mahesh Krishnan: Yes, and so that that makes sense to me then so maybe (Claudia) did you guys do a sensitivity analysis as to whether it makes changes overtime or is it constant, year over year?

(Claudia Miller): So we ...

Mahesh Krishnan: Is that how we change your validation results?

(Claudia Miller): So with did compare the results of the validation of the overall measure with the individual measures, however, we could not do it for the pediatric, P.D. measure for the individual measure because there are two few cases in order to calculate the – predictive impact of caterer beyond – on mortality. But for the adult H.D. measure as an example, the validity results using SMR and SHR where in the expected direction as they were for the overall combine measure. We didn't do other separate sensitivity analysis.

Mahesh Krishnan: Sorry, let me reinstate the question, so when you do this for let say KTRB, we assume the KTRB is relatively constant and that makes sense, but by doing what was just described and a unit may actually vary. So one day, one year it may have 90 adult patients and 10 pediatric patients the next year. It may be 99 percent hemodialysis patients, one P.D. or one pediatric patient. That would change, right, over time so because that was valid in one year doesn't necessarily mean it's the same another years unless the relative balance stays about the same the mix of the patients. Did you guys see the analysis that way?

(Claudia Miller): So we do not do it that way. But that's because in the estimation of mortality takes into account patient mix.

Mahesh Krishnan: No – Sorry, but – yes …

(Crosstalk)

Mahesh Krishnan: Anyway I'm making myself clear. The SMR as I understand it, that you valid against this four year. It uses multiple years, right. But the correlation that you are – so much to say, this year, you're using 2010 data to 2014 but you are validating that against the 2014 mix, facility mix today. But doesn't necessarily mean that in 2013, the facilities have the same mix, right, because that may change overtime because the dynamic function (low base) from the proportion?

(Claudia Miller): Yes, correct, correct.

Sarah Samspel: And I think, this is Sarah. I mean I'm going to bugged in a little bit here because as in the in-person meeting, we wanted – we want to kind of segregate the conversations from having the conversations that important and gap – so evidence and gap which is the overall important and then we'll move in to scientific acceptability and the vote will follow that.

So, Mahesh, if you have other questions can we come back to those? I just want to make sure that people are clear on the information.

Yes. OK.

Mahesh Krishnan: Yes, no, I'm good. I just want to understand.

Sarah Samspel: OK, super. So then, Alan, if you didn't have anything else to add on the importance or specifically on evidence which I think you just said you thought things have been clarified, I'll turn it back over to Poonam and let's go ahead and start voting on the importance to measuring report and specifically evidence.

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

So as we did last week please just select the option you would like for – as we're voting on evidence for 2705. High, moderate, low with insufficient at your option. We should have 20 people voting.

Female: And just a reminder for our committee members if the box would fail to appear, you can refresh your session by pressing F5 on your keyboard for a PC or Command arc for a Mac.

Poonam Bal: OK. So we have 1 high, 12 moderate, 7 low, 0 insufficient. And we can move forward to gap. And I'll open up the discussion at this point. Where there any comments on gap?

Alan Kliger: This is Alan. I mean, again, I think the developer themselves in the question just speak moved to reserve status, have agreed that there is not an adequate gap here.

Sarah Samspel: So, you know, and this is where – I just want to make sure that we're clear on something with gap and so we don't repeat something that happened last week.

So in the event that this committee, and Poonam feel free to use different language if you want. But if the committee feels that there is a need for this measure, remember this cannot be a reserve status measure because it's a new measure.

However, as a committee, if you feel that this is a measure that should have a different threshold or different interpretation because there it, you know, and

there is no gap, you would vote high or moderate and do not vote it down on gap.

We do have to go through the actual voting process and if you actually like this measure and think it could be an important measurement and you'd like to see CMS considered in the future then, you know, we need to pass it on gap because if we settled on gap it means that it says one or most has criteria. And I know that's a little bit culinary intuitive but if you think this measure would move forward although you agree there is no gap, you would still vote high or moderate.

Alan Kliger: Wow.

Sarah Samspel: I know.

Alan Kliger: I mean, you know, the logical of that – I apologize for butting in but what we've always done before is to vote according to the specifications we've always had and if we need to do something else then it's been redefined as the developers suggested that this be brought back as a modification of another measure rather than a denova measure.

But as a denova measure I would have trouble voting that there is no gap, yes, I have trouble saying that performance gap is high when the performance gap is minimal and – because you're redefining what this vote means, I just have trouble with that.

Poonam Bal: This is Poonam. I completely agree with you Alan. I think the wording is – this is not really what do you think that gap is high, so much high that you feel that for this measure is it appropriate.

So that's what we mean by taking out of consideration. Again, you can vote saying no, this is a really low gap, there is no opportunity for growth, having this measure is not going to add anything and then go with low or insufficient.

However, if you feel that for a certain type of measure, this gap is acceptable than you go with moderate. So that's kind of the logic behind it.

So it's not necessary that you think that the gap is quite large and that's high or moderate, do you think for the take a measure that you haven't in front of you. And the needs of this measure in the committee, do you think the gap is sufficient enough to move forward?

And you can – There is no – So it was not that you should put it one way or the other and as (Joel) mentioned earlier, its measure doesn't pass and they joined the annual interview, if they make updates to it, makes updates to the other measure, it could come back for not have a review and so on.

So there is no more of the, you know, push it through gap when there is no gap, who are losing this measure, there is different opportunities later on for the measures to be reviewed again.

That makes more sense Alan?

Alan Kliger: I think we should just vote.

Male: Yes, I'm so confused. Sorry, guys.

So you're saying we're – the performance gap is not – is there an actual performance gap but do you believe that his measure makes sense during the gap that exist?

Poonam Bal: Yes. Yes. So considering the measure, is the gap appropriate?

Male: And the alternative here would because they can't go to reserve status, it's basically as was described before the KTRB measures versus this one as we face that discussion.

