

NATIONAL QUALITY FORUM

Moderator: Lauren Richie
September 9, 2011
12:00 pm CT

Operator: Welcome to the conference. Please note that today's call is being recorded.

I'd like to turn the call over to your host, Ms. Lauren Richie. Please go ahead.

Lauren Richie: Good afternoon everyone or good morning depending on where you are. Welcome to the Renal Endorsement Maintenance Steering Committee Meeting where we'll be reviewing the vascular excess, patient education and quality of life measures today.

We are joined here by Karen Pace from the National Quality Forum as well as myself. WE have a full agenda today. For two hours, we have six measures we will try to get through so we're going to get right into that very quickly. But before I do so I will turn it over to one of our co-chairs, Dr. Kristine Schonder for any opening remarks.

Dr. Kristine Schonder: Hi everyone. Thank you all for calling in today for the review of these measures. I - we have a full agenda so Karen and Lauren will be taking care of introducing each of the measures and then we'll have some time for comments throughout.

That's all.

Lauren Richie: Okay. Thank you. And just really quickly I just want to take a really quick poll of the committee members that we do have on the call. So far I'm showing Andy Narva, Connie Anderson, Jeff Berns, Jerry Jackson. Are there any others, Renal Endorsement Maintenance Steering Committee members on the call?

Peter Crooks: Yeah, Peter Crooks is here.

Lauren Richie: Okay. And Peter, I don't see you logged into the Webinar. Are you on your way?

Peter Crooks: Working on it.

Lauren Richie: Okay, sounds good. Okay, with that I think we're going to get right into...

Female: We also have, of course, Kristine Schonder on.

Frederick Kaskel: (Rick) Kaskel is on.

Lauren Richie: Okay.

Female: And are there any other committee members on that we didn't call names or see on the Web site, on the Webinar?

Okay, with that I think I'm going to turn it right over to Karen Pace who will start us off with the vascular access measures and just a couple of quick notes for the documents that we're going to be showing in the Webinar, you might want to maximize your screen in the upper right hand corner as we show some of the Word documents from the measure submission forms and other documents.

And Karen?

Karen Pace: All right. So what we sent out prior to the meeting was a summary of the sub-group, the work groups, preliminary evaluations and then, as you know, at the meeting we actually did start evaluating the patient education measures. And as far as we got with that we also included that information.

One of the things that - so what I'm going to do is kind of walk through the measure, the description and the preliminary evaluations and what we will do is highlight any issues or concerns that may have shown up and ask for the committee members to discuss that.

We do have measure developers on the call who are available to respond to any questions that you may want to direct to them.

So we'll start with 0256 which is the hemodialysis vascular access minimizing use of catheters as chronic dialysis access.

This measure is the percentage of patients on maintenance hemodialysis during the last dialysis treatment of the study period with a chronic catheter continuously for 90 days or longer prior to that last dialysis session.

So the numerator, obviously, are the patients who are using the catheter for 90 days or longer and the denominator is patients on maintenance hemodialysis that have been identified during that study period.

Exclusions are patients on acute hemodialysis, peritoneal dialysis patients or patients less than 18 years of age. There's no adjustment needed. This is a facility level measure and it's a - the measure (steward) is CMS.

So we'll get on to - one of the things, and I already kind of missed the boat on this but one of the things that we wanted to just kind of stipulate at the beginning is that based on the preliminary evaluations and discussion of similar measures at the steering committee, it appears that there's no question about this being a high impact aspect of healthcare for these patients.

So for these vascular access measures that we're going to be reviewing we thought we would suspend any discussion of impact but certainly wanted to give an opportunity for the committee to raise any issues if they think that there are any that should be called out and discussed separately.

Andrew Narva: I was wondering if Jerry, you know, looking at the preliminary scores, it was pretty strongly supported by our subcommittee but Jerry had consistent questions about reliability and testing.

And I was wondering, Jerry, if you could comment on that?

Karen Pace: Okay, and who was that that just spoke?

Andrew Narva: Andy.

Karen Pace: Andy, okay - and could we...That would be great. And what I'd like to do is just - we'll try to systematically go through these criteria and we definitely want to address any of the questions that were raised.

So if you could hold that for just a second Andy...

Andrew Narva: Sure, I apologize for jump....

Karen Pace: No, that's okay. So if we move on with, after, impact the next important sub-criteria is performance gap and the preliminary eval's generally rated this either high or moderate but there was a question about the range of performance indicated that there was a prevalence of 5% using catheters and that seemed to be lower than the actual experience.

So I just wanted to see if there was any discussion about performance gap on this particular measure?

Peter Crooks: Five percent sounds awfully low.

Karen Pace: Right, and if we go to the measure submission form we ask for data - because this is...And, by the way, all of these vascular access measures are up for endorsement maintenance so we did ask for performance on the measure as it's specified.

And that data is in 1B2 and it said that data from CROWNWeb January 2010 - the (post) quartile was 0%, median was 2%, third quartile 9%. And that the average was 5% of patients.

Peter Crooks: This may be low, this is Peter Crooks, because of maybe the 90-day requirement. Maybe that explains it.

Male: Would it be fair to say, if I'm interpreting this correctly, that the fact that there are units with as many as 47, tell me if I'm interpreting this correctly, units with as many as 47% of patients that are dialyzed in with catheters for more than 90 days?

Peter Crooks: Where are you seeing that?

Male: The second line in the blue ink under 1B2 distribution, between 0% and 47%.

Peter Crooks: Oh, so that's a maximum reported as 47%?

Male: So the mean is 5, if I'm interpreting this correctly, there are a substantial number of units with a much higher percentage of patients with chronic dialysis catheters. So the mean itself doesn't sound so horrible but the evidence of a performance gap, I think, is there.

Karen Pace: Okay...

Male: If you look at the outline.

Karen Pace: Right.

Male: Am I interpreting that correct?

Karen Pace: Could we ask if the measure developer can shed some light on that?

Joe Messana: Yeah, this is Joe Messana. I believe that that is a correct interpretation here that we have - the extreme facilities have as high as 47% chronic catheter use to use the term that's associated with that greater 90 days continuous use.

Male: And then obviously there's an important performance gap here.

Karen Pace: Okay, all right, so any further discussion about that, or sorry, disagreement?

Jerry Jackson: Jerry, I don't disagree. I think if we looked at network data, and I tried to get our network quality director on the phone and couldn't get her a little while ago to confirm this, but I think our

greater than 90-day percentage is quite a bit higher which would say that there's more of a performance gap than the application or the developer document is showing.

And it may be that the source of the data being a relatively narrow timeframe in CROWNWeb is the issue in network data with a longer (swap) of data.

So I agree that there is a performance gap.

Karen Pace: Okay, great.

Male: Another point quickly may be that CROWNWeb data is on a limited number of facilities at that point in time. So maybe those are better performers or whatever but I think it's not the full (swap) of data.

Constance Anderson: This is Connie. That's absolutely correct. It's a very narrow (plot) of data from just those facilities that are in the pilot in CROWNWeb.

So I agree that looking at our network data if it's a much higher percentage than the 5%.

Karen Pace: Okay, all right.

Joe Messana: This is Joe Messana again, I've got (fiscal) first data up here and it looks like there's been a decreasing trend, (see) 90 days by (fiscal) first down into the single digits into - starting early in 2010.

So although there is a bit of a difference between the CROWNWeb data and the (fiscal) first data the prevalent catheter use, I think, has been trending downward and the national data looks like it's in the 8% range based on (fiscal) first data which is a more expansive set of facilities.

Karen Pace: Okay, so we can go ahead and move on. So under scientific acceptability measure properties, this first area is reliability and there was a question about this and one of the things that I want to point out is this is something that came across the CMS process measures about doing correlations of time periods and the question was raised about whether that's a demonstration of reliability. In the responses that they sent to questions prior to our in-person meeting, CMS did provide some reliability analysis of the measure score, the precision and the signal to noise analysis.

And so that is in that supplemental document, the developer responses, and the table with the reliability statistics is on page 25.

