

NATIONAL QUALITY FORUM

Moderator: Lauren Richie
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1:00 pm CT

Operator: Welcome to the conference. This call is being recorded. You may now begin.

Lauren Richie: Okay. Good afternoon everyone. This is Lauren Richie from the National Quality Forum.

Male: Hello?

Lauren Richie: And you have called in to today's ESRD Steering Committee conference call to review the public and member comments received on the ESRD measures.

We will open the call today briefly with just a roll call of the Steering Committee members and then we will go onto review the agenda briefly and get right into reviewing the comments.

So for the committee members present on the call just really briefly, I know Peter Crooks is on the call.

Peter Crooks: Hello.

Lauren Richie: Kristine Schonder is on the call.

Connie Anderson?

Connie Anderson: Here.

Lauren Richie: I know Sue Barnes will not be able to make it today.

Jeff Berns? No Jeff Berns.

Barbara Fivush? Not yet.

Jerry Jackson?

Jerry Jackson: Present.

Lauren Richie: Thank you. Rick Kaskel? Not yet.

Myra Kleinpeter? Not yet.

I know Alan Kliger will not be able to join us.

(Lisa Lett)?

And Kathy LeBeau?

Kathy LeBeau: Yes, I'm here.

Lauren Richie: Thank you. I know Joe Nally is on the call already. Andrew Narva will not be able to make it.

Jessie Pavlinac?

Jessie Pavlinac: Yes, I'm here.

Lauren Richie: Thank you.

Bob Provenzano?

Bob Provenzano: Here.

Lauren Richie: Joe Vassalotti?

Ruben Velez?

Ruben Velez: Here.

Lauren Richie: Thank you. Roberta Wager? Not yet.

And Harvey Wells?

Harvey Wells: I'm here.

Lauren Richie: Thank you. And I know a few committee members will be joining us late. Here at the NQF we have Karen Pace, Lauren Richie and Tenee Davenport.

Just really briefly before I turn the call over to the co-chairs I just wanted to go over a few logistics for the webinar today.

We will be showing several documents on the webinar. And in order for you to see them as large as you can and to be able to read the text on them I will ask that you one, in the upper right hand corner of the webinar just make sure that you have the screen maximized, just click on maximize and/or click on actual size once I have either a word document or an excel spreadsheet. And that will allow you to see all of the comments just as I display them.

And also for the Steering Committee members if you could just remember to reference the comments number that you are returning to. That will help us as well as the audience follow along with those specific comments.

With that I will turn it over to Dr. Crooks and Dr. Schonder for specific comments.

Peter Crooks: Well good morning everyone or good afternoon depending on where you're located.

Thanks for calling in. This is another important phase of our work as the Steering Committee. And we have quite a lot of comments to go through today.

Kristine do you have any other comments?

Kristine Schonder: No, I'm not going to add anything so we can get started.

Peter Crooks: Okay. I guess we need to do a roll - we've done a roll call so we know who's here.

Female: Okay.

Peter Crooks: And Lauren do we need to review the purpose of the call any further?

Lauren Richie: No. I think that's it for now. I think what I want to do is actually open up the call to the committee now just to see everyone has had a chance to at least review the comments.

And I just want to make sure that there weren't any other priority topic areas or measures that the committee wanted to discuss or felt that the full committee should review before we go ahead and get started.

Otherwise we will follow the format that - of the memo that was forwarded to the Steering Committee of a few areas that we have identified here at NQF.

So if there are any other priority issues or measures that any of the Steering Committees want - Steering Committee members want to bring forward please do so now.

Peter Crooks: Well this is Peter Crooks. I think we just need to make sure that we have time to review the comments on phosphorus which there were quite a few. I presume we'll get to that. And I'm not saying it should be at the top of the agenda but that we make sure that we have time to consider those.

Lauren Richie: Yes, absolutely. That's on the agenda. Okay.

Peter Crooks: Anyone else? Okay.

Lauren Richie: Okay with that I am going to turn it over to Karen Pace and she will get us started on the first kind of overarching theme that we identified here at NQF and that's looking at the target population for some of the measures.

Karen Pace: Okay. And Lauren do you want to put up for the webinar that section of the memo for those that - the public that are following...?

Lauren Richie: It's coming up now.

Karen Pace: ...along?

Lauren Richie: Yes, it's coming up now.

Karen Pace: Okay. So one of the things that we had identified as we were going through the comments is tried to identify, you know, some themes or recurring comments. And there's one area that came up in a variety of ways and that was expanding the target population for various measures.

And the first set of these specifically addressed suggestions to include home hemodialysis and peritoneal dialysis patients in the measure unless the evidence required exclusion.

And this applies to frequency of adequacy measurement for pediatric hemodialysis patients which is number 1418, measure 1424 monthly hemoglobin measurement for pediatric patients, 1433 use of iron therapy, 1438 periodic assessment of post-dialysis weight by nephrologist, and 1454 proportion of patients with hypercalcemia.

So I thought we'd - I know the committee discussed this a bit during the meeting and subsequently and we had some exchange with the measure developer about it.

But I thought since this came up in several of the comments for several of the measures that it might be something to just get your thoughts about to see what your thinking is and then we can also ask the measure developer if there were any issues with that.

But I'll stop there and ask for the committee to make any comments.

Peter Crooks: This is Peter Crooks. Do you want us to indicate that we want to speak on the webinar necessarily or not?

Karen Pace: No. I think right now I think you can just speak up on the call. You don't have to indicate that on the webinar.

Peter Crooks: Okay.

Karen Pace: If we start having problems taking care of, you know, making sure everyone gets recognized we can go to the webinar but...

Peter Crooks: Okay, very good. I would like to say a couple things. I think, you know, first of all the general comment that as a Steering Committee we can only consider what the developers have submitted and so that for most of these if it wasn't submitted that way it isn't within our preview to expand the denominator of these metrics.

But and one of these I think it was the hypercalcemia 1454, the developer responded that - oh as okay, as reported in the denominator's statement the measure applies to adult hemodialysis and peritoneal dialysis patients treated.

But I guess rather than making a change what the developer is saying in fact this does include that proof. So that's just a clarification on that, not a change, right?

Karen Pace: But I wonder if - I'll have to look at those specifications if that is also restricted to in center or - I think that was how some of them are.

So and let me just make a clarification. Obviously the measures were submitted one way and as you said the committee does not in general engage in measure development or measure construction.

But, you know, this is something that could be discussed and recommended and, you know, obviously we'd have to have some discussion with the developer. So it's not totally off the table.

Peter Crooks: Okay.

Karen Pace: If it's seemed to be indicated but we will look at that real quick.

Peter Crooks: Okay other comments on this?

Joseph Nally: It's Joe Nally Peter.

Peter Crooks: Hi.

Joseph Nally: I guess my concern at first blush one could say well sure I guess that would apply. But my concern is that I'd like to hear more from the developers, make sure we're not overlooking something major here or unintended consequences.

I - you know we spent a lot of time going over each of these measures with a full discussion which is now four months ago. And I just feel like there's a half a dozen different measures that might be altered with a quick yes without giving it a full do.

Karen Pace: Right.

Joseph Nally: So is there some information that we could hear from the measure developers that might have thought about this in a little more detail?

Karen Pace: Sure. Tom Dudley from CMS is on. And Tom do you want to respond to that?

And Lauren I don't know if you want to bring up the spreadsheet for any particular comment but because I know CMS did respond to some of these comments.

So Tom you want to just...?

Thomas Dudley: Would it be okay if I had Bob Wolfe...?

Karen Pace: Sure.

Thomas Dudley: ...weigh-in on this? Bob you're on, correct?

Robert Wolfe: I am. This is Bob Wolfe. Thank you all very much.

There are two issues generally that might have led to exclusions. One is data availability and another is appropriateness for the population.

So some of those are medical issues which were brought to our attention by our TEPs basically. And the other data availability which we are aware of working with the data sources.

I wonder if it would be better and I just offer this as a suggestion, to do this measure by measure because there may be different issues for certain measures than for others.

Peter Crooks: I think that's a good idea.

Joseph Nally: I agree.

Karen Pace: Okay, that sounds good. So Lauren do you want to - so perhaps we should first talk about measure 1418, frequency of adequacy measurement for pediatric hemodialysis patients.

Joseph Vassalotti: Hi. This is Joe Vassalotti. I joined late. I apologize.

Lauren Richie: Okay.

Peter Crooks: Welcome.

Karen Pace: So...

Peter Crooks: Okay.

Karen Pace: So in this one I'm just - I'm going to just tell you what's in the current specifications. The denominator is pediatric patients receiving in center hemodialysis.

Peter Crooks: Okay well...

Karen Pace: So obviously this one doesn't - this one is specifically for hemodialysis not peritoneal dialysis. So I guess and then it's restricted to in center.

Jessie Pavlinac: Are any of the pediatric nephrologists on the telephone?

Karen Pace: Barbara Fivush I think said she wasn't going to be able to make it. And has Rick Kaskel joined us?

Male: But didn't - Barb, sent her comments. Didn't she?

Male: She did.

Jessie Pavlinac: Yes. I was just going to - this is Jessie Pavlinac. And I think it's, and then the nephrologist would have certainly have to confirm this but the incidence ((inaudible)) in anything but in center hemodialysis for pediatric patients I think is pretty low. I mean it's not a big population like, you know, perhaps as it is in the adults.

