NATIONAL QUALITY FORUM

Moderator: Sheila Crawford
April 16, 2015
1:00 p.m. ET

Operator: This is Conference #: 25684602

Poonam Bal: Welcome to the first workgroup call for the Renal Standing Committee. We are reviewing seven measures today. Again, sorry for all of the confusion, but we did want to make sure that we have the right measures (putting) together. Also, as a reminder, please mute your computer and mute your phone if you're not speaking.

OK. So, we'll go into a little more breakdown of how to go through the call, but first, I wanted to ask Alexandra to just do a roll call of the committee members that are assigned to this workgroup.

Alexandra Ogungbemi: Frederick Kaskel. Myra Kleinpeter.

Myra Kleinpeter: Present.

Alexandra Ogungbemi: Michael Somers.

Michael Somers: I'm here.

Alexandra Ogungbemi: Dodie Stein.

Dodie Stein: I'm here.

Alexandra Ogungbemi: John Wagner.

John Wagner: Here.

Alexandra Ogungbemi: Bobbi Wager.

Bobbi Wager: Here.

Poonam Bal: Thank you. OK, and then is there anyone – any other committee member that's on the line that was not called?

Peter Crooks: Yes, this is Peter Crooks, listening in.

Poonam Bal: Hi, Peter. Anyone else?

Karilynne Lenning: This is Karilynne Lenning, I'm also listening in.

Poonam Bal: Perfect. Is there anyone else? OK …

Renee Garrick: Renee Garrick is listening in from the RPA.

Poonam Bal: OK. I was just going to ask the developers if we had anyone from CMS or the University of Michigan.

Female: University of Michigan is here.

Poonam Bal: OK. And then is there – I know that we heard one voice from RPA, but are there other representatives on as well?

Amy Beckrich: It's Amy Beckrich from RPA listening in, and we may have another expert, Dr. (Paul Lesley) joining us as well.

Poonam Bal: OK, perfect. And then I just wanted to see if anyone from our KCQA was in.

Female: Yes, KQCA is.

Poonam Bal: OK, perfect. Thank you so much. So, the basic setup of this meeting will be kind of a preview for the in-person meeting. We'll ask the two assigned discussants to start off the conversation. So, first, we'll ask you to basically do a quick overview based off of the information in the top kind of box area of the measure worksheet so just going over the basic information. Then we'll ask you to start on speaking to evidence starting with your own opinion and

also going over what committee members may have said in their pre-meeting evaluation.

Once you discussed evidence, we'll open it up to the other workgroup members, ask them to give their feedback, if they had any additional. And we do not vote on this call, we just generally speak to it and kind of build up an opinion if we feel like it should be high, low, or moderate in general. And then, once we've discussed that, we'll move onto the next category with the scientific acceptability and we'll just keep going like that. So we'll go step by step, and staff is online to help you with process and to help you with any questions you have about (material). So I guess, if we want to start with Bobbi and Myra, are you …

Michael Somers: Excuse me, this is Michael Somers. I just had a question. I could never – I was never – I can't access anybody else's responses on the committee. Is …

Poonam Bal: So, if you go through the survey application, you'll only be able to see your own responses.

Michael Somers: I see.

Poonam Bal: But if you look in the measure worksheet, we had input it – input all the responses from other committee members.

Michael Somers: All right.

Poonam Bal: So there's a section underneath each criteria that was the different evaluations. Alexandra, if you could just show an example real quick.

Michael Somers: Yes, I guess I didn't know that you're going to input it in that fashion to know to look back there at those.

(Off-mike)

Poonam Bal: And that's OK. This is a test run. And, you know, you – obviously, you can – you know, in the presentation, you can also look at this real quick and offer those feedback. If you don't feel comfortable just kind of reading off, we can

– we're going to open up to the committee and then they can provide their rationale as well.

Were there any other questions?

Peter Crooks: This is Peter Crooks. I – the web link – there's, I guess, two of them. And the first one was I think (inaudible). I'm not getting anything it just says this meeting is scheduled to start at 10:00 a.m. and doesn't open (inaudible) link goes to a National Quality Forum page which is blank. Is there another web link where people able to see or connect in?

(Off-mike)

Peter Crooks: Are others on the call able to see …

Female: Peter, which – what web browser are you using?

Peter Crooks: Uh oh, you know what …

(Crosstalk)

Female: … Internet Explorer, Google Chrome, because sometimes what you – the problem you're having is a problem with Google Chrome, and it should work on Internet Explorer.

Peter Crooks: I think I diagnosed the problem. I was trying to open the meeting for workgroup number three. Never mind. Please proceed. But another question, so you say the comments that are made by committee members or reviewers are not visible on the input section and a comment is, you know, also knows that once you submit it, you can't go back and reedit it, which is kind of problematic. (Bruce) might want to do that, but that – I guess that's just the way it works, is that right?

Poonam Bal: Actually, you should be able to edit it, if you go under to Show All Responses at the bottom of this main survey page. Once you go in there, you should be able to click one of your responses and edit it.

Peter Crooks: Oh, OK.

Poonam Bal: If you're not able to, let us know.

Peter Crooks: OK, that's good. And you said that we can see the responses that have been submitted so far. Where did you – where do you go to see that?

Poonam Bal: So, you would go to the actual measure and the measure worksheet that we've created for that measure. And Alexandra has it up right now. As part of it, there'll be a, I guess you could say, (PT) orange color, which will indicate that this is all the pre-meeting comments from the committee.

Peter Crooks: OK, very good. Thank you so much.

Poonam Bal: No problem. And then also another input is the public and member commenting, and Alexandra is going down to that. So, at the end of the more worksheet section, we have a purple section which we've listed all the comments from the public that we receive before the meeting.

Surprisingly, we had a lot of comments, usually we only get a couple but we have a very active community out there. And so, this is another factor that you should be taking to consideration when you review the measures and move forward. Obviously, they are the short turnaround time, so we understand that if you were unable to read them before the meeting, but it's something to have before we have the in-person meeting. Were there any other questions?

OK. So then I'll ask Myra and Bobbi to start by just giving a quick overview of just what this measure is, which is the title, the number, steward, and the description and so on. Basically, what you can see on the screen right now, and I will leave it up to you to decide who wants to go first, or if you guys want to switch off and to, you know, work together on that.

Frederick Kaskel: And this Rick Kaskel. I'm not at a computer (right now), so if you had me up for that, I'd like to pass on that for now.

Poonam Bal: OK. None at this time, but we will get to that when we get to one of your measures.

OK. Bobbi and Myra?

Bobbi Wager: I'm sorry, isn't it 1424, this is Bobbi, isn't Dodie Stein?

Poonam Bal: Am I looking at – one second.

Dodie Stein: Yes, I'm here, mine was switched. I'm not on 1424 anymore.

Poonam Bal: Yes. Yes, so it was changed, 1424 is Bobbi and Myra. But if you weren't aware of the new assignment, we can see if Myra feels more comfortable starting off.

Bobbi Wager: I'm sorry but I was not aware of the change. This is Bobbi.

Poonam Bal: No problem. We understand. There was a lot of changes going on. So, completely understand.

Myra, are you still on the line? Well, is there anyone on the committee that would feel comfortable just introducing the measure, if you – I believe most people have reviewed it at this point.

Michael Somers: This is Michael Somers. I'll start introducing it, hopefully.

Poonam Bal: Thank you so much.

Michael Somers: Someone else will join in. So this is a process measure that the steward is CMS. And the overall focus of this measure is monthly hemoglobin measurement for pediatric patients. The numerator for this process measure is the number of any patients less than 18 years of age on dialysis who has had a hemoglobin measured, and the denominator is outpatients less than 18 years of age and the exclusion or transient dialysis patients only.

Poonam Bal: OK, thank you so much. And we'll go into more detail about all of these different sections, but were there any comments from the committee overall on that introduction?

Peter Crooks: This is Peter Crooks, I …

Myra Kleinpeter: This is Myra. Somehow I disconnected. The only information was the small number of facility that actually reported this was small to come up with a valid sample size.

Poonam Bal: Well, that's actually something that we'll discuss in scientific acceptability.

Myra Kleinpeter: OK.

Poonam Bal: Hold that thought for a second.

Peter Crooks: This is Peter Crooks. But let me …

Frederick Kaskel: This is Rick Kaskel. I had some comments. It's also about the small sample size and the lack of information that might affect disparities, ethnic age, and gender-related issues that they put down as a concern.

Poonam Bal: Yes. And we'll definitely get to that scientific acceptability. We try to go in a …

(Crosstalk)

Frederick Kaskel: Oh, I see, I'm sorry, OK, OK. OK.

Peter Crooks: This is Peter Crooks. Just in terms of this first section, it's confusing, let's say, in the numerator state but the hemoglobin value reported for the end of each reporting month is used for the calculation. That's just wrong. I mean what they're doing, there is kind of number of hemoglobin measures, they're not using the value. And I am confused about why they put that in there.