Is that right?

Poonam Bal: Are you talking about how …

Alan Kliger: What I heard – I apologize. But what I heard (Joel) say was that the alternative is that this failed, as a new measure but that they come back and asked for revision of the previous measure.

Male: A revision of a previous KTRB measure which should get reverse status.

Poonam Bal: Yes.

Alan Kliger: Right.

Male: OK, I think.

Poonam Bal: Yes, so that would basically we told that earlier that this is one of the measures that we reviewed earlier. This is a measure that builds upon that measure and they – that measure isn't eligible for the reserve status and it's not for the decision of the committee made on that measure.

So if layered down the road, this measure does not go through and they decide to update that measure with this new information. They could do that during the annual review and then they could come up with ad hoc or they could wait until the next real project comes and updated and they would still come up then it will be reviewed at that time.

So there are options after this point. But we do want you to review this measure on its merit as it is now. Not at what it could be later and so I'll …

Male: You know I …

Poonam Bal: I think that's correct.

Male: I think we just vote.

Poonam Bal: OK.

Male: Franklin has his handout so.

Poonam Bal: Yes.

Franklin Maddux: Yes, Poonam, I've – I'm reading the definitions sitting right in front of us here for (1B) performance gap and my concern if we adjust that to what's been described is that there will be a record of this but basically has this definition

in front of us with that all the explanation that we've had and the vote that really means something different in order that actually says.

And so it just strikes me that I think they've done a good job explaining how they've gotten to this particular measure. But I'm very uncomfortable with personally with voting under a different set of rules than what's been described for this unless we change worth the definition as – of gap.

Poonam Bal: Definitely agree, again for committee...

Male: That as well is my point as well Frank.

Poonam Bal: We completely agree with you and that is how you should be voting as how you see it.

Again, the vote is, how do you perceive the gap based on the measure? It's not that you'd want to push this measure through so you vote higher moderate on the measure. I think that was misunderstood. It's more you feel that the gap that's been displayed is appropriate for this measure.

That is the definition but in (step close) with and there's no change in that. That's not just, oh we want to pass that measure so let's just – let go our gap and vote anyway we don't agree with.

If do you think the gap (inaudible) and so I think I won't see neither hands up. But I think we can go ahead and vote and I'll open up the voting process now so for gap for 2705, it's high, moderate, low, and insufficient are the options.

OK we're just looking for one more vote, currently at 19 and we had 20 voting member.

I'll give it one more second and then – oh, there we go.

OK, so we have zero high, three moderate, 17 low and zero insufficient. So we do not move forward on this measure on gap. With that said, I'll give it back to Sarah to start the discussion on 1660.

Sarah Samspel: Actually I think with 1660 Poonam, these are measures that we went through the discussion last week so I mean we should be pretty close to going to vote on those.

Poonam Bal: OK so then in that case with 1660 we'll start over with gap. I think there was some confusion last time when we voted so we'll go and start the gap again since last week we did briefly went (go) through this measure.

Give us one second to pull up that slide. All right and I'll give – just ask one time. If anyone would like to discuss gap before we move forward? OK, Peter, you have your hand up.

Peter Crooks: As opposed to the last measure, you know, kind of looking at the same issue, again, but I think this is a little different and – that you might decide that the performance gap is appropriate for the measure. There never was really a high gap in hypercalcemia. And so I would find it acceptable for my perspective to vote moderate on this performance gap because it is appropriate for this measure. That's one person (result).

Poonam Bal: Great. Thanks Peter. I don't see any other hands. Was there any other comments before we move forward? Oh OK, Alan, go ahead.

Alan Kliger: So, Peter, can you or somebody else remind us what the gap is. How many patients have hemoglobin less than nine?

Peter Crooks: I think it was …

Male: The pull ups – (Katie), and I speak to that?

Poonam Bal: Yes, go ahead.

Male: So we went back in and hold the data from USRDS.

In January of 2007, 1.8 percent of patients had a hemoglobin of less than nine. In December of 2012, the last months that there is data reported that had increased to 6 percent, so more than tripling of the number of patients with a hemoglobin of less than nine in that six-year period.

Poonam Bal: All right.

Male: That was a comment in that same period if you look at hemoglobin less than 10 that increased from 6.1 percent to 22.4 percent of prevalent patients.

Poonam Bal: All right. Thank you so much and then, I will see if it's – Alan, does that satisfy your question or did you have an additional question?

Alan Kliger: No, that's – thank you very much for that answer.

Poonam Bal: Perfect. Thank you so much and I again don't see any hands.

I just want to give everyone a second. OK so we have no hands up, so we'll vote on gap again.

Just as a reminder, this measure is not eligible for reserve status so if that falls on gap and we do not move forward. OK? So options are high, moderate, low, and insufficient, and, again we're looking for 20 votes.

OK. The results are zero high, 7 moderate, 13 low, zero insufficient and this measure does go down on gap.

And so we can move forward to our next discussion which is 1454. This measure is – we had previously decided to vote on reserve status, however, (after further) discussion, it seemed that the committee would like the option of moving forward to revote on gap and then move forward at that point.

So for this measure, basically, what's going to happen if we are going to revote on gap? If the measure goes down on gap, the committee did previously vote to consider for reserve status. And then so we'll continue to vote through the criterion till we get to the reserve status section or if the measure falls in scientific susceptibility.

If we – the community revote on gap and then it passes gap, we'll revote as a regular measure and if the – if it gets to all the criteria it will – the final decision will if – I'll recommend it for endorsement and not recommend it for reserve status.

Does the difference make sense to everyone? I see a hand by Alan.

Alan Kliger: Yes, so can I ask the primary reviewer or the developer again to tell us how many patients currently has calcium levels of greater 10.2.

Poonam Bal: I guess I'll open it up to the committee this (eve) anyone has a response for that and if they don't then we can go to the developer.

