

NATIONAL QUALITY FORUM

Moderator: Karen Pace
October 13, 2011
1:00 pm CT

Operator: Good day, ladies and gentlemen, and welcome to the National Quality Forum conference call.

Today's call is being recorded and please go ahead.

Karen Pace: Hello this is Karen Pace and the first thing I need to do is apologize to the Steering Committee. Apparently, I gave you two different phone numbers. So if you're currently - if you're hearing music and not on a speaker line, please as the Steering Committee, please press star 0 and the operator will transfer you to the speaker line. So I apologize for that.

And while we're getting everyone into the speaker line, maybe I'll do a quick role call and then we can get started.

Okay can you send (Jessa) a note because I can't get it.

Okay so we have Peter Crooks and Kristen Schonder and is Connie Anderson?

Connie Anderson: I'm here.

Karen Pace: Good, Jeff Burns I know is trying get on the speaker line so we'll come back.

Lorien Dalrymple?

Andrew Fenves? Okay I think he's also trying to get in.

Michael Fischer?

Jerry Jackson?

Jerry Jackson: I'm here.

Karen Pace: Okay, Rick Kaskel?

Dr. Andrew Fenves: Hello can you hear me? This is Dr. Fenves.

Karen Pace: Oh good, good. Thank you.

Dr. Andrew Fenves: I'm here, okay thanks.

Karen Pace: Great, Rick Kaskel?

Okay Myra Kleinpeter?

Alan Kliger?

Dr. Alan Kliger: Yes.

Karen Pace: Great okay, Lisa Latts?

Lisa Latts: I'm here.

Karen Pace: Great, Kathe Lebeau?

Kathe Lebeau: I'm here.

Karen Pace: Thank you, Stephen McMurray was not available.

Joe Nally?

Joe Nally: Present.

Karen Pace: Thank you, Andrew Narva.

Dr. Andrew Narva: Here.

Karen Pace: Okay, Jessie Pavlinac? I believe she was going to only be able to be on part of the call.

Michael Somers?

Michael Somers: Yes, I'm here.

Jessie Pavlinac: And I'm sorry if you couldn't hear me, it's Jessie; I am here. I have to leave early, but I am here now.

Karen Pace: Okay thank.

Jessie Pavlinac: Thanks.

Karen Pace: Ruben Velez?

(Bobby Wager) - (Wiger)?

Janet Welch?

Jeff Burns: This is Jeff Burns. Are you able to hear me yet?

Karen Pace: Yes, yes we are, Jeff.

Jeff Burns: Thank you.

Karen Pace: Sorry for the confusion.

Jeff Burns: That's all right.

Karen Pace: Janet Welch?

Michael Fischer: Gene, (Liz), somebody?

Karen Pace: Who is that?

Michael Fischer: Karen, this is Michael Fischer. Can you hear me?

Karen Pace: Yes, yes we can hear you now. Thank you.

Michael Fischer: Yes.

Karen Pace: Janet Welch had a family emergency so I don't think she'll be able join us.

Harvey Wells?

Harvey Wells: I think I'm here.

Karen Pace: Great, yes you are. I can hear you. All right so let me just double check on a few that I didn't hear. Lorien Dalrymple?

Female: She has a message that she's trying to get on the speaker line.

Karen Pace: Okay.

Male: Operator, can you place her into the speaker line please?

Operator: Yes her line is open.

Karen Pace: Okay Lorien?

Dr. Lorien Dalrymple: Can you hear me?

Karen Pace: Yes.

Male: Yes.

Dr. Lorien Dalrymple: Okay.

Karen Pace: Okay, Rick Kaskel?

Myra Kleinpeter?

Ruben Velez?

And Roberta Wager?

Okay so is any of the Steering Committee still is hearing - or cannot speak or is not being heard, please press star 0 to signal to the operator.

Okay with that I'll ask Peter or Kristen, if they want to make any opening remarks and then just a reminder that this is an open call and is being recorded. And I'll let Peter and Kristen make some remarks and then I'll just quickly go through the agenda and process.

Peter?

Peter Crooks: Yes good morning everyone. Thanks again for calling in and as we work our way through this process. I think the good news today is that after this call we'll be able to do final voting on some 15 metrics which will give us the satisfaction I think of getting a big chunk of the work done, although as you realize there's still more issues to work our way through.

You know, and were hoping that the subcommittee work can help guide us to move things along, but along the course we would - we want your comments and Karen for people to comment, do we want them to type something in the chat line or just to speak up? Do you have any recommendations there?

Karen Pace: I think for the most part the Steering Committee can just speak up. If for some reason we're not recognizing you, definitely send us a note through the chat line, but I think for the Steering Committee we'll - you can definitely just speak up. That'd be fine.

Peter Crooks: Okay good and one other question I just wanted to be sure we all understand, the votes from the subcommittee's after they did their work and we voted and be viewed on the latest summaries that you sent around. Is that right?

Karen Pace: Yes.

Peter Crooks: So...

Karen Pace: And so we'll - I'll just kind of summarize those as we go through the measure, but yes those were on the summaries that were sent to the Steering Committee, what the work we spoke for.

Peter Crooks: Okay very good, just some news that Karen will share from CMS on adequacy measures and of course we have the letter from RPA/PCPI to discuss which we will later on in the agenda.

So Kristen before I turn it over to Karen to review the agenda, any thoughts?

Karen Pace: Welcome to everybody as well, good afternoon for those of us in the East Coast and I just want to remind everybody that whenever you're not speaking to please put your phone on mute.

Karen Pace: Okay great, so basically what we're - the goal of today is to review the status of the measures and what came out of the workgroup discussions and any measures that they may have revoted on, but think of it in terms of what clarifications or discussions the Steering Committee wants to have.

Okay what questions, clarifications or discussions the Steering Committee wants to have in order to feel that you're prepared to vote on these measures which will happen after the call as Peter indicated.

So what we're doing is we've organized the agenda so that we're first going to run through the measures that we think are ready for full Steering Committee action that you will be able to vote on after the call.

And then we're going to move into follow-up on measures reviewed at the meeting and then just a brief introduction to measures that - where there were revised submissions. And although we sent those to you, we really hadn't had time for any of the workgroups to look at those in depth so we thought that - and just given the volume of the measures we need to get through that that's the reason that we are scheduling one more conference call which we promise will be the last before this goes out to comment.

So with that we'll go ahead and get started unless the Steering Committee has any questions before we start through these measures?

Okay so we'll be starting in the Document 3 which was the summary from the dialysis adequacy workgroup review and as Peter mentioned what came out of the workgroup discussions was with the measures of assessment frequency or method assessment, there was a recommendation out of the workgroup for us to go back to the developer and see if those could be incorporated into the associated outcome measures.

So for example 0247 was the monthly measurement of the delivered dose and 0248 was about the method of the measurement of the delivered dose and you had previously reviewed 0249 at the meeting and approved that which was the actual minimum dose for dialysis adequacy.

And CMS responded that they were willing to do that to incorporate those into the outcome measure and in the latest call that I had with CMS, they indicated that they didn't think that they needed to revise the outcome measures, but also believed that with having the outcome measure they did not need to have these two assessment, either the frequency or the delivered dose.

So their thinking was that with the regulatory payment structure that there was sufficient safeguards that facilities would measure dialysis dose on a regular basis and that the key thing as you all had indicated was to have the minimum delivered dose as the intermediate outcome measures.

So I'll stop there and see if anyone has any questions or concerns about that. Tom Dudley from CMS is on the line as well if you have a question.

So are those of you who are on the dialysis adequacy workgroup or that call - does that - are you comfortable with that resolution?

Peter Crooks: This is Peter Crooks. I think that's a positive step and I think what it means too is that we don't have to - these are effectively 247 and 248 are effectively withdrawn and we don't have to discuss them further if the committee agreeable?

Male: I mean this is becoming part of the QIP or the proposal, that this is part of the QIP for 2014 so there will be a financial penalty in place for not meeting the Kt/V standard?

Karen Pace: Well the measure 2049 is the Kt/V...

Male: Exactly.

Karen Pace: Right.

Male: That's supposed to be built into the QIP funding mechanism I guess in 2014.

Karen Pace: Right, do you have a question about that or?

Male: I'm confirming that it makes sense.

Karen Pace: Oh okay, thank you. Thank you and also I forgot to mention this earlier, if you would identify yourselves as your making comments. That will help everyone kind of be oriented to who's speaking. That would be useful, thank you.