Poonam Bal: OK …

Peter Crooks: Because as you go through the measure, you realize they're not using the hemoglobin value in the numerator in any way.

Poonam Bal: And that's something that also we'll bring to the scientific acceptability so hold on that thought. So that's definitely going to keep in mind. So we have two things to keep in mind for that category. But I guess we'll just start with the first section.

So, in the in-person meeting, this is how we'll also format it where we'll start with evidence and we'll have the committee speak about evidence and then vote on that. So, Myra, now that you're back in the line, would you like to just introduce the evidence and what your analysis was?

Myra Kleinpeter: So the evidence is from the (KW) clinical practice guideline from 2006 in pediatrics. And of note, it has not been updated since 2006. But they did have additional information and additional references listing morbidity and mortality, and why it's important to use this measure with the clinical reporting as well as a measure of quality.

Poonam Bal: OK, thank you for that. Is there any response from the committee, or do you overall agree with Myra's analysis?

Michael Somers: I just wanted to add that non-guideline, you know, evidence came from large pediatric database, the (NatPedTics) database. And the other evidence seemed to be a review of USRDS data as well.

Peter Crooks: This is Peter Crooks.

Female: And I say, Peter, before you go on, I just – the question that were – since this is a process measure that we're trying to piece out a little bit here as well, is if the evidence as it's presented whether the guideline or the additional USRDS, et cetera, does that support the concept of measuring this process of measuring hemoglobin?

Peter Crooks: Yes, that was my comment that, you know, the – it's the assignment or the duty of the developer to present evidence in such a way that links the measurement of the hemoglobin to an improved outcome such as mortality, hospital days, cardiovascular morbidity and mortality. And there's nothing in the evidence base linking the measurement per se. There are some evidence linking, you know, anemia to poor outcomes. So I think that's kind of a weakness that they're asking us to believe that just the measurement itself will link it somehow to improve the decreased mortality, et cetera.

Michael Somers: But if you never measure, you wouldn't know. So, it's kind of a little bit of a conundrum there, right?

Peter Crooks: Well, yes, this has happened with our measures on past …

Michael Somers: Yes.

Peter Crooks: … workgroups, too.

Michael Somers: Because I think the data that they do present in terms of the (NatPedTics), you know, a data showed a higher risk of death with anemia as well as higher rates of hospitalization. And the analysis at the USRDS, you know, it looked at – it didn't look – it looked at, you know, stratified hemoglobin levels more than 11 and less than 10, but they said that, you know, higher hemoglobin levels decrease your mortality risk significantly.

Peter Crooks: Yes, the evidence, there's no – you know, there's no systematic review presented, there's a KDOQI expert recommendation, but – and then there's observational cohort studies. And I understand, you know, we all understand that when you don't have clinical trials and enough data to do a systematic review, we have to go with what we've got.

Poonam Bal: OK. Well – and then I think – you know, actually, those are the types of things that we would like you to pick up and discuss about the evidence. And we can move on to the gaps and care and opportunities for improvement as well as disparity comments.

Myra Kleinpeter: OK. So in terms of performance gaps, there were only 59 facilities that were reported by the measure developer from the CROWNWeb data set, and at least in those 59 facilities they had 11 pediatric patients to be able to report.

Many facilities didn't have the number 11. So there's a lot of variation in the interquartile range, in the report, it was 22 percent. And because of the small sample size, the developer actually admitted that the performance goals considered too small, (in fact, that was) too small for have any useful disparity data.

In terms of some of the comments that are listed on the report that are on the screen – actually, I can't get those any bigger so I can't see it that well.

If you go down a little bit further, whoever is doing the WebEx. They have a large clinical trials are needed. The available electronic data at this point is only from 59 units, and it may be difficult to actually identify disparities from the sample size that's very small.

That's all the comments that I have at this point regarding the performance gap.

Poonam Bal: OK. So I'd like to open up to the committee now to see if there's any additional comment.

Michael Somers: This is Michael Somers again. I think that – I think this is going to be one of those things where there are never going to be a lot of facilities because, you know, the average pediatric dialysis, you know, only has 13 patients, and there aren't very many of them. So actually having 59 facilities with more than 11 pediatric patients may be almost as good as we ever (gap), you know, to look at that data that was provided from CROWNWeb.

Peter Crooks: This is Peter Crooks. The did they show that the performance gap is closed quite a bit, it was – in 2008, it was 40 percent, had three or less hemoglobin measurements in the six-month period. And now, they're up to mean of 75 and a median performance of 85 percent. So, I don't think that I'm seeing that there's a big obvious gap. I suppose that if the median is higher than the mean, that means that there's a lot of – there's a significant number of really low performers. But it's hard for me to see – and again, realizing that there's a lack of facilities in patients, but it's – you know, I think it's hard to make the case otherwise for a significant performance gap that merits continuing this measure.

Myra Kleinpeter: OK, let's go on to …

Michael Somers: Well, I guess – but I guess, when you're seeing an improved performance, then I think we need to weigh as a committee the evidence that they've given us in terms of the ramifications of the problem. Would that be appropriate to

do? So, like, you know, granted that they say the mean was 75 percent and whatnot, but would – should we then consider, well, what about the, you know, 25 percent who aren't meeting this and the evidence they've given us about the adverse effects? Should that come into our thinking here or not?

Peter Crooks: Sure, yes.

Michael Somers: Yes.

Peter Crooks: It certainly can.

Michael Somers: Yes. So I guess, you know, I would say, yes, we've seen that improvement but, you know, the measure developers, you know, just gave us that evidence that there's a, you know, 50 percent increased risk of death. So, you know, maybe that's something we need to keep in mind even though there may only be 25 percent of the population that isn't meeting the measure.

Myra Kleinpeter: This is Myra. One comment in talking with the pediatric nephrologists that we have, a lot of the peritoneal dialysis patients, particularly some of the younger ones, they are not able to measure because they have difficulty in performance phlebotomy. So they try to measure at least every other month so that may account for some of the gaps in performance.

All right, going down to the next area …

John Wagner: John Wagner. Can I just ask a question? So, in thinking about this measure, obviously, anemia is the important outcome that is linked to other important outcomes or it's the measurement that's linked to other outcomes. Do we know that monthly measurements apropos of that comment that the difficulty in phlebotomy? Do we know that monthly measurement is superior to every other month measurement? And is that an issue?

Michael Somers: Well, I'll just say from experience as a pediatric nephrologist, I mean it's relatively rare that you wouldn't be able to gap phlebotomy on – I mean it can be difficult, but it's relatively rare that you wouldn't want to check it monthly because, obviously, you're going to be wanting to know how to adjust your ESA.

John Wagner: So the 25 percent gap is not certainly going to be explained by difficulty in phlebotomy? Do we have any understanding of what that gap is? Is it just really that there are practice patterns out there that units don't believe it's important to make this measurement on a monthly basis? Do we have any understanding of that?

Female: Well, this is where – the developer is welcome to chime in here.

Poonam Bal: Is anyone on from the University of Michigan or CMS that would like to respond?

Joseph Messana: Well, this is Joe Messana. I'm a clinical nephrologist at University of Michigan. I don't know if anyone from CMS is on and wishes to respond. If they are not, I can briefly mention that the data sources that we have available, the administrative data sources don't – CROWNWeb and claims data, but CROWNWeb for this measure don't indicate cause that the data was not there.

In developing the supporting information, we identified where hemoglobin's value was available, and that it was within the plausible range of 5 to 20 grams of hemoglobin as described in the metric. We have no additional information about why the data was not there, but I think the basic issue is, if there are 16 percent or 20 percent of pediatric patients that are not having the hemoglobin measured, there are potential risks of incompletely monitoring anemia management. And I think that's – well, that's all. I'll leave it at that.

John Wagner: Could it be the case that there were some mistaken idea that because these patients weren't on ESAs that hemoglobin need not have been reported? And again, I'm speculating that they weren't on ESAs. But if they were not on ESAs, that the hemoglobin is somehow did not end up getting reported on claims or something similar to that?

Joseph Messana: Well, these data are based on CROWNWeb, certainly, in claims prior to 2012, there was not a requirement to report a hemoglobin if there was not ESA in the month of claims. But that changed at least for Medicare claims in 2012, these data are from CROWNWeb. And I'm not aware of any requirement or

any instruction that says you do not have to report hemoglobin on CROWNWeb if the patient is not on ESA.

John Wagner: Do we know if other data on these patients were missing in those patients who had absent hemoglobin days? In other words, was this a generalized problem with CROWNWeb data entry versus specific problem with reporting hemoglobin?

Joseph Messana: I do not have the information in front of me or available at this point to answer that question. That's a good question.

Poonam Bal: OK. In that case, we do recommend that when we have the in-person meeting, we take that opportunity to bring that so the committee can review that information as well.

John Wagner: OK, thank you.

Poonam Bal: Were there any additional comments on performance gap?