Male: Yes so Alan given of – I object to this last time and I was confused. I went through all the data set. It's a little confusing. There is DFC data that was presented last time that show the gap. There is QIP data that we have previously thought through. Where (Joan and I) are kindly tell us about the differences and to opt out and then there is one other definition as well and …

Alan Kliger: Percentage and dialysis and facilities, yes.

Male: Right and so as far as I can tell, looking through this based on the definition that's provided. There does seem to be a gap which is consistent with the DFC data that was provided before.

One little new nuances that business rules are slightly different as pointed out before between all these different measures.

So when we get to the – if we get that further on, we can talk through how to define patient in a facility. But I think there is a gap as was pointed out on the last from the DFC data that fits this definition with inline and modification.

Mahesh Krishnan: So I'm Mahesh, again so that's not looking at a percentive patients per unit which I think is a flowed and measure myself. But looking at the absolute numbers of patients with calcium is greater than 10.2, what was that number?

Male: I don't think that was provided, at least I don't see that number provided in, I'm just looking through my notes on all the different things. I don't see that number. I just see the facility distribution.

Mahesh Krishnan: Yes, I mean if that's all we have. I'd be anxious to hear the developers answer because if all we have is the facility distribution, I would have insufficient evidence to make a decision about the gap.

Poonam Bal: OK so we'll pass it to the developer right now, to see if they have a response. Would anyone from CMS or University of Michigan like to respond to that?

(Claudia Miller): Hi, yes, this is (Claudia Miller) University of Michigan so we did not do but announces that the patient level. Everything we provided is at the facility level. And we did this because this is the facility level measure.

Mahesh Krishnan: Yes, but you expressed it as a presentive patients with patients with high calcium in each unit without providing a denominator for those units for us. So it's just – it's, you know it's at a difficult statistic to interpret.

(Claudia Miller): Right so we expressed – yes it's the percentage of patient month based on the patient and the denominator.

Poonam Bal: Okay, thank you for that response. Alan do you have any further questions?

Alan Kliger: No, thanks.

Poonam Bal: Mahesh Krishnan I see your hands is up? Manesh are you're still there or did you put your hands up?

OK. Were there any additional comments before we voted on gap? OK, I do not see any hands up so we'll go ahead and vote on gap. The option for gap for 1454 is high, moderate, low, and insufficient. Yes we need 19 votes right now.

(Sean) could you just confirm if there's 19 vote that are able to vote, I'm only seeing 17 votes right now

Operator: Yes, I'm checking the account just bear with me one moment.

Poonam Bal: Thank you.

Operator: I've got 18.

Poonam Bal: OK and we've just got that vote. Perfect. Thank you so much.

So give me one second.

OK so the results are zero high, 7 moderate, 6 low, 5 insufficient and this measure does go down on gap but as I mentioned earlier, the committee already voted to consider the total reserve status.

Let's move on to our next vote and I'll open it up for reliability. Would anyone like to make any comments about for the reliability of this measure?

Yes I see that Mahesh, has his hand up, go ahead.

Mahesh Krishnan: Yes the only concern I had on reliability when I went through all the different specifications where the definition that's included here is patients that have been in the unit. It's the text-based definition which is patients that have been in the unit for at least 30 days or weeks or month I think as specified.

And I just wondered whether or that definition can be tightened up. I think in the adequacy – one of the adequacy measures that we looked at are hasn't improved before. The number seven was used in terms of defining that, numbers of treatments per month so that was the one specification that I saw that kind of jump out at me in terms of that could be tightened.

Poonam Bal: OK, were there any other questions or comments?

OK, we'll go ahead and vote on reliability for 1454, the result are zero high, zero mod – I'm sorry what do I say. That's the result. The options are high, moderate, low, and insufficient and we are still looking for 18 votes, thank you.
OK we're at 17. Could the last person please put their vote in? We do have enough for quorum. I just wanted to catch that last vote if necessary. I mean if possible. OK. We've not received the vote, but we can move forward. The results are zero high, 15 moderate, 2 low, zero insufficient, and we can move forward to discussing validity on this measure. Were there any comments on validity? OK I'm not seeing any hands, so we can go ahead and, I'm sorry, Peter, you have a comment?

Peter Crooks: Well I was going to just mention that they submitted empirical validity as well as (temp) validity which was rated valid, and they did correlate hypercalcemia

with mortality, and I think that was a significant result. So that was I think outlines the validity testing.

Poonam Bal: OK thank you for that, Peter. Were there any other comments? OK I'm not seeing any additional hands, so we'll go ahead and vote on validity. So the options are high, moderate, low, insufficient. We are looking for 18 votes. If you're having difficulty in turning in your votes, as (Shawn) said, please refresh your screen. Thank you. (Shawn), could you confirm that we still should have 18 people? I only have 15 votes. Oh there's 16.

Female: We do still have 18 showing as online.

Poonam Bal: OK we have 17 votes, so (without telling who hasn't left) we can keep moving forward. I'll give it one more second for anyone putting their last vote in. OK, so results are zero high, 17 moderate, zero low and zero insufficient. So we can move forward to feasibility. OK, I'm not seeing any hands, so we can go ahead and vote. So the options are high, moderate, low and insufficient for feasibility. OK the results are 12 high, 5 moderate, zero low, zero insufficient, and we'll move forward to use and usability. Were there any comments? OK I'm not seeing any comments, so we'll go ahead and vote.

The options are high and moderate, low and insufficient. OK so the results, we got the vote back. I'm glad to see whoever was missing is back. So six high, 12 moderate, zero low, zero insufficient, and we can move forward to the overall vote for reserve status.

Were there any last minute comments before we go to that vote? Give us one second; we are having some technical difficulties. All right, so there we go. You are voting yes or no to recommend stature for reserve status. OK I guess we have two additional people voting now. So the results are 19 yes, zero no, and this measure is recommended for reserve status, and we can move on to our discussion for 1460.