So on this particular one minimizing the use of catheters, 0256, they have an inter-unit reliability of 0.84. The interclass correlation was still relatively low, 0.08, but that inter-unit reliability which is supposed to be an indication of how much of a difference across facilities is (true) difference versus random noise and so that 0.84 is a pretty good number.

So I'll stop there and I think Andy, do you want to -Andy's question is relevant here about the preliminary reading about reliability. So Andy do you want to proceed or Jerry, one of the two?

Jerry Jackson: Oh, this is Jerry. Andy addressed it to me and we had a bridge discussion debating about this. I have still some reservations about measuring data across points of time as a measure of reliability but I understand where they're going with this in a better way now after reviewing the document on page 25.

But it really sways more positively towards this measure is the validity testing with the correlation with hospitalizations. I think that adds a lot of strength to the measure and whereas I had in the preliminary voting just based on our direction of scientific reliability looking at this very closely I

had reservations before but this additional information provided by the developer causes major change mode on this measure and I would be more affirmative.

Karen Pace: Okay. Any other discussion about the reliability or the validity testing and results?

Okay. So then we would move to usability and we didn't - I mean, basically in the preliminary evaluations everyone thought that this would meet our criteria for usability. Any disagreement or new issues that should be brought forward?

Okay. And then feasibility, again, on the feasibility that was rated consistently at the high level and so I'll just ask if there's any new issues or concerns that anyone would like to raise in terms of the feasibility of this measure?

Okay. So the preliminary assessment then of whether this measure was suitable for endorsement was generally yes but the one no and I think that was probably related to the concerns about reliability and validity that seemed to be resolved but I'll ask if that's the case.

Jerry Jackson: Yes, I was - Jerry, and I'm changing the vote to yes.

Karen Pace: Okay. All right, are there any other issues that we need to address before we move forward?

Male: Karen, just describe for us where this measure goes now, how we will do final (loading)...

Karen Pace: Good question. So what we are wanting to do on these focus calls is to really go through each of these measures and see if there are any additions or changes to those preliminary evaluations.

And what we will do then, the idea is that these final kind of evaluations will be compiled for the full steering committee. The full steering committee including you all will need to do a final vote on these measures.

But generally the fact that, you know, that you've said that this is suitable for endorsement, I mean, that's what this steering committee wanted was the kind of recommendations from these workgroups and then we'll set up a process for the full committee to weigh in or bring up any other issues that might not have been addressed.

And the idea would be that we will summarize these workgroup results, get those out to the full committee, have them do a voting online and then we will have the full steering committee call where we can just, again, just deal with any problems or issues that arose during that voting, so just...

Male: Karen, do you anticipate sending the vote out in groups, for instance, after we've done today assuming we get through six?

Karen Pace: I'm open to suggestions about that. We can maybe talk more with you and Kristine about that offline or at the end of the call if we have some time if people have some suggestions of what would make - be most efficient for everyone, we're certainly open to all ears about that.

Male: Just off the top of my head, it seems maybe it's easier to do it in bite sized chunks than all at once and...

Karen Pace: Yeah.

Male: ...the committee has finished its considerations and is ready to make recommendations on a set of measures, maybe we should go ahead, you know...

Karen Pace: Okay. All right...

Jeffrey Berns: This is Jeff Berns, I'm sorry to interrupt. Just a question since I don't have the - I'm not able to flip back to the beginning of the measure.

Male: Would home hemodialysis patients be included or excluded in this measure, because many of those (role) dialogues intentionally with a permanent catheter?

Karen Pace: Right, they are not excluded.

Male: For maintenance hemodialysis - so that would include in center hemo patients as well as home hemo patients and I'm wondering then whether the home hemo patients should be excluded from the denominator?

Karen Pace: But is the use of a catheter indicated simply because it's home hemodialysis? I guess that would be the question.

Male: No. Some of the patients prefer to dialyze with a catheter and my understanding is that when the patient is using the catheter that the infection and inflammation risks are very different than when a patient dialyzes with a catheter in the center.

So it's not very many patients so that it's not going to probably influence the denominator very much but for facilities that have large numbers of home hemo patients it will.

And since they may intentionally or some of their patients may be dialyzed chronically with a catheter I think we need to be thoughtful about that and perhaps consider having those excluded from the denominator.

Male: Can we ask the measure developer how they're doing this, whether the home hemo patients are excluded?

Karen Pace: Yes, yes. Definitely. I mean, I was - from what I can read in here they're not excluded but...

Male: But in practice maybe they really mean in-center hemodialysis to make (aware) on this call?

Karen Pace: Right, but I think that - yes. Let's first clarify...And I think that actually was a recommendation from the last process was to include home hemodialysis patients in any measure for which it was appropriate.

So someone from CMS or (Arbor)?

Joe Messana: Yeah, this is Joe Messana from (Tech). Home hemodialysis patients are included based on my understanding and what we've put in the NQF form. So if you've got specific recommendations about whether that's correct or incorrect, certainly we're listening.

Constance Anderson: This is Connie...Oh, go ahead.

Male: I think that they should probably be excluded or have a similar measure with an without. Again, the most units that won't - most facilities it will not make a difference but there are facilities, and hopefully they'll be more of them, who have a relatively significant fraction of patients on home hemodialysis and they will look like a poor performer than they are when it may be for a different reason than most would...

Karen Pace: Right, but do we have any evidence that says catheters are appropriate for home hemodialysis or recommendations? I guess - I understand you're saying that they may have more catheters. The real question is, should they have more catheters?

Joe Messina: I mean, I'm not an expert in home hemodialysis. I can consult with them if that would help but that's my understanding is that the need to use a non-catheter access is much less important in a home hemo population.

Constance Anderson: This is Connie and we have a large home hemo population. And in those patients that are dialyzing six or seven days a week on daily dialysis, some of them opt for catheters but I will honestly say that the catheter infection rate does still occur and so, you know, I wax and wane on this one.

In particular, from the patient's perspective they're doing daily dialysis. Catheters are much more convenient than a fistula and/or a graft.

Peter Crooks: This is Peter Crooks; I would suggest that catheters, while making home hemodialysis possible for some patients, are still less preferable than a non-catheter access.

But maybe one way to handle this would be to have the reports made where the home hemo patients are broken out into a subcategory so you'd have an ((inaudible)) 24:33 facility rate and then you could also see what percentage of that is due to patients on home dialysis.

Is that doable or...

Male: Let me make another suggestion and that is that the value of the measure, and I think it's a valuable measure, will not be lost at all for 95 or 99% of facilities if home hemo patients are

excluded. So that it will retain its value given the fact that such a minority of patients are on home hemodialysis without muddying the waters any.

Karen Pace: Yeah, but we're back to the primary question is not whether they have catheters but whether they should have catheters.

Male: Well, that's the individual patient decision. You know, if having a catheter permits a patient to be on home dialysis the good may outweigh the bad. That's a - you have to kind of...I don't think we can legislate that.

Male: I don't think we're ready for performance measure for home hemodialysis patients. I just - I don't know that the data is so clear yet that catheters are so inferior to a graft or a fistula in terms of long-term outcomes and patient safety and infection and, you know, there may be a little higher infection risk and a better compliance and so forth, so...

Karen Pace: Okay.

Male: So then are you proposing that we recommend the measure to the home hemodialysis patients?

Male: That would be my recommendation.

Male: So Karen if - how do we proceed? Do we vote on it as it is and then if it doesn't carry then we vote on it with the suggestion?

Karen Pace: Right, we would have to - well, I guess the first question is do you think that there's any evidence or data that exists that could help answer the question?

Female: I don't think that there is...

Karen Pace: Okay.

Female: ...any evidence available because there's so few home hemodialysis programs and so few patients on home hemodialysis.

I honestly believe that it isn't going to change the measure to exclude them.

Karen Pace: Okay. Is there anyone - any of the committee members that think that home hemodialysis patients should be included in the measure?

Harvey Wells: Do we just jump in here?

Karen Pace: Yes, please.

Harvey Wells: This is Harvey and I really don't think it would matter one way or another because the numbers are so few.