Okay so if there's no questions or comments about that - and let me just ask - well let's go onto 0318 then which is the next one in that group. And this is the Peritoneal Dialysis Adequacy of the delivered dose of peritoneal dialysis above the minimum and this is for adult patients and it's the percentage of peritoneal dialysis who's delivered peritoneal dialysis dose with a weekly Kt/V urea of at least 1.7 which was dialytic plus residual during the four month study period.

So there was - this was discussed on the last workgroup call and you can see that in the voting - and there is one correction I need to make in the information that was sent out to you regarding the voting on scientific acceptability. There was still some split in the thinking of the workgroup about whether this measure met scientific acceptability, but generally the majority voted to rate this as higher moderate so instead of a no that should be yes in terms of the majority thinking this would meet scientific acceptability.

I think one of the issues that came up that was discussed on the workgroup call was that the inter-unit reliability was .57 and that the validity testing really didn't show that there was an association with the mortality ratio. We had some discussion among the workgroup, then committee members on the call and the developer about one of the difficulties with this measure

is the small number of patients and so resulting in wider confidence intervals as kind of explaining those findings.

But I'm going to stop there because I think that was the major point of discussion and probably what you're seeing reflected in the workgroup vote so I'll stop there and see if anyone wants to make any comments or have further questions or clarifications about that, so...

Peter Crooks: Yes well I think just to summarize that again, that on that call the group felt that it was sort of unavoidable because the were small numbers in that by-and-large we would accept reliability and validity because there wasn't a way for them to narrow the confidence intervals.

Karen Pace: Right.

Peter Crooks: So...

Karen Pace: So we can come back to that if anybody wants to. In addition, you know, we also had two measures - the next two, 0253 and 0254, which are the - 0253 was to have measure solute clearance at regular intervals and 0254 was again the standard method for measuring that.

And again the recommendation from the workgroup and the members on that call was to address that within the one measure, the outcome measure. And again, you know, basically the same response from CMS. They were willing to do that and then the further conversation was that they thought that the outcome measure as it was specified would be sufficient.

So and I'll just ask Tom Dudley, do you want to say anything more about that? Am I characterizing what you told us properly?

Tom Dudley: You summed it up quite well Karen, thank you.

Karen Pace: So then this would be the similar situation that we would have the measure of the delivered dose, but not the associated assessment measures because obviously you have to assess in order to get to that delivered dose. And CMS thought that there were adequate safeguards or regulations and other things in place that there was not a concern that facilities would not be measuring this.

Peter Crooks: So Karen this is Peter, for clarification and we will be voting on 318 and we won't need to vote on 253 and 254.

Karen Pace: Right I will in the follow-up, we'll probably just ask people to be in agreement with that, that we don't need 253/254 to make sure we haven't missed any issues. But basically you'll be voting on 0318. Correct.

Okay any questions or comments before we leave the area of dialysis adequacy?

Dr. Alan Klinger: This is Alan Klinger.

Karen Pace: Yes.

Dr. Alan Klinger: Just one that the working group had two additional recommendations moving forward from here. One is that measures of adequacy for hemodialysis did not include endogenous kidney function while those for peritoneal dialysis do include endogenous kidney function. And the working group didn't see there was a systematic reason for that difference and so for the future we're suggesting to the developer to adopt 100 for measuring both.

And the second that we discussed for the future is moving to a standard weekly Kt/V for hemodialysis, rather than single-pool Kt/V for the reasons we've discussed.

Karen Pace: Right, thank you. And just one comment about the endogenous kidney function, you may have recalled that there was actually a measure that had been recommended in the prior ESRD project that brought in some of the issues regarding residual kidney function and CMS was not able to implement that data element and so had not been able to test it.

But I think, you know, we definitely need to include this recommendation for the future - the next round that these measures come back so is there any other discussion about that or disagreement?

Tom Dudley: Karen?

Karen Pace: Yes.

Tom Dudley: It's Tom Dudley.

Karen Pace: Yes.

Tom Dudley: I just wanted to respond to Alan, we have - we're in early stages of planning ((inaudible)), the focus is on frequency with dialysis. We'll have to see which will probably lead to what you were recommending there, the standard weekly Kt/V. So we there will probably be a step in the very near future and we'll take the residual renal function, we'll reconsider that as well.

Dr. Alan Kliger: Great, thank you, Tom.

Tom Dudley: You're welcome Alan.

Karen Pace: Okay so let's move on then to mineral metabolism, but so let me just - before we leave here - there are obviously some other dialysis adequacy measures that have some outstanding issues that we'll come to. But the idea was to group these according to the ones that we thought would be ready for you to vote on.

So we'll go ahead and, you know, have this on your final voting and we'll move on to mineral metabolism then which is Document 4 was the summary from that workgroup call. And we can start with measure 0255.

And in the - this was discussed by the workgroup and then subsequently revoted on by the workgroup and those results were provided. Generally the majority I guess felt that this measure met our criteria.

I think the major point of discussion was as we had with many of these assessment measures is that they are not proximal to the outcome and in this case there was discussion about there's no evidence that changing the ((inaudible)) actually changes survival or mortality.

But I think the bottom line was that the workgroup and committee members thought that it was an extremely important issue and the current state of science doesn't really allow a performance measure of an actual value and so the Steering Committee thought with the current state of science this was the best that could be done for performance measure.

And I will stop there and let the workgroup or other members comment on that or add to it or correct anything.

Joe Nally: It's Joe. I think that's a very accurate and diplomatic summary.

Karen Pace: So I think that it's obvious that so the difference between this measure and the one's we just talked about that will be going away is that we don't have an associated intermediate outcome or any kind of, for example treatment process performance measure that would be - might be considered better. But we just don't have those, so.

Jeff Burns: This is Jeff Burns. Just a lingering concern I have and again if we're going to think about evidence basis even if one concedes to the need to check (phosphorus), the specific requirement this be monthly is kind of a nagging problem for me.

And part is we're thinking about healthcare costs, not that this is a major contributor, but you know one could argue that checking it quarterly or some frequency less than monthly still sufficiently adequate is the goal here is to just make sure that people check it from time to time. I'm not sure that we can change the performance measure or, you know, that we necessarily should.

But it still remains a problem for me just thinking about how these measures are constructed.

Karen Pace: Right, no that's a good point and I meant to mention that because that was definitely one of the other issues that was discussed. So do you want to make a proposal to the committee or to the developer or should we ask the developer to respond to that?

Jeff Burns: You know, we can ask the developer to respond. I would be just as comfortable - actually I'll be very comfortable with having a single measure that encompasses non-dialysis, CKD as well as dialysis CKD requiring or based upon quarterly measurement and eliminate one performance measure and just include both groups as a single measure.

Others could argue otherwise, but I think that's also - would be a reasonable approach.

Karen Pace: So CMS or Tom I don't know if you want to answer this or your developer, but is there any reason this should be at a monthly measurement frequency?

Tom Dudley: This is Tom again and I wasn't involved with the most recent discussions about this, but I think originally it was based on kind of the clinical standard, the ((inaudible)) population.

Bob, you're on right?

Karen Pace: Pardon me?

Tom Dudley: Is Bob Wolfe on?

Karen Pace: Yes.

Bob Wolfe: This is Bob Wolfe. Hi and Tom and I cannot speak to the experience with the clinical standard, but that is what we typically see in the data that are available to us as a monthly report so this was based upon what we see in the data rather than any real clinical basis for saying it has to be done at least this often.

Karen Pace: Right.

Bob Wolfe: But it seemed consistent with the practices that we were seeing.

Karen Pace: Right so I guess my question would be is it - those of you who are more involved in the practice - is it done that way just because it's easier to get all these lab values at the same time on a regular basis rather than having different frequencies or is it grounded in any kind of clinical...?

Dr. Andrew Fenves: This is Andrew Fenves. I think it's grounded in grandfathering down clinical practice.

For the last 25 years it would get monthly CMP's or competency panels that would include (phosphorus), at least at our place.

Karen Pace: Okay.

Jeff Burns: This is Jeff Burns again. We get it because it's paid for on a monthly basis.

Dr. Andrew Fenves: I don't disagree.

Dr. Alan Kliger: You know, this is Alan Kliger. Actually more than 25 years.

Dr. Andrew Fenves: Okay.

Dr. Alan Kliger: But we've always obtained since we've had formal dialysis facilities working, we've got monthly based on no data, but on seat of the pants and it's been paid for so it's been carried forward.

I believe Jeff's question is a very good one based on the current data that we have. My advice would be to question that for the future and to because there are no data one way or the other, to leave this measure as it is and to vote on it as it is.