As you may remember from my email last week, 1460 we did disucss this measure, however the committee decided not to reconsider it. since then CDC has decided to remove the arm aspect of the measure and to move forward

with just the (inaudible) aspect. Were there any questions about this before we, I'm sorry, were there any comments about reconsideration of this measure? Would the committee like to reconsider this measure with this new change?

Female: I think there is one of those things that really should be mentioned here is that this is a prefviously endorsed measure, and their, part of CDC's impression is it was some of their changes to a previously endorsed measure that caused some concerns by the committee, so they wanted to revert back to the previously endorsed measure. And we just wanted to make sure everyone is clear on that. But (Alan) I see your hand up.

(Alan): Yes, I just wanted to clarify exactly that. So with the arm removed and using just the SIR, is this measure exactly what it was in its previous endorsed form? That's my question.

Poonam Bal: And we'll need CDC to answer that.

Female: Hi, this is (Prithy) I think that my understanding is that originally when we submitted the measure it was really the BSI rate. We added the standardized infection ratio subsequent to that, so that may have come a little bit later from my understanding. So the only difference from what was in the original form is the SIR which seems like most people you know were, appreciated the method behind it and didn't have concerns about the methodology here in (reprobation) for the SIR.

(Alan): OK and (Prithy) just to confirm again that the methodology for the standardized rate is the same as what used for the SMR and you know all the other SR's that we've done. Is that correct?

(Prithy): It is, yes. I think the only unique aspect is what we adjust for the SIR we adjust basis of vascular access, which I think is in line with the description of the original measure that describes the stratification by vascular access type, and so that's what we use to calculate the SIR which might be different from how an SMR is calculated.

(Alan): Thank you.

Male: It's two different adjustments, (Alan), right? Because the SMR and the SHR utilize a 27-28 day, then a bunch of other data, and I think as (Prithy) said, the SIR utilizes data exclusively from NHSN which doesn't contain a lot of those other data elements.

Female: Right. So the concept is the same and the calculation is analogous. The only difference would be what are the adjustment factors.

Male: Thank you, (Mahesh) and (Prithy).

Poonam Bal: OK well are there any additional comments? So with that said we will go ahead and ask for a hand vote if the committee members would like to reconsider this measure. So if you would like to reconsider this measure at this time, please put up your hand. OK we have a lot of hands up for reconsideration, so we can move forward. This measure did go down on validity, so we'll start with that vote. Give us one second to have it up. In the meantime I am going to clear the hands. Were there any comments that the committee would like to make on validity? (Maureen), go ahead.

(Maureen): This is (Maureen). I actually just had a question for the committee and its other members, I don't know, perhaps the developers. So what is being risk adjusted in the SIR that's coming from NHSN? Could we review that?

(Alan): This is (Alan). I was one of the principal reviewers, but I would ask (Prithy) perhaps to help us with that.

Poonam Bal: Sure. (Prithy) could you respond to that please?

(Prithy): Sure. So I think this is in the measure specifications under the you know the algorithm where the calculation for the measure. But the bottom line is that if we had a BSI rate that was stratified by multiple different access types, we would not be able to present one measure. So what the SIR does is allows us to risk adjust on the basis of vascular access type. To create one basically one measure that we can assess facility performance on the basis of. So the only risk adjustment factor that's used is vascular access type. So all of the rates, all of the information that's reported to NHSN, both the numerator and the

denominator are stratified by vascular access, and that's what we used for the risk adjustment. Does that answer the question?

(Maureen): Yes thank you.

Poonam Bal: All right, Thank you. I just want to say I misspoke earlier. I said validity, but I meant reliability. So were there any comments on reliability. (Maureen), is there a hand up again, or was that just a leftover from earlier?

(Maureen): I'm sorry, that's the leftover.

Poonam Bal: OK I can clear it, no problem. So were there any comments about reliability of this measure? OK, I'm not seeing any hands, so we can go ahead and vote. (Shawn) is telling me we should have 19 people voting, so one more person; I'll give you just a second to put your vote in. ok. So the final results are one high, 17 moderate, zero low, zero insufficient, and we do move forward to validity.

Were there any comments on validity? OK, I'm not seeing any hands up, so we can go ahead and move forward. The options are high, moderate, low and insufficient. We are looking for 19 votes. Thank you. OK, I'm missing a vote. One more second for that last person to vote. OK. So the final results are two high, 15 moderate, one low and zero insufficient, and we will move forward to feasibility.

Were there any comments about feasibility? OK, I don't see any hands. Oh, sorry, (Ramnish), you have a comment?

(Ramnish): Yes I just had a question around feasibility. Because all of this data is coming from NHSN, which is fine. (Prithy), just so I understand, NHSN assumes that data is collected not just from the dialysis systems but also at times from hospitals or emergency rooms, as definitions allow. And I just wondered. I never see any assessment of the feasibility of doing that incremental data collection underlies NHSN, but could you comment on that? How difficult or how comprehensive, or how do you know that it's feasible to do that consistently across the populations of clinics? Not just get your own lab results but also get from other sources as well?

(Prithy): So we know that's a challenge, particularly for freestanding facilities. In terms of understanding how comprehensively difficult or not difficult it is, we had different sources of information. I mean we've heard and seen information published in the literature from large dialysis organizations that say that they, for example, Fresenius published in a paper that they think that they have upwards of 85 or 90 percent of all of their positive blood cultures going to their centralized laboratories. So depending on the facility or the company, it may be less of a challenge. We also have information from small validities and studies that have not been published to suggest the gap could be quite large. What we are doing to try to address this in the future is we in the upcoming release of NHSN will have an additional variable that identify for each positive blood culture reported whether it was identified in the dialysis center or in a hospital, to help us understand what kind of variability we're seeing in facilities. And then we're also working with (EF 30) networks and other to try to improve the connection between hospitals and the dialysis facilities, you know, where their mutual patients going back and forth. So we think that that transition of care is important for more than just surveillance, and this particular measure. So if there's information that's not being transmitted from the hospital to dialysis centers, it's obviously problematic for a number of reasons. So we're trying to work to improve that communication between hospitals and dialsys centers, and I would say we're in the early stages, but there are facilities, and if any works better working together with health departments and hospitals to try to improve that situation.