Northwest Kidney Centers are probably the largest and, I mean, do you have an idea of how many use catheters? I know some centers won't even let people go home with catheters. So I don't think it really changes anything and I'm not sure that excluding them or excluding them one way or another are going to change the numbers to any...

Constance Anderson: Right. I agree with you Harvey. This is Connie from the Northwest Kidney Centers.

And I think the numbers are going to be so small to include them or exclude them it's really not an issue. I am perfectly comfortable with the measure the way it is written because I think the subset

doubt of the home patients is so small and there's so very little evidence on home out there that it will make that much of a difference.

I don't think it would really - from what I've observed and I think there may be some studies out there but I don't know how large they would be, but it seems that catheters at home patients don't have the infection rates of in-center but I may be incorrect on that but you only have to have one person that messes up in a center and, you know, it's going to affect you. Where, at home, the people that are responsible are only taking care of you, so...

Karen Pace: So let's ask the measure developer if they know they would have any data on the home dialysis patients. And, well, let me stop for a second. So I guess what we should do is find out then from the work group members on the call, the committee members on the call, whether they want to proceed with the measure as is or suggest that home dialysis patients be excluded.

So that's what I'm trying to get...

Male: Do you want to do a quick poll?

Karen Pace: Okay.

Male: I'm kind of in favor now of letting it go as it is and - let's ask how many on the call...Are there any on the call who still would hold out for not passing it as it is?

Jeffrey Berns: This is Jeff. I would prefer that it be removed, it's just one vote.

Male: Okay, anyone else? Okay, so I think we can make a note of our concerns about that but move on from there.

Male: You know, there may be data from the (FHN) that looks at this. I know that there's data on events related to vascular access but we're looking at a huge number of patients, the total number of patients studied in, but I remember being surprised at what a large percentage did use catheters. But I don't know if the infection rate has been looked at but that's one possible source of information.

Karen Pace: Okay. Okay, so we will definitely note in the discussion the question that arose about home hemodialysis patients and, you know, it's something that may come up in the comment period that may come back to the committee again if there is additional data or discussion about that.

Okay, so let's move on to 0257 which is another CMS measure that's up for endorsement maintenance and this one is the percentage of patients on maintenance hemodialysis during the last treatment of the month using the AV fistula with two needles.

And this is a facility level measure and again, I think we can skip the discussion of high impact. The opportunity for improvement, the performance gap, the preliminary readings from the workgroup were three high and one moderate so it seemed there was agreement that there was room for improvement and I will just stop there and see if there's any questions or concerns about this measure in terms of performance gap.

Constance Anderson: This is Connie and this is another one where in my note it's exclusive to AVF's and AVG's aren't included even though we know AVF is the gold standard, there are many patients who can't have AVF. And so I think we need to look at the measure to also include a permanent access minus catheters so that AVG's could be included.

Karen Pace: Right. And that's a good point because that was something that came up about the measure that you did evaluate at the meeting and actually had stopped evaluating based on that

issue. That was one of the issues, there were several, about the permanent graft. So other discussion about that?

Jerry Jackson: This is Jerry. I was the one who had brought that up, measure 0251 which is...

Karen Pace: Yes.

Jerry Jackson: ...the percentage of patients with a fistula with two needles and alternatively have had an (insane bath) surgeon for fistula consideration within the past year.

And my concern was not that grafts are as good as fistulas, we know they're not, but that there was an additional burden on the system to force patients with a working graft to go and see a surgeon every year and every year have the same thing said...

Karen Pace: Oh, okay.

Jerry Jackson: ...that if the graft is working we don't need to do a secondary fistula yet.

So the same...

Karen Pace: In the context of that measure that included being evaluated every year?

Jerry Jackson: Yeah, so the nephrologists, especially within the interventional facility, actually it's the radiology or nephrology could make that assessment of whether it was time to move towards secondary fistula without mandating an actual visit to a surgeon's office once a year.

I think the idea of this measure is more with fistula first which is kind of the gold standard of getting up to at least 67% prevalence and beyond hopefully like in Europe because it has been

shown to have such better outcomes and so I think we're kind of two kind of different points of view on the two measures.

Karen Pace: Right. No, I think that's an important distinction and Connie was that you, do you agree with that or do you have...

Constance Anderson: You know, yeah, that was me that brought up about the AVG's. Really the focus is catheters out, catheters are bad and let's get rid of catheters.

And a permanent access is really considered either an AVF or an AVG. And so I would hate that we just focus on AVF with two needs when there's a great percentage of patients that do have grafts that lies with grafts and are successful with it.

So I'd like to ask the measurement developer why they excluded AV graft.

Joe Messina: This is Joe Messina. So in the introductory comment that I made when you all were in Washington, when we were all in Washington, I pointed out that we think that catheter rate and fistula rate are linked. I fully agree that there are some people who are not candidates for fistula and would be better served by having a graft rather than a catheter.

And so the idea is minimizing catheters, maximizing fistulas, probably results in the best outcomes for the least cost in terms of grafts being better than catheters for outcomes but much more costly to maintain.

But when this measure was originally written and when we reevaluated it, most of the recommendations, a fistula first and the KDOQI recommendations, were consistent, parallel this submission.

And so we did not include grafts because the current clinical recommendations suggest trying to optimize fistula creation and that's kind of the national - that has been the national approach with fistula first and with the KDOQI guidelines.

Karen Pace: Right, so any measure like this doesn't mean 100%. It does have to be based on, you know, patient factors as well but I guess if you included grafts in here then you may be lessening the incentive or priority of fistula. But what do the others on the committee think about this?

Peter Crooks: This is Peter Crooks. I think that the discussion, fistula versus graft, has been going on and that we shouldn't, at this point, be suggesting a change in focus.

There are - I think the standard - the goal is 67% which means that two-thirds fistula's, one-third grafts. I may be wrong, maybe that one-third would have to include the catheters also.

But also, you know, in a facility if you look at the total patients, a certain percentage have fistulas and a certain percentage have catheters then you know the rest have to have grafts also.

Basically I'm going to say I'm not trying to change this at this point and try to include grafts and keep it consistent with all of the national work that's been done on fistulas.

Jerry Jackson: And this is Jerry, just echoing that, assuming that 2006 when we previously talked about today...

Peter Crooks: You're breaking up Jerry.

Jerry Jackson: Can you hear me better now?

Karen Pace: Yes.

Jerry Jackson: Assuming both the larger committee endorses and goes through the whole process of endorsement of both of these measures then we'd have one measure that stated the long-term catheter use and another, the fistula use, and then you could assume the difference would be grafts or nearly so.

Karen Pace: Okay. Okay, other comments from the steering committee? Connie do you want to say anything else or...

Constance Anderson: No, I'm fine.

Karen Pace: Okay.

Constance Anderson: I'm fine with it.

Karen Pace: Okay. So this one also on scientific acceptability of measure properties, I don't think the initial preliminary values reflected it but this also had the question about the reliability and the developer did provide additional reliability information on this one in that supplemental document on page 25.

So I don't know if there are any other comments or issues, questions, about either reliability or validity that the committee wants to bring up or question?

Okay. Then, on usability the preliminary values we're pretty consistent, no questions were - let's see...I think everyone had the...The preliminary values were all rated high so I'll just see if there is any additional questions or new issues that anyone would want to raise?

Peter Crook: Karen, this is Peter again. Just to - I need to back up to scientific acceptability.

Karen Pace: All right.

Peter Crook: Alan Kliger had sent in an email with, I think, a really good point. He was unable to make the call today. He had two points and one of them was that there are a significant number of patients who are doing - that are stuck with single needle dialysis. There are machines, devices, that alternate blood flow and in some patient's that's the best you're going to do.

And he thought it might be good to change the description to be - and I don't have his email up here, he had a specific wording he had...

Karen Pace: Yeah, he said changing the definition to one needle, to two needles or a single needle device.

Peter Crooks: Right. Which is a minor change and I think would be an improvement. His other suggestion, I'm getting his email out now, is...

Karen Pace: Yeah. I think the other suggestion was specifically related to that evaluation by a qualified....

Male: ...nephrologists.

Karen Pace: Right.

Peter Crooks: And that would be for the next installation I guess, not this one.