Karen Pace: Right.

Jessie Pavlinac: but I'm not sure if it's even much of a point for this particular measure for not - for including others in in center.

But again I defer to them as to...

Connie Anderson: This is Connie Anderson. And I think that comment is very true.

And if I remember rightly from the discussion we had at the Steering Committee Meeting the population numbers were so very small and most of them got dialyzed more than twice weekly and therefore the single-pool Kt/V may not be an appropriate standard for the home hemodialysis pediatric population.

Karen Pace: Lauren can you highlight the response because I think we have a development - developer response so if you would move your - so we could see that?

Okay. Okay, and that the - Bob your position is this should remain to be just the in center hemodialysis patients.

Robert Wolfe: Yes. The - part of the issue has to do with data availability. And the frequency of dialysis in order to be appropriate the single-pool is designed for twice weekly.

And in order to identify a twice weekly we literally look at the claim line items and count the number of dialysis sessions being delivered on the claims in order to screen out those that have more than twice weekly.

Karen Pace: Okay. so maybe so we can move onto - so then are any other comments by the Steering Committee? Any disagreement with the leaving it as specified?

Joseph Nally: Again it's Joe Nally. I have no disagreement but - leaving it as specified.

But there was in another half page or so, another item directly related to this and others as to what constitutes a measure. Is that something we want to talk - in other words, just measuring this a frequency?

Karen Pace: Yes. We'll get to that. We'll address that issue separately. That's a good point.

And we wanted to specifically talk about the target population and then you're right, there were several questions about...

Joseph Nally: I mean to be the next sentence down, that's all.

Karen Pace: Right. So maybe the most efficient way to get through this is to identify if there are any of these measures listed that you want to speak about.

Well let's just go onto the next one, 1424.

Peter Crooks: Right.

Karen Pace: Monthly hemoglobin measurement for pediatric patients. And I will tell you here in a moment.

Peter Crooks: Because the developer response in the notes already too.

Karen Pace: Okay, and Lauren you want to go to that one.

This one currently is - oh I believe this is not restricted. It says all pediatric hemodialysis and peritoneal dialysis patients. Oh yes, the exclusion is patients who are not in the facility.

So first let's just clarify with CMS that this measure is also intended for just patients in the center being - receiving their treatment in the center.

Bob or Tom?

Robert Wolfe: Yes, that is the intent.

Karen Pace: Okay.

Robert Wolfe: And it's for the same reason.

Karen Pace: Okay.

Peter Crooks: But there's some language about that it could be misconstrued slightly. And I think that was addressed in the developer's comments.

Karen Pace: Okay.

Peter Crooks: So I think it in actuality measures the group that the comment wants measured. Commenters want measured.

Karen Pace: I'm sorry Peter. Could you say that again?

Peter Crooks: So my interpretation is that the comments - there was a comment that was a slight modification in the denominator statement about which patients should be excluded. And I think the developers answered that adequately.

Karen Pace: Okay.

Peter Crooks: And in fact it's - it will in effect give the same result.

Karen Pace: All right. We'll look at that one separately and that's been addressed.

Lauren this particular comment isn't about the home patients.

But are there any comments from the Steering Committee that - regarding whether this measure should be considered for home patients or a monthly ((inaudible))?

(Crosstalk)

Peter Crooks: This does include home patients as I read it.

Karen Pace: No. The developer just clarified it does not. It's excluding patients who are not in the facility.

Peter Crooks: Well...

Robert Wolfe: It includes centers - patients who are in the center. But that can include PD patients...

Karen Pace: Right and it...

Robert Wolfe: ...if they are in center.

Karen Pace: Right. It includes peritoneal and it's definitely hemodialysis and peritoneal but only those who are receiving their treatment in the center. Is that correct, not home patients?

Peter Crooks: No. That - the term in center is unfortunate there because that would seem to indicate that the treatment is given in center. Where what it means I think is that the patients are followed and managed by that center.

PD is - I don't know that PD is giving in center to pediatric patients. I don't think so.

Thomas Dudley: Karen or Lauren may I speak?

Karen Pace: Yes Tom.

Thomas Dudley: This dates back to my pediatric nephrology days. There are instances where the peritoneal dialysis is provided in center for - with the pediatric population at least dating back ten years ago when I left clinical practice.

You're correct...

Peter Crooks: So...

Thomas Dudley: ...that most peritoneal dialysis is home treatment. But there are instances especially with the neonate population where it's done in center because of some of the technical challenges with that - with the small children.

Robert Provenzano: Yes. This is Robert Provenzano. You're absolutely right. I think almost all the programs do have a few patients that are done on some scheduled PD in the center.

So again the numbers are very small. But I do know it's true. It's true in our program.

Karen Pace: So I think the question is if patients are followed by a facility but not receiving their treatment in the facility should they also be getting a monthly hemoglobin measurement?

Peter Crooks: So the answer to that is yes. But is that what was intended by the developers or not? That's what we don't know.

Karen Pace: Well they're on the line, Tom Dudley from CMS and Bob Wolfe from Arbor.

And at this - my understanding of what you just said previously is that the intent is not to include patients on either home hemodialysis or home peritoneal dialysis.

Robert Wolfe: And this is Bob Wolfe. The constraint is not that it would be inappropriate. I think we agree that it would be appropriate to measure it. It's the availability of data for those patients.

Peter Crooks: Right.

Karen Pace: So just so we understand. So even though home patients are followed by a facility they're not required to enter any data into CROWNWeb for patients that are on home therapy, is that...?

Robert Wolfe: That will be different from CROWNWeb when the measure is based upon CROWNWeb I believe. But I - that would be better for Tom to respond to.

Thomas Dudley: Bob your statement is correct for the CROWNWeb. Some of the issue with the home patients are not necessarily followed on a month - they're not seen on a monthly basis within the center so there may not be a monthly value.

Karen Pace: But in the pediatric population I think it's more likely. I don't know that specifically.

Thomas Dudley: Yes, I...

Karen Pace: But they follow them much more closely because of growth and developmental issues than the ((inaudible)).

Male: That's correct. They come in almost weekly so as opposed to adults. Okay. We may miss a monthly cycle. So that's true.

Karen Pace: Okay.

Peter Crooks: So is there a way we can ask the developer to check the date? Well this is going to be CROWNWeb data, right, so it's not coming in yet so we really can't...

Thomas Dudley: The CROWNWeb data is not coming yet, right, or not nationally, right.

Peter Crooks: All right, so we - so you can't tell us right now whether that will be coming in or you would expect it to come in because that's...

Thomas Dudley: We expect it to be coming in for...

Peter Crooks: Okay, so...

Thomas Dudley: ...100% of the patient population.

Peter Crooks: Right, so why exclude them then because it sounds like the expectation is that they'll usually measure it at least monthly and if they're not they should be measured monthly. Is that what our pediatric nephrologists believe that monthly would be a minimum?

Karen Pace: Barbara and Rick are not on the call Peter.

Peter Crooks: Right, okay.

Karen Pace: Okay, well we can - we'll follow-up with that. I guess at a minimum, well I guess one of the things that also could be recommended is that when these measures come forward for endorsement maintenance that, you know, the home patients be included wherever it's - unless it's contraindicated by the evidence.

But it sounds like on that one which is just a monthly hemoglobin measurement it sounds like there's not a lot of rationale to not include them at this point.

Peter Crooks: That's what I'm hearing. Unless their TEP had scientific reasons not to I don't see why they should be excluded.

Karen Pace: Okay, well let's - we can move onto the next one, 1433, use of iron therapy for pediatric patients.

And we'll get back to a couple of these also regarding the comment about CKD.

But so Lauren do we have one of the comments about - but let me tell you right now what's in the denominator. So this is for all pediatric hemodialysis and peritoneal dialysis patients in the facility.

Peter Crooks: There was a comment about extending it to Stage three/four, CKD Stage three and four.

Karen Pace: Right.

Peter Crooks: Is that why this one hit your list?

Karen Pace: Yes. It's next on our list about the CKD patient.

But this was also commented - there was also comments about restricting this to patients in the center.

Peter Crooks: I see. Okay, so this is the same logic as we just went through on the last one.

Karen Pace: It seems like it would be but I'm - we're just kind of seeing measure by measure if there are any different issues.

Okay, so it sounds like this would follow the same logic we were just talking about.

Any comments specifically about that one? Anything from Tom or Bob Wolfe about home patients with use of iron therapy?

Robert Wolfe: Bob Wolfe. The only issue would be data availability and if the data are available they should be included. We agree.

Karen Pace: Right. Okay, so we can...

Peter Crooks: Okay, good.

Karen Pace: ...follow-up with you specifically on these and see what the potential options are.

The next one where there were also some comments about home patients was 1438, periodic assessment of post-dialysis weight.

And that one currently the denominator is patient in and outpatient dialysis facility, chronic maintenance, chemo dialysis.

So again it appears that this is restricted to in center hemodialysis patients.

Peter Crooks: Now in comment 46 the developers respond that we agree that it would be clinically meaningful to extend to this home of peritoneal dialysis patients and not restricted to (directly) to hemodialysis.

So is that signaling that the developers are okay with adding that group in?

Karen Pace: Lauren would you put that comment - that comment...?