(Ramnish): OK, because I think you'd probably agree that depending on the comprehensiveness of that data collection, it could change an individual facility's SIR, right? If one was only getting their own labs versus getting everyone else's, all the other labs. It could change the perception of the underlying SIR as being compared?

(Prithy): Absolutely.

(Ramnish): Yes. OK. Thank you.

Poonam Bal: Thank you. Were there any other questions or comments that any would like to make on feasibility? OK, I'm not seeing any hands up, so we can move forward. The options are high, moderate, low and insufficient. And (Shawn) assures me we have 19 people voting, so please make sure to put your vote in, and if you're having difficulty with the software, please try refreshing your screen. If that doesn't work, please chat the leader so we can know. OK, we're at 17. Whoever the two remaining are, please (enter) your vote. OK we have one more. I will give you one second for the last vote. OK. So the results are two high, nine moderate, seven low, zero insufficient, and we move forward to usability and use.

Were there any comments? OK, I don't see any comments, so we can go ahead and vote. The options are high, moderate, low and insufficient. OK, we're still at 17. I will give that remaining two people a moment to vote. OK there we go. We are missing one vote, but we can move forward with 18. The result is five high, 10 moderate, three low and zero insufficient, and we can move to the overall vote. Were there any last minute comments before we do our overall vote for (inaudible)?

OK. I see no hands. So we'll go ahead and vote. Your options are yes or no for overall suitability for (inaudible). (OK). And I think we got our (person) back. All right. So we have 18 yes and one no. So this measure is now recommended for enforcement. And that finishes all the measures that we needed to reconsider. At this point, I'll give it to (Katie) to go over any other updates we have.

(Katie): Hi, everyone. We wanted to use this time to briefly go over additional developer updates that were made. As you may recall during the in-person meeting, (there were) several requests given to the developers to make various changes or provide additional information in their (measure) information worksheets.

So beginning on page 9 in your memo that we provided, we placed all of the updates that were made in a chart, and they are separated by developer. All of the updates that were requested on the measures that were recommended for either reserve status or endorsement were made. The developers had an

opportunity to submit these changes during the comment period. The only thing – the one thing we did want to point out, there was one measure from (RPA 0323). There was a request about excluding residual kidney function. The updates were not made. That was the adult kidney disease hemodialysis adequacy measure.

We also wanted to see if there were any questions about the changes or the information that we provided to you, and open it up for discussion at this time. OK. Oh, Peter?

Female: You may be on mute, Peter.

Peter Crooks: (If I may speak) as a developer for a moment, I'd like to just give a little information back to the committee about (2594), the (optimal ESRD starts). We did make some changes based on the – yes.

(Katie): (Fourteen) – we've already discussed that measure at this point. It would be unfair to the other developers, if we allowed you to make those updates (specifically without) reconsidering the measure.

Peter Crooks: I thought that's what this section was for. I thought I clarified that with you earlier. I apologize.

(Katie): I'm sorry. I must have not been clear. This section is for the official measures that were recommended. No – the comments were not enough to (quasi-theme). But there were updates made – requested during the in-person meeting that we wanted to just bring to the attention of the committee members.

Peter Crooks: Well, that's – that's exactly what I was going to do. I – I – I may not be understanding you, but. . .

(Katie): OK. If you can make it very quick, Peter, then you can. . . .

Peter Crooks: Are you asking, then, for measures that were passed, but there were suggestions made to the developer that this was the point where we could say,

"Yes. We took this advice, and here's some changes we made. " Is that what you're saying, or not?

(Katie): Yes. That's what this section is for. We were hoping to just do it in a – just a written form, in the sake of time. But if you can quickly make your comments, we can allow that.

Peter Crooks: We were – there was a discussion about whether a (home analysis with a) catheter should be included as an optimal start. We did some work. We contacted (Robert Lockridge), who has a lot of experience with that. We reviewed the literature. In the end, we discovered that these patients have the same (sepsis) rate as other catheter patients, and we're not – we decided not to include that as an optimal – as an optimal start in the updated specs.

The – one or two – one other important point. Oh, in the – it was pointed out to us during that time that pediatric (got) excluded, and we've amended that so that it is now specified to be 18 years and older.

There's a few other small things, but I think I'll just leave it at that, unless there's any – any other questions.

(Katie): OK. Thank you, Peter. Would there be questions by the committee on the measures that were recommended, the changes are requested and the developers have updated the measures? Are there any comments from the committee – on these that they felt that what they asked for (wasn't) taken care of, or anything of that sort?

Male: (If I) could just make a technical question. Given that you're doing it now for the ones that we approved in the in-person meeting. And given that we just approved a number – small number of measures now. (Would) we have (a) same conversation around these as well? Or, is that it?

(Katie): We can, if you feel that the updates that were made were not what you approved. So if, at the in-person meeting, you recommended the measures on certain conditions, and you feel that those conditions were not met and would like to change your decision, we can do that at this point. However, if the

changes were made, and you feel that those met what you requested, there's no need to reconsider them.

Male: I'm sorry. So there were X – nine measures – let's it make (up a) number that were approved in the in-person meeting. There was two clarifications set. Those were the ones that are listed. We just went through (four, six) additional measures. Does that – (is there) some more process for the (four, six) measures we just approved between Friday and today? Or do those only apply to the ones that were done in the in-person meeting?

Female: Could you ask (this) question again? I'm sorry. I don't think I comprehended.

Male: So what we have listed here are the changes that were made to the measures that we approved or recommended during the in-person meeting in May. Correct?

Female: Yes. That's correct.

Male: And – and between Friday and today, we approved an additional number of measures. Right? Whatever that number is.