OK. And then, Myra, I'll ask you to move forward.

Myra Kleinpeter: OK. In terms of specifications, it is a process measure, and it does assess the number of pediatric patient month where hemoglobin was actually done in the day that it was documented. The data is readily available from CROWNWeb and it's part of the normal care process for providers. And there was no risk adjustment in this measure.

Poonam Bal: OK, perfect. And I would actually like to start with Peter's comment because this is where it would fall into with your comment about the numerator. If you just want to repeat that and I'll provide the developer an opportunity to respond.

Peter Crooks: Thank you. Yes, in fact, I think they just answered the question that the reason for hemoglobin value appears to be that it's between five and 20, in other words, it's a believable value. Is that correct? So that justifies the statement that that value is used in the calculation.

Poonam Bal: OK. So in that case, were there any other comments about the specification? All right, then Myra, go ahead and start with reliability testing.

Myra Kleinpeter: So in terms of the reliability testing, data was provided in terms of Pearson correlation coefficient. And this indicated there were moderate to strong, and the measure is reliable over the time periods of measurement that were reported. And (IUR) suggesting the measure was reliable. The distribution of the performance score was skewed; therefore, the (IUR) value should be interpreted with some caution. And I presumed this was related to the small size of the samples overall.

Poonam Bal: Yes, so we can definitely bring that back now about the sample size if the committee would like to discuss that more.

Myra Kleinpeter: So in terms of the total sample size, I guess, throughout the nation, it was only 1,280 patients out of the hundreds of thousands of dialysis patient that were studied. And, of those, all those 59 facilities that provided care for pediatric patient actually had 11 patients that were eligible. And I'm not aware of the usual size of the pediatric units. So based on the comment from our pediatric nephrologist on the call, this is expected in terms of the overall small numbers of patients at these units. So it may be somewhat difficult to get better reliability testing if you're dealing with just a small number of patients overall.

Michael Somers: And I think that the 1,280 is, you know, a pretty significant chunk of the pediatric dialysis patients across the country. And I have a better idea of a number in pediatric facilities, but I think, you know, nationwide, it's probably less than 2,000 or close to 2,000 pediatric patients on dialysis at any point in time. So that's a pretty good chunk.

Myra Kleinpeter: OK, are there any other comments? So the next section in terms of related testing, the evidence supports the need for ongoing hemoglobin measurement in pediatric patient from the information that is listed from the references for the rationale for the measure indicated from the observational cohort that measurement is important of hemoglobin pediatric patients.

The testing, the next section, the Spearman correlation coefficient was minus 0.2. The result is just the facilities with the higher percentage of pediatric

patient that was calculated in terms of patient month with hemoglobin measured, and those were associated with our lower risk of mortality relative to those facilities that had lower rates of measurement. But once again, there was the fact it may have been attributable to the small sample size overall.

So, are there any other comments at this point regarding the validity? There were no exclusions that were listed on this measure. So, the threats of the validity aren't applicable here.

Peter Crooks: This is Peter. They tried – they associated the results with mortality and did find the difference not statistically significant but probably that's a sample size issue. So I think they've done the right – they've done the work in terms of connecting the result of the test to an important outcome.

Michael Somers: Yes, I agree with that.

Myra Kleinpeter: So, in terms of the comment that were on the screen, in terms of other reviewer comment, disagree with the developer and disparities may exist, and the need – this may need to be further examined. I'm not certain if there was somebody on this subcommittee that put that comment in or somebody from the whole committee at this point.

John Wagner: I just – this is John Wagner. I just – just going back to this association between mortality that does not reach statistical significance. This really invites the whole conversation that we had in the original discussion of the value of ESAs in treatment of anemia of (ES) or CKD, which is to say that if there's a correlation between anemia and mortality, is it ameliorated by therapy? And the fact that we don't have statistical significance has to be respected for what that says, namely that it's not – we cannot link the two or definitively by statistical analysis and to wish that it might – that it's in the right direction so at least it's not opposing our preconceived notions. And I don't know that that helps us.

And then, of course, if you believe that there's a linkage between the hemoglobin and the mortality, then understanding disparities within the groups would be useful. And we don't have the data on that but, you know, I think first thing first is, is there a real association between low hemoglobin

and mortality that lends itself to interventions that affects the mortality, then affect the mortality.

Peter Crooks: Well, in making the case for validity, they also can cite face validity. And they do, I believe, if you dig deep down into the submission a little bit more that from other evidence and expert, you know, that we believe that on its phase improving anemia, improves mortality cardiovascular risk and so on. So that's also allowable in order for them to make their case that it's a valid – that's a valid measure, whether or not you buy it, you know, that's an individual decision.

Michael Somers: Well – and they're evident – I mean some of the step they provided under their evidence spoke to that, too, right, so.

Peter Crooks: Yes, right. And that's another thing of it. The evidence – the medical evidence from the previous section is another way of, you know, the validity argument is influenced by what the literature says as well. That goes to the face validity argument that, you know, the medical evidence demonstrates that's it's important to do this. So therefore, it's valid. If you improve the measure, you will improve the outcomes.

Myra Kleinpeter: OK, moving on to usability. The data source was CROWNWeb and it collected as part of the normal course of care by health care providers. And then, I guess, usability currently is not being used so …

(Crosstalk)

Myra Kleinpeter: OK.

Poonam Bal: I just wanted to give the committee an opportunity to see if they had any comments on feasibility before we move on to usability.

Peter Crooks: Looks feasible to me.

Poonam Bal: All right, perfect. All right, go ahead, Myra.

Myra Kleinpeter: That's OK. In terms of usability and use, currently it's not in use. And this would be available to the traditional NQF stakeholders in terms of – for both accountability and performance improvement activity.

Peter Crooks: Yes, this is – I'm sorry.

Myra Kleinpeter: (Inaudible).

Peter Crooks: Sorry. It's bothersome to me that this is a re-endorsement and a measure is still not currently in use. And I think one of the obligations, it's expected that if you're coming back for re-endorsement that the measure is being used.

I'm also confused because somewhere it said – I think if you scroll down a little bit further, it says something about it's publicly available. Can you scroll down a little bit more? Yes. The measure is reported and available for public use, so that's kind of that adds with the statement that the measure is not currently in use. Please some clarification on that.

Poonam Bal: I'll ask the developer to provide a little more explanation.

Female: Yes.

Joseph Messana: So, what Dr. Crooks, I think, just referred to is from a comment, not from our information, is that right?

Poonam Bal: Yes, we're just confirming if the measure is in use or not.

Joseph Messana: Based on the information we submitted, we're not aware if it's being used right now. It is public – the measure description and measure is publicly available on your site, in your measure inventory. But we don't believe it's being used.

Peter Crooks: To the mission of the NQF, which is to, you know, measures that matter, there's going to be increasing focus that developers present a case that this measure will be used and will be used for, you know, accountability and public reporting and that is going to matter. And I think it's a little weak on – this submission is weak on that front.

Myra Kleinpeter: So this is Myra. I didn't know at network 13, they do look at the hemoglobins in those pediatric facilities that report in our network. And the rationale for us (inaudible) providing a safety signal, making sure that those people who are at risk for anemia-related complications have the opportunity for treatment.

And then one of the comments in one of the references that was provided, there was a potential decrease in adverse outcome morbidity and some of the risk of hospitalization if you identify those individuals at the high risk, or if there's a quality signal, echo units that tend to have a lower hemoglobin that may prompt performance activity, performance improvement activities at that facility.

Peter Crooks: Yes, I would argue, Myra, that that was going on without this measure. This measure is just a measure. It isn't even measured. It's not even looking at the hemoglobin value. So the activity that you're doing, which is clearly, you know, important, would you be doing that without this measure being present?

Myra Kleinpeter: Well, it's fair enough.

Male: If I …

Michael Somers: I would just say that, you know, there aren't very many national for that would probably allow this measure to be applied nationally. And I know that, you know, there's a great deal of interest now involving pediatric patients more in QIPP things. But up to this point in time, you know, pediatric patients haven't been part of a lot of those measures. So, potentially that's why the measure couldn't have been used. I don't know.

(Joe Anders): If I may, this is (Joe Anders) from CMS. And I would point out the fact that there does appear to be some continuing gap in performance. There's evidence that kind of monitoring isn't necessarily happening without the measure's use.

I think the implementation of the measure of, really, of any pediatric measure in this area is one that has to be taken with some care in part because of the relative (income or) status of the data system that's collecting that. But also because of the fact that it is not a broadly-reaching measure at a very specific

target population. And that requires some considerations on the part of anyone who's implementing that and how they would – did it within the rest of the program. It's not a measure that's going to be applicable to most facilities regardless of one particular program it's included then. And so that's also been areas for some concern.

But as it has been pointed out, there are also the – there are also other, you know, countervailing issues, the further number of countervailing issues, the lack of trial data, the – but also the desire to incorporate pediatric patients more fully in various programs, like the QIPP and public reporting. And I think you'll find as we go through more measures that we've made some efforts to include the (morphols) away. And this measure is one more opportunity for us to do so.