Karen Pace: Okay, all right. Any other comments?

Male: I would second Alan's comments because although we have talked about different tests individually, the reality is on a frequency which tends to be monthly. You're getting an electrolyte panel, calcium, of phosphorus, etc., etc. and no matter what our deliberations would be say

calcium versus phosphorus, if we want one but not the other, the reality is both are going to be obtained because they are - come together and are paid for together.

But clearly I think phosphorus contains the most weight at least in terms of implications related to mortality and I really think Karen did a wonderful job in summarizing the thought of the committee right up front.

Dr. Andrew Fenves: Yes I agree.

Karen Pace: Okay any other questions?

Male: And I guess I would only add that that is part of what we would call a CMT which is a different discussion then say a PTH level and that's why I think we've looked at the data a little differently too.

Karen Pace: Okay, all right so we'll move onto measure 0261 which is measurement of serum calcium concentration. This is another frequency of assessment measure and the recommendation that came out of the workgroup discussion for this measure was similar to what we've already discussed with the dialysis adequacy in that in the previous project a measure was endorsed which was they measure of hypercalcemia.

So the intermediate outcome measure and the recommendation or request of the workgroup to CMS was again to have one measure that dealt with assessment plus the value. And like the other CMS was agreeable to this and their latest thinking was that having the measure 1454 I believe it was of hypercalcemia was sufficient without needing the assessment frequency measure.

Male: All right Tom.

Tom Dudley: You're welcome.

Karen Pace: Okay so any questions or other comments about that, that we need to address?

Okay then we'll move onto to 0574 and I - okay this is another measure of monitoring calcium and the difference with this that the measures that I was just talking about was about facility level and specifically for the ESRD, the dialysis population. So this measure is chronic kidney disease monitoring calcium and its monitoring blood calcium levels at least annually.

The denominator are patients with at least one inpatient diagnosis of chronic kidney disease during the year prior to the measurement year or with at least two diagnoses of chronic kidney disease in an outpatient setting during the measurement year or prior year.

Okay so let me get onto what the workgroup discussed this measure on their call and then revoted on the measure, which are provided in your summary document. But basically it looks like the workgroup and committee members involved in the discussion did not feel that this would meet our criteria for impact performance gap or evidence. And then also had some concerns about the reliability and validity data that were provided.

Now and I'll just mention because some of these comments reference measure 0570 which the workgroup did ask for - did say that they would look at some additional information which has been submitted by the developer, but again this is one of those revised submissions that we're going to delay because we really didn't have time for everyone to look at that in advance.

So my understanding from that workgroup call is that you specifically wanted to look at 0570, but have not called that out for these next two measures. But I will stop there and see for the

workgroup if they want to make any other comments or comment on what their concerns were about this measure.

Peter Crooks: Karen I think it's pretty clear reading through the notes it was a pretty strong feeling that this wasn't meeting the criteria.

Karen Pace: Okay.

Peter Crooks: So I think we can (imply anybody has questions).

Karen Pace: Okay, all right so the next one is 0571 and this was chronic kidney disease monitoring parathyroid hormone and this was the percentage of members who received a PTH level test during the measurement year. And the denominator are patients with chronic kidney disease during the prior year with at least two diagnoses of chronic kidney disease in an outpatient setting during the measurement year or the year prior. For members on dialysis or who utilize dialysis during the year prior to the measurement year.

Again the workgroup members and committee members on the call discussed this during that call and then revoted on this measure and those results are provided in the summary and it appears that the majority of the group voting on this did not think it met criteria for impact for evidence. And also had concerns about the reliability and validity data.

Peter Crooks: This is Peter again. I think one of the parts of the discussion I recall was that in terms of making sense, the denominator group includes (Stage 3A) patients I believe. We wanted to try and understand who we're supplying to and didn't think it made - well no one's, you know, saying (PTH) shouldn't be measured in the use when appropriate. Supply it to the entire group really doesn't make sense.

Joe Nally: Yes it's Joe, I think that was fundamental in several of these tests in that we teach certain things in renal physiology about progressive CKD, but as we tried to apply this to the clinical arena and recognize that there are many millions of patients with Stage 3A CKD trying to associate some of these values, in this case PTH, with any outcome or behavior pattern. It became very difficult to recommend it to millions and millions of patients, particularly with the earlier stages of CKD.

Karen Pace: Okay any other questions or comments about that measure or any of these measures that we've discussed under mineral metabolism?

Okay so we'll move onto patient education and vascular access which are in Document 5 workgroup summary and we'll start with the patient education measures. And Dr. McMurray was not able to be on the call, but he sent some notes that I forwarded to the committee just a short while ago so hopefully you received those and I can - I'll mention that as I go through the workgroup summary comments.

Okay so if - I'm going to just pretty much talk about these together, but I will make some distinctions where needed. 0320 these are ((inaudible)), 324 are about patient education, 0320 is at the physician level and 24 is at the facility level.

And I'll just give a brief description, these are for adult patients with documentation of a discussion of renal replacement therapy modalities including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors and no or cessation of renal replacement therapy at least once during the 12 months reporting period.

I'll mention a couple of the issues that were raised on the workgroup calls and also the full Steering Committee actually started through the evaluation of these measures at the meeting, but unfortunately we didn't get through the entire measures and you may have recalled that there

were discussions about the evidence presented did not necessarily match the way the measure was constructed.

But the Steering Committee at that time had voted that they wanted to proceed with reviewing the measures because of the importance of this topic area, but at that time they hadn't gotten through the full evaluation. So a couple of the issues that were addressed on the workgroup call and clarified that these measures are not - the data for these measures are not currently ((inaudible)), the developer has had some discussions with CMS about that as a future possibility.

But just to clarify, that doesn't mean that the measures could not go forward, it just means that to implement them currently would require looking at the medical records and that's how they were testing so that's not really a problem in terms of moving forward if you choose to.

The other discussion was about that there are regulatory requirements now for facilities to make sure that patients have this education regularly and there was some discussion that if that's case then it's a performance measure needed. Again that doesn't necessarily mean that we can't have a performance measure, there could be reasons to do that - it was also noted that the survey process is often times behind schedule and, you know, having performance measures may actually inform the survey process.

So in and of itself does not necessarily mean the measures should not go forward, but there obviously were other issues that were discussed about the measures. The other question that came up was physician versus facility responsibility and again, you know, they're obviously a shared responsibility and I don't think the intention is to try to parse out what physician responsibility or the facility responsibility.

But there is shared responsibility so again that would be okay to have that measured for both facilities and clinicians. Having said that, the workgroup and committee members that were on

that call revoted on these measures and still had quite a bit of concerns about them in terms of their meeting the criteria.

So I'm going to stop there and let some of the workgroup members maybe fill in while I just check to see if there are some other things from the discussion that I should note for you.

Connie Anderson: This is Connie. I think one of the other issues we had with this measure was it just talked about the documentation of a discussion and that doesn't reflect whether, you know, did you hand somebody a piece of paper and did they understand what it meant. There's no measure, it's just documentation of a discussion and I think it's a checkbox, you know, did you mention this and really no reflection on what kind of quality of education or discussion there was.

Lisa McGonigal: Right, this is Lisa. I agree with you -- I completely agree with you, but in the absence of that, you know, I guess my thought is that it's not.

Andrew Narva: I'm not sure it's better - this is (Andy) - I'm not sure it's better than nothing and especially since it doesn't go beyond the scope of work requirement and it could end up just institutionalizing an inadequate process. I mean I think everybody thinks that a performance measure on education of patients is absolutely critical.

This isn't it and I mean we need more than what's there and if we have something that's inadequate and actually doesn't add anything to what CMS requires. I'm not sure what we've gained.

Jeff Burns: This is Jeff Burns. I would echo that and in addition when I think when one considers the burden this is going to impose in terms of collecting the data particularly for the physician level assessment that there's little gain, certainly no guarantee of any gain for what's potentially high cost.

Dr. Alan Kliger: Yes this is Alan, I wonder why this measure was brought before us at all I must say because as I understand the new requirements, we need evidence of adequate testing of the measure in order for us to be asked to examine it and unless I'm missing something, I don't see that there was adequate testing of the measure.

Karen Pace: Well the measure was tested using medical record chart obstruction and both of them were tested that way so the question is whether, you know, and that's again the measure currently, you know, there's no data in CROWNWeb so that was an appropriate way to look at the measure as it's specified and to look for documentation in the medical record.

Is there some other aspect that you had a question about Alan?