Female: Yes.

Is there a similar process for changes for those four to six for any changes that we recommended, or no?

Poonam Bal: Yes – I don't believe any additional recommendations were made on these measures that need to be confirmed. Correct me if I'm wrong. But all these changes are going to be documented in the (member) submission form. (On QPS), all the measures will be updated to reflect the changes that the committee – the developers have mentioned. These are only the measures that were recommended and (that) weren't a (significant) amount of comments on. However, if you go through the memo, the other measures do have updates listed for those as well.

Male: Oh, God. OK. I understand. Sorry. Makes sense.

Poonam Bal: No problem. Were there any additional questions?

OK. I'm not seeing any. So we'll go ahead and move on to (harmonization. Sarah), are you ready to do that discussion?

(Sarah): Sure. So in your memo, there were a number of tables that were put together that identified which of the measures had been identified as potentially related and competing by staff prior to the in-person meeting. As a reminder, only measures that are recommended for endorsement by the committee are considered for – during this related (and) competing conversation.

And then there are some key points that are in your committee guidebook that I just – so I just wanted to refresh folks' memories. But there is a rating scale for the evaluation of competing related – related measures. However, there are some questions that we ask you all to consider.

There are also some additional key points (in) that (NQF) prefers endorsement of measures that assess performance for the broadest possible application. For example, as many possible individuals, entities, (setting) levels of analysis for which the measure is appropriate, as indicated by the evidence.

The endorsement of multiple competing measures should be by exception, with adequate justification. And then harmonization of related measures should be done to the extent possible. Differences (in) specifications should be justified.

So what I did earlier today is went back to the memo, went back through the related and competing conversations – I'm sorry the tables of measure that were identified as related and competing – as well as looked at the appropriate measure developer responses. And just really wanted to update you on what we found and then have you make some determinations as we did during the in-person meeting.

So, basically what we want to do is triage the measures and determine if the measures address both the same target population and the same measure focus. Or, if they address either (of) the same target population or the same measure focus, which would tell us if they are related or competing. So if both are the same – target population and same measure focus – they would be

considered competing measures. And it would be up to the committee to either strongly encourage harmonization of the measures or choose to pick a best in class. Or, the measures could be related. And in that same case, you would – you have consideration of should those measures be harmonized.

So the first set of measures that came before us would be on hemodialysis dosing and that (severe 249), which is the liver dose of hemodialysis above minimum. And as that measure was recently discussed a little bit, that's a measure that you have so far recommended for endorsement. It's a facility-based measure. It includes adults only at this time.

Then there's (0323), which is the (RPA) equivalent of that measure, except for its add to the clinician level. So (0249) and (0323) are both looking at hemodialysis adequacy, and they're both looking at the adult population. So you would assume that's the same (measure) focus. However, they are reported at different levels – the (CMS) measure at the clinician level and the (RP) – I'm sorry (CMS) at facility and (RPA) at clinician.

And then we have the measure (1423), which is a (CMS) measure. That's also very similar, but it's looking at the pediatric population. And in the memo, you'll see that there were comments received by both (CMS) and (RPA) regarding harmonization of the measure and that historically the measures (had) been harmonized.

This year, when (CMS) had resubmitted the measures, there had been some differences, which made them no longer harmonized. But I think – and I could be wrong here – but I think with the changes for the measure plus the in-person meeting that these measures are now harmonized, and really their biggest difference is the fact that they – one is at the clinician level for (0323), one is at the facility level, which is (0249). And then (1423) is looking at the pediatric population.

So what I would do now is open up to the committee and see if anybody has any strong thoughts on if you would consider these measures when thinking through similar populations, similar measure focus, if these measures are all

competing and if there should be further discussion about harmonization. (Manesh).

(Manesh): Yes. I think (it's from) the in-person meeting given that data is being generated from the same subset of patients, my recommendation would be to try to harmonize them as was done before. I saw the (RPA's) comments which (related) to the upper bound, which has now been removed. But I would wonder whether or not denominator definitions and some of the ground rules that are in the existing (CMS) measure should be applied to the (RPA) measure as well so that we're dealing with the same data set – the larger data set for dialysis patients at a clinic and a subset of those – relative subset of those for an individual clinician's patients.

(Sarah): OK. (Alan)?

(Alan): (Well), just quickly. It really is important, when we can, to harmonize the measures. The burden of – of accounting for basically the same measure that have slightly different definitions is really hard and very confusing. And so when there are two measures like (0249) and (0323) that are virtually the same, we ought to assure that the numerators and denominators are the same. And if not, urge the developers to come to consensus to have them the same so that we can get them harmonized.

(Sarah): OK. So what I think we need to do then is ask (CMS) and (RPA) to comment regarding denominators. And I know for some of these measures, there have been some additional harmonization discussions prior to the in-person meeting. And I know the information that's actually in the memo was (all) received prior to the in-person meeting.

So due to, kind of, some of the changes in the measures from your first submission to your subsequent submission, you know, have you identified where your measures – you know, whether it's (RPA) or (CMS) – where they still differ and where there might be opportunity to work together. Because I think, you know, we are hearing from this committee that they are recommending harmonization.

So either (CMS) or (RPA)?

(Bessie): (Sarah), this is (Bessie Garrett) for the (RPA). We certainly support the concept of harmonization. I think that if we don't hear on this call, we should do this as (Alan) has suggested and make sure that the numerators and denominators are consistent, because it is the right thing to do.

(Sarah): OK.

(Bessie): I don't know if (CMS) is available on the call right now. But I would think that that would not be a hard task to just look at the measures and (that the upper bounds has) been removed and harmonized in the (major) denominator.

(Sarah): Yes. This is (inaudible). We think we should meet after this meeting and go through what those differences are and try to harmonize.

(Bessie): Great.

(Sarah): Poonam, was there anything additional you wanted to do process-wise, other – I mean, do you want to do a hand vote? Do you folks agree that these should be harmonized and that the responses from both developers is adequate?