Karen Pace: Right, right.

Peter Crooks: Okay. So I agree with Alan's suggestion and I would, you know, I'd probably not vote for it but basically I think it would be something to measure that we could recommend the measure. I don't think we'd have to resubmit it Karen if they just wanted to make that minor change.

The developer comment on this is, is that acceptable or do we have to think about it?

Joe Messina: Well, this is Joe Messina; I don't want to comment for CMS. I don't think I'm able to. But we certainly would take any recommendations for improvement back to them and see what Tom and others at CMS would say about that and what the data availability is based on the specifications that are out there.

Peter Crooks: Yeah, so my position I would ask that some usable and feasibility are also okay with the recommendation that we look at, including those patient's also.

Karen Pace: Okay. Other comments from the committee about the single needle device and whether that's...

Jerry Jackson: This is Jerry. I think that to raise an unintended consequence if you just state it as a single needle and not include with use of a single needle device there's a fairly common practice in fistulas that are marginal at best. They put one needle in and return to a catheter. And so if you just define it as one needle and then you...

Karen Pace: No, I think it was specifically the whole terminology, single needle device.

Jerry Jackson: Okay.

Peter Crooks: Right, that by Alan's suggestion.

Jerry Jackson: Okay.

Karen Pace: Is that common terminology or does it need to be further...

Joe Messina: That would be mean, I think. It distinguishes it from the situation that Jerry was talking.

Karen Pace: Okay. All right, are there any disagreements with that recommendation?

Okay, so it sounds like the recommendation is that the measure is suitable for endorsement but the preference would be to have to add or with a single needle device and we will have to get a response from CMS about that.

Okay, then let's move on to 0262. This is catheter vascular access and evaluation by a vascular surgeon for permanent access. And this is the percentage of patients age 18 and older with a diagnosis of ESRD with a catheter after 90 days on hemodialysis who are seen and evaluated by a vascular surgeon or other surgeons qualified in the area of vascular access at least once during the 12-month period.

This would be - and this is a measure submitted for endorsement maintenance, a measure by the kidney care quality alliance and probably the companion measure - this is a clinician level measure versus facility level measure and would be the companion measure to the 0251 that you all were referring to earlier that the committee reviewed at the steering committee meeting but stopped review pending because of the issues that we've just talked about.

And we did get some response from KCQA about that 0251 which I assume would also apply to 0262.

So let me just - again, I think we'll stipulate that the impact is fine. And on this one, 0262, and we can come back to the discussion about 0251, I was just kind of putting that in context but on this one when we look at performance gap there were some concerns about whether information had been provided on performance gap and so we probably need to take a look at that in the measure submission and I think the developer may have clarified that in responses.

So let me just check here on 0262. I think what's been a little confusing is that these physician level measures the developer also used facility information to get at the physician information but also did some testing in four nephrology office sites.

And I think in the measure submission, I don't know Lauren if you can bring that one up under 1B2 on page 5, it said in the middle of the page it said physician office performance was calculated for those four physician practices and then it said a (mean) facility performance rate of 18%. That probably was supposed to mean physician performance...

Lisa McGonigal: Yeah, I'm sorry. That's an error.

Karen Pace: Okay. That's Lisa from KCQA but one of the questions that the initial reviewers brought up is in the same document where they looked at the facility it says the mean performance for facilities was 69.3%.

So I guess there was a question raised about why the big discrepancy there. So let me just first ask Lisa, it's not the same - the physicians that were not necessarily from the facilities where you gave that facility rate?

Lisa McGonigal: No, they were not. In fact, we tested with (AMA PCPI) and they had already had four physician offices that they were going into. So we used the same offices that they were not part of the facility sample as well.

Karen Pace: Okay. So I'll stop there and just ask the committee to - to see if they have any questions or any thoughts about that, on the performance at the clinician level, the physician level.

Constance Anderson: Can I clarify with the developer when this information was extracted? If I'm looking at page 5, is it really the data from July 1 of '07 to June 30, '08? Is that the data that reflects that percent, 18%, versus the 69%?

Lisa McGonigal: No, our evaluation, our field testing, started on September 1 of 2008 and went through August 31 of 2009. So that's where all of the data is collected from.

Constance Anderson: Okay, thank you.

Lisa McGonigal: You're welcome.

Male: Hello?

Karen Pace: Yes, go ahead.

Male: I thought I got kicked off the call. Sorry.

Karen Pace: So committee members that rated this low or insufficient, what is your thinking now? It's minimal information from clinician offices but...

Go ahead.

Lisa McGonigal: Karen, I'm sorry. We also wanted to point out that the reason that we tested within the facilities is that this measure has been - CMS has indicated that it's planning on including it in it's

CROWNWeb and CMS has indicated that that is how it will collect the information. So we thought it best to test it in the manner which is why we went through the facilities and we note that the information obtained in the field facilities can be linked through an (attempting) nephrologist data field.

Karen Pace: Okay so I guess we know that CMS is mandated to do performance measures for the facility, is anyone from CMS on? So you're saying that they're also going to do physician level scores?

Lisa McGonigal: We have the two vascular access physician level measures that were included in the CMS list of (CPM)'s that was released in April of 2008. They have indicated to us since then that they still intend to include them.

Constance Anderson: This is Connie again. My concern with this is that you will be relying on the surgeon or the vascular access individual to provide you with the data and then you're going to have to be entering that into CROWNWeb at the facility level because that's going to be the - that's the force that they're going to use for data and I think that really has a potential for lots of inaccuracies.

Lisa McGonigal: It doesn't require information to be provided by the vascular surgeon per se. There can be a note from the nephrologist or even a note from the facility indicating that the patient was seen an evaluated by a qualified vascular surgeon.

Constance Anderson: Well, I'm not sure that the facilities are really going to know that they've been evaluated unless they do get something from the surgeon and/or the nephrologist.

So I just feel it puts a real undo burden on facilities to try and attract the information, and B, it is not a field in CROWNWeb right now and so I just have some significant concerns about getting the information and then having to manually enter it versus download it directly through an EMR.

Karen Pace: So I think those are good questions that we need to address. Before we get to that specifically can I just check to see if there were any other concerns about performance gap? I mean, does the committee generally agree that there - I mean, obviously tend to agree in terms of performance gap for this measure. So that's the first question and then we can certainly get into the specifics about the specifications and certainly the feasibility of whether that data is going to be in CROWNWeb, so...

Peter Crooks: This is Peter Crooks. I have some - I'm not convinced either about the performance gap. You know, what we're trying - what's trying to be measured here is very granular process and a physician, you know, and the patient make decisions about things based on a number of factors and to endorse this without knowing that physicians really aren't doing their job.

And I think on one level patients and physicians generally try to do, provide, the best vascular access for the patient and they do respond to pressures within the medical care system but without really knowing there's a gap it means that this is going through a lot and it may not be the best route.

Constance Anderson: This is Connie again. I agree Peter. I think that's well said. I'm not sure I see a gap. In particular when you look at the facility level data, clearly it shows that people are being evaluated for permanent vascular access and having them placed and whether or not the physician office data at 18%, is that lack of documentation or lack of the fact that the individual wasn't seen by a vascular access person.

So I'm not sure that there is a performance gap. I don't know if we know that from the data that's presented here.

Peter Crooks: I agree.

Karen Pace: Okay. So it sounds like we need to - and one of the things that, let me just - because this may bring up a process of what we need to do, it's a bit difficult to do this voting on the call.

So if there - as we go through any of these measures if there are kind of additional questions and discussion that kind of leads us to the direction maybe we need to have you revote on it, we may suggest that we do that right after the call like, you know, we would get something out to you after this call for you to weigh in on that.

But I just wanted to see what the - if there's any other thoughts about performance gap. Someone preliminary thought that there was a high level of performance gap, so maybe ask that person wants to weigh in on this discussion?

Male: Is that person (Nate)?

Karen Pace: I'm not sure. I don't have that in front of me.

Male: Maybe I'm a little bit confused here. Are we saying that the performance gap is the number of patients that aren't being evaluated for an AVF over a 12-month period if they still have a catheter? Is that what you're saying? Are...