Lauren Richie: Yes.

Karen Pace: ...number 46 up?

Lauren Richie: Yes, it's up now.

Peter Crooks: And the draft response. Yes.

Karen Pace: Tom or Bob?

Robert Wolfe: Yes, that would be all right.

Karen Pace: Oh it's to both home and peritoneal dialysis patients, okay. All right, any comments from the Steering Committee?

Male: No.

Peter Crooks: Sounds good to me.

Male: That's reasonable.

Male: Yes.

Karen Pace: Okay. And then the...

Frederick Kaskel: This is Rick Kaskel. No one could hear me before for some reason.

Karen Pace: Oh.

Frederick Kaskel: And I had comments. And I was talking to myself but...

Karen Pace: All right.

Frederick Kaskel: ...on the pediatric issues I want to just echo what everyone said. And also there are a few patients from time to time in the very young age group that actually stay in the hospital for long periods of time on peritoneal dialysis until we have effectively trained them and sometimes they have to come in for retuning, etcetera.

And we do follow the hemoglobins very closely. Obviously this is something we pay attention to very frequently.

Karen Pace: Okay, thank you. Operator would you make sure all the lines are open then? We thought you had already opened all the lines.

Operator: Yes, all the lines are open.

Karen Pace: Okay. Thank you. All right, glad you got to us Rick.

Frederick Kaskel: Thank you. Thank you.

Karen Pace: And then the last measure in this discussion about home patients is 1454, the hypercalcemia measure.

Jerry Jackson: Sure. Karen, this is Jerry Jackson. Could we go back to the post-dialysis...?

Karen Pace: Yes.

Jerry Jackson: ...weight assessment? There was another comment or several people made this comment that the way it's currently written it requires a new prescription each month.

And it was suggested that to be reworded to require a segment that has been assessed and either changed or unchanged.

Peter Crooks: Yes, that was changed Jerry during our meeting. I think we had language clarification.

And I think the commenter didn't - hadn't seen the latest version.

Jerry Jackson: Oh okay. I missed that.

Karen Pace: Right. The - what the measure language, it stated new prescription. But it said irregardless of change. So let me just find that for you.

Lauren Richie: It's comment number 30.

Karen Pace: Okay. Yes, we - 1438, so basically it now says that the numerator is documentation or receiving a new post-dialysis weight prescription irrespective of whether or not a change in post-dialysis weight prescription was made so.

Peter Crooks: And that's what we voted on.

Karen Pace: Right.

Peter Crooks: Yes.

Karen Pace: Now Lauren I think CMS also provided some comments. Is that - or not, do you...?

Lauren Richie: Well not to this specific comment but...

Karen Pace: Okay, all right.

Lauren Richie: ...this was something that the committee had already addressed so we did not forward it to (CMS).

Karen Pace: Right, okay.

Peter Crooks: Okay.

Karen Pace: Any other comments about that?

I think there was also a comment of, you know, just wanting documentation of assessment versus a prescription.

But CMS had come back with this particular response to the committee's concerns about the confusion and this is what the committee had voted on it. So unless there's any other concerns we can move on.

Peter Crooks: So we're moving to 1454 Karen?

Karen Pace: Right. So this was another one about home patients.

And again the denominator is hemodialysis or peritoneal dialysis patients treated at the dialysis facility.

The question was raised of should that be treated by the facility meaning it would include home patients.

So Lauren do we have a comment about or so I'll ask CMS and Arbor if you have any comments about home patients for this measure.

Lauren Richie: Okay. And that's comment number 119. It's highlighted on the screen right now...

Karen Pace: Okay.

Lauren Richie: ...with the correct response.

Karen Pace: Right. So the comment was that it does apply to peritoneal dialysis patients treated at the outpatient dialysis facility.

And I think...

Peter Crooks: So this is the same.

Karen Pace: Go ahead.

Peter Crooks: Well this is the same type of issue I think. Is there any reason from a scientific point of view to exclude patient's dialyzing at home? And or was it a concern about data availability?

And if it's the latter maybe, you know, we could seek to include them if the data is coming in.

Robert Wolfe: That's - this is Bob Wolfe. That's exactly right. This is again related to the data availability issue.

And my understanding from our medical advisors that it was - would be appropriate to include them. And this constraint was there because of data availability.

If it is possible to access those data then they would be included. The intent of saying at the center was to include everybody for whom we have data. That's in a sense the - a code language that is being used there. But...

Karen Pace: Right. And I think the commenter was saying that it would be more accurate if you would say by the center rather than at the center.

Robert Wolfe: Yes.

Karen Pace: So I know it's just a minor word but it conveys a little bit different. So it seems like you're onboard that if they have the data they would be included.

Peter Crooks: The denominator stating it could be amended to something like all dialysis patients are managed or, you know, followed at or by a center whose data is available on CROWNWeb.

Would that satisfy everybody then?

Karen Pace: Okay. Well we can follow-up with CMS about these and just if there are any clarifications that might help we can get those into the specifications.

Peter Crooks: Okay.

Karen Pace: Okay.

Robert Wolfe: Well it would be nice to harmonize this since I think these - it's entirely the same discussion with the calcium and the hemoglobin...

Karen Pace: Right. Yes, it is. As you go through these the denominator and exclusions, there's some like differences in how they're worded. And so that would be nice to have those the same wherever it's appropriate.

Robert Wolfe: ...because conceptually clinically there's absolutely no difference.

Karen Pace: Right.

Connie Anderson: Right.

Karen Pace: Okay so...

Connie Anderson: Karen this is Connie Anderson.

Karen Pace: Yes.

Connie Anderson: There was another comment about also specifying that this was a pre-dialysis serum calcium. And it should be specified as that in the measure.

Karen Pace: Okay and...

Peter Crooks: The developers' comment, they agree with that. I think it's in the same...

Karen Pace: Right.

Peter Crooks: ...comment on number 119.

Connie Anderson: Oh yes.

Peter Crooks: Developer. So we appreciate the recommendation but agree that pre-dialysis serum calcium should be specified in the measure title and the description. So that can be changed that way.

Karen Pace: Right.

Male: Peter does that mean to say that all of our requirements for blood work need to be restated that they're pre-dialysis laboratory studies? I mean whether it's hemoglobin or potassium or whatever you're looking at? Is there...?

Peter Crooks: Well I'm not sure we want to go back on every one that we've done and make that clarification. Maybe it's understood that the usual practice.

Male: I mean that is the normal practice.

Male: Well I don't know why you're making an exception for calcium.

Male: Yes, I was going to say then yes. So I mean drawing calciums is routine with just all the other labs which is pre-dialysis. That's fairly standard. So either we remove it from that or I guess we're obligated to say it everywhere else.

Karen Pace: And I think based on the CMS session on Wednesday there was concern about it being specified that it should be specified as pre-dialysis. And anemia was included in that part of the discussion.

So I think there is concerns out there for consistency sake that we're all drawing it at the same point and then having valid data that we're comparing apples to apples versus apples to oranges that people are drawing particular hemoglobins at different times.

Male: I guess my only comment would be that is an awfully prescriptive recommendation.

And although I don't disagree with it because it tends to be the standard, what precisely is the reasoning or the data that this now needs to be stated?

Ruben Velez: This is Ruben. I definitely agree that because this is the standard that I don't think there's any need to restate this on every single measure.

But again there may be some information we don't know about.

Karen Pace: So Tom or Bob do you have a thought about - I mean I understand what the committee is saying is, you know, if you do it for one it seems like you need to do it for all or is...?

Robert Wolfe: Yes.

Karen Pace: ...that a standard or...?

Robert Wolfe: Actually does CROWNWeb specify when blood work need be obtained?

Karen Pace: Not to my knowledge.

Thomas Dudley: No.

Karen Pace: No, it just has the value in there.

Peter Crooks: Yes. And I think the silence on that is that it's typically the clinical standard to draw - it's free treatment blood draws is pretty much standard but...

Peter Crooks: You know what...?

Peter Crooks: But I'm not sure if we can just say that 100% of the time.

Peter Crooks: And, you know, we know that but somebody from a health plan looking at the metric may not know that.

And it seems to me we have an opportunity during this year now to maybe add that clarification as we're reviewing metrics again for continuation and maybe that's something we should think about putting in all the laboratory measures. When is the blood drawn?

Ruben Velez: Well, you know, if we get there then it becomes very prescriptive because then as we all know, then you can really say well do you do it at the beginning of the week or do you do it at the end of the week, do you do it in midweek.

And that may change some of the parameters. And I'm not sure, you know, if we want to get to that detail.

Karen Pace: Right. But pretreatment wouldn't specify that level. It doesn't matter which treatment during the week. It's just that it should occur before versus after, right, is that what the issue is or?

Male: Yes, that's the issue. But the standard is to do it before.

And again my fear is the policing of this. And now you're talking about state regulators looking at this. How are we going to prove we're doing it?

I mean I just worry that it's an unnecessary burden, it's overly prescriptive, maybe misinterpreted by state regulators. And is going to I just think send the wrong message. I do think that every provider in the U.S. is trying to do the right thing, select the appropriate data, etcetera, and that they'll view this as an overreach. And I just don't know if it's worth, you know, going to the mat for.