Poonam Bal: Yes. We can go ahead and do a hand vote to make sure that the committee's all on the same page. So a hand vote would basically be saying that you feel that the measures need to be further harmonized, and you're basically satisfied with what the developers (have) for a plan moving forward. For both measures to (inaudible) this individually.

OK. We have 14 hands saying that they agree. (Then) we can move – we can go forward with that recommendation. (Sarah)?

(Sarah): Great. OK. Then the next set of measures, I think will probably be a fairly similar discussion. It's the (peritoneal) dialysis dosing measures. And that's (0318), which is a (CMS) measure that's (delivered) dose of (peritoneal) dialysis above minimum, (0321), which is the (RPA) measure, adult kidney disease (peritoneal) dialysis. Then there is (2706), which is a pediatric (peritoneal) dialysis adequacy measure and then (2704), minimal delivered (peritoneal) dialysis dose.

Where (0318) is facility level adult, (0321 RPA) clinician level measure adult, (2704) is (CMS) facility combined population of pediatrics and adults. And then (2706 CMS) measure facility level pediatrics only.

And all four of these measures are recommended for endorsement. And you'll see on the screen as well as in the memo the original comments from both (CMS) and (RPA) regarding harmonization. And again, it seemed that the differences in the measure had to do with the upper threshold as well as the time frame for the physician-level measure. It was not – (RPA) did not feel that it's appropriate to have the same time frame between physician and facilities.

So we'll open it up to the committee to discuss any issues they see with these measures. Or if they are very similar to the last set and, you know, if the developers would agree to harmonize.

Any comments or questions from the committee to the developers?

OK. So can we have, I guess it would be (Claudia) and (Dr. Garrett) comment on, you know, any additional efforts you would make on your end regarding harmonization?

(Dr. Garrett): So this is (Dr. Garrett) again. On the (peritoneal dialysis), I need – we need to be thoughtful about the issue of the time frame of the inclusion criteria. But if we can harmonize that, then I think that (you) should be fine in terms of a facility versus an individual practitioner. And again, I think it goes back to the same (need). The upper is out, so I think that (the ability) to harmonize should be achievable. And it certainly is a goal because – (this was) already pointed out – it's very cumbersome to have measures that have the same topic but substantially different numerators and denominators in (inclusion) criteria. So I think we'd certainly be happy to come to – to that with (CMS).

(Claudia): And this is (Claudia) (inaudible) (in Michigan) and yes, we will arrange a call to discuss harmonizing the – the numerator and denominator and also address the issue of just time frame. In the previous review of these measures, we also underwent harmonization talks with (RPA). And I – I believe that both

measures were – were very closely harmonized. So I think we – we're pretty much 95% there.

(Dr. Garrett): Yes. That's my recollection as well.

(Claudia): Great.

(Sarah): (Great. Peter), you had a comment?

Peter Crooks: Yes. It seems to me that if these measures are harmonized in all of the elements other than the time frame, that that's close harmonization and there may be very practical reasons for having a different time period. So in my mind, that doesn't constitute a major problem.

(Sarah): Yes, Poonam?

Poonam Bal: OK. So then, we'll just go do a quick hand vote. If you feel that these measures are related and should be harmonized but are content with the plan updated by the developers and – but do not feel these measures need to be combined, please put your hand up.

OK. We have 17 votes saying that they agree with that. So we can move forward there.

Poonam Bal: OK. OK. So the next two measures are pediatric hemoglobin measurement. They're (1424), which is (the) one for hemoglobin measurement for pediatric patients. It's a (CMS) measure, and it is a process measure. And again, it's at the facility level. And then (1667) is pediatric kidney disease. (ESRD) patients receiving dialysis, hemoglobin levels less than 10 grams. And it's an (RPA) clinician level measure.

So in this case, we do have some differences in measures in that the (CMS) measure is a process measure where the (RPA) measure is an intermediate outcome measure. And you know – I think – you know it would be a conversation here with the committee is if you feel that warrants the difference in the measure and identification of these measures may be related. But because they are different overall reporting levels as well as different

measure mechanics being processed (in the) intermediate outcome, is there a need for both measures? Or, again, would you like to see some harmonization, if it's possible. Although I'm not sure with (some) measure dynamics it's really possible at this time. So any comments or questions from the committee?

(Laurie Hartwell): This is (Laurie Hartwell). I would like to see them harmonized, because I think it's important as a measure. But (given) the fact that they're so different. If there's a way for them to be harmonized, I would like that.

Female: So I think the difference here, (Laurie), is the fact that – I mean, frankly, the numerators and denominators are sufficiently different, that I'm not sure, you know, that this is a case where, you know, if (CMS) would reintroduce a measure that was looking for hemoglobin below a certain threshold, et cetera, then they may need to be harmonized. But I think that the way that (CMS) actually retired their measure that was – that actually competed with the (RPA) measure, I think it's important to acknowledge that these measures are related. But I'm not sure that they're competing and there would be a strong need for harmonization, unless somebody feels that there is. Even that possibility.

(Maja): Yes, it's (Maja). I agree with you.

Female: (Andy)?

(Andy): Well, I'm not sure. I think these are two really different measures with different evidence bases and different intents. And so it seemed hard – it would seem to me that these are not appropriate for harmonization.

Poonam Bal: OK. Peter, I thought I saw your hand up. But it went down?

Peter Crooks: Well, I was just going to say – (Andrew) said what I was going to say, basically. I agree with him.

Female: OK. So let's – I mean, this time, you know, if everybody agrees with – how about if you agree with that statement that these are sufficiently different measures, if you put your hand up.

Poonam Bal: (OK). We have enough votes that the committee agrees that these measures do not need to be harmonized. But (Sarah), before I give it back to you for the last measure, I do want to open it up for public and member commenting, since we're at that time. So operator, if you could just open (this) up for public comment, please?