Karen Pace: Yeah they - the numerator would be patients who are seen or evaluated by a vascular surgeon or other qualified surgeon and that's out of the patients who are on catheters for greater than 90 days and that...

Male: Okay. Well, I guess is the concern here about what the others have said is that they don't have a AV fistula, or they're not seen, or that the data's not there to determine whether or not they've been seen. I guess, I'm a little confused on that. Maybe I didn't state then as well as I could.

Karen Pace: Peter do you want to respond? I think what you're saying is that it's hard to determined from what we've seen whether it's a, or maybe Connie said this, whether it's a lack of documentation or a lack of being evaluated?

Peter Crooks: Yeah, my point was that the - that I'm not convinced that it demonstrated a performance gap and that's one of our criteria that we should show this performance gap and...

Lisa McGonigal: Can - may I interrupt? Can I ask - in the facility data we do...The performance ranges from 0% to 99% and the mean performance was 69.3%. So to me that seems to demonstrate a pretty significant gap and I'm not quite clear on where the concern is. Same as in the physicians offices, the mean performance rate of only 18% so that there's significant room for improvement on this major.

In addition, as far as the documentation goes, technically yet we - if you are not documenting that the patient is seeing, that's a problem in and of itself. The facilities and the physicians need to be documenting that this patient's have been seen and evaluated by a vascular surgeon for permanent access and so we did exclude patients who did not have proper documentation but we think that that is appropriate.

Constance Anderson: This is Connie again. Here's my concern. This is a clinician level measure and it really is in terms of a relationship between the nephrologist and the vascular access people and - but you're evaluating the performance based on the facility data which is not what the measure is. The measure is really at the clinician level, how's the patient been seen?

The other quarrel with this is that there are patients that have been seen, evaluated and documented and it's not part of the exclusion that these are pertinent access efforts. They will always have catheters and so I just feel that the way it's written I'm not sure that there is a demonstrated performance gap.

Karen Pace: Okay. We need to kind of, I know, move on to some other measures. But, so, I think this is one that we will want to have you all, you know, register on after this call but I just want to point out that, you know, so there could be a performance gap. It may not be specifically about this measure and then we have to deal with the reliability and validity of the measure as specified. Obviously with these endorsement measures, we first ask for information about the measure as specified.

This particular measure did not yet get implemented so there's not going to be a lot of data on the measure as specified. And Lisa, this measure specifications have actually changed from the original endorsement, isn't that correct? Because it was originally specified to CPT2 coding on physician forms, is that on claim forms?

Lisa McGonigal: Yeah, that's not correct. We included CPT2 codes just - we did not test it that way, we just included them and said that it could be used that way as well. It was not tested in that manner.

Karen Pace: Right, right, right. Right, okay.

Okay. So let's just - is there any questions about the reliability and validity information that was provided? The initial preliminary evaluations were kind of across the board in terms to high to insufficient information and it looks like the validity information as well. So perhaps we could have a little discussion of what the concerns or questions were?

Peter Crooks: This is Peter Crooks. I just wanted to step back for a second. I am reassured someone on performance gap the information we were given. So I just wanted to say that.

Karen Pace: Okay.

Peter Crooks: And then we were hearing some concerns about, it is really validity Karen or feasibility about the issue of really capturing the data because it has to be translated from a chart and put in.

It does seem to me that, again, from what's evaluated, I mean measure sponsors are saying, physicians would be incentivized to make sure that this data is entered because, are they going to be dinged if it's not entered or are they just removed from the denominator?

Lisa McGonigal: Okay. Are you asking me that?

Peter Crooks: Yeah. If the documentation...

Yeah, go ahead.

Lisa McGonigal: I'm sorry. If it's not entered, if you have a patient with a catheter who was seen but it's not documented, then the physician would be held accountable for that. They would not get credit for that patient.

The other thing we wanted to add is we can't speak for CMS as to how they intend to incorporate these data elements into CROWNWeb. And it's - we're not...We doubt that they intend to go back and require a chart review but we can't speak to exactly how they intend to do that. We do know

CROWNWeb, it's obviously a very sophisticated instrument and that it would probably be (failing) to presume that this is - will be a problem with feasibility.

Peter Crooks: And Karen, for specifications, Alan Kliger had made the suggestion that we include (interventional) nephrologists as being equivalent to seeing a vascular surgeon.

Lisa McGonigal: Right, right.

Peter Crooks: I was wondering how...

Lisa McGonigal: Yeah, we responded to that with the previous measure that you guys had evaluated. The current specification to (read) vascular surgeon as a qualified surgeon, the steering community previously noted that interventional radiologist be excluded under this current construct. And we acknowledge that interventional radiologists are qualified so we agreed to it. I meant the numerator statement to evaluation by a vascular surgeon, other qualified surgeon or interventional radiologist.

Peter Crooks: Okay, thank you.

Karen Pace: And the edition that Alan is suggesting is that there are qualified...

Peter Crooks: Nephrologists, interventional nephrologists.

Karen Pace: Interventional nephrologists.

Lisa McGonigal: The interventional nephrologists, is that what you're saying?

Karen Pace: Yes.

Peter Crooks: Right. May do essential what an interventional radiologist does.

Lisa McGonigal: Right, I don't think that will be an issue. I can take that back from my committee. I think that would be fine.

Peter Crooks: Thank you.

Karen Pace: Okay. So in the interest of time and getting on to the other measures, is there any other discussion about reliability and validity and then, of course - so that's the measure as specified reliability and validity. And then, you know, certainly we can note the question about that the data elements are not currently in CROWNWeb.

Are there - and as I said I said, we will have the workgroup reevaluate this measure so that we make sure that we capture everyone's current thinking on this but any other pros and cons to raise for the workgroup and steering community's consideration.

Male: It maybe overly nit-picking but I'm not sure there's data that links just being seen by the surgeon with a decreasing catheter prevalence and increasing fistula prevalence. Did anyone else share that concern?

Jeffrey Berns: Yeah, I agree with ya. I think - as I'm thinking about this, this is Jeff Berns, the goal here is to have a permanent AV access in place and we already have performance measures assessing that.

You know there is data that comes from (Michael Alon)'s group that even under the very dust of circumstances dedicated nurse practitioners and databases and extraordinary efforts to get

patients, to get access, a lot of patients just don't do it despite the best efforts by the dialysis unit and the clinicians and nurses involved.

And they had 50% of patients at a year who had been referred for access still didn't a permanent AV access in place for a whole bunch of different reasons. So you know, on the one hand the facility would look good in that they had made a referral so they'd look good on this measure but they hadn't accomplished a goal which was to get the catheter out. So I'm not sure that this measure really gets at the heart of the matter sufficiently to be worth what sounds like a lot of effort to get the data.

Lisa McGonigal: I also want to clarify that more than just a referral is required for this measure, that it actually does require that the patient be seen and physically evaluated.

Peter Crooks: Yeah, and I - what I said still applies. You can be seen by surgeon to never get - and there's a lot of patient's who are seen by the surgeon or somebody and never get an access place for a whole variety of reasons despite, you know, again, the unit would have done the right thing but it didn't accomplish the goal and we have other measures in place that assess the goal.

Karen Pace: Okay. So we will get something back out to you to give us your best evaluation of this measure so that we can actually have some time for the rest of the measures unless there's any additional comments on that one, we'll move on the patient education measures.

Any other final comments?

Okay, Lauren, do you want to...

Lauren Richie: Sure. Okay. So moving on to the patient education and quality of life measures; I did send out some email yesterday just kind of overarching issues pertaining three of the measures

relating to some discussions that came up during the in-person meeting that relates to some of these measures being possibly addressed under the conditions for coverage and I won't go into all of the details of that email but if you do have it handy that might be good to pull up now during this discussion.

We started with 0324 at the meeting and I think we kind of get maybe halfway through that measure before we had to stop so I think I'm just going to pick up there and maybe we can just kind of start over again fresh with these measures.