Karen Pace: Okay. So the rest of the committee, do you have a - there's - we have two options. One is to let this be specified in all the lab measures. And the other is (confusion) sets the standard of care but it doesn't need to be specified in the measures.

But I'm hearing it really doesn't make sense to specify in one of the lab measures and not the other.

Male: I mean that's...

Peter Crooks: I think we'd all like to see consistency. And I'm kind of neutral on it. I don't know how - are there other committee members who feel strongly one way or the other?

Male: Well let me weigh back in since I brought it up. So calcium shouldn't be separated out. We all agree on the consistency.

But the other thing is there's a standard of care and there have been NQF measures related to dialysis for a number of years.

And if it's never required to say pre-dialysis, I agree with Bob. I wouldn't rock the boat and look like we're being overly obsessive about this unless there are lots of other questions across the

board as to when things were drawn. I think it's a given that there are, you know, pre-dialysis labs.

Karen Pace: Okay.

Thomas Dudley: Karen?

Karen Pace: Yes.

Thomas Dudley: This is Tom. May I...?

Karen Pace: Definitely, yes.

Thomas Dudley: ...I mean just make a comment? By stating pre or post or with this would it virtually handcuff us if there were research that came out that said that perhaps you should draw the blood post-treatment?

Karen Pace: Well you'd obviously want to have that change made.

Thomas Dudley: Yes.

Karen Pace: And that's something that could change pretty quickly but...

Thomas Dudley: Pretty quickly, okay.

Karen Pace: ...I think the, to respond to the prior comment, the prior ESRD measures to my recollection do not specify pre-dialysis, you know, that the labs were drawn pre-dialysis.

So why don't we - it sounds like and we can follow-up by email with the committee just to make sure that, you know, we do have...

Thomas Dudley: Okay.

Peter Crooks: And my sense of it is Karen that the committee is not over - is not really moving in that direction that we should amend all of them and we should not...

Karen Pace: Right.

Peter Crooks: ...we should probably leave this one alone and not...

Karen Pace: Right.

Peter Crooks: ...specify.

Karen Pace: Okay.

Peter Crooks: And I think that's the feeling of the committee right now unless others here have a - you know want to voice other opinions.

Karen Pace: Okay.

Peter Crooks: Okay.

Karen Pace: All right. So the next three and I think we can handle pretty closely - quickly. There was some comment about the hemoglobin measures or the anemia measures should also include CKD stage three and four.

And I'll just make a general comment. Obviously these measures were submitted to NQF for consideration just based on the ESRD dialysis patients or the ESRD patients. The call for measures did not restrict measures only include ESRD patients if a particular measure or focus was applicable to chronic kidney disease.

But regardless these measures were submitted this way. And CMS basically hadn't even considered including the CKD patients in their measure development.

So that would be a fairly substantial change that is probably not appropriate in the timeframe we're currently working on.

And Tom I don't know if you want to say anything more about that from CMS's standard point but it sounds like you're - you really want these measures for ESRD patients at this point in time.

Thomas Dudley: Yes, the focus right now from a CMS perspective is on the ESRD population. And also ties into data availability. We do have - right now we're using claims data and we will be using CROWNWeb which is inclusive of ESRD patients but not CKD in the earlier stages.

Karen Pace: Okay.

Peter Crooks: Yes. I think that settles the matter pretty strongly, you know, the data collection is only on dialysis patients. So we can't even if we'd like to.

And I think you can for as a general comment between CKD and dialysis patients, you know, these patients there is a difference. You know a patient not on dialysis there's one set of consideration and patients on dialysis it changes, you know, the landscape enough that I think that justifies things. You know these have to be considered separately.

Male: Peter to use your analogy of whether there's kind of two issues, one's data availability and then the other is the science of the question, and in both cases Peter it's a no that they have to be widely available and CKD patients are different than the ESRD anemia man.

Peter Crooks: Right.

Karen Pace: Okay.

Peter Crooks: So I'm...

Male: Both of them.

Peter Crooks: So we'll craft the responses to that.

Male: And I would include that for all times it comes up, you know, rather than reinventing the wheel.

Peter I think you're right on.

Karen Pace: Okay.

Peter Crooks: Okay.

Karen Pace: Well Lauren do you want to pick up on the discussion about the measures that we received comments on about not meeting NQF criteria? Do you want to...?

Lauren Richie: So this goes back to the point that Dr. Nally brought up earlier about some of the frequency and method measures not providing information on whether the data values actually

themselves are capturing - I'm sorry, whether or not the information (or the data) are being used in a way that actually will improve dialysis treatment.

And that they only provide information on whether or not the center recorded the patient's values or data and that having the measures or having the data themselves is not necessarily important and like as Karen mentioned does not meet the NQF criteria.

So I don't know how we want to do this. If you want to take this one measure at a time or do we just want to kind of consider the group of measures as they're listed there in its totality and see how the committee wants to respond to it.

Peter Crooks: Well I can start off. The - I would prefer - you know I don't think that we need to go through this measure by measure. I think that it's a general comment and we can discuss it that way.

The - and I would say too that...

Joe: This is...

Peter Crooks: ...too that in the comments, the draft comments I read I think you responded very well to. Who was about to speak?

Joe: It was Joe. To me this is the exact discussion we had at the meeting whether or not the simple tracking or measurement consistent with the measure.

And I think Rick and Barbara thought that each was different and therefore this was the first step of the equation.

So I mean I'd really be interested in what Rick has to say in terms of the measure.

Peter Crooks: Can I comment? Someone is typing on their keyboard and it's coming through pretty loud.

So if you're not speaking could you please mute if you can? Thank you.

Male: Yes.

Joe: Rick will this move the field forward?

Frederick Kaskel: Hello?

Peter Crooks: We hear you now.

Frederick Kaskel: Hello?

Peter Crooks: Yes.

Karen Pace: Do we still have Rick on the line?

Frederick Kaskel: Yes. Hi, there you go.

Karen Pace: Okay.

Frederick Kaskel: Intermittently on and off. Can we just rephrase that again so I make sure we have the right response here?

Joe: Yes Rick, it's Joe. And what I said was this - the last sentence here, you know, is an important step.

But the data don't set the bar particularly very high which was our discussion in Washington.

Frederick Kaskel: Right, that's right.

Joe: And so hearing those comments what's the pediatric nephrology response? Is this worth the effort to start here?

Frederick Kaskel: Right. On this last one. Hold on. Let me just read briefly here.

Karen Pace: Well it's about, pretty much about all of the measures that are just about the frequency or method of measurement.

And I think some of the - Joe's right. This was a...

Frederick Kaskel: Discussion.

Karen Pace: ...discussion at the in-person meeting. And I think there were two things that came up and as Joe mentioned there was discussion that this is a new area of measurement and the committee thought...

Frederick Kaskel: Right.

Karen Pace: ...it'd be better to error on the side of these measures than not to have the measures.

Frederick Kaskel: Correct.

Karen Pace: And I think the other thing at least for some of these even though I think the committee agreed that they were pretty low bar is that CMS has presented data that they weren't even being done.

And so I think the two things in combination kind of swayed the committee to go ahead and recommend them.

But I...

Frederick Kaskel: That's correct. I agree.

Karen Pace: ...think I was wondering if you have - and, you know, does the committee still feel that way or anything else to add to that I guess?

Frederick Kaskel: And when we sent this around for review we didn't get that much new additional information either.

Connie Anderson: And I think it really was. We've got to start somewhere. So let's star and then we can always as we collect data and get more information, make changes.

But it's a starting point. And I think that's the basis of the comments.

Frederick Kaskel: That was what - so I'm remembering now that there was so little. There is so little out there.

Connie Anderson: Right.

Karen Pace: Right.

Frederick Kaskel: That this is what Barbara and I were trying to review again to everyone that there isn't a lot of baseline data because we don't have it. And if you want to make any changes you need to start accumulate. That was how we phrased this.

Connie Anderson: And I think also part of the discussion was we don't even know if people are measuring it on a routine basis until it meets.

Frederick Kaskel: That's right.

Connie Anderson: We will begin to get that kind of information in the data as well.

Frederick Kaskel: That's why we went to this extent...

Connie Anderson: Yes.

Frederick Kaskel: ...because it is an unknown. And it should allow us to gather at least for the initial time period some baseline data to interpret whether this should go forward further after the time is - you know the allotment time is over to readdress it.

Peter Crooks: I think that the Steering Committee position could be reflected in the comments back - our response to comments that committee agrees that the more possible an outcome is the more useful it is to those who are interested in the results.

But in this case we do - have to do consideration to thought that is the first step and better than not putting something in place.

Bob: You know this is Bob. And I would like to broaden this out a bit because I absolutely agree. And Barb and I have had multiple conversations on this in other walks in life. And I think we've got to start somewhere is true.

But the committee as everybody knows has gotten a lot of pushback on this phosphorus measure particularly since in 2014 it's going to be in the bundle and CMS may indeed include it.

So if indeed we're going to go down the path with pediatrics which I absolutely agree with, we may look schizophrenic by not giving a little bit of consideration to how we're going to deal with a "Starting point" with a phosphorus measure knowing full well that we don't have ample data for that much like we don't have ample data on some of the other items we've discussed.

So I just think we need to be sensitive to how we word things.