Dr. Alan Kliger: Well I guess I was looking for a more proximal - I mean if we're simply looking at whether we have a checkbox that checks off if that is the only piece of the measure and we're looking for that then I join...

Karen Pace: Well I think and I'll ask Lisa McGonigal to respond in a moment, but my understanding is that they didn't create it as a checkbox. Their way was to actually look in the medical record for documentation of all of this information, not to look for a checkbox. But I think the discussion about it is that in terms of a measure it could be kind of looked at that way, it's kind of a check whether it was done or not is the actual performance.

But Lisa McGonigal, you actually looked for narrative documentation of this or in the medical record, is that?

Lisa McGonigal: Yes that's correct Karen.

Connie Anderson: This is Connie again. I guess I would also question the reliability of extracting it from a medical record in terms of the documentation process, you know, it could possibly be that the education was done, but the documentation wasn't there. So I have real concerns even about the reliability of - or the validity actually - of this measure.

Lisa Latts: Guys, this is Lisa. I really think we're imposing an impossible bar. I - based on what you guys are talking about and what I know is a performance measurement, I don't see how you could ever get a measure that does what you're talking about in this area. I mean the only other way to do it is to have somebody recording every patient intervention and then viewing the recording to see if it happened.

I mean if you don't look at the documentation, how else would you assess whether it was done and what else do we have besides ((inaudible)). I just think it's - this is incredibly important and you all are saying that we need a better measure. I would agree with that, but I think in the meantime we need a measure.

Dr. Alan Kliger: So Lisa, this is Alan. Let me merely respond to that, of course we've agreed and published data on the importance of education, but there are ways of measuring and assessing the effectiveness of education and it would be a more proximal measure than simply a checkbox about whether or not somebody discussed some educational piece.

So our job is I think to be clear about following the rigor of an NQF for given measures, not to say we do or don't agree that something is important. That's the first step, but it's not the last step and if measured developers can be encouraged to develop measures that have more meaning, I that's part of our job as well.

Joe Nally: It's Joe and maybe this is a question then for Karen because we've all struggled with the absence of evidence and the difficulty with the methodology of this and its companion measure.

But I think in our heart of hearts, we're all in favor of the patient education process and particularly, you know, mentioning dialysis or other dialysis options, etc., etc. And in fact I think most of us would very strongly vote for education much more proximal in the process prior to dialysis.

My concern here is if we end up doing nothing in terms of passing neither of these measures, what are our options such that we can deliver a clear message that we are pro-education, but have standards suggesting we need a better measure to vote upon?

Karen Pace: Well it's a good question, I mean the mechanism we have is in the report to explain your vote on these measures and to, you know, include in the recommendation a strong recommendation of development of measures, of patient education and to be more specific about what you see is a better measure.

The I guess, you know, I don't know that this is a formal thing. I mean the other way is to, you know, put this measure forward or move this measure forward with the strong recommendation that by the time of next maintenance review expect this measure to be replaced by a much better measure. You know, I...

Joe Nally: My gut tells me that if we don't at least have some stance here along the lines of minimum of a checkbox this time around, but place impact that much more that the view is sending a message that education is not considered to be important. And I just don't want to send that message I guess.

Karen Pace: Right.

Lisa McGonigal: Karen, can I explain - can I speak for a second?

Karen Pace: Yes Lisa?

Lisa McGonigal: Yes this is Lisa, I just wanted to point out that KCQA does acknowledge that educating - doing an assessment of patient comprehension of education is very, very important, but it is an entirely separate major. There is evidence in the recent (cost) study that educated patients ((inaudible)) even though there's no additional or separate patient comprehension attachment.

They used standardized, readily available material there and just to set that the education had taken place, as you will on the second checkbox and there was significantly improved outcomes with that. Again I think voting this down is as you said, it's - education is very important at patient's center and this is the measure that's available at this point in time and it has been shown in studies to improve outcomes.

Jeff Burns: This is Jeff Burns. If I can make a comment. I think it's far-fetched to believe that anybody is going to look at what we do as committee and take away the measures that we opposed to patient education. That's really just completely absurd in my mind. I think it's worth getting back to Alan's comments earlier in that every measure developer knows the criteria by which measures are going to be deemed appropriate or inappropriate or acceptable or not for endorsement.

And I think we should keep to that and if, you know, taking emotion out of this - and I think there's a lot of that involved here - if we just look at does this meet criteria for endorsement, the decision should be made - that criteria, those criteria alone, not sort of the mom and apple pie issue of whether we think education is good because none of us disagree with that concept.

Lisa Latts: Actually Jeff, I would disagree with that - this is Lisa - for a couple reasons. One is I think that we have an absolute bar, but that bar becomes so high that you end up with frankly what I sort of believe this committee which is an absence of measures and I think that...

Male: Hello?

Female: Hello?

Male: Poor Lisa, somebody gave you the hook.

Male: I didn't do that.

Male: I think Jeff has a mute button.

Lisa Latts: Can you guys hear me okay?

Karen Pace: Is that Lisa Latts again?

Lisa Latts: Yes, yes.

Karen Pace: Okay, all right.

Lisa Latts: Well I'm just saying it's a real problem for me not to have measures and would I rather have not perfect measures and have the measures then wait for perfect measures, absolutely. I do think that having no patient education measures, it may not be a message, but it certainly leaves a huge void in the field of performance measurement as well as what it opens the door to is even more variation because people will put measures out there that aren't NQF approved.

Because next time - Karen, when would be the next time a measure developer could submit a measure? Would it be three more years?

Karen Pace: It would be in - yes about three years. Though we do have a project that's coming up next year on patient experience with care - and this is something I don't know off the top of my head - it's whether the ESRD (CHAPS) instrument addressed education because that measure - ((inaudible)) was not able to submit the information, you know, that information was endorsed last time around and they didn't have the resources to submit the measure for this project, but are planning to bring it in when we have a broader patient experience with Care project next year.

So does anyone know off-hand, otherwise I will definitely get that information for you whether that ((inaudible)).

Dr. Alan Kliger: No this is Alan, but I guess the one thing I'd say Lisa is, we could adopt that position. The problem with it is that systematically it means that we should throw away all the criteria that we use and simply use the criterion is just an area that really must be addressed, whatever the content of the measure and, you know, we could do that.

My own sense is that that would not serve the community well.

Lisa Latts: And one more question for Karen, maybe if you can talk about to how this measure compares to other patient education measures in other specialties and fields. Can you speak to that at all?

Karen Pace: Not really off the top of my head, I will say that this is an issue that's come up more frequently when measures get to the Consensus Standards Approval Committee so, you know, that is definitely a question that would be asked at that point in terms of it may be backed by criteria.

I mean the general discussion at the Consensus Standards Approval Committee for patient education measures is really looking to move to measures from the patient point of view which could still be not even comprehension, but did they receive information, you know.

So the idea is in general, you know, the goal is for performance education measures to start being measured from the patient perspective whether the first step is just them acknowledging they received information and, you know, obviously as you pointed out the challenges of measuring, understanding and comprehension are, you know, things that are probably further in the future.

But the idea that they've discussed is trying to get at this from the patient perspective. That's why I brought up the question of what's on the (CHAPS) instrument and I will definitely check into that and get information back to all of you, but I'm sure that we have measures from prior projects that are in this vein.

But as you all know and QF has been, you know, strengthening their evaluation criteria so I'd have to check, you know, and I certainly am willing to find that out for you and give you that information as well.

Joe Nally: Karen, its Joe Nally again with another question. As I'm reading under comments under 2A reliability, it seems like there's a good observation there since this is being endorsed for three or more years, there would have been an expectation for additional data.

So is there any information about having patient's be exposed to education and how they might have changed in there - in this case they used switching to home dialysis or kidney transplant - is there a measure development on the line that could answer whether they've looked at any data at all from this measure for the last three years?

Karen Pace: Right, well let me just put things in a little bit of context for you. When this measure was endorsed in the 2007 project, it was endorsed as time limited at that time because it had no

testing and the testing that was presented in this submission is what was done to fulfill that initial testing which hadn't been looked at until last year.

So they really haven't had time to do additional testing, but the other question is, you know, how is this measure currently being used and I don't know that it is in any systematic way.

But Lisa McGonigal, do you have any information on the current use of these measures?

Lisa McGonigal: The measure is not being currently used as we noted in the metrics submission and in previous discussions with the Steering Committee. It has been indicated since CMS are very interested in including it, but it does look like there's a widespread implementation plan on a national basis. But as of yet, it has not been implemented and so we haven't been able to collect that additional data which was referred to.