So again, as Karen said, we will kind of skip over the high impact question and move right into the performance gap, opportunities for improvement. It looks like there was, on this measure, some variability in terms of the review in the initially review that we had a couple of high ratings and one low and one moderate. So if I could, maybe just ask...

Karen Pace: Could we - we're starting with 0324, right Lauren?

Lauren Richie: Correct. Yes.

Karen Pace: Okay. So this one the steering committee did vote on importance to measure and report? I guess the question is whether the workgroup wants to re-discuss that or pick up where the steering committee voting left off which I think was at...

Lauren Richie: I think it was scientific subsibility.

Karen Pace: Right, I don't think we - yes, I think they voted on reliability but we hadn't yet gotten to validity. So maybe we can, you know, we can go either way but I just wanted to see what this workgroup thought would be preferable to them? Do you want to go back and talk about importance to measure and report again or pick up where the steering committee voting left off?

Laurie Richie: And the other thing to, just to think about too, is as we look at this measure which is the facility level measure that we should also kind of keep in mind the next measure which is at the physician level.

If we want to try to maybe approach both measures at once or look at the two separately, they're essentially the same measure except for the level of analyses.

Karen Pace: Right. And so I think, I mean, we could go through the one measure and then you know just see if there were any distinctive differences. Let me just check with Lisa.

Lisa, they're essentially the same specifications and the only differences in the level of analysis, is that correct?

Lisa McGonigal: That's correct and during the meeting, I believe the steering committee was going through them together if that helps you at all?

Karen Pace: Right.

Peter Crooks: This is Peter. I think we don't need to review importance of measuring and reporting unless one of the reviewers wants, or one of our committee, wants to do that.

Constance Anderson: This is Connie and, once again, this is a measure that in the new conditions for coverage is requirement. And so I do this as the facilities are obligated to do patient education and so I have concerns that we're looking at this as an NQF measure for endorsement since it's already been under the purview of the CMS surveyors and performances of the facility level is being evaluated.

Male: I agree. I think we agreed - the issue is important, no one's in favor of patients being ignorant about this. The question is how well this measure would address this issue and also how it will advance things since it's already a condition of coverage.

And we did vote on, you know, there was a vote on the level of evidence which is low but then there was a question as to whether we should proceed because the detriment to the patient was so minimal. But I would like to ask one question if this were voted into place, it could potentially make a more meaningful measure, educational measure, less likely?

And I think that actually is an adverse outcome on the patient.

Lisa McGonigal: If I may speak to that, the KCQA steering committee actually felt that this measure was quite important because the surveys that are going on in the facilities right now, they felt weren't sufficient to address this issue.

And, in fact, the GAO has indicated that the surveys are falling short. CMS currently has a policy that the time interval between surveys at any one specific facility should be no more than three and a half years but the states obviously have various levels of success in meeting that target.

In 2009 a total of 19 states were unable to meet the survey interval for three and a half years for 100% of their facilities and then Medicare data indicates that as of October 2010, almost one in ten facilities hadn't had a top to bottom check in at least five years and about 250 facilities hadn't had a full recertification inspection at seven years or more.

So it's clear that the surveys aren't getting to this issue and it's not going to be good enough to ensure that the education is occurring on a yearly basis.

Male: I guess what I was getting at was you could pass this measure and still not really be doing much to educate your patients.

Lisa McGonigal: I agree.

Male: Is that because it's a - because I don't think we - I mean, I guess I would like to actually look more at how much the patients understand some measure, that the patient's have some comprehension.

Lisa McGonigal: Right.

Male: I'm just - you know...And there's nothing wrong with this but it just - it isn't...Some sorts of measures that NQF endorses, if there's a - they can be implemented at a different pace if there is no existing measure in that area, isn't that correct?

Karen Pace: Well, we use - we have a category for time limited endorsement of measures, if they hadn't been tested. This measure was originally endorsed as a time limited endorsed measure and then they submitted their testing data which is also in the submission form that you have. So I think that - so the question is, you know, whether this should be recommended for continued endorsement based on our criteria.

And I think you know, certainly the question of things that are mandated and regulation and whether that should be a performance measure is worth questioning. You know if the - but that doesn't necessarily mean that there's no, benefit in having a performance measure that actually makes that kind of information acceptable. And if the surveys really aren't happening on a regular basis or if surveys are mostly based on a sample, I'm not sure in the dialysis facility world, than, you know, there could be a reason to still have a performance measure but then that's also based on if a performance measure meets our criteria, so...

Peter Crooks: This is Peter Crooks. I would just say I agree. I think this is complementary to the fact that it's a condition for (crowd region) and those inspections.

In California, we have units that have gone ten years without an inspection. So I think this is a complementary - that's assuming that it does what it say's it - it actually does what it says it can do.

Karen Pace: Right.

Peter Crooks: But if it did I don't have any problem with the concept that this is also a conditional coverage. It's complementary to that, I believe.

Lisa McGonigal: And in addition, to NQF as no similar measure at this point in time and as far as I know there is no measures in the works addressing whether or not a patient understands what has been taught to them. So that - I don't believe that's a solid reason to negate this measure because a measure may come down the road.

Karen Pace: Well that's - you know, and...So the real question is whether this measure, as it's specified, meets the NQF criteria. And you know it's - it really did not pass evidence but the committee thought that an education measure could meet the exception to having empirical evidence because there would be no detriment to the patient. The - so where we're at, which is where I think we should pick up, or we can have you rethink that if you'd like, but then the question is, really, is this measure as specified reliable?

And probably I think the heart of the question that you all are raising, is it really a valid indicator of quality? Is it really going to tell you what you're hoping to know or driving improvement in the area that you want? And I think that's what some of the comments are about.

So do you want to go back to the evidence question or do you want to pick up with reliability and validity of this measure as its specified?

Peter Crooks: Well, I think the reliability limiting issue may come down to kind of just a check box nature of this. If this was the check box in CROWNWeb, you know, does that correlate to the patient and get them some true education or not? Is that some of the concerns that were stressed?

Male: Yeah.

Karen Pace: Yeah. And I guess a question too, and I don't know if Lisa knows this or if someone from CMS, is this a data element in CROWNWeb?

Lisa McGonigal: I think this was included in their list. They have since indicated that they are very interested in, still interested in, including this in upcoming versions of CROWNWeb.

We have no indication that this is not intended as a check box measure and I think it's dangerous to presume that that's what CMS will collect, again, because CROWNWeb is highly sophisticated and it's inappropriate to think that this is just going to be a check box measure.

Karen Pace: But currently there's nothing in CROWNWeb where this could actually be computed. So the only way we could endorse this measure is as a medical record measure because there isn't anything in CROWNWeb.

Lisa McGonigal: But they have indicated that they will be building that element in.

Karen Pace: Okay.

Peter Crooks: So then if we have to evaluate our current data collection method, would we have a description of that and how do we do - is it 100% of patients or is it just a sample or how are we supposed to go about it or about doing that?

Karen Pace: Well, the data collection would be what was specified in terms of the details about the numerators and denominator. Let's see if we can - in zero, two, three, four....

Because we don't have any CROWNWeb data elements so those are not in there. So let me just see what - so they've provided some specific information in (2A 1.3) on page 9 about how - and this is how they tested the measure by doing medical record review abstractions.

Do you have that up Lauren? Yeah.

Lauren Richie: Yes, it's up.

Karen Pace: Okay. So they have those details about what's required to meet the numerator conditions and then I think the denominator is pretty straight forward.

Yeah. So if you look at those numerator details that's basically how the measure was tested and we don't have any CROWNWeb elements that go with that that to say that it would be any different. We just don't know. So I mean...

Male: So - so are we being asked to consider endorsing a measure that doesn't have - or either the data has to be extracted from charts in a very labor intensive process which hasn't really been tested except to do some limited feasibility testing and/or the data will be collected possibility to CROWNWeb in future.

It's - from a feasibility and I'm obviously ((inaudible)) that I'm not sure it sounds that we should be endorsing. Does that - actually if the data can be collected and if it will ever be electronic? And even if so, it hasn't been tested.

Karen Pace: Well the - it's been tested, you know, in a sample and currently that's all our criteria requires is that there be reliability and validity testing and it can be done on a sample.