Poonam Bal: Were there any additional comments?

John Wagner: John Wagner. So I guess again, I would emphasize that we – if we understood why we have this gap, then, you know, because we have a unique issue with respect to the limited number of pediatric dialysis before we can qualify in this measure. We obviously don't want unintended consequences, which is essentially a very scarce – maybe not a scarce resource but a limited resource. So I think we have to be careful about how we impact those units that are doing pediatric population to the extent required in this measure and understand why they are not reporting this metric at the frequency that we might otherwise expect.

And then understand that this is useful would beg the question then, what do you do with the information once you know a patient is anemic in the pediatric population that affects outcomes, and if it's – you know, if it's (avoiding) some transfusion, that's obviously – that's one potential outcome by managing anemia better and/or through using ESAs to maintain the hemoglobin. You're going to have to argue that you know what hemoglobin should be maintained at and that results in different outcomes.

Poonam Bal: Were there any additional comments? OK. Then we will be talking about related and competing at the in-person meeting, but we won't be talking about

it in the workgroup call. So we have concluded the first measure, which is 1424, and I have (to do this) in the record time. Thank you, Myra, for leading us through that.

Just some clarifications, the role that I'm taking on right now will be taken on by the co-chairs at the in-person meeting so you can get familiar with that. And also, I do want to remind everyone that when we sent out the workgroup assignments, we also sent out a list of committee member conflicts. So that is one of the situation in this (inaudible) the same.

Originally, this was not the case since we moved our measures over. Bobbi Wagner is (inaudible) is the (tough conflicts) with the good number of these measures. So, during this discussion and during the in-person meeting, we'll ask that she not speak to the measures. Same goes for every other committee member that has a conflict, we'll ask that they not speak when there is a measure they are conflicted with.

So with that said, I will start with 1660, and Myra, it's you again, and also Michael Somers, to see if you, Michael, you'd like to lead …

Michael Somers: Yes …

Poonam Bal: … (maybe the last one).

(Crosstalk)

Michael Somers: … give Myra a break. So this measure is 1660. Overall, the percentage of patients with hemoglobin is less than nine on HD or P.D. with the rationale being that anemia leads to more adverse outcomes and decrease quality of life and adverse effects on physical capacity and neurocognition and cardiac function.

The numerator for this is the calendar months in which the patient has a hemoglobin less than nine. And the denominator is all calendar months on hemodialysis or peritoneal dialysis. And the exclusions are medical reasons for hemoglobin less than nine unrelated to renal disease.

Poonam Bal: OK, perfect. And I'll actually have you start with evidence.

Peter Crooks: Can I – this is Peter Crooks. I like to make a comment on this first page. They've identified this as an outcome measure. And this is going to be, I think, a recurring theme from my perspective that this is not an outcome measure. It's an intermediate outcome measure. And it's – having been a developer now, it's kind of perplexing to me to how. It is a tricky thing kind of trying to decide what your metric really is.

But it's clear in the application process that outcome measures are – the evidence is – the job is to link that outcome to a process or something that, you know, be poor. Whereas, in this measure and others that they're claiming their outcomes, what they're doing is (send it), if you do this outcome, then you get good outcome, like lower mortality, lower cardiovascular risk and so on. So, it's like the plan for developer that this is really an intermediate outcome. And it is, in fact, identified in the staff review as an intermediate outcome, not truly an outcome.

Poonam Bal: All right, thank you for that. And I'll just give RPA an opportunity to respond to that. Is anyone on the phone?

Renee Garrick: So this is Renee Garrick for the RPA. So, I think that point is well taken, it is an intermediate outcome measure, obviously. The data from target and other derivative data do suggest that maintaining a hemoglobin in the target range above nine does have some improvement in quality of life and does have some improvement in terms of cardiovascular outcome data. But certainly, you're right, this is an intermediate measure. It's not the final outcome.

Poonam Bal: Great. Thank you for that. And then, is there anyone else in the committee that would like to make a comment on this before we move to evidence?

(Shawn Ryger): So, just so I understand the rules, this is (Shawn Ryger). So are we then – are we still to consider measures that are intermediate outcomes? Or is that in fact a dead stop for a metric if it's an intermediate outcome?

Peter Crooks: No, no, not at all. This is Peter. The issue is that the developer has a responsibility to identify their metric. They can choose from outcome,

intermediate outcome, process, and a couple other wrinkles or patient reported status – (and Stef) can help me if I'm missing one.

So the issue here is that they've misidentified their outcome right up top. And – but if they have said it's an intermediate outcome, then the rest of their submission flows in that vein. The process, the types of evidence and so on, is different for an outcome metric than it is for an intermediate outcome metric. In an intermediate outcome metric or a process metric, you have to show that doing that thing or measuring that thing leads to an improvement of a health outcome, such as mortality, hospitalization, et cetera.

Does that clarify that?

(Shawn Ryger): Yes, thank you.

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

All right, well, then, Michael, I'll ask you to start with evidence.

Michael Somers: All right. So for evidence, first is given the KDOQI anemia guidelines, and – which, you know, sets a target hemoglobin between 11 and 12. And they also offer us evidence on updated systematic review of randomized clinical trials that look at targeting different hemoglobin levels with ESA treatment. And that was – that updated review seems to have been done for the anemia guideline update in 2007. And those were generally randomized trials that were supporting a hemoglobin value between 11 and 12.

So, I guess in terms of my comments about that, you know, there's obviously no specific evidence from the guideline that looks at hemoglobin levels less than nine or why that particular level would be more meaningful than another level of those. Certainly, nine is lower than the target – the guideline set. And again, there's no evidence in the RCTs about a hemoglobin level of nine specifically, although, again, nine is well below the target range that (fit) those RCTs claim there was benefit for.

Peter Crooks: Yes. I – this is Peter again. I agree that the job of the developer would be, ideally, that say that we can link – the medical literature links hemoglobin less

than nine with the poor mortality cardiovascular hospitalizations, and, you know, other outcomes.

There isn't literature supporting that. Their evidence is all focused on, it's good to be in the range of 11 to 12, it's bad to be outside of it. So, there's nothing really to (pin it) to nine.

Renee Garrick: So …

Peter Crooks: Sorry, go ahead.

Renee Garrick: So this is just Renee Garrick speaking about the – this is really the search for a threshold for a floor for the hemoglobin measure. It's not to adjust the concept of the current KDOQI. It's really looking for a place to have a lower limit for safety. And for some outcome data, certainly, the targets – the treat study which was the only study that had a placebo arm that looked at the utility of rescue therapy. And so that did use nine as the bottom floor for the hemoglobin.

So the concern here has been the issue of having hemoglobins that actually are well below the target of 11. And is there a place at which we should be seeking a floor. And while there is obviously no crisp threshold for choosing a lower limit for hemoglobin, the measure development is this – needs to be putting patient safety first. So the KDIGO trial guidelines which are the new anemia guidelines for CKD5, they're actually in their current guideline for CKD5 patients, does set a suggested nine as the floor for where, yes, a therapy should be initiated.

And they do say, again, in the next part of the guideline, that therapy does need to be individualized stating that it may need to be higher. So no one is seeking a hemoglobin floor of less than that. The next guideline in the KDIGO is seeking actually a higher number for the hemoglobin, not lower.

So the concern that's been raised has been the need for a lower limit of hemoglobin, and in part, there are two groups of concerns around that. One is that there are some quality of life data in the treat trial and there are certainly data in the cardiovascular literature about the risk of hemoglobins that are too

low. And the second is that the threshold for rescue becomes very narrow. So, if patients have hemoglobins of eight and they're not on an ESA or in that range and develop a complication, the ability to transfuse and to rapidly repair the hemoglobin becomes more limited.

So, this intermediate outcome measure is really a look to try to achieve a lower limit for the hemoglobin at which point. We believe that it would be appropriate for treatment to be initiated. So that's the quality issue here, is this very lower limit for the hemoglobin.

Poonam Bal: Would anybody from the committee like to respond to that?

Renee Garrick: And, again, there are data suggesting that the transfusion numbers have gone up in the ESRD world, and there's some concern about that, especially because of allosensitization.

Poonam Bal: All right. Thank you.

Peter Crooks: Yes, this is – (inaudible), this is Peter Crooks here. I think as a nephrologist and, you know, and – you know, we all know that treating anemia is important. It's tricky, it's difficult, and there's a lot of controversy about how to do it and what the right target should be. The only, I think, issue I have that the evidence doesn't link to nine. And I understand arguments why that may be a good number if that's where treatment really should be begun or, you know, you have to pick a number somewhere but …

Renee Garrick: Right.

Peter Crooks: …I would say the evidence supports treating anemia doesn't really support that particular number.