Karen Pace: Okay. And just to, you know, there is a difference in the type of measure because the phosphorus was an actual level. These measures we're talking about right here were all about just doing the lab test versus the...

Bob: That's true. No, no, absolutely true.

Karen Pace: Right.

Peter Crooks: Is there a - I try to remember now from the original work. Is there a metric in place before that phosphorus should be measured for adults?

Karen Pace: I'm not sure.

Male: Wasn't that part of the last Steering Committee's...?

Karen Pace: I think it is.

Male: Yes.

Karen Pace: But I'll try to look that up as we - before we get to that measure because that's definitely one we want the committee to address so I'll double check on that.

Peter Crooks: Yes. If that's the case then I think we can strengthen our logic by saying yes, indeed, we're doing this for adults and but we haven't moved beyond it because, you know, back to scientific evidence that lowering phosphorus changes outcomes.

Karen Pace: Okay, I'll look that up and be able to tell you that by the time we get there. Okay.

So all right, Lauren you want to - let me just make a comment about the next two on our list if that's okay Lauren and then I'll have you take over again.

We did get some comments about harmonizing or combining with adult measures specifically on method of adequacy measurement and minimum of the Kt/V.

This also is something that the Steering Committee discussed. And as you know and it looked like some of the commenters picked up on the Steering Committee's recommendation or suggestion of if these were based on a standard Kt/V versus the single-pooled, I'm sorry. Single-pooled Kt/V that then you could do more with having all patients included regardless of frequency and, you know, kept one measure that could be stratified for pediatric and adult.

But CMS's response to the committee's question about that before we put this out for draft - this draft out for comment was that they didn't feel that there was enough data and study right now to move to a standard Kt/V.

So I just wanted to mention that. It is some things that were commented on.

But I don't know that there's really anything else to do at this point but wanted to see if the committee wanted to address that again in any way.

Peter Crooks: I think your comments - responses to the commenters are very good on this. And I think the committee's position is that we would love it if we have a standard Kt/V and use that and replace it for all - throughout all the adequacy metrics. But it's not ready for primetime.

Does the rest of the committee more or less agree with that or feel differently?

Karen Pace: I agree with that. And I think that was part of the discussion again that what may be appropriate for adults may not be appropriate for pediatric patients.

Frederick Kaskel: This is absolutely right. I mean I'm voicing the same thing you're saying. But it's Rick. And we're different. The kids are different.

Karen Pace: Yes.

Frederick Kaskel: And we don't have the real answers on this when we deal with growth and development and needs that are completely different in the adult population.

Karen Pace: And I think that was the discussion at the Steering Committee. And that's why we didn't harmonize them with the adults.

Peter Crooks: And the preponderance of the commenters who commented on this issue of should pediatrics be harmonized with adults said no, they shouldn't because they have to be considered separately.

And there were a few that thought otherwise. But I think most of them were favoring keeping them separate.

Karen Pace: Okay. So Lauren you want to move on then?

Lauren Richie: Yes. So we'll - now we'll move onto the measures or other measures that just had kind of general comments that just (focuses on) starting with 1463, hospitalization ratio for admissions. There were quite a few comments to recommend to include only those hospitalizations related to the outcomes of dialysis treatment.

And that there were questions to - for the committee to reconsider or carefully look at the calculation of the expected hospitalization rate.

So that the question for the committee, one, do you actually want to kind of go through that methodology and calculation. And two, whether that should be revised to include the outcomes of dialysis treatment for hospitalization.

Karen Pace: Well and let me just revise that just a bit. It would be very - that would take a considerable rework of the measure...

Lauren Richie: Right.

Karen Pace: ...to change the focus. And we can have CMS speak to that.

But generally trying to identify specific causes for admission becomes a very difficult issue in terms of reliability at least in terms of many of the other measures we've looked at for readmissions.

But I'll ask CMS and Bob from Arbor to - and Lauren, I know that they send a response to that.

Lauren Richie: Sure.

Karen Pace: But you may want to pull that up. But CMS or Bob you want to speak to that issue?

Robert Wolfe: Yes, this is Bob Wolfe. I can speak to a couple of issues. There was a TEP which met about this. And the recommendation of the TEP was that the primary measure overall hospitalization was appropriate.

In addition CMS I know is looking into specific hospitalization measures and is intending to convene a TEP to develop those.

But as somebody just mentioned that is a difficult and complicated issue having to do with a combination of balancing the quality of the data with the goals of coming up with appropriate measures.

The advantage I'll say - an advantage of the overall hospitalization rate is that we do have those data available in the claims very completed for Medicare patients. And we can count those hospitalizations and it does represent an important aspect of the overall burden of disease for ESRD patients.

Joe Messana: Bob this is Joe Messana. I'd like to add that I recollect from the TEP deliberations when the SHR was being debated and cause specific hospitalization came up, there was some concern expressed by several of the TEP members that as soon as you restrict to certain causes you create potential incentives to effect coding and that the general SHR, that's one of the advantages that several of the TEP members suggested for a general SHR rather than a cause specific.

Peter Crooks: I think there's at least two issues that we've kind of taken on overlapping. One is the restriction of cases. And I think that's one of several strong arguments that you - it just isn't possible or correct to try to pull out those that are related to line sepsis from other causes of hospitalization or ESRD related versus non-ESRD related.

And that's going down a path that leads to all sorts of unintended or extra consequences.

The other set of comments that we started talking about here is the comments about is this a valid methodology for standardized hospital days. And whether the Steering Committee should review the methodology.

And I wanted to comment that it seems that that's beyond the ability of our Steering Committee. That's a very technical exercise and one that I would not be comfortable making a judgment on.

I think the developers responded, you know, very well in one of their response to the commenters that this has been published. It's been reviewed in several ways and, you know, from what I said I don't have any way to know absolutely for sure that this is a good or the best available method or that it's valid.

But I think at this point I have to trust the developers and stay with, you know, and trust that the method is valid.

But it is something that I can't say for sure.

Do others have reservations about the methodology or concerns?

Connie Anderson: This is Connie again. I think we do need to go with the developers. This is way beyond I'll say at least for myself my own expertise in the methodology in terms of deriving the value.

Karen Pace: This is Karen. You know the - in the measure submission the developer did report on the validation of their method. And I think, you know, everything they reported was within norms of expectations for this type of measure.

But certainly, you know, since there were a couple of comments we wanted to bring it to your attention to see if there were any issues that you wanted further information about or, you know, clarification from the developer. You know we can certainly address that if, you know, if the committee needs more information or more explanation.

Male: So more information was provided by Bob and Joe to me was very helpful to keep things just as it is.

Peter Crooks: Yes I agree.

Connie Anderson: I agree as well.

Male: Yes.

Male: Yes.

Male: Yes.

Karen Pace: Okay.

Lauren Richie: Okay, it sounds like we have consensus to keep it as it is for measure number 1463.

Before we move into the measures that were not recommended I just wanted to make one comment about number 1460, the bloodstream infection measure. There were a lot of positive comments about this measure. There were really no kind of large overarching issues or questions about this measure.

So I think everyone is pleased with the two developers coming together for one measure. We don't have all the details yet but we are hoping to work with CMS and CDC on a one combined measure.

So now moving into measures not recommended, measure number 1427, the infamous phosphorus measure. As we've already touched upon a couple of times so far there was just multiple comments for the committee to reconsider endorsement for this measure on the basis that the evidence is just as strong as for the hypercalcemia measure and as well as for the point that was brought up earlier that this measure may or may not be included in the 2014 requirements.

So with that I will open it up to the committee.

Karen Pace: And this is Karen. I did look up and Peter your memory is great. We do have a measurement of serum phosphorus concentration that was endorsed in the project several years ago.

And it's a measure that will be under endorsement, maintenance review in the next phase of this renal project. So that measure does exist.

Peter Crooks: Okay, well that's good and...

Bob: So - I'm sorry Peter. Go ahead Peter.

Peter Crooks:well one brief comment I wanted to make is I don't buy the logic that because CMS has put this in the bundle, therefore we have to pass it. I mean I am almost offended by that logic because, you know, CMS is going to put what they want in the bundle or have and they're going to measure what they think is important. They would love to have NQF validation or support for all of their measures.

But they're not going to have it. And to say that we have to act as a Steering Committee because CMS is going to do it is backwards logic.

Bob: Yes. So Peter I absolutely agree with you. And I'm trying to look at this conundrum because you're correct. CMS is going to do a lot of things that is important to them. It is important for them to measure.

That being said facilities are going to be split with a lot of energy being spent on NQF approved measures for all the type science that are required for approval and in addition those measures that for whatever reason CMS has either financial or clinical feel also needs to be measured.

The question becomes, you know, where do we draw the line? Maybe this is a point to draw the line. There are many people out there that feel a little bit less strongly as we've indicated that there is some reasonable relationship between phosphorus and poor outcomes. Others disagree.

But it is going - there are - there is going to be a vehicle now to measure this. And much like we've argued for pediatrics where a lot isn't known because there is just any data, the question I think that people raise reasonably and this comes from across the board is if there is not a requirement for 6 or 5.5 or whatever how is that going to impact patients inasmuch as this product, this, you know, phosphate binders are going to be bundled. There is going to be a financial relationship between the use or the non-use and some number of a phosphorus.