Connie Anderson: This is Connie Anderson. I guess I have to say one more time remember this is part of the conditions for coverage right now and the surveyors -- and I know that there's some states where they don't get surveyed often -- but in the surveyors interview of patients they do ask about the quality of education and in the CAHPS survey I think there is a question in terms of presentation of the information/education of patients.

With that having been said and Lisa maybe this is a little bit towards you to help you a bit, patient education is a high priority in terms of CMS and the CMS surveyors and so there is a mechanism of oversight at least at the facilities and in terms of the Medicare surveys and the patient education and the quality of the education.

So I think there's another mechanism for oversight until a better measure can be developed.

Lisa McGonigal: And how often are facilities surveyed?

Connie Anderson: Well I can speak to the state of Washington and having just been at the NRAA meeting, there are - most of the states are on a three year cycle, although they are changing that process to a priority process so that with some of the indicators that are being sent through the network, if there are concerns then they move down to a higher priority and we'll do them ore frequently.

There are states, California being one, that some facilities haven't been surveyed in a long time, but they are changing that process and (Junes Cary) from CMS was at the NRAA meeting and said that they are catching up and they will be surveying at, at least a two year cycle.

Dr. Alan Kliger: I just want to make one, Alan, one quick additional comment which is -- again some of the work Finkelstein here in New Haven has done -- is to look at the gap between the perception of caregivers in giving education and the perception of patients in receiving education.

And I just want to really underline and what the research showed was that often caregivers virtually always believe that they gave education and remarkably/frequently patients do not perceive it as having receiving it. And so as a patient-based measure, it seems to me this is something we should look critically in that direction.

Karen Pace: Okay I think we're going to need to move on, I will follow-up with some information on the questions that were brought up to get that out to you. And if you think of any other questions, send them to me.

Peter Crooks: Karen?

Karen Pace: Yes.

Peter Crooks: Karen, this is Pete. I just want to make one other point we haven't touched on yet. And I think we heard both sides of this ((inaudible)) discussion that keeps committee members when they decide which they're voting out. What they think, but we spent some time talking about the tradition level, metric and the facility level measures.

And I was in the group that felt that, you know, the responsibilities been assigned to the facility by Medicare and not the tradition in that, you know, I had problems with that measure and we discussed that ((inaudible)). So I just wanted to raise - let the committee know that that was another issue.

Karen Pace: Okay.

Joe Nally: Karen, its Joe with another generic question. I mean some of these measures that we've reviewed it looks like or kind of in the process of being or having then decided and then there's a measure like this where there's difference of opinion.

When we have the subsequent conference call for the final voting, is that going to - how much discussion opportunity will be there?

Karen Pace: Actually this call was intended to be the discussion of the measures that we're going over now before the committee as a whole does their final voting. So the idea was to air any questions or issues so that the full committee was aware of them before they voted.

But the intention was to have this discussion and then vote on these measures, the final vote. So the last call is to really address the things that we won't be able to get to on this call.

So are you thinking that we'll need to hold these over for more discussion on the last call? Is that what you're suggesting or?

Joe Nally: But to be honest with you I'm not sure there's any great resolution...

Karen Pace: Right.

Joe Nally: ...for this particular measure.

Karen Pace: Right.

Joe Nally: I was asking the generic question about the process...

Karen Pace: Right.

Joe Nally: ...that eventually it's going to be a thumbs up/thumbs down type of voting.

Karen Pace: Exactly and that will happen after this call, though I will make sure that you have the answers to your questions that were asked of me so that you have that information as well.

Joe Nally: Thank you.

Karen Pace: Okay, all right so let's move on to the vascular access measures. The ones that we thought were ready for, you know, discussion on this call and voting are these two CMS measures. As you know there are some other measures that will - the two KCQA measures they've resubmitted the information taking some of your suggestions about the specification into account.

But again because you haven't had that long enough for full evaluation, we thought that any of those revised submissions that we would hold until the last call. So I just wanted to note that that's they're on this list right here, but later on.

So in terms of these two measures on the workgroup call, basically the workgroup and committee members that we on those calls were in agreement about both of these measures moving forward. They didn't revote on them because their preliminary vows were pretty consistent and they resolved any differences of opinion.

Now the one thing that I will note that I did not get into your summary and if you would go to measure 0257 - no in the memo - go to Page 6.

Go down further.

So one of the recommendations from the workgroup was to add single needle device to the definition of a functioning fistula and we did pose that to CMS who - if you're online you'll see the highlighted area with their response - to that question which basically that they don't currently have that information in CROWNWeb to add it to the definition of the measure right now.

So I just wanted to bring that to your attention and see what your thoughts are in terms of the measure without having that as part of a definition.

And Tom Dudley's on the line, Tom is that something that - so what happens now in CROWNWeb if a patient or facility is using a single needed device, how is that - how would that be recorded in CROWNWeb now. Do you know?

Tom Dudley: It would be coded as other because a fistula indicates with two needles and they're on CROWNWeb. Just to let you know what we're thinking as far as future that we just can't do at this point, one is to put a clarification in the claims manual. If anyone's familiar with the V5, V6 and V7 modifiers that were added a little over a year ago, for vascular access type we're looking at clarifying the definition for the fistula and graph to accommodate the single needle.

And we're also working with the CROWNWeb developers to find out how soon we could get any modification made to the CROWNWeb system and I don't have any answers to that one at this point.

Jeff Burns: This is Jeff Burns. Just a question, is the impediment then to changing performance measure to just read percentage of patients using an AV fistula? The issue of CROWNWeb?

Tom Dudley: It's data collection really ((inaudible)). Does anyone know how prevalent single needle devices are at this point? My experience goes back to the 80s.

Dr. Alan Kliger: Yes this is Alan, they're not very prevalent, but I can tell you there's recently been great interest in a new single-needle device that will sort of be a sort of, you know, dual needle and a catheter in a catheter type so it's dual flow. And I'm the one that raised the question because to the extent that becomes more prevalent since this is a measure that's going to last many years, I just hoped that we could define it in something other than two needles in there.

Tom Dudley: Just take out two needles from the performance measure and would that allow it to evolve over time as the data collection tools evolve?

Karen Pace: It would, but wasn't the reason that the two needles was put in there so that it was a functioning or?

Male: We were trying to avoid...

Male: Using an AV fistula is the same performance measure whether without the modifier with two needles.

Karen Pace: Oh.

Dr. Alan Kliger: Right, correct that had been my recommendation as well.

Karen Pace: So the recommendation that you're putting forward is to say using an endogenous AV fistula and removing them with two needles from the...

Male: Can I propose one other wording?

Karen Pace: Yes.

Male: Could you, you know, possibly worded as the sole dialytic access - vascular access?

Male: That's tough.

Male: Yes the part, you know, I think...

Male: I mean you want to - the reason it had two needles was...

Male: For using a catheter, that's a pretty rare - I would not worry about that happening enough to be a problem.

Jerry Jackson: This is Jerry. I think where it's saying CMS is going with this is that there is a practice of using needle and the fistula returning to a PERMCATH. That could go on for sometime so the actual start of the fistula being fully functional will be when two needles are being used in it and then a PERMCATH might be left in for one, two or three weeks to be sure that the fistula is working.

But once you have the two needles in, it's considered functional.

Dr. Alan Liger: It's Alan, actually we look at the FHM database as we're putting our stuff together for vascular access and surprising to me Jeff, the incidents of patients at any given time having two different active sites like a fistula and a catheter overall for us was about 7% so it was not trivial.

Jeff Burns: That would get picked up though on a second performance measure based upon the presence of a catheter? You know there would still be a motivation to get the catheter out as quickly as possible so it shouldn't go away. But it might be - I mean I don't feel strongly one way or the other, it just makes it feel much more complicated as a performance measure.

Karen Pace: So I think at this point, you know, we have the measure as specified with the two needles, I don't know if there's a way to in the details say, you know, if the CROWNWeb data collection evolved to be able to pick up single needle devices that they would be included. I don't know if that would pose a problem to CMS or whether that would really satisfy, you know, the issue that we're talking about.

Peter Crooks: This is Peter. I'm in favor of correcting the wording by removing the two needle requirement in that even if the AV fistula is one of two accesses being used ((inaudible)) moving in the right direction. And maybe that's to - the best solution for the time being.

Male: Let's recall that NQF that deals with measures that are proposed to us so I guess you're making a recommendation to the developer Peter, is that right?