Renee Garrick: So, the current data suggest that you …

Poonam Bal: I'm sorry to interrupt, but we can have more of a thorough discussion about this in the in-person meeting. So I think we need to move forward and see if there's any other discussions on evidence. OK. And I would just recommend the developer to come prepared to have the rationale for the in-person meeting

and we can continue that discussion at that point. So, we'll ask Myra and Michael to move forward to gap.

Michael Somers: So, for gap, there's data presented from the 2008 PQRS that shows that a little over 35 percent of patients didn't receive optimal treatment, with performance going from 10 percent to 95th percent to 10th percent to 98th percentile. There's also data presented that in 2012, about 20 percent of patients had hemoglobin value is less than 10 and 5.4 percent of those were hemoglobin value is less than nine. And that the proportion of patients with hemoglobin value is less than 10 has been increasing from 2008 to 2012.

Peter Crooks: You know, 5 percent of patients is not a big gap but, you know, if you view it as a safety net that they still be justified.

Renee Garrick: Right. And just to expand that for a second, you know, there – with the hemoglobin less than 10, you know, there are data that there's a linear increase in mortality, again, looking for that safety net lower end threshold.

Poonam Bal: Was there any additional comments from the committee? OK. Then I think we can move forward to specification.

Michael Somers: You know, in terms of specifications, I thought all the data elements were well defined. I can go on then if people want me to do reliability testing.

So, for nephrology practices across the U.S. were used with patients who are both on hemodialysis and peritoneal dialysis. And there is a data presented that there is inter-rater agreement of 99.45 percent with the anemia measure.

Peter Crooks: That looks good.

Michael Somers: Right. In terms of the – can I move onto validity? Is everyone OK with that? All right. So in terms of validity, they used an expert panel to assess face validity. On the expert panel, people could vote from one to five, with five being the highest degree of support that this measure had high face validity (inaudible) measure, garnered a score of 4.37 over five.

Poonam Bal: Were there any comments on validity?

Peter Crooks: It's the same …

Michael Somers: Can I …

Peter Crooks: Oh, go ahead.

Michael Somers: Can I just ask, Peter, maybe, you can comment on the idea of how often we see the use of expert panels like this to give us validity data versus some of the other validity testing that we were – like we saw with the first measure we discussed?

Peter Crooks: Yes, ideally, you know, they would be able to do a test of, you know, on patients that were less than nine and link that to an outcome to make the case study if you lower the percent of patients with hemoglobin less than nine and the health of the group is improved. They are unable to do that. And so, you know, we're left with, you know, as doctors and as scientists, we have – and patients, we have to decide if we buy their argument.

What they're trying to say is if you use this measure, it will improve outcomes, you know, and that's what the validity is about. And the expert panel thinks so. You know, now the community members have to decide.

Poonam Bal: Were there any additional comments before we move forward?

If we just want to go down and take solutions and see if there's any comments about that. If not, we can move on to feasibility.

OK. So, I think, feasibility. Michael or Myra, you may start.

Michael Somers: So, in terms of feasibility, it's going to be included in the RPA KQRR in 2015, otherwise at – you know, that the data elements that are required are part of provision of care defined elements as part of the (H.R.'s) or other registry.

Poonam Bal: Any additional comments?

Peter Crooks: I'm happy to – this is Peter, I'm happy to see that this measure – there's a plan to put it to good use, and that will be for the registry and be – I guess, it looks like it's going to be in the PQRS registry as well. So, I think that it's laudable,

I think, in terms of feasibility, I don't think that's a problem from my assessment so far.

Poonam Bal: Any additional comments?

Hearing none, we can move forward to usability and use.

Michael Somers: Again …

Peter Crooks: Yes, we …

Michael Somers: …it's going to be included.

Peter Crooks: Well, I think we are – we're kind of talking to both points at the same time, usability and feasibility.

Poonam Bal: OK, perfect.

So then, again, just a reminder, please look at the pre-meeting member comments before the in-person meeting, but we have included this measure. And we can go on to our next measure, which is 1667, and I will ask if Bobbi or Frederick is on the line to start the discussion.

Bobbi Wager: Hi, this is Bobbi again. I totally apologize. I did not get an e-mail or anything stating that my measure was changed.

Poonam Bal: That's OK, I know that there was a lot of confusion with the changes. So, I'll see if Frederick is on the line, I know you can't see the screen, but are you able to just kind of guide us through this measure? I'm not sure if he's still on the line. Is there anyone else in the committee that would feel comfortable starting the discussion?

Michael Somers: Well, I guess since it's a pediatric measure, I can start it off.

Poonam Bal: Thank you so much.

Peter Crooks: Thank you very much.

Michael Somers: So this is 1667, it's looking at the percentage of calendar months within a 12-month period, in which dialysis patients less than 17 years of age who are either on HD or P.D. have a hemoglobin level less than 10. And the rationale, again, goes to what we've discussed with previous measure in terms of anemia and adverse outcomes in terms of quality of life and other physiologic measures of well-being.

The numerator is the calendar month of patients less than or equal to 17 years of age with hemoglobin value is less than 10. And then the denominator is the calendar months that patients less than or equal to 17 are on HD or P.D.

The exclusions to the denominator, again, are non-renal forms of the anemia …

(Off-mike)

Michael Somers: … with post-op bleeding infection or other medical reasons.

Frederick Kaskel: I'm sorry, this is Rick. So, keep on going, I guess you couldn't hear me before.

Michael Somers: No, I let you take over.

Frederick Kaskel: Well, where are we? (Inaudible) sign in here.

Poonam Bal: Rick, do you feel comfortable taking over?

Michael Somers: All I did – just did, Rick, was I just introduced the measure in general. We haven't gone to talk about any evidence yet.

Poonam Bal: Michael, you may actually need to keep going once again.

Michael Somers: OK.

So the evidence that's provided with this, again, KDOQI guidelines for anemia which date the children who have hemoglobin value is no less than 11. And then there were also, I said it was (inaudible). I'm not sure if there was –

someone else may need to help me here. I'm not sure if there was any other evidence reported here.

Renee Garrick: So this is Dr. Garrick, just the evidence impede was more – in terms – again, in terms of floor that you – that we just talked about that in children, the data regarding low hemoglobins had more impact on quality of life and developmental milestones.

Michael Somers: Right.

Renee Garrick: So again, this was a need to try to set for hemoglobin with the concept being that for children, hemoglobin of less than 10 rather than what we just talked about in adults of less than nine. And, again, it's the quality of life data and cardiovascular data, with the same comments that we just talked about in terms of continuous variable and looking for a floor.

Frederick Kaskel: Also neurocognition isn't evaluated. That is another comorbidity …

Renee Garrick: Right.

Frederick Kaskel: … of the hemoglobin level section. You put it to context also.

Renee Garrick: Yes, thanks.

Frederick Kaskel: And again, there's no target hemoglobin that we can accept just yet based on the data.

Poonam Bal: OK. Were there any further discussions on evidence?

OK. Then we'll try to jump to gap.

Frederick Kaskel: You want me to go on, Michael?

Michael Somers: Yes, if you're on the call now, it's all yours.

Frederick Kaskel: Yes. So, you know, the information on the gap did not include the thorough investigations of the pediatric cohort, obviously. So we – and also we can't evaluate any effect of gender, age or race on desired outcomes. And then

really the lack of sufficient data to apply current adult standards of target hemoglobin to children of different ages and gender and race, so.

Michael Somers: So the measure developer's quoted some data from the 2008 PQRI that showed that the 50th percentile level of performance is 66.2 percent. And then they also quoted some 2010 ELab data so that 20 percent of patients had hemoglobin value less than 10, which actually was – well, a tad higher than 2009 when it was 18.6 percent.

Frederick Kaskel: OK.

Poonam Bal: OK, was there any other point of discussion before we move forward?

OK, then let's move onto specification.

Frederick Kaskel: OK. So, measure was felt to be well defined and specified. It could be implemented consistently across organizations for comparability. But again, it would be helpful to have data on gender, age and race to fully evaluate each factors in patients with hemoglobin less than 10. And specific codes could facilitate this analysis and important developmental time lines, if available. And can all patients who meet exclusion criteria be reliably excluded while there's an issue of the CPT II codes for exclusion and their availability? Is there any data since a measure in place has suggested exclusion is happening appropriately?

Peter Crooks: This is Peter Crooks. Just one question for the staff, what – in what – in terms of what we're looking at here, the double asterisk, does that imply that this is a comment by one of the reviewers on the committee?

Michael Somers: I didn't put that in on my review, so I don't know where that came from.

Peter Crooks: Yes, the …

Female: Alexandra or Poonam, can you comment about the double asterisk?

Alexandra: The double asterisk?

(Crosstalk)

Female: … before there is a statement where the comment come from.

Poonam Bal: Unfortunately, it's difficult to say from just looking at this, they are from our committee member, but it's hard to say which one commented …

Peter Crooks: OK.