You know, NQF does endorse measures that are specified for medical records and, you know, hopefully in the future some of those will be converted to measures that can be extracted from electronic health records. Or, in this case, the goal would be that eventually this would be available in the CROWNWeb data.

So I'm just saying that basic - you know, so it's not that we can't endorse it. I think what you're speaking to is the likelihood that a medical record extraction data measure would be widely implemented. But, you know, I can't answer that. NQF is not the implementers. But it doesn't prohibit us from endorsing a measure but I think it's a point.

Peter Crooks: Well, it's speaks to feasibility, you know. Is this ever going to be used by anybody in this current form, you know, other than a few tested?

List McGonigal: We have received indication from CMS that it will be used in CROWNWeb so, yes, at this point in time we can say that it's very likely that it will be widely used.

Female: Although if you look at the description in the numerator details, it really is just a check box. Did the patient receive education? Yes. If yes, which type of modality was discussed? It's not anything about the quality or the - it is, it's a check box; yes, no.

Lisa McGonigal: This is designed - it was designed to reflect the current and is consistent with the CFC's.

So yeah, at this point in time this is - we're making sure that the facilities and the physicians are educating their patients on all available modalities as is required in the CFC's.

This measure does not specifically look at whether or not the patient understood and so on and so on but we're confirming that the conditions for coverage are being met.

Karen Pace: Okay. So I think this - these are measures that we also will have to have you, you know, rate and vote on after we finish our discussion. But - so let's continue to see what are kind of the pros and cons in terms of making sure that all of the information that is relevant to evaluating this measure is available and has been discussed.

So any suggestion for those who....

Constance Anderson: Since this was an 0324, a facility level, in the reliability testing, I guess I'm curious from the developer why the physician office testing, on page 12?

Karen Pace: I think that - let me just say that they put the facility on the physician office level testing in both measures even though one measure is facility and one is physician.

Lisa McGonigal: Right and...

Constance Anderson: Sorry. Go ahead.

Lisa McGonigal: Yeah, that's just how we completed the form. See, the physician office obviously refers only to the physician level and the facility to both.

Karen Pace: But are you proposing as well that the physician level measure would also be eventually coming from CROWNWeb data? Are you maintaining that that would still be done through physician records?

Lisa McGonigal: Again, CMS has indicated that it does tend to collect that the physician level measure through CROWNWeb.

Karen Pace: Okay. And is Tom Dudley on the line by any chance or anyone else from CMS?

Kimberly Smith: Yes, this is Kim Smith. I believe Tom was involved in these conversations and I actually just sent a note to CROWNWeb team to see if I can confirm whether that will be built into the system but I don't know the answer to that offhand.

Karen Pace: Okay. Well, that's something we could also get some more information on if you don't - if you get a response before we end the call, please break in and let us know.

That would be good.

Kim Smith: Okay. Great!

Karen Pace: Okay. Any other comments from the committee in terms of positives for either the facility level or physician level measure or any other issues that you want to have the committee discuss?

Okay. And then just in terms of, you know, as we said at the outset these are the facility and physician level measures are basically the same just the different level of analysis. Are there any different issues or considerations, pros or cons for physician measure versus facility measures?

Male: Yes I have a little concern at least in our clinics which are run by one of the LDO's, you know, there are facility level protocols in place. In this case the social worker would primarily be a team member most directly interfaced with a patient on education and should do that throughout the unit for all patients.

The physician will add some additional education during that doctor's rounds. I'm not quite sure how we split that out. You see where I'm going? It's something that flies across the board about the staff analysis unit. It's going to be a facility level measure but how will the physician component of that education be documented and split out from the rest of the team interventions?

Karen Pace: Lisa, do you want to address that?

Lisa McGonigal: When we were going in the facilities and we did our field test, the facilities actually were documenting who provided the education. With the data that we collected we did not differentiate that but we could go back and look at that data and provide you that information if need be.

Karen Pace: So is the kind of framework that this is looked at, at the patient level out of the facility record but then the physician score would be based on the same data it's just that for the physician of record would be attributed the same score as the - for an individual patient it would be based on the same information that was going into the facility score, is that what you're...

Lisa McGonigal: Well, I can't say that for sure. Obviously that's a question of implementation and it depends on how the measure is implemented and used so I can't really speak to that.

Karen Pace: Okay. All right.

Peter Crooks: But I think it seems that at least to this point in time you've been taking similar documentation. In other words, you're not looking for documentation of the nephrologist or anything it's just that there's documentation of modality education.

So if that's the case then I - you know, I think the secondary concern, in addition, you're not really capturing physician component is that the (physicians) recovery - if it's Medicare they've taken responsibility for modality education on the dialysis so not on the nephrologist.

So it's all your - I think the nephrologist might...I'm not saying that nephrologists aren't ((inaudible)) shouldn't be doing it but the nephrologist might feel that, well this isn't my job. My job is a facilities job to gain more valuable education. You know you get paid, they have to do it, they have to document it and that's they're job.

Lisa McGonigal: I know that the case in QA committee really disagreed with that. They strongly believed that the physician has a large responsibility, actually the primary responsibility, to educate their patients on available modalities.

I'd also like to - just to point out that this is a patient-center measure. The point of the measure is to strive to fully inform the patient on all available options. To them, again, this is consistent to the CFC's and I just wanted to see if there was any input from the patient's on the steering committee on this measure, if anybody had anything else to add from the patient's point of view.

Harvey Wells: Well, I mean the only thing I'm really concern about is what everybody else is concerned about. If it's just the check box, I don't see what good that it is.

If it's actually being done, I mean, I think it needs to be done and I think that's the biggest problem with dialysis care today is if you go into the centers, I mean, very few people are either aware of all of the modalities as far as in the large numbers, I'd say 80% to 90% of the population.

The ones that are aware, then they seem to be doing pretty well. But I think the data suggests that patients just aren't in the...So I think it's important but I do have a concern that if it's just a checkbox that it's really not doing that much good. And I'm not sure that you can track the data. So you know I...

Constance Anderson: Oh, go ahead Harvey.

Harvey Wells: Well, I mean I think this is a very worthy measure but I don't know if it's going to meet the criteria to endorse it. I mean, emotionally I say yes but I think, you know, when I hear the concerns I've got to agree with them.

Constance Anderson: And I guess - this is Connie again. My biggest concern is you have two measures; one at a facility level and one at the physician level. And I just am not sure that you're going - it's going to improve care or the way the measure is written it's going to demonstrate that there is quality. It's just - I just don't think it's ready for prime time yet.

Lisa McGonigal: Does the steering committee have any recommendations for KCQA that I can take back to our steering committee or...

Male: I still have reservations about the importance of breaking at the physician. I know that your committee feels that it's the physician's responsibility. I think it's - there is some responsibility by the physician and by the medical director; particularly the medical director of the facility. But I think it's arguable that trying to do a physician level measure is really going to have any impact. Doing the facility one makes sense, as I said before, because they're signing responsibility and it's a complementary, the fact that it's a condition for coverage.

Karen Pace: Right but I guess the point is, is that if everyone is - if it's a team approach then everyone - it's kind of a shared accountability issue whether it's a small portion or a large portion, its shared accountability.

Male: Well without evidence we're kind of shifting responsibility from the facility to the nephrologist and you know, so...

Female: Yeah.

Male: It feels right to say it's the nephrologists responsibility to do this and we all agree that the best of our (world) that's the case but Medicare says this is not the nephrologists responsibility, it's the facilities. So we're kind of saying this is a feel good thing to measure the physician level. It seems right but I don't think there's a lot to - at the end of the day it's a lot to...It's really valid.

Male: It's almost like - as long as you have both of them there that's supposed to be doing, you're hoping that one of them will. I don't know, maybe...

Male: Yeah, that's true.

Jerry Jackson: This is Jerry. I just want to go on the record that I fully agreed that the nephrologist should be heavily involved in patient education. That was not my point it was just that we have two separate measures, the facility staff level, the people and physician being separated that it can be very, very hard to (tease) that out.