Peter Crooks: That's right; we had just been discussing possible word changes.

Karen Pace: Right, I mean where this plays out with the Steering Committee is whether this is an issue of voting down this measure or making that a condition of the measure going forward. So you're

right, you have the measures as they come to you, some things can be suggested. In terms of, you know, we need to see this in order for the measure to go forward, other things they're, you know, you made the suggestion, they came back with their response with their limitations right now with CROWNWeb.

Peter Crooks: Right.

Karen Pace: And the question is whether, you know, I think either way the reality is in CROWNWeb it's going to be identified by the two needles so it's still an issue of future data capability versus current I think.

Tom Dudley: This is Tom Dudley.

Karen Pace: Yes.

Tom Dudley: Is it something that we could leave as is right now and make sure it's addressed with the next maintenance or at which time we'll probably have the changes made and the means to collect the data and we'll clarify it and claim submission for the Medicare population.

I know it's still not addressing everyone's thought on there, but I'm trying to figure out a way to capture the data.

Dr. Alan Kliger: So Tom, this is Alan again, I guess since I'm the guy who originally raised the question, at least for me personally I think that that would be a good solution.

Karen Pace: Okay just before we leave 257, again Stephen McMurray sent one of comments was about this measure and he was talking about looking at this in relationship to some of the discussion

you had about the KCQA measures about AV graft and was wondering if this should be added to this measure.

So does anyone have any comments about that?

My recollection about the discussion about the AV grafts was in relationship to being evaluated by a surgeon, not necessarily the ultimate performance measure, but I'll ask others to.

Jerry Jackson: Yes I believe - this is Jerry - I think the other measure he's referring to was looked at patients who did not have a fistula and requiring that it had to be evaluated by a surgeon annually and our discussion was that if they had a working graft, that would not be reasonable.

But these are sort of two different types of measures. This 0257 is encouraging fistulas, at least documenting the percentage or prevalence of fistulas at a facility and I don't think we want to co-mingle grafts and fistulas in 0257.

Male: I agree.

Male: Right.

Karen Pace: Okay, all right and then Stephen's other comment about - is about 0262 which we'll get to when we look at the revised measures submission.

So okay - so let's move on then and I'm sorry we're - we have the next group is cardiovascular and anemia measures and that would be in Document 6. And I sent out a revision to this summary because I didn't get the workgroup revote on 0626. And maybe we'll take a look at that first. This was lipid profile monitoring and this is the percentage of patients with chronic kidney disease that have been screened for dyslipidemia with a lipid profile.

Numerators, patients with a lipid profile. Denominators, all patients, males greater than 10 years, females greater than 13 years of age diagnosed with chronic kidney disease.

So the measure developer had asked to submit some additional information on their performance gap in testing so the workgroup did have their revised submission and it's also in the materials that we spent to the full Steering Committee. In terms of the workgroups revoting on this, they still did not think it met performance gap and was kind of a split on evidence and testing.

So let me just look at a couple of these comments, insufficient data on incident of lipid profiling for CKD 3-5. Okay it seems that testing is done in most patients if one excludes those for home testing is not indicated. He's very elderly, although not much of a performance gap. The bigger issue is statin treatment.

Okay so I'll just stop here and ask perhaps if some of the workgroup that reviewed this revised submission that - look at it Kristin and Rick Kaskel and Alan and Michael and Jeff if you want to make any comments or if the Steering Committee has any questions about it.

Michael Somers: This is Michael Somers. The measure applies to boys who are greater than 10 and girls who are bigger than 13 and, you know, if you read the comments that I put in there in terms of pediatric concerns and there wasn't much data specifically given to show of performance gap for children.

And I was also concerned about how they were defining some of the population for children because Nephrotic syndrome is one of their diagnoses to electronically retrieve data and certainly children of that age group with Nephrotic syndrome really aren't the same as adults with their Nephrotic syndrome in terms of chronic kidney disease.

Karen Pace: Okay.

Dr. Rick Kliger: This is Rick. I echo the sentiments that so nicely expressed.

Karen Pace: Okay any other questions about that or if the committee feels that they'll be ready to vote on this measure?

Okay then the measure 1667 really was not here that needs to be revoted on. The Steering Committee had already voted on this measure. The reason we've had further discussions about 1667 which is the pediatric measure for patients receiving dialysis with hemoglobin less than 10 was that the Steering Committee had recommended this measure, but not the comparable adult measure and we just wanted to make sure that we had the correct rationale for that difference in the recommendation.

And we've had some conversations with Rick and Michael specifically from their perspective with the pediatric population and then discussed it on the workgroup call and I guess in a nutshell my understanding is that the group thinks that the evidence for the harm with hemoglobin levels less than 10 in children is clear and that there is no evidence that children have been adversely affected in the studies that have prompted the FDA continuation of their concerns about ESA use.

I'll ask if Michael or Rick want to add anything to that summation or clarify anything or correct anything I said.

Michael Somers: I think that summarized it well.

Dr. Rick Kliger: That's it, yes.

Karen Pace: So unless there's any other questions or issues that the committee wants to discuss, you know, we don't have to go into it any further or even vote on this again.

Okay so let's - I know I'm running behind time here - but I would like to get into our next agenda item which is to begin some of the follow-up on the measures that were reviewed at the meeting. And the first item which you all received was a letter from RPA, the American Society of Pediatric Nephrology and the Physician Consortium for Performance Improvement.

And what I'd like to address on this call obviously, you know, there are other things that NQF can address, but basically a request for reconsideration of the three measures that you reviewed at the Steering Committee meeting and did not approve for one reason or another. And the first one is 1660 which is hemoglobin level less than 10, 1663 blood pressure management and 1662 which was the use of ACE and ARBs.

So I will stop there and see what your thoughts are about that, whether there's anything that you want to reconsider or questions or clarifications that you would like.

Peter Crooks: Karen this is Peter, we had thought that maybe one way of handling this would be to let the committee members read through the letter and then put this on the vote coming up whether they thought there was enough new information presented in the letter to reconsider one or more of the three metrics to let a committee go on whether there's information strong enough, you know, to reopen this.

And as I thought about it, I thought maybe we would want to do that for each of three ((inaudible)).

Karen Pace: Right, right, right and we can certainly do that. The question is, you know, I think, you know, we have an opportunity right now for the Steering Committee to talk to one another and see if

there are, you know, what their thoughts or questions or if they've identified something new that they want to point out to the full Steering Committee.

Jeff Burns: This is Jeff. To make a comment that the - although it's not finalized or available for public review and comment at this point, the preliminary draft KDIGO guidelines for dialysis patients that ESA anyway have been used to avoid hemoglobin fall below 9.

So there's a - it's not a very - I mean the evidence to support that's not great, but there would be a discrepancy between this performance measure and what that body recommends as an appropriate hemoglobin target with a much greater movement I think through the guidelines and elsewhere to individualize therapy and make decisions about whether because some patient's transfusion may be appropriate, hemoglobin of 9 is perfectly appropriate.

So I think we have to be careful about using a performance measure to actually make physicians do what might not be the appropriate thing for their patient.

Joe Nally: Karen, its Joe. Can you remind me, my Alzheimer's is acting up again. Was this 1660 considered and voted down by us or was it drawn by CMS after the FDA proclamation.

Karen Pace: Actually 1660 is a RPA/PCPI measure so it's for the physician level. CMS had withdrawn their similar facility measure and at the committee meeting, the Steering Committee actually did not think - this measure didn't get beyond the evidence criterion.

Joe Nally: So again there were the two measures, this one and the CMS one, one of which was withdrawn.

Karen Pace: Yes.

Joe Nally: And then the comments that Jeff Burns just made right now were some people think the number may be 9.

Jeff, specific question. The comment about transfusion, if one uses a threshold of 9 or 10 and then looks at transfusion, does the (KV gold) document comment directly on that?

Jeff Burns: Basically what they end up coming away with saying is that you have to make an individual decision whether transfusion is safer than ESA therapy and iron or more or less appropriate. You know, so the decision then comes into play in terms of age, prior exposures, transplant issues and so forth.

So it's not as cut and dry as we would perhaps like it to be.

Ed Jones: Karen, this is Ed Jones. Are we able to comment as a developer?

Karen Pace: No, but if the committee has a question for you though they will ask you.

Ed Jones: Thank you.

Karen Pace: Okay.

Dr. Alan Kliger: All right well this is Alan, I'll open that door because what we're asked to do based on the RPA letter is to examine in a different light than we did. We're being asked to look at it as a patient safety measure to reduce the incidence of transfusions so I personally would like to hear the developer's rationale for us sort of changing the way we're looking at this.