(Off-mike)

Michael Somers: Well, I commented about the CPT codes because I didn't – I mean there was something in there about that. So I wasn't sure whether all patients could be excluded …

(Crosstalk)

Peter Crooks: So the double asterisks are comments from committee reviewers?

Poonam Bal: Yes. Sometimes …

Peter Crooks: Not from the staff. OK.

Poonam Bal: No, no, sometimes unfortunately the double asterisk just shows up in the system. It is how it populates.

Peter Crooks: OK.

(Off-mike)

Male: OK.

Poonam Bal: Were there any additional comments on this section? OK. We can move forward.

Frederick Kaskel: So you want reliability.

Poonam Bal: Yes.

Frederick Kaskel: The exclusions – this was added by myself. The exclusions should include temporary illnesses that might affect the hemoglobin determinations for that period of reporting. Also insights with fewer pediatric patients in reports, are there differences in comparison to larger pediatric data?

The expert panel, this was data from before. On the top, the expert panel convened and asked a comment on face validity and they said it was a high degree of validity, signed by the panel. This does not seem to be a strong in argument for validity as for instance some analysis or impact of performance by meeting this measure and decreasing adverse outcomes for instances specified in measure 1424.

Peter Crooks: Yes. From the comments and having not been able to review this (price) of the developer's (release), I haven't reviewed this one in depth so I'm not making a lot of comments. But it's not really telling me how they tested the reliability. And I don't know if the workgroup feels that they understand that OK and – or whether you should maybe show the staff's comments on reliability as well as the reviewers.

Michael Somers: Well, they – in terms of the reliability testing. I thought they looked at med records abstraction for practices. And there were over 2,000 patient visits and they showed 99.5 percent agreement with the (KAPPA) of 0.98.

Peter Crooks: OK. That looks good. OK. Thank you.

Female: All right. And that's outlined above.

Peter Crooks: Yes. And the validity testing …

Male: With the expert panel, you know.

Peter Crooks: Expert panel, yes, OK.

Frederick Kaskel: Yes, (inaudible).

Poonam Bal: OK. Were there any additional comments?

Frederick Kaskel: You just said incorrect entry of data, encodes? And this could affect harmonization of the data regarding specific time points that may have affected the results. I think this goes back to (crime lab) and (errors) of data entry. And then the missing data, the other issue was sample was adequate for large spread implementation but normative adult data again should not be used for patient to pediatric age, gender, and race specifications.

And finally, the medical record abstraction data from over 2,000 patients because it showed appropriate reliability from med record abstraction. These are data looking at reliability abstracting data more comprehensively from the EHR other than the manual record review.

Poonam Bal: OK. Were there any additional comments? All right, we'll move forward to feasibility then.

Frederick Kaskel: So the – basically, the main comments here were electronic reporting needs to be more complete and uniformed across sites. Analysis of the data needs to target specific factors such as age, gender and race that may influence outcome. And again, normative adult population data should not be used to attest performance in the pediatric population. And also the data elements are part of provision of care and these are only part of many registries in the EHRs.

Poonam Bal: What while taking this can come into the registry automatically and this would be able to be used as part of that as data elements and registries that can come over electronically.

Frederick Kaskel: I think that's – I think they should be able to come over electronically, right?

Female: Absolutely.

Frederick Kaskel: That's feasible, you know.

Female: Yes.

Frederick Kaskel: Again, we lack the normative adult – to apply the normative adult data is an issue.

Female: Yes, which is why the different – we agree. And then part of the reason for looking for a threshold for pediatric population is different than the adult population. It's a data support, a higher floor in children, again, looking for this concern of letting the hemoglobin get too low. And you mentioned before about neurocognitive function which is an important point as well. And that's why the (floor) was different in the pediatric range at 10 rather than nine within adults.

Frederick Kaskel: Right. Right.

Poonam Bal: Were there any additional comments?

OK, let's move forward to usability.

Frederick Kaskel: Again, there was accountability and transparency potential for improvements. But what about other intended consequence as well? So public database. The data is used to determine adequacy in anemia management. Deviations from expected (norms) can be used to investigate specific ideologies of an aggregate response to anemia treatments. Nevertheless, benefits at present outweigh any unintended consequences. And, again, the publics for use for public supporter are the PQRS, the RPA registry. And the other issue was to be helpful to see more recent data than the past up to 2010.

Poonam Bal: Any additional comments? OK. So that concludes 1667. We do only have about 30 minutes left and four measures to go. So we're going to change up the structure just a little bit so we can discuss each measure on this call.

I request that moving forward the discussants do a brief overview of what measure is. And then instead of going into each category just to go over any areas of concern that they have. So any areas they feel that the committee should do a little discussion on before we get to the in-person meeting. Does that sound (inaudible) everyone?

Male: Yes.

Poonam Bal: OK. Perfect. So we'll start with 2699, and I would like to see if Dodie or John Wagner are on the line.

Dodie Stein: I'm here. John, are you there?

John Wagner: Yes. I'm here as well.

Dodie Stein: Would you like to start?

John Wagner: OK. So I – this is a little bit of (blurt). I found out on Sunday that I've been assigned measures and then I had three new ones. And that one that have been assigned has been taken (inaudible). So I – it's a little bit of (blurt).

But, anyway, so this is a standardized transfusion ratio, and it's an attempt to use, I guess, administrative data sets and other sources to identify transfusions in the dialysis population. And this is something that is available presently reported on dialysis facility reports. And it's – in this case, I think the rationale is that it's been linked to outcomes with respect to our (fertilization) and barriers to transplants as well as other adverse events related to (inaudible) transfusions.

The issue for – the exclusion criteria I think I had some issue with because the exclusion criteria have to do with the usual hemoglobinopathies and solid cancers and such things. But I don't believe its exclusion criteria. It includes adjustments for surgery with expected blood loss and/or G.I. bleeding or GYN bleeding. So it's – I think that's, you know, an issue that one might address.

With respect to the data sources that were used to actually develop this measure by the – I think there's an issue as to how complete the record is with respect to the ability to capture all transfusions relation to dialysis patient. And of course accountability for transfusion but not necessarily reside within the dialysis facility itself. But decisions are made obviously by non-ESRD providers with respect to our transfusion.

In other aspect of this, is that's a ratio so that as one attempts to seek an improvement in one practices, it's going to be the case that there will some variability and when that this – that occurs that we'll put some units with an appearance of being better than other units even though all of them or most of them may have reach a standard of practice, which we – one might consider to

be acceptable. So in the sense of a ratio is and perhaps a little judgmental with respect to – just like a comparison where it may reflect patient population characteristics or randomness as opposed to actual differences and practice that lead to better outcomes.

I think there are – I can't remember without scrolling a little bit further I will have my notes in front of me. But the – I can't remember about the discussion reliability and validity testing, but I don't think I recall anything (more). And this is data that are available as I've discussed to a various meetings and it's currently, publicly reported in both (inaudible) reports and the dialysis compare website.

So that – and I think that in terms of this being a measure that we might want to embrace, I think the problem I have with it is that it doesn't adjust for all of the factors that may lead to need for transfusion. The association with adverse outcomes is indirect. You know, there's no – and the – and it doesn't really allow one to decide that a unit has actually good practices or not in the sense that it's ratio and compares units one for the other and it doesn't necessarily account for a patient population (inaudible). But this is a measure that is apparently or is sort of trenched at the present time. So I doubt it's going away. It's part of the QIPP, so..

Dodie Stein: There are no standardized data for expectation with these ratios. And – are there?

John Wagner: Well, all we had so far as they were usually report is whether they're, you know, whether the (company's intervals) are consistent with a ratio being compatible with one or not. And that, you know, rarely a unit will be set to be better and then a little bit more common (inaudible) maybe set to have a ratio with (inaudible) significantly greater than one. So that's all can say. And this is really a measure of variability, it's not – that's going to tell you why a facility has the result that it has.

Peter Crooks: This is Peter Crooks. I have a comment about the process being used here, and I think this is important for the developer to think about when they do their in-person presentation. They've claimed this is an outcome measure.

And I can see in a sense where that maybe true that this is mortality as an outcome. This could be considered an outcome. But the n the job of the developer is as stated in 18.2, if this is (inaudible), you can briefly state a diagram, the path between the health.com and healthcare structures, processes, interventions or services that influence it. And by claiming is to have outcome then they can bypass, then they get to bypass systematic review of the data, guidelines and other things, you know.

So the path they've chosen requires them to convince the committee that it does to illustrate for the committee the path between (health.com) structure process intervention or sources that influence it. And I'm not seeing that here. I see in that response to 18.2, information about, you know, the effect of blood transfusions and blood products and so on.

But it's not really relating back to those four things. So – and I don't know if the staff has any comments about that. We're used – we're very used to looking at intermediate outcomes and processes. And I don't think this committee has really looked at health outcomes before in this way. But from what I'm seeing, I'm not seeing that linkage that needs to be there.