So I guess it comes down to the preponderance of evidence. You know kind of the OJ Simpson argument that, you know, if we're going to operate in a criminal environment where you have to have evidence that you're refutable or a preponderance of evidence as in a civil case, so be it.

But I just - these conundrums make a lot of people uncomfortable and I guess my only point is would this be something because it may negatively impact patients if phosphorus starts floating up.

And in an attempt to save money or God knows what reasoning because this will be a bundled drug, is this something that we should in a time limited way take a look at?

Peter Crooks: I think we can also...

Male: But Bob wouldn't you think that then we should look at this as a process measure not an outcome measure where you...?

Bob: No, no, a process measure would be fine.

Male: Okay.

Peter Crooks: Well we have a process measure at least as far as phosphorus should be measured. What other process measure could there be?

Male: It could be something about plan of action. It's just like the weight. It's just like the post-dialysis assessment of weight. It's just what assessment or what did you - this is, we all know that this is a sticky point because in this measure if it becomes a measure this is a measure that the physician has only a small percent. I mean the physician might be doing all the right things.

But a lot depends on the patient, on the system, on the dietician. It's not like adequacy of dialysis where I control the adequacy of dialysis. Whether the patient shows up or not, that's a different thing.

But on phosphorus we all know what - you know all the components of the phosphorus aside from the science and the limited science.

And so if we decide on a process of what did you do to try to improve phosphorus versus just measuring phosphorus. That's one way we could look at it.

Bob: Yes. I mean there's no doubt we could tighten it up. And I guess I'm just more or less speaking my mind because this is a conundrum to me. I am actually very concerned as Ruben said if there's no accountability to a number or to something we believe to be reasonably valid.

CMS is linking phosphorus to money. I mean it's going to be in the bundle so I'm just - I don't know if that's going to have an impact. I just don't know.

Male: Listen I...

Peter Crooks: I'm afraid that even if, you know, if we were to pass this it almost may lead to reverse quality in that if by passing it then there's an inclination to use more of the expense of phosphorus binders, then there's less money available for other things.

And maybe...

Bob: But not in a bundled environment. Not - in a bundle environment it's always going to be avoiding the use of an expensive medicine. That's my concern.

Peter Crooks: I see what you're saying.

Jeffrey Berns: Jeff Berns, if I could weigh-in. I apologize for joining the call late. I would like to I guess reinforce what a couple of others may have said which is largely out of the control of the dialysis unit or the nephrologist, it's largely in control of the patient.

And there are potentially adverse consequences that could follow, you know, namely just continuing to blindly add phosphate binders instead of intending to diet or to the dialysis prescription or dealing with a noncompliant patient by just simply prescribing phosphate binders which may or may not improve this.

And none of it really relates to quality. You know there's nothing really around phosphorus that relates to the quality of care provided by the dialysis facility or the nephrologist involved.

And having said all that already there's not any way to defend six as the right number.

Bob: And Jeff this is Bob. And I absolutely agree with you. Can't defend 6 or 5.5 or 6.5.

But in a bundled environment as opposed to what occurred in a non-bundled environment where there's direct reimbursement for using expensive drugs, now the opposite is true.

So the argument that a doctor or an LDL or somebody would be over utilizing a product much like they accuse many people with EPO that flips on its head.

And my only concern is that if the opposite, if we're going to see phosphorus now floating up because the less binder you use the less, you know, the less - the more you have left over in the bundle. And you know that it's going to be problematic from the other end. That's my concern.

Female: (Well)...

Joseph Vassalotti: Bob this is Joe Vassalotti. I'm very concerned that we raise this logic. To me this sounds almost perverse because we could start to make the argument that well you know there's going to be a financial incentive for physicians to prescribe intravenous iron. This committee didn't pass the iron overload metric.

There's going to be a financial incentive for physicians to shift care from the dialysis center to the emergency room to avoid the cost associated with intravenous antibiotic administration.

Once you start talking about this as being the sole justification for performance measure I think you're really opening a can of worms that we should not approach.

Bob: And I accept your argument. I - and again I'm trying to have an open conversation here. And I hate that slippery slope.

But, you know, it was only a few months ago we had everybody in Congress pointing at doctors and LDOs and saying you guys are purposely overusing this or that, period. And we all know it's not true.

I'm just and again maybe this isn't right. But this is going to be a bundled item that I can bet my bottom dollar CMS is going to require be measured.

So I'm throwing it out there because we are getting heat. And we're going to no a cogent argument.

Karen Pace: Well it is the - this is Karen.

Joe: This is Joe. Let me...

Karen Pace: I just want to mention, it is - we do have the performance measure that phosphorus is measured on a monthly basis. So CMS is already requiring that it be measured.

The question is whether, you know, that something should be monitored or whether it...

Male: Right.

Karen Pace: ...should be turned into a performance measure at the greater than six level.

Female: (Not really).

Bob: Well let me make a specific comment there because if you recall I thanked you all for assigning this measure originally.

Male: Okay.

Bob: Given how contentious it was. But the spectrum would be there is a measure in place that it should be measured, should be followed. Then we had discussion about what constitutes a performance measure that level of science as opposed to a clinical guideline.

And then we have data available to the renal community which gets review in this contentious era by the (KDGO) and then a (KDOKE) commentary which states point blank the data aren't sufficient for a CPM on phosphorus and PPA.

And then we have a letter to us, lots of letters on this but at least one of the AINS also weighing in that the evidence isn't there.

So in my judgment there will be lots of people with their own agendas and own concerns about what might happen but right now there isn't sufficient evidence to tie you down to a six that makes morbidity and mortality better. We can all be faulted for not having this data in the well done trials.

But the bottom line is evidence-based medicine rather than worrying about CMS may do or this or that. Some of the arguments that Peter and Joe Vassalotti already articulated.

I mean unfortunately our hands are tied with a paucity of data and expert panels weighing in saying that the data do not permit the construction of a CPM.

And there's no question there's going to be heat on this. But I think we're sitting in the appropriate seat having made the decision we did in Washington and...

Joe Vassalotti: Yes and this is Joe Vassalotti. I wanted to say one other thing about that. I agree with you that monitoring patient safety in a bundled environment is a very important concern.

But there may be other ways to do it besides performance measures, things like ((inaudible))...

(Crosstalk)

Male: No doubt. And again I don't disagree with what's being said. I'm just trying to really get my arms around this.

And although Joe I absolutely agree with you, one could make the same argument about much of what we just said about standard hospitalization rates. You know lack of control, lack of definition, etcetera, you know, lack of clarity on the calculations.

You know we don't live in a perfect world and I just think it's good to have this discussion.

But I defer to your expertise and your comments because I don't necessarily disagree with them.

Jerry Jackson: Bob this is Jerry. I would just expand on what Joe just said. If CMS desires to kind of place - had level of importance on patient safety and to avoid unintended consequences it could use the Quality Incentive Program to set a cap on this.

So I think we should separate financial considerations as a separate issue not to be commingle with our discussions after safety. You know I think we should focus on the importance to measure for how we're reporting and quality improvement. And the financial considerations can be dealt with through other means in the system.

Bob: Yes. And I appreciate your comments. And I don't know if Tom Dudley is still on the phone.

Tom do you have any comments?

Thomas Dudley: Unfortunately I...

Bob: You can't.

Thomas Dudley: I can't. I do have some thoughts.

Bob: Okay, Tom thanks. Okay.

Thomas Dudley: I can give you my little opinion. But unfortunately where we are with making comment
((inaudible)).

Bob: Okay, all right, well I'm glad you were able to listen. How's that?

Thomas Dudley: No. It's very - it's a valuable conversation.

Jeffrey Bernes: This is Jeff Bernes. If I can make another comment, it may be a minor one but, you know,
I think one of the advantages of not having a performance measure in this regard is that it may
open the door more towards doing the studies that need to be done.

Whereas having a performance measure sort of, you know, sort of negates the need or may
reduce the incentive for anybody to do the studies that we need to answer this question.

It may not be an overwhelming reason to not endorse this measure but at least in my own mind it
reminds a consideration.

Peter Crooks: Yes, thank you. I think that's a good point.

Jeffrey Bernes: Yes.

Peter Crooks: It's a time for me to summarize and move on or should we continue the discussion further?

Bob: I've said my piece Peter.

Peter Crooks: Okay, thank you.

Male: Peter?

Peter Crooks: Well I thank the committee for really a good discussion. I think we've kind of touched on many aspects of how we decide this and what the criteria should be.

And I think the sense of the committee is we're - yes, we'd like to see the data that lowering phosphorus impacts mortality and morbidity.

And when we do, you know, we'll be jumping out in front and saying there should be a national consensus standard on that.

But short of that or other compelling quality arguments we're going to hold fast where we are.

Is that a reasonable summary?

Male: I'm good with that.

Karen Pace: I'm good with that too.

Male: Sounds good.

Male: Yes, thank you.

Peter Crooks: Okay.

Male: Got it.

Peter Crooks: So what's next on the agenda?

Lauren Richie: Okay, thank you Peter. We will - there were a few other measures that were not recommended that CMS asked the Steering Committee just to reconsider.

And they are listed on the memo there. And I'll just point that out quickly.

Measures on 1431, 34, 35 and 32. We can go through these kind of one by one or if there are any measures that kind of jump out at you here that you feel like there was some issues that came up in the comments that perhaps you want to bring forward to the committee again for reconsideration for endorsement.