Ed Jones: Thank you, I think we summarize it in the letter and clearly we are looking at this as a patient safety measure issue with the available data that's there. I don't think KDOQI is presenting new

data, they're evaluating what's out there and we try to present the information where transfusions start and indeed there is some data there that we presented that transfusion increases even as hemoglobin stood below 11.

And this would provide the community and patients in particular with a reflection of how many patients are falling through that number, which not suggesting what the number is, it's providing available data. And that's why we're asking things you have to look at is to relook at the data that's there to provide a measure that give us some patient reflection that transfusions will not increase.

Because we know from the hematocrit studies that we presented that transfusions were clearly double what they were when they went through 10. So that's the data that's there and I would think that the committee would not want to look at another guideline to say what the measure should be, but what - use the data that is available to reflect the measure.

Dr. Alan Kliger: It's Alan, can I just ask the developer do we have any evidence of relative risk of transfusion versus ESAs because that's really what you're asking us to examine.

Ed Jones: Could you rephrase that or me again Alan?

Dr. Alan Kliger: Yes are there data comparing the risks if this is a safety measure, the risks of transfusion versus the risk of ESA use? I believe there is not such data.

Ed Jones: I believe there are not such things.

No there is none, I mean we - that's the only data that's available for transfusion to occur to give them hemoglobin or not. As you know, there are data about the risks at lower levels on hospitalization that isn't there at the higher level.

Dr. Alan Kliger: Nice so it's just I guess hard for me to look at the blood transfusion issue without data that helps me compare the risks of blood transfusions to the risks of ESAs?

Ed Jones: Similar to the discussion that went on in a previous measure, I mean having nothing may not - better than having a marker that would allow us to at least take our thought processes is that we're allowing higher transfusions to occur.

Harvey Wells: This is Harvey. The blood transfusion doesn't that include...

Karen Pace: Harvey we can barely hear you, can you...?

Harvey Wells: Can you hear me better now?

Karen Pace: Yes.

Harvey Wells: Okay with the blood transfusions, does that increase your PSA's?

Ed Jones: Yes there is data that an increase in number of transfusions is increase in PFTRE's which decrease until getting a transplant.

I think that would be something we need to consider as far as the risk.

Male: Is there not also - is there a transfusion measure at all that looks specifically at transfusion?

Karen Pace: No that's the question of whether, you know, if this is about transfusion. Is that what the measure should be or?

Ed Jones: Well that's very difficult to track that now as you probably now because transfusions are not generally given to the centers, it's hard they, you know, track as well as we can do other things. So this is meant to be a surrogate for transfusion.

Karen Pace: Okay and I also sent - Jerry Jackson had sent some comments and Jerry are you still on the line? Do you want to make any comments?

Jerry Jackson: Well I just - probably the only one - probably right now it's the group of patients who have malnutrition inflammation syndrome and I think that's a very substantial number. I'm not sure what it is, maybe 10-15% of the dialysis population. They tend to have very high ferritin levels, low T sets and refractory anemia and then of course low albumin's.

And those patients in our experience are on maximum doses of ESA, cannot receive iron and you're doing everything you can to get their ((inaudible)) up and I can see situations where in that group of patients, if you have this as a performance measure, you would be transfusing to keep it at 10 so you don't fall below the performance measure and not basing the transfusion on clinical symptoms, but just on the performance measures.

So at least on that sub-group, it could actually increase the number of transfusions. I'd be interested in the developer's response to that.

Ed Jones: I'll make sure I have a response that correlates to what we're talking about Jerry so I really don't have a thought on that.

Jerry Jackson: There was an article fairly recently ((inaudible)) was felt to increase the ESA responsiveness in that group of patients, but it's - I guess that's all I have to say.

Jeff Burns: This is Jeff again. As much as I believe that most patients ought to have hemoglobin of around 10 or higher, most are many patients - you know, I am worried that this is going to put us back in to a position that we're trying to get out of which is either was just mentioned transfusing people just to get to a hemoglobin level or continuing to increase the ESA dose, continuing to give more iron because we want a hemoglobin level of a certain point even though it may not be the right thing clinically to do and maybe a dangerous thing to do clinically.

So this may force behavior or encourage behavior anyway that is not what we really want to have happen.

Dr. Alan Kliger: This is Alan. I just want to - one more comment from me which is we now know that targeting hemoglobin's more than 13 causes harm. We don't know how low that targeting danger exist because it's not been tested. We don't know if targeting 12 or 11 or 10 causes harm, it's untested. But there's surely targeting 13 and perhaps at some level below that.

The second thing is that we really no credible evidence in adults that hemoglobin's of less than 10 or at least 8-10 cause any harm. No evidence that I've seen or that I've seen presented to us, that it causes harm.

And so given that combination of a performance measure that targets 10, I don't think test is the evidence test.

Male: Alan if I can say, we're not saying targeting 10. What this would be is a measure that would have in comparison to national averages to see if the numbers of patients falling below that number is increasing which may trigger people to look for if its triggering more transfusions.

Dr. Alan Kliger: You know well I understand that, it's just that I guess I shared Jerry and Jeff's concern about a level of 10 that surely will be seen as a target by clinicians or facilities without clear evidence that it makes any difference to outcomes.

Joe Nally: Ed it's Joe. A concern I think is that the less than 10 in 10 infusions are true, true and unrelated and then the other thing is the unintended consequences perhaps of people doing things via transfusions or EPO or other things to be above this target of 10 which I'm not sure people agree is necessarily the right target.

And a combination of those factors plus I think CMS backing away for their reasons, I'm having trouble being convinced here that this is the right thing to do.

Karen Pace: And just to clarify, CMS also withdrew their pediatric hemoglobin measure for less than 10 which you all had looked at in the prior project that they took off the table before that was endorsed.

Male: And they did it to be in concert with the QIP discussion and the package insert, not because of what could be done as an appropriate measure, I think.

Kathe Lebeau: This is Kathe. I, with all due respect to the (former) proceeding conversation, I do think that if we are looking to evolve these measures to sometime from the patients perspective, certainly this is one those issues especially since we're talking about patient safety.

I think the (sensitization) issue is huge, I understand a lack of evidence, but speaking as a patient I would feel - I know it's a quality of life issue. Sorry, I know how I feel when my hemoglobin drops low. I know that ESAs take a while to get a response so it would continue to drop. I don't want to risk a transfusion.

So considering all those things, while I realize we need to use consistent criteria, some of the things are harder to hold when evidence does not exist or when it's an issue that needs to be looked at somewhat differently.

Dr. Ruben Velez: This is Ruben. I think we need to make the clear distinction between what this measure tells us which is, you know, the percent of hemoglobin less than 10. This is not related to the use of ESA so and there's more data even from the USRDS that people with natural high hemoglobin's have as good prognosis or better than other people, hemoglobin's of 12 and 13 and that has been reported this year.

So it's not the hemoglobin of 13 is bad for a patient, it may be how we get to 13 that is bad for the patient, but this measure if I recall only measures patients with hemoglobin less than 10. It has nothing to do with ESA which is the concern we all have and it goes with the FDA, most recent FDA, you know, literature or guidelines and I in a way I have to support this understanding that, you know, there's no strong evidence. But there is direction on this.

Male: Yes one just last point, Kathe, I hear clearly what you're saying and I do think clinicians need to work with individual patients to treat best for those patients including, you know, you and your blood count.

But a performance measure, an endorsed performance measure, needs evidence that for a whole general population there's a best way of doing things rather than in addition to individual best treatments for individual patients.

Peter Crooks: This is Peter. I just wanted to point out what we've done in our last seven minutes or so and what we should do at this point.

Karen Pace: Okay thank you, let me just make a couple comments and then we do need to open the lines to see if there are any public comments and if you all could bear with us for just maybe a few minutes beyond 4 o'clock.

I do want to address the question that they posed about the blood pressure management measure and I did put this in your memo that it's true that in the cardiovascular project they - it's not final, it did recommend a measure for blood pressure control of 140/90 I believe, less than 140/90 with the understanding that that would be changed pending JNC-8.

I'll just mention the differences with the maintenance measure, now a new measure you had before you, but also the question is that measure is a physician level measure and it includes all patients with hypertension. But it excludes specifically ESRD patients - dialysis patients I believe.