Dodie Stein: And it doesn't account for any kind of socioeconomic or psychosocial variation in units and could make a big difference. I guess I would expect what's expected, what's the standard, and then how is that standard affected by specific (unit) characteristics. Maybe that's not reasonable to do.

Peter Crooks: And that again – go ahead.

John Wagner: You know, again, this is a facility measure. There are no data that speak to how much control facilities have over the decision with respect to transfusion that occurred. Obviously, a facility that allow patients to have lower hemoglobin by – based on their practices with respect to (EFA) use (might quick) – their patient population is more at risk, so in that sense, units maybe held accountable. But we don't know in the case of units where that ratio appears to be high, that the decision making, it has been at the level of the facility and related to this validity factors or related to other things.

Peter Crooks: Yes, I think the case could be made that if a particular unit or entity is not having a sufficiently low transfusion ratio, then the services that they're offering are influencing at their process, their intervention and so on. And I think that's what their going for. But I'm not quite seeing a clearly (put forth) here.

John Wagner: And we have data. I mean you can look at the dialysis compare website and it will tell you how many units have the value that is greater than expected or less than expected. And I think it's a few hundred that are greater and expected out of 5,000 plus units. So, you know, so one could drill down and look at that and say "OK, are those units that have had this higher ration, are their hemoglobin values lower or not, the typical dialysis unit and at least try to understand whether in fact it's related to unit factors or not. So I know (you're troubled) by this idea. So I think …

Joseph Messana: So this is Joe Messana from the University of Michigan. I'd like to address just a couple points. First point, the comment about observed over expected. The expected value in that ratio is the value expected from a risk adjusted model for that individual facility not based on – not just the national average. It is, I think, incorrect to criticize metrics that you standardize methodology as just being measure of variability because there are a number of NQF endorsed metrics that use that presentation with the denominator being expected from a robust risk adjusted metric that have been around and NQF endorsed for a number of years.

The point regarding the link between this outcome and facility practices is related to anemia management. And certainly in our submission, we have not attempted to convince you all that anemia management is the only factor related to transfusion-met ratios.

The concept of shared accountability has also been discussed around the NQF for some time. We referenced a recent publication from the esteemed Dr. (Collin's) group that shows that facility achieved hemoglobin is one of the strongest predictors of facility transfusion ratio. There are some other data as well.

Thank you. Sorry to take up time.

Peter Crooks: Yes, so to summarize, I think that in an outcome metric, the assumption is that the measure is good. It's a good thing. It's an outcome that we seek. And I think they're simply making the case that there are processes of (inaudible) and improve it. And I don't think that that's really a hard argument to make either. So I think, you know, I'm satisfied. But I just wanted to point out and probably for our own education as a committee that the process of the data chain and the logic of approving and evaluating a metric is different if it's an outcome versus an intermediate outcome or a process.

John Wagner: And, again, I apologize if I – and sorry, that I didn't think there was risk adjusted. I did think it was risk adjusted. But I guess the issue is the facility may not be the source of the decision-making with respect to transfusion. So I don't know how, you know – I think that's a problem obviously. The facility is also the source of the decision making with respect to transfusion, then obviously, the facility is accountable in total to that.

(Joe Anders): So if I may. This is (Joe) from CMS again.

John Wagner: Yes, yes.

(Joe Anders): I think that we can certainly respond to that in writing. I think just very briefly here, there are other circumstances in which outcome measures include outcomes where the decision to enact an outcome is not necessarily within the purview of the facility being assessed. I think readmission is a good example here.

A hospital may be held accountable for readmission even if it's another hospital that makes the decision that the readmission occur. But I'm thinking, in that case and as we envisioned this measure and as well just – we'll provide description for you ahead of the in-person meeting to kind of walk down exactly where the thinking is.

It's the fact – it's our belief that the behavior or the treatment provided by the dialysis facility is responsible for getting a patient to the point where that outcome is deemed to medically necessary by any provider, not necessarily

just the facility that we're interested in capturing for the measure. And I think we are trying to ascertain that dialysis facilities are responsible for the decision to transfuse. It's more of a concern that their treatment of anemia results in, may potentially result in an excessive need for transfusions in some patients. So that's what we're trying to capture.

Poonam Bal: All right. Thank you for that explanation. And please compare and discuss it further in in-person meeting. At this time, we're getting – you know, we're cutting down the time. So we do need to move on to 2700. I also want to remind the committee that we have a public and member commenting. That's for 02:50. We may take a – if we're not doing the measure, we make take a little break in ask the public, make any comments they would like and then keep going. But we do need to get three more measures. So I want to keep the conversation going and now move on the 2700. And that would be Dodie and Rick, if you are on the line and prepared to discuss this measure real quick?

Dodie Stein: Yes, is Frederick there?

Frederick Kaskel: Yes, I'm here. I'm here if you need me. I'm here. Hold on. OK, is this 2700? Yes. Right?

Male: 2700.

Poonam Bal: Yes.

Peter Crooks: Right.

Frederick Kaskel: Good to go.

(Off-mike)

Male: … the rationale here is that measures …

(Off-mike)

Male: … but despite the majority of these patients …

(Off-mike)

Poonam Bal: All right, any additional comments?

Peter Crooks: Yes, this is not an outcome measure. This is intermediate outcome.

Poonam Bal: OK. And we'll definitely have the committee keep that in mind for in-person meeting. Were there any other issues, major issues, we wanted to discuss on this measure before moving forward?

Poonam Bal: Yes, I …
(Crosstalk)

Male: Oops. Sorry, go ahead. I had a question about the data collection. This seems to be from the – with respect to the reliability of the data, it seems to be from the proprietary databases of large dialysis organizations. And the measure itself, I think, calls for using data from CROWNWeb. I just had a question as to whether we knew or whether the same results would be seen with respect to the types of results that were recorded and its reliability and gaps.

Joseph Messana: This is …

(Crosstalk)

Joseph Messana: This is Joe Messana from University of Michigan. Twenty-seven hundred uses CROWNWeb data for validation of reliability. The measure from KSQA uses data from the proprietary data from the large dialysis organizations. I'm not sure there's much difference in terms of the reliability and validity associations that are drawn from those two separate measures. But to be clear, 2700 proposes to use data from CROWNWeb and validates and demonstrates reliability using quick data from CROWNWeb.

Poonam Bal: And then speaking to 2701, it uses the data of the three (LDOs). And these are the data that are fed into in batch to CMS for CROWNWeb.

Dodie Stein: This is Dodie. I had – go ahead.

(Joe Anders): I'm sorry, this is (Joe). I think my understanding is that the – that some of the data that are used in that measure are provided in batch to CROWNWeb. I think there are some data that are not – that are also included in the 2701 measure.

Female: Right because we rely on three data points, whereas 2700 relies only on (inaudible).

(Joe Anders): Right.

Female: But it is the same records.

Dodie Stein: This is Dodie. I had talked to a couple of our docs around here about this measure, and they were both concerned about from practical issues in terms of, it's not patient-centered. The patient is not able to make the decision based on lifestyle and consequences and you take the control away from the patient at this level. And when am I talk to who things are set up at least around here, I guess they determine what the (inaudible) is going to be first within those four hours. And then the other – the milliliter measure kind of comes from that, am I right? And units are not going to be really necessarily, I don't think, to extend time to be able to get the no (reader) measured down.

(Crosstalk)

Peter Crooks: That could be a positive outcome if this is the doc that in fact that facilities will need to do that in order to provide safer and ultimately more effective dialysis treatments

Poonam Bal: So we would like to now the committee to have a full discussion on this. And again, we'll continue the discussion at the in-person meeting. We have brought up – were there any additional issues that we wanted to bring up that have not been brought up about this measure during the time, or are we ready to move on to the next one?

Peter Crooks: And this Peter. I'll just make a quick observation on the evidence. This is, you know, week on the medical evidence. I think, you know, there's most systematic review. There is no little guidelines out there. There are some

observation studies which I might comment, were not fully summarized for us in the application. But on the other hand, I thought, there is and I think committee members realize this is an important measure, but I think that is a concern here.

Poonam Bal: OK, were there any additional comments before we move forward? OK. We're doing pretty good. I know that this is set up version and we'll have plenty of time to talk about it during in-person meeting. We do want to get all the measures before the end of the call. So I'll – let's start with 2701. And is John and Michael on the line?

Michael Somers: So 2701 continuous on (this theme) about (U.F.), but what it does is look both at (U.F.) rates and duration of dialysis. So it's specifically looking at patients who have dialysis durations less than 240 minutes. And in the numerator including patients who have (UFR) is greater than 13 who have time periods less than 240 minutes. The denominator is the total number of patients and exclusion are home dialysis patients, children, people who aren't in routine sort of standard during of dialysis treatments per week.

For evidence, the KDOQI guideline is quoted with some workgroup consensus opinion about the importance of (bulimia). Again, you know, as a guideline there is no real evidence regarding outcomes and why this process is worthwhile. There's also literature review that's presented. There are 13 different studies that are sited. Three of them are more or less opinions one stated from a registry nine or data from different types of cohorts or other sorts of analysis.