I'm not sure that makes it a very usable or feasible measure if you have to divide in between what the staff of the facility educates the patient about and what the physician education about.

When I make rounds I have my social worker standing next to me when we see each patient and we have a joint discussion. It's hard to (tease) that part and that was my only point.

Lisa McGonigal: But again the KCQA would be willing to entertain any suggestions that you might have to strengthen this or make it a better measure in your opinion.

Male: If they want to think about including - you know, some evaluation of comprehension that would be - it's very difficult. And, you know, it would be great to have some input there.

Male: Agreed.

Male: Yeah, I would agree with that too. I mean it's always good to hear what the patient thinks his level of education about the disease is because, once again, I remember when I was in the center and I'd just check our forms but my comprehension level was very limited. It probably still is.

Karen Pace: Okay. Well, I know we are getting down with the wire with our time here so we will follow-up with you all with those two measures and Lauren do you want to give an update on the process measure on the quality of life instrument?

Lauren Richie: Sure. Well, actually in terms of content for the measure, we don't have much of an update versus what you last received. However, we have been in communications with (RAND) who is the measure steward and they have agreed to submit some additional information specifically as it pertains to the opportunity for improvement and the performance gap data.

They are also working with, I guess, kind of subcontractors if you will, (Best Witten & Associates) who help develop the measure the first time around. They - we have also been in talks with them as well and between the two (RAND B) and the measure steward and their counterpart agreed to submit additional information on the measure.

So we all agreed that an outcome measure would be obviously the proffered measure but I think in terms of - we also all agreed that this is an important measure and want to keep it endorsed if possible so that we will move forward with the process measure for now once we get additional information from them and then we will forward that to you for your review and then we may have to convene again once we get more information from the measure steward.

Karen Pace: Right. So the first step is actually just getting the information that you can evaluate against the criteria because we haven't had that. So if we do get that we will definitely have you take a look at it. If we don't, of course, the measure won't go any further though there is interest in developing an actual measure that's based on the patient reported physical and mental functioning.

So - and the group that Lauren mention that (Witten) and her group had been working with facilities and collecting this information and may be able to develop something that would be an appropriate patient reported outcome measure.

But we wanted to see if - you know, I know we talked about it briefly at the meeting and, of course, as Connie had pointed out this is also something that it's not specifically mentioned in the regulations but in the interpretive guidance to the surveyors but I think the same discussion that you have previously about the potential problems with the survey process and that doesn't necessarily negate having a measure but the question is whether the measure as specified really gets to what you're interested in since it's really just, did you give a quality of life instrument annually?

And you know, the reason that measure got through the last time was it was seen as kind of a start to get down to eventually get to some point of having a measure more about the actual information rather than just that process. So I guess if you have additional thoughts you can

mention them now and we can, you know, be sure to have that in their mind when we get the information from the developer.

Male: Well I think that that's a similar concern as you mentioned that just because the survey is done, what some of that information - how does it help patients? It's sort of distal to the outcome you like which is that, you know, patients quality of life is not (improved) by the analysis process in some fashion.

Karen Pace: Right.

Constance Anderson: Karen, the other comment that I would have is the - I think a better way to look at this measure is the percent of patient's in your facility that have below average scores.

The KDQOL of this measure is written and basically directly out of the FAQ's in the conditions for coverage and it's also in the MAT that if it's the number of patients who have taken the test...

Karen Pace: Exactly.

Constance Anderson: More significantly would be a measure that identified how many people had below average scores in the physical and mental and then look at that as improvement overtime.

You know, actions that were taken. KDQOL, in our QAPI meetings are dictated by the conditions for coverage and are supposed to be reviewed and those that are below average and those outliers are supposed to be incorporated into the patient's plan of care.

Karen Pace: Right.

Constance Anderson: So I'm - I feel an outcome measure is a much better measure than a process measure because the process measure is already in place.

Karen Pace: Right. And you know that that's definitely the direction that everyone would prefer. So we'll see what more information we can get for you and, as Lauren said, you didn't even really have sufficient information to do anything with and perhaps, you know, we'll see. I mean, you know, just because they provide more information doesn't mean that it's going to meet our criteria or that you think it would be worthwhile to recommend for endorsement.

Okay and I guess Lauren, we need to...

Lauren Richie: Yes. So before we go to the member and public comment period, I'll just recap really quickly that measure 0256 and 0257 passed with a couple of conditions relating to changing the language and excluding the hemodialysis patients from 0256.

The other measures we will...

Karen Pace: Yeah, I think they didn't - ultimately did not...We're going to make a comment about that. They did not recommend that that had to happen.

Lauren Richie: Okay. So - and for the other measures we will take a revote on those and you will receive some instructions from myself. We'll just administer another survey (monkey) and then if you could, if you're response...

Male: Are you going to survey just the initial reviewers or all of the people on the call?

Karen Pace: We'll do all the people on this call plus the initial reviewers.

Male: Okay.

Lauren Richie: Yeah, and if your responses change drastically from the initial survey then we'll just kind of ask you to clarify or justify perhaps maybe why your responses have changed. So we'll hopefully get that out today or Monday at the latest. So with that, I think that's it and...

Male: So it shows what your review of competing measures are.

Lauren Richie: Yeah, obviously we won't have time to get to that either today. We will...

Karen Pace: Right and I think what we're going to do is if - we'll take on more...We've put together a comparison table. We'll look at that more closely and I think our first step will be to ask the measure developers to come back with a plan for harmonization if it's indicated versus having to have the steering committee recommend something and then have them reject it. So that might be a more efficient way to deal with harmonization if it's still an issue.

Male: Sounds good.

Laurie Richie: Yep, and just a quick reminder, our next call will be for the mineral metabolism measures on Monday the 19th from 1:00 to 3:00 and that's Eastern Time. If you can attend that call, even if you're not in the primary group, that would be great.

And with that, I think we have just enough time to open up the call for the member in public comments period.

So operator, Anthony, if you're there can you open the public line please?

Operator: Yes ma'am, all public lines are now open.

Karen Pace: And...

Male: Okay...Does anybody have ((inaudible)) a public comment? Anyone care to comment? Hearing none I guess we don't have any additional comments today.

Karen Pace: Okay...If you all think of any additional questions or information that you need, please, or suggestions for us, please let us know. But, as Lauren said, we'll get something out to you Monday at the latest on the measures that, you know, we think that were sufficient questions and discussions that we need to have you do, you know, based on all the information and review of the measures to (rate) so that we can provide that information then to the full steering committee for their consideration.

Any suggestions for us for process suggestions that we - all of this is kind of new territory in terms of trying to get through this work so currently any suggestions you have are welcome and willing to give it a try.

Male: I might just say Karen, I think this wasn't - what actually a pretty good forum. You know, and to - we had subgroup, you had subgroups, before but I think having this limited number and a group that's focused on these and studied them was productive. I think we got to a lot of key issues and aired them out. So just my perspective, it seems like it was a good process.

Female: I would agree with that as well.

Female: I would echo that too.

Karen Pace: Okay. Well thank you. And if anything this occurs to you, you know, definitely contact either of us. We're definitely interested so I appreciate your comments and your attention to all of these issues.

Female: Karen or Lauren, do we have a date for the full committee re-review yet?

Lauren Richie: Not yet. I'm going to send out something today or Monday. I'm just trying to get a last few minute responses in and hopefully I'll have a date settled for you today.

Karen Pace: And - but you can kind of...It's going to be, what, mid October?

Lauren Richie: We're looking at mid-October possibly the 11th or the 13th.

Karen Pace: Okay.

Female: Oh, perfect. Okay. Thank you.

Lauren Richie: We'll get that to you as quickly as possible but we will do that soon.

Male: But the other three committee meetings are set?

Lauren Richie: Right.

Male: Okay.

Male: So when you sent out the announcement Lauren, and in all of these - putting the whole schedule of meetings...

Lauren Richie: Absolutely.

Male: I would suggest...Okay. Thank you.

Female: Okay, thanks.

Female: Thank you all.

Female: Thanks.

Male: Thanks everyone.

Karen Pace: Thanks everyone that participated. Bye.

Male: Bye-bye.

END