So and we can decide how you want to proceed with this so there's a couple levels of question as Peter mentioned earlier whether, you know, there's any information that you want to reconsider, but also in reconsideration whether the measure that's going through the cardiovascular project actually would suffice for physician level measurement with that eventually being changed to be consistent to JNC-8.

And then - so maybe what we'll do just real quickly operator is open the lines to see if there are any comments from the audience and after that maybe just address these other measures or any questions the committee has about these measures.

So operator, would you open the lines?

Operator: Yes all lines are now open.

Dr. (Ashput): Yes this is Dr. (Ashput) from AmGen, I have a few comments. Number one I think one of the committee members mentioned KDOQI and there was a discussion about (9). I think the what we are reading is that, you know, ESA should be initiated at hemoglobin later than 9 and less than 10. It wasn't 9.

The second thing I wanted to say is that the United States packaging should suggest that ESA should be initiated less than 10 so maybe the 10 wording there.

And the third thing going back to the KDOQI which I think Dr. ((inaudible)) mentioned. On Page 51 in the transfusion section and again this are the draft guidelines, but there's a sentence which says that the rate of transfusion increases markedly when the hemoglobin falls below 10 and the reference is 1 and 7.

And the other thing which I think one of the other board members suggested that there is no harm between 8 and 10. If you look at the United States Renal Data system, there is a suggestion that hemoglobin falls below 10, the risk of transfusion increases. The clinical trials including the normal hematocrit studies suggested that there were increase in transfusions and the lower arm is compared to the higher arm.

And also in the ((inaudible)) study there was increase in transfusion in the lower arm than the higher arm. Now one can argue that there is no direct data to suggest that there is harm, but if you include transfusions there are people who are waiting for the ((inaudible)).

There is data from the USRDS which suggests that there's an increase in wait time in the patients who actually can get on the waiting list because salaries are low enough that they can't get a transplant. And the people who are lucky enough who get the transplant, the transplant outcomes in those patients are even worse with (BR) rate.

So and then I think Kathe Lebeau mentioned about the quality of life and Dr. Kliger knows this data well that, you know, patients with hemoglobin greater than 10 actually have some patient outcomes which are variable.

So yes there may not be direct evidence, but there is sufficient indirect evidence that there is harm when patient's hemoglobin's go below 10.

Karen Pace: Okay thank you, any other comments from the audience?

Andrew Narva: Karen, I have a question. This is (Andy) Narva.

Karen Pace: Yes.

Andrew Narva: It's not clear to me what the ((inaudible)) is on the blood pressure measure. And I wanted to mention I'm on the (JNC-8) and I can't really say what it's going to recommend, but I can say that what's likely to come out would not be in harmony with this.

Karen Pace: With that 018 or with the measure that was submitted to the...

Andrew Narva: One six three three.

Karen Pace: I'm sorry, say it again.

Andrew Narva: One six three three.

Karen Pace: Yes and I know that was the discussion at the hearing committee meeting that, you know, since the major body that's been reviewing all the evidence and recommendations that it was probably not the time to put forward a performance measure.

Ed Jones: Karen, this is Ed I think you're still in the open mic section. If I could just bring out a point, again the (JNC-8) I believe is looking at data that's out there, not new data. We presented the data that was most recently published and was most recently summarized and that the NephSAP journal so just because another guideline's coming out, that's not necessarily new data. It's perhaps relooking at it, we present it to the committee the available data about hypertension as well as using ACEs and ARBs.

Male: Well the editor of Neph on the JNC-8, Ray Townsend as well.

Karen Pace: I'm sorry, (Andy), would you say that again?

Andrew Narva: You know, the editor of - the associate editor of NephSAP is part of JNC-8, Ray Townsend.

Karen Pace: Okay, okay other thoughts from the Steering Committee about the 1633 blood pressure management or 1662 angiotensin converting enzyme ACE inhibitor or blocker therapy?

Joe Nally: It's Joe with a comment. We are number one quite short of time to discuss a very important issue. Number two I think when we're discussing the issue we should have in front of us the actual measures rather than an observers letter commenting and making requests.

Karen Pace: Right, right.

Joe Nally: So very, very specific about our subject matter and I'm concerned that this measure or this discussion won't get as full due unless we postpone it and have specifics in front of us.

Peter Crooks: Yes what we were proposing to the committee is that we vote on whether these three measures should be opened up again based on this request for reconsideration and maybe that's still a good approach because if the committee does say let's open these up again then we'll have another chance to go through them in detail.

Does that sound like a reasonable way forward to the committee or does the committee want to just, you know, state right now that we are going to reopen these for consideration and just do that?

Karen Pace: So what Peter brought up is that one approach that we could do that when we open the voting for the measures that we did get through to have a separate question about each of these measures to see if you would like to reopen them. We can provide you with - again with the actual measure submission if you want to look at that in terms of making your decision about whether it should be reconsidered, so that...

Peter Crooks: Yes we should remind the committee that we had already considered each of these measures at the full Steering Committee and they had not passed.

Karen Pace: Right.

Peter Crooks: So it's not like we're talking about that for the first time and so I think it's still germane to say, you know, should we open them again? Just because somebody, one of the submitter's, you know, has an objection that we go back and start over again. I don't think that's right, we should at least vote and say I exchanged some information that I think means we should reopen this as the first step before we, you know, do a whole process.

Jeff Burns: This is Jeff. I don't know whether it's the appropriate time to voice an opinion or not, but I would think the approach that we voted on this we have new - we don't have new information, we

have new comments, but not new information. And therefore I personally wouldn't consider to open it for consideration. My own opinion.

Karen Pace: Okay.

Peter Crooks: Is there anybody to speak in favor of reopening any of these three metrics again?

Dr. Alan Kliger: This is Alan. I guess I don't feel I've had enough understanding of the context of the concerns to vote on that. We did have an adequate discussion on the first, but not of the second and the third so my feeling I guess is this is a serious request of us and I would prefer to spend a little bit more time, the ACE and the blood pressure measures before we're asked whether we want to open them or not.

I would be prepared to vote on opening or not the first one.

Male: Karen, could these actual measures and our comments from our original meeting when we were voted down be sent around and they we have a vote as to whether we want to reopen based upon whether or not there is new data submitted?

Karen Pace: Yes and it doesn't necessarily have to be new data, it can be, you know, looking at it in another light. But generally it would be if there's new information that you did not consider.

Male: As a minimum to see before us say 1633 a swell as pasted below that or whatever the comments that..

Karen Pace: Right, right we can do that. It's actually in the - one of the documents that you received which has the summary from the Steering Committee meeting.

Male: I understand that, but I'm not looking at that right now.

Karen Pace: Right we can organize it together for you so that you have all of the information about the measures together which I understand there's lots of different things going on here and so I can certainly put that all together for you so that you can entertain, you know, whether you think we should have further consideration.

And then we can go the next step which would be to re-evaluate each of these measures, but Alan do you have a specific question for the measure developer besides what they put in the literature?

Dr. Alan Kliger: You know, I'm anxious we have bunch of really smart people on our committee and I'd be anxious to hear a reconsideration of the issues brought before us for 1633 and 1662 before I'd be prepared to have an opinion about it. So now I don't have a measure developer question, I would like to have an opportunity to just spend 10 or 15 minutes with each of those measures before I have an opinion.

Peter Crooks: I guess this would extend our timeframe because next call we were hoping to wrap up these things, but what you're saying now is next call we would then discuss 1633 and 1662 followed by a vote on whether to open them up again. And if they're opened up, that would be quite another call.

Karen Pace: So let me...

Dr. (Ashput): ((inaudible)) Karen?

Karen Pace: Well we're already kind of short on time. Would people be able to stay on this call say another 20 minutes so that we can at least have some discussion about these two measures?

Dr. Alan Kliger: Unfortunately I cannot, I have somebody waiting outside my office right now.

Karen Pace: Okay, all right well I think perhaps what we'll do is put all the information together for you so you have it in one place and ask you to at least give us your thoughts online so we know whether you feel you can make up your mind as a yes/no or if it's that, you know, you need more discussion.

We can give you those three options and then we'll have to determine what our next step is based on your input.

Dr. Alan Kliger: Karen, that's a good solution.

Karen Pace: Okay well I know that everyone needs to run because you've got busy schedules and I thank you all for taking the time and your due diligence on all of these measures and your discussion.

And we will get an email out to you very shortly about what you can act on now and we'll go from there.

Thank you all very much and we'll be in touch soon.

Dr. Alan Kliger: Thank you.

Female: Thank you.

Male: Thank you.

Peter Crooks: Thank you everyone.

Male: Thank you.

END