Peter Crooks: Lauren was that question for us?

Lauren Richie: Yes, that's right.

Peter Crooks: Okay, sorry about that. I'm daydreaming I guess. Bob can you...?

Bob: Yes.

Peter Crooks: ...speak to this for us please?

Bob: Hello, can you hear me?

Peter Crooks: Yes.

Male: Hi Bob, yes.

Bob: Oh thank you. I'm sorry. I was picking up my phone.

We sent rationales for each of these and they - we believe that they are important. And if the committee has looked at any of those rationales and agrees we would be delighted to clarify any further discussion or help with any further discussion if there are remaining questions about them.

The - there are five of them there. I'm not going to try to make a general statement about them. I defer to the committee at this point.

Male: It seems to me that the three related to sodium we had a very pointed discussion about that issue in our in-person meeting that we probably all believe that those are good things to do. It's the question about level of evidence that would be sufficient for a CPM.

Male: I agree with that statement. We - even though in our heart we believe it there's again very difficult to find a good strong evidence for it.

Lauren Richie: And I would just like to ask the committee are there - of these measures listed here are there any rationales that you would like to review from CMS that we can pull up in the Excel spreadsheet?

Peter Crooks: Well regarding standardized hospitals, hospitalization, the number of days, 1464, I think there was a committee's sentiment that that measure - that metric is not appropriate for to be judged at the dialysis facility level that once a patient is in the hospital the dialysis facility has little or no control.

And does the CMS rationalization address that point?

Or Bob you may be able to recall whether you responded on that.

Robert Wolfe: This is Bob Wolfe. The two measures do reflect different measures of burden of disease on the patient.

And there are differences in the types of hospitalizations that patients face so that the total days in hospital captures a different or measures a different aspect of the hospitalization burden that the patient faces.

We have carried out analyses. Those have not been published that suggest that about half of the variation in hospitalization amongst facilities is attributable to the dialysis facility rather than to the hospital.

I will just state that as an informal piece of information which suggests the dialysis facilities as they do have a substantial component of attribute ability for hospitalization measures.

And I say it's informal because we have not yet published it.

And we do believe that this is an important issue about attribute ability. I will just give you that information for your own interpretation.

Peter Crooks: And in that unpublished data does that - you just mentioned hospitalization burden. Does that go further and say the total days versus the total number of admissions? Does it break it down that way?

Robert Wolfe: I'm not going to try and give that detail because the answer is each of them is attributable to the facility. What I don't know is whether they make independent contributions after the other is already accounted for.

Peter Crooks: Right, yes.

Robert Wolfe: And we haven't answered that question.

Karen Pace: Lauren you want to go over and highlight the measure developers, the comments on this one? Yes, there you go.

Peter Crooks: But I think Bob said though is a maybe an important point that if we are saying that we're holding dialysis facilities for excessive hospitalization that that may address and overlap with the same kind of things that would come out if you were holding them accountable for total number of days. And that by adding days would you really add anything to the effectiveness of what we've done.

It sounds to me like maybe not and...

Male: Yes, I think that makes sense.

Peter Crooks: I don't know. Does anybody else in the committee want to address these five measures, questions to the developers or whether we should be reopening any of them?

Male: Not me.

Karen Pace: Not me. I think we've thoroughly discussed these at our Steering Committee Meetings.

Male: Yes, I think I'm happy with our discussion. If Rick is - I don't know if he's in perpetual use there, but if he could comment on the first one that might be helpful, the iron stores for pediatric patients.

Frederick Kaskel: Right. This was an issue we addressed how appropriate this was in the measurement of the true set of iron homeostasis. And that got a couple comments to it didn't it, when this was sent out for review?

Karen Pace: Right. And as you recall, the committee did recommend the measures of actually managing the iron, the use of iron therapy.

Frederick Kaskel: Right. I don't think there was anything to change on that. I mean that was...

Peter Crooks: So that measure implies that iron stores have to be measured.

Frederick Kaskel: They do, yes.

Peter Crooks: So in a way this is a redundancy.

Male: To proceeding measure, yes.

Frederick Kaskel: Yes.

Peter Crooks: Proceeding, right.

Frederick Kaskel: But we do measure the stores. I mean that's part of the analyses that we (need) data for.

So would you want to change anything on this?

Peter Crooks: No. Okay, so hearing none, no other movement from the committee, I think we can move onto the next step in the agenda.

Lauren Richie: Okay. Towards the end of the in person meeting that the Steering Committee had there was a recommendation for a list of areas of performance gaps for future measure development for ESRD care.

And as a result of a comment period there were some additional topic areas that were ((inaudible)) for the Steering Committee to consider.

So what we wanted to do was just kind of throw this out to the committee to see if one, if you agreed with these general topic areas if they should be included in those future recommendations for measure development care and/or identify ones that should not be included or other topic areas that should be included that are not here.

So are there any objections to these topic items or any clarification needed? I will ask the committee that.

Peter Crooks: This is the last paragraph of the document sent out and...

Lauren Richie: Correct. I'll just pull this up.

Peter Crooks: And one - the second one, prevention of catheter-related infections was also in your response to the - to a commenter's number 39. You're asking the Steering Committee that question. Should that be on the list I think.

Lauren Richie: Correct.

Peter Crooks: Prevention of catheter-related infections and thrombosis be added as performance measure gaps.

Lauren Richie: Correct.

Peter Crooks: So.

Myra Kleinpeter: This is Myra. On the (amino core) resistance should that just be limited to pediatrics because we're finding an increasing number of resistant organisms in our adult population as well?

Karen Pace: I think that's a good point. Yes, right. That doesn't - wouldn't have to be limited to pediatrics.

Myra Kleinpeter: And perhaps one of the things in terms of autoimmunizations I know we were focusing on pneumovax. But as there are other vaccines in development what's the role of those other vaccines in our ESRD population?

Karen Pace: So what is your suggestion?

Myra Kleinpeter: Particularly when we - the - for shingles because we have seen a few cases.

Peter Crooks: So you're saying we could add to the list appropriate use of vaccinations in ESRD patients.

Myra Kleinpeter: Yes.

Peter Crooks: Okay. I think that sounds very reasonable.

Female: I like that suggestion.

Peter Crooks: I've got - this is maybe more for my information. But what kind of metric did you have regarding resistance that would improve quality or help us monitor because that's a complex phenomena. Would we be saying by facility, how many resistance microbes came up and what can we do about that?

I'm not sure how that would work out.

Myra Kleinpeter: So our issues are those that are coming from the nursing homes that are dialyzing in our units. I don't know if their level of routine antibiotic at those facilities is higher or that they're getting so many patients in and out of the hospital that they're getting colonized from all over the city.

So I'm not certain if we can have a performance measure that's geared towards those high risk patients which is nursing home residents as opposed to having that then become part of our general antibiotic resistance pattern for our particular unit because other patients have been exposed to these other patients.

Peter Crooks: So what I may be hearing you saying is that the resistance problem isn't so much for behavior in the dialysis units. It may be prescription behavior in the hospital or at the SNIF.

Myra Kleinpeter: At the nursing home and then we are now - if they're going to give us the responsibility of all these other hospitalizations we don't have any control over that. And yet we're being as that other measure above, number 1464 for the standardized hospitalization ratio, being forced to I guess look at that as one of the things that we need to address.

Connie Anderson: This is Connie again. I guess I would have some concern that if it's not in the realm of the dialysis facility and we're really looking at outside of the dialysis facility, the antimicrobial resistance in nursing home patients that those that have been hospitalized, I would hate to see that as a measure that we are responsible for at the facility level.

Myra Kleinpeter: Well perhaps the research should be geared so that we can show that we are not part of that problem so that it would not come back to us.

Peter Crooks: Well is there any research out there indicating that an antibiotic use from a dialysis facility is contributing to the antimicrobial resistance problem? Because I have no idea so I...

Myra Kleinpeter: I can't say. I'm not ((inaudible)).

(Crosstalk)

Karen Pace: And I guess, right, and I guess the question would be are there - you know what are the recommended practices for antibiotic therapy to prevent resistance and are those being done in dialysis facilities? I don't know.

Peter Crooks: Yes. Well that makes some sense as a possible metric that patients - that well correct antibiotics are being prescribed. But man that gets really complex, you know.

Male: I guess what I'm having trouble with Peter is that antimicrobial resistance would be the difficult problem.

But it's often facility or region related. And to try to apply this then to a national policy and hold a dialysis facility in some way accountable to it is difficult I think.

Peter Crooks: Yes. I agree that's a big step and...

Male: Part of the problem but it may not lend itself to ((inaudible)) of CPM.

Peter Crooks: So I'm not comfortable saying that this should be on a list of Steering Committee recommended areas for research.

Karen Pace: Okay.

Peter Crooks: Personally. Anyone else disagree?

Male: No.

Female: No, I agree.

Peter Crooks: Okay.

Male: And then on the other end of the list about the standard Kt/V about all dialysis patients included, doesn't that go back to our pediatric population and not simply just little people? I mean do we want to make sure that we always discriminate between a pediatric population...

Karen Pace: Right.

Male: ...versus adult regs?

Karen Pace: Right. I think...

Male: Yes.

Karen Pace: ...any measure that could be - you would always want to at least always stratify so that you could get different results for the - you're right.