There are a large number of patients when you look through all the summarized table of those studies and what that covers. The gap analysis look at more than 4,000 chemo facilities more than 400,000 patients and showed that median proportion of patients who met – wouldn't meet this goal, optimal care would be 11 percent. It showed a minimum of zero, maximum of 50. The interquartile range was 8 percent.

In terms of reliability, again, they looked at more than 4,000 facilities in these three large dialysis organizations. They showed an interclass correlation

coefficient of 0.6 to 0.7, good level reliability within the facilities and between facility variance was greater than the (Woodlands) facility variance.

And for validity, they looked at facility specific scores compared to SMR and SHR and some things to be statistically significant in the proper direction. And I think for feasibility, again, it's generated or collected during the usual provision of care in HSR. I didn't have any huge red flags to bring up about this.

John Wagner: I guess – they're averaging the values during the first week, so I don't think that those data are collected presently, if I'm not mistaken. They're asking the additional data for – that would allow when to calculate the (UFR) rate on the treatment that I guess which (inaudible) obtained, (is collected), so there's a little additional data collection, I think also – to me, I think it's a little bit of (inaudible) measure, and that there is either a time of dialysis factor or the (UFR) factor and the literature doesn't really speak the relative importance of one versus the other unless there's misunderstanding in literature. So …

Michael Somers: But they – I mean they did give us evidence, some literature looking at duration.

John Wagner: Well yes, there's no question that they're both important factors why he would say if you don't get this (UFR) rate then at least at the time of dialysis is more than 240 minutes. That's the same, you know, we all know that the two achieving – one or the other goal would be equivalent in terms of outcomes.

Dodie Stein: Should I adjust that now, or did you want me to wait for committee, the submission form (inaudible) address?

Poonam Bal: Please wait until the committee …

(Crosstalk)

Dodie Stein: That's what I thought.

(Crosstalk)

Poonam Bal: Thank you.

Dodie Stein: Yes, that's what I thought.

Poonam Bal: Great. Were there any additional comments and we'll take a little break, do public committing and then quickly discussion 2702? OK, operator, could you please open up the line for public and member committing.

Operator: At this time if you would like to make a public comment, please press star and then the number one of you telephone keypad. There are no public comments at this time.

Poonam Bal: Good, perfect. So let's finish up with 2702, and then we can get done with this workgroup call. And, again, we will be discussing these measures more in detail in the in-person meeting so don't feel like we're – if we didn't get to spend a little more time …

(Off-mike)

Poonam Bal: So I will ask Myra and John, to see who would like to start.

John Wagner: I don't have my notes in front of me, but …

(Off-mike)

Myra Kleinpeter: I can start. Can you hear me?

Poonam Bal: Yes, go ahead.

Peter Crooks: Yes.

Myra Kleinpeter: OK. So 2702 is the post dialysis weight above or below target weight and it comes from kidney care quality alliance measure in the percentage of patient with an average of post weight gain 1 or – 1 kilogram above or below the prescribed target weight. And the rationale that they stated was the increase focus on the identification and correction of post-dialysis and target weight discrepancies will help attenuate large fluctuations in fluid balance and blood pressures that continued to contribute to (inaudible), hypertension, cardiac

hypertrophy and associated morbidity and mortality as well as additional hospitalization.

The numerator statement is the number of patients from the denominator with leverage post-dialysis weight above 1 kilogram, above or below the prescribed target weight during the calculation period. The denominator statement was the number of adult in hemodialysis patients with in and outpatient dialysis such an undergoing chronic maintenance hemodialysis during the calculation period. There are multiple exclusions that are listed, the pediatric population home patient -- patient in the facility of less than 30 days, patients who have less than seven treatments in the facilities during the reporting month, patients without a completed 2728, those individuals who have a functioning kidney transplant (inaudible) and those individuals treating a certain number of patients they're trying to determine what number needs to be the minimum threshold for this reporting.

Female: We'll have that number for the committee shortly.

Myra Kleinpeter: OK. Are there any comments at this point?

Poonam Bal: Anybody wanted to respond to that, you could. We do have – now that we've (gone) through everything, if you want to do a quick response, you can, if – you don't have to hold until in-person as well.

Female: But to the issue of exclusions, that's under review and approval right now, so I can't find that.

Poonam Bal: Great. Thank you so much. And, yes, please open up to see if there's any additional comments on high level issues with this measure.

Male: I guess, the issue here is that the subject that this target weight represents the (bulimic) weight. And obviously, that's – that will be the hope. But the evidence-based – actually will focus on the poor health outcomes resulting from hypervolemia and inability to achieve the (inaudible) for the most part. So, obviously, this measure assumes that the target weight is a correct weight for that patient.

Myra Kleinpeter: OK. Moving forward, it's a process measure and the evidence to support the measure focus is outlined. Focus on identification of the correction of post-dialysis and target weight discrepancies will also help attenuate the large fluctuation of fluid balance that tends to occur with the associated blood pressure changes that will contribute to volume overload, hypertension, cardiac hypertrophy consequently resulting in increase cardiovascular morbidity and mortality.

The performance gap, there's a significant cardiovascular morbidity and mortality in the patient populations, particularly those who have large fluid fluctuations as included in their references. Two reports (inaudible) reported with 25 percent to 50 percent of the patients with excess volumes. This indication has a performance gap in described weight and target weight.

And in terms of the pre-evaluation comments the data is from greater $400,000 – 400,000 patients that's in three organization was provided. The median facility performance, once again, show 22.5 percent with excess volume per measure, definition within a quartile range of 14 percent, demonstrating there's a significant population at potential benefit.

This high priority associated with high (prevalence) and high cost, high priority that needs measure assessment. And then the other comment was (change) the Q.A. provider, just some general language, regarding the large numbers of patients that are affected and potential social patient and societal impact.

Any comments on the first section?

Peter Crooks: This is Peter. I like to just – regarding importance and medical evidence. Their evidence is basically a KDOQI guideline. And I don't think the guideline says, plus or minus one kilogram. And they claim that the greater the evidence is A.

As part of the instructions, we're completing this submission, they were to fill out section 18.7, findings from systematic review, which would have been systematic review used for the guideline and they didn't fill that section out. So I think that's – from my perspective, that's a major area in the submission

that they didn't – they just ignored that section, which is the systematic review of the evidence. So I think, overall, this evidence section is weak. While we may believe that this is a notable – a good thing to do that the developers have an early – done a good job of at least convincing me that the medical evidence is there as required for this submission.

Poonam Bal: And I – unfortunately, we are at the end of our call, so I will have to cut the discussion short on this measure as well. Thank you for everyone's hard work. It's been a very efficient workgroup call. And I feel the committee is prepared to the in-person now. Were there any questions before I go over some next steps with the group?

OK. And if you have any questions, feel free to e-mail the renal@qualityforum.org e-mail or to contact any of the staff members. Our contact information is on the SharePoint site.

So next step, everyone should have received travel information. If you have not, please contact us and let us know so we can get that out to you. We will have – we will be having workgroup calls basically every Tuesday, Thursday, until the end of this month. And you're – while you are not required to attend the other workgroup calls, if you would like to attend them and hear what you're fellow committee members are saying about the measures or if you just want to be become more familiar with the measures, you are free to join them.

The invites are on everyone's calendar. So after that, we will be having our in-person, May 6th and 7th. And we will be going to the same process, but a little more lengthy, we'll also discus competing and we'll, you now, keep the conversation going to. So that's next step.

Was there any questions from the committee at this point about next step? Is there anything else about how the in-person will be run?

Female: Poonam?

Poonam Bal: Yes.

Female: Can I just respond to the issue that was raised about the deficiency and the submission on the literature? The guideline that was (target) was consensus (state), so that's why there was no further articulation in that section.

Poonam Bal: OK, thank you so much for that.

Male: In the in-person meeting, are we likely to be asked to present to the group one of the measures, you know, within these set of measures that we've all reviewed?

Poonam Bal: Yes. So at the in-person meeting, the assignments will stay the same. So the measures that you were assigned for the workgroup calls will be the same measures that you will be assigned for the in-person meeting. And you will basically be doing the same thing where you'll tag team discussing the introduction and then going to through (e-section). So rest assured that whatever measure you were assigned for the workgroups, you will be assigned for the in-person.

Male: Thank you.

Sarah Sampsel: And the other thing I would – this is Sarah. The other thing I would add to that is we would also want you during the in-person meeting to be able to capture, kind of what the work – the highlights from the workgroup call as well to say that, you know, this were the other issues that were brought up during the workgroups, so that the committee can all benefit hearing at least what you would all raised require.

Poonam Bal: Yes, perfect. Thank you for that Sarah. Were there any additional questions?

OK, perfect. We'll see you in D.C. soon or another call. Have a great evening. Thank you.

Male: Thank you, everyone.

Male: Thank you.

END