Operator: At this time, if you would like to make a public comment, please press star 1 on your telephone keypad. And there are no public comments.

Poonam Bal: Perfect. All right. Back to you, (Sarah).

(Sarah): OK. So the next set of measures was hemoglobin (level, but peco 1660) is not recommended for endorsement. We do not have the related (and) competing discussion. Angio – and so the (8th R) measures (1662) and (0066) – both of these are (RPA) measures, and one of them is (1662), which you all considered, whereas (0066) is specific to the coronary artery disease measure. And I believe these were picked up, because (RPA) had acknowledged in their member submission forms that these measures are related. But they don't believe the measures should be harmonized, since they address different patient population, and they're not competing measures.

So really, this is on the agenda as a conversation topic to see if any of the committee members feel differently and that if you wanted to consider these measures as either related or competing and needed to have additional conversation about harmonization or best in class.

Female: I just wanted to let the committee know that we actually made an error by saying (that an RP – 0066) is an (RPA) measure. It is not. It has a different developer. However, I think what (Sarah) said is still correct where the measures are different enough where they may not need harmonization. But I will let the committee decide if they agree with that. Were there any comments? (Maj)?

(Maj): No, I don't think they should be harmonized. I think they're (actually –) they're two different populations.

Female: OK. So let's just do a quick show of hands in support of that. OK. We have enough votes saying that they do not feel these matters need to be harmonized. So with that said, we do conclude the related and competing measure discussion. So we'll just talk about next steps.

So what will occur is that we'll take this information, the measures that you continue discussing or the ones (that) you (upheld) your decision. We'll make sure to include that in the draft report. We will be going out to vote (Sept.) 18, and that will be for two weeks – I'm sorry, Aug. 18 – next month. (And then we'll go) Sept. (2) (inaudible), and the recommendations made by this committee will be shared with (inaudible). And that will be in. So we will go then, and then we'll see what moves forward. (inaudible) thank the committee for all their hard work. You have been a wonderful committee, and we really appreciate all the hard work that you put in and how detailed you are. And we'll keep you updated on what's occurring and what's happening with the measures and if we need to meet again to discuss anything. Were there any questions before we let you go?

Male: No, just that (you) did a really good job. So thank you.

Female: Oh, thank you.

Peter Crooks: Yes, I also want to say (that you're) doing – also want to – this is Peter. I also want to thank (Sarah) and Poonam for excellent leadership (in) helping us get to a very difficult list of measures. And so thank you very much.

Thank you. We appreciate it. We have a great staff (team) here.

Male: (Inaudible).

Where'd the voice – (that's why) we have (Katie) (inaudible) here doing all the background work here. (All right), was there any other comments or any questions?

Peter Crooks: Poonam, this is Peter again. Let me just ask about our status as a committee. We're a standing committee now as opposed to a, you know, one-time

meeting. What do you see going forward in terms of our role in the next coming year or two?

Poonam Bal: (Well), this committee will still be active (for) this measure – for this renal (review) period up until December. After that point, (you) may call upon the team – the committee to do ad hoc reviews as necessary. We may call upon you to act as advisory members on some of the work – the additional work that we do. We're really a – standing committees while not a super new concept is a fairly new concept. And we're really working through what's the best use of our committee members while we're in (this) kind of down time.

So those (are some of) the concepts (that) have come up so far, really using you as an advisory body. Obviously, if ad hoc reviews or anything come up like that, you would be the ones we would bring back together. Unfortunately, I think that's what we have planned for now. But there is going to be a much thorough plan coming out very soon. And we will always keep you updated on what we would need from you as a committee.

Female: So and what I would add to that, Peter, is that, you know, as Poonam indicated that there is some planning going on on how to keep the committee members engaged when we're not in an active review cycle for new measures or for measures that are under reconsideration.

And so one of the things that we'll be doing is going back through the report (and) your conversations and say, you know, are there things that are standing out as kind of additional issues that the committee, you know, may have some additional insight on that we (can) put into a white paper (and) other report, et cetera. But we don't – we don't have a strong – or we don't have a finalized plan yet. But we would actually anticipate providing you more information in early 2016, based on the timing of this committee, specifically.

Male: Can I – I got an e-mail the other day about the (MAP) process. Does that have anything to do with the standing renal committee? Or is that separate.

Female: That is a separate body. So the (MAP) work is starting now. And, you know, we would encourage our committee members and (inaudible) – and (guest)

members – to keep track of what's going in the larger community. However, the renal committee would not have a direct role in the (MAP) work.

Male: Thank you.

Poonam Bal: Were there any other questions?

Peter Crooks: This is Peter again. In past meetings, we had a section in our agenda for thoughts from the committee on measures that might be needed in the future. And I don't have any (burning) suggestions right now. But that might be something that you might seek from the committee going forward. I haven't been through all this. (Are) there gaps (in quality) that might be addressed by measure (develop).

Female: We actually had that discussion at the in-person meeting, Peter, and we have a (long) list of those that were in – that are in the draft report. But yes, that would be something that, you know, we'll continue to monitor and maybe in your off-cycle process of any updates we've received through the measure incubator or the measure pipeline that we could provide updates on.

Peter Crooks: Excuse me for blanking out on that. I guess it was at the end of a – a busy day. So yes, I do remember that. OK. Thank you very much.

Female: And as (Sarah) mentioned it earlier, (but) I'll just put another little ad in their for the (measure) pipeline. If you have concepts or ideas that you really feel like there should be measures made, we do encourage – you know – members of the public to put in those ideas so we can work with the developers and try to get those (made). So that is another feature (inaudible) (we) encourage you (so). Were there any other questions? OK. Not hearing any, we can conclude this call. Thank you, again. And we'll – you'll hear from us soon on what's the next (steps).

Female: Thank you very much. You guys have done a great job. Have a good time.

Male: Thank you.

Operator: This concludes today's conference. You may now disconnect.

END