Male: Yes. So the way that reads makes me really pretty nervous about...

Karen Pace: Yes, right. Okay.

Peter Crooks: So ((inaudible)).

(Crosstalk)

Male: The specific answer.

Karen Pace: So but you would recommend using standard Kt/V for adults and for pediatrics, right, but not to combine the results. Is that would you're saying?

Male: Correct.

Karen Pace: Okay.

Frederick Kaskel: I would agree. This is Rick. Definitely.

Karen Pace: Okay, yes. We can - we'll definitely get that clarified or make that clear.

Peter Crooks: I think what we should do with this is, you know, we already have a list I think from our meeting of areas for consideration for future metrics which is sort of a request list. The Steering Committee sort of requesting the, you know, community to submit metrics on various topics.

Karen Pace: Right.

Peter Crooks: And so maybe, you know, we can combine what's left over from this list with our other list and send it around again to the Steering Committee because I - you know there are some things that we would all agree we need research on, you know.

And but to say that we think they're ready for submission of performance measures may be a different...

Karen Pace: Okay.

Peter Crooks: ...thing. So maybe we should review them again before the final report goes out.

Karen Pace: Okay. That's good. So we can do that. And then if anything else comes to mind people can let us know as well.

Male: I think it would be great if we - there could somehow be some harmonization with whatever the CKD measures will be. Is there some issues like transplant and access to home dialysis that I don't really know how to address those in this domain but which might be addressed in the CKD?

Peter Crooks: So you're suggesting it would be appropriate to look at metrics that address availability of kidney transplant or home dialysis modalities, as a list of needed metrics?

Male: Be considered I think. I don't know how those would be constructed but...

Karen Pace: Right.

Male: ...to be considered and then I guess what I'm really saying is there are a lot of what I think you do in the dialysis facility is you play catch up because of what happened to the patient and the transition to ESRD.

So I think that these two processes need to be integrated either by having the same committee members or by some kind of oversight because having these committees distinct and completely separate I think would - might not be the best way to approach this. But that's just my opinion.

Karen Pace: Right, well...

Peter Crooks: Well...

Karen Pace: ...in the prior list we did include the transition thing so and we'll do what Peter suggested, add these things and send that out to you again.

And then Lauren you want to mention the renal project?

Lauren Richie: Sure. Actually we are slated to start the Renal Endorsement Maintenance Project next week.

And I do believe the majority of the current committee will remain on for the upcoming renal project.

And we don't have an idea yet of the number of the volume of measures but we certainly will get that out to the committee and we'll certainly forward the list of - include this list of performance measure gaps in the call for measures so that the new measures coming in will hopefully be inclusive of these topics as well as reviewing the list of currently endorsed measures so.

Peter Crooks: So for clarity Lauren the next generation of this committee will have two basic jobs. One is to review measures that were endorsed in the past.

Lauren Richie: Correct.

Peter Crooks: And decide whether or not they should continue endorsement or not.

Lauren Richie: Right.

Peter Crooks: And the second is a new group of submissions. And in that new group of submissions can be both metrics aimed at ESRD and metrics aimed at CKD.

Lauren Richie: Correct. As well as any other renal-related diseases out there besides CKD and ESRD.

Male: That's very great. Thank you.

Lauren Richie: Okay. So with that I'll just kind of quickly summarize. For the measures that were recommended we have a few that will remain as is and then for the others we will follow-up with CMS for clarification.

For the measures not recommended they will remain as they are, not recommended. The committee decided not to change their decision on the measures not recommended.

And for the list of performance gaps for future measure development we will review that list and circulate back to the committee.

Finally, I do believe we have to open the call for our...

Peter Crooks: Before we opened it I wanted to comment on...

Lauren Richie: Sure, I'm sorry.

Peter Crooks: ...three of your comment responses that I think we should handle real quickly.

The number - comment number 116, very interesting from the American Academy of Hospice and Palliative Medicine saying that they would like to see comment.

And I think we all would agree. You know what is the proper way to be handling this?

And what I thought you might include in the response is invite them to develop and submit such a metric...

Lauren Richie: Okay.

Peter Crooks: ...because they're the experts on it. And they may be able to help us out. I don't know where else it's going to come from.

Another - on comment number 83, you know, raised a question in my mind. You know they're asking how can we calculate this and how - and the tone was how do we - how are we going to be able to use these metrics?

And it raised a question in my mind, once these metrics have proved that CMS is calculating them, I would say a health plan, a quality person access the metrics and see how different dialysis facilities are doing. You know are they going to have to calculate it themselves or is CMS going to allow them - share the metric calculations with them.

Karen Pace: So Peter could you say again what you want us to ask?

Peter Crooks: Okay. So what I'm asking is once, you know, once these metrics are proved and CMS has - is doing them on a regular basis, will the metrics themselves be viewable by the public or...?

Karen Pace: Tom are you still on? I assume that you're planning to do a compare or maybe you already have an ESRD facility compare web site.

Thomas Dudley: Yes, we do have a dialysis facility compare. And that's the question about public reporting, correct.

Karen Pace: Yes.

Peter Crooks: So for these new metrics that the - that'll be added to facility compare.

Thomas Dudley: Once there's sufficient data and we're comfortable with the validity of the data that's being in completeness there's a probability that these measures, data for these measures would be reported on CMS web sites.

Peter Crooks: Yes, I think that's, you know, important that we're doing this work and we're being sponsored by various healthcare entities and health plans and those who need to know.

And you go through all this work and so at the end of the day they as members of NQF wants to be able to see that the outcomes of these.

Karen Pace: Right.

Thomas Dudley: And there's a strong portion. And to be as transparent. And if we're taking the time to require providers to submit the data we want to make it available.

Karen Pace: Okay.

Peter Crooks: Okay. And my final - there's a - one of your comments I wanted to make a correction. This is in number 115 and then the response, it starts out with the sentence, almost all dialysis care is paid by CMS. I think that's not really accurate.

Karen Pace: Really? Okay.

Peter Crooks: Yes, there's - I've seen slides and there's probably data out there what proportion of dialysis is paid for by CMS and how much is commercial, how much is others.

And I think the proportion paid for by CMS is probably more in the range of 50 to 70% and not - so I think nearly all (over states).

Karen Pace: Yes, definitely. Okay, thanks.

Do you know - and maybe...?

Male: I would check with CMS to get the numbers though.

Karen Pace: Okay.

Thomas Dudley: And I don't know the numbers off hand.

Karen Pace: Okay, but Tom that's something you can - you would know or be able to find out.

Peter Crooks: Yes, especially with the sort of 30 month - with the 30 month exclusion commercial has to -
cares have to take on much greater burden then they used to.

Karen Pace: Okay. All right, well now thank you very much for...

Myra Kleinpeter: So Karen from the U.S. RDS Annual Data Report (Alan) can give you - (Alan Collins)
can give you an idea. I think he said at the meeting last week in NQF somewhere around 70% is
paid for by CMS and the remainder being paid by commercial insurance.

Peter Crooks: Yes.

Karen Pace: Okay. Well we'll check that. That's good, thank you.

Myra Kleinpeter: Sure.

Peter Crooks: Okay, those are my comments. And before we open it up for NQF member and public
comment are there other left over issues from the committee?

Okay, well let's open up the lines for public comment then.

Lauren Richie: Operator if you can open all the lines please.

Operator: All the lines are open.

Karen Pace: Okay, are there any audience members that would like to make any other comments?

Okay.

Peter Crooks: Wow. We silenced all the...

Thomas Dudley: Karen can I make a comment?

Karen Pace: Yes.

Thomas Dudley: This is Tom Dudley again. I appreciate the - on behalf of CMS I appreciate the time the Steering Committee has devoted to reviewing of the measures that we submitted. And it was very valuable to us.

Karen Pace: Well thank you. And thank you to all the committee. And Lauren you want talk about next steps then? I know you recapped what we need to do yet. But you want to just tell them what the next steps are?

Lauren Richie: More than likely you all will be receiving an email from me just to kind of recap the call today and offer any clarification on some of the things that we will go back to CMS for and get back to you on those so you'll be getting something from me in the next week.

Peter Crooks: So do we anticipate anymore means for phone calls for this version of the committee?

Karen Pace: No I don't believe so. I think the things that we are going to follow-up on are just to talk with CMS just about clarifying those denominators in relation to the home versus not home patients.

Peter Crooks: Right.

Karen Pace: And we'll just can follow-up with the committee on email. So after we get these last few things clarified the next step is to indicate any of these changes in that draft report. And it will go to the NQF membership for voting and then from there it goes to the Consensus Standards Approval Committee and the Board for endorsement.

So unless some additional issues rise that we haven't already addressed we shouldn't need another conference call.

Peter Crooks: Okay. Good. Well let's take this opportunity to thank this version of the committee and for your time and focus and continue to watch the emails. There's going to be a few things we need to take care of.

And I think that's it for today. We made it under two hours. Good work.

Karen Pace: Excellent. And thank you all for your time and efforts and we'll be in touch as Lauren said next week.

Male: Thank you.

Female: Okay.

Female: Thanks.

Female: Bye. Thank you everyone.

Karen Pace: Have a good weekend.

Male: Bye.

Operator: This concludes today's conference. We thank you for your participation.

END