

## **NATIONAL QUALITY FORUM**

**Moderator: Sheila Crawford**  
**September 19, 2011**  
**12:00 pm CT**

Operator: Good day everyone and welcome to the Renal Steering Committee's conference call on mineral metabolism measures. This conference is being recorded.

I would now like to turn the conference over to Lauren Richie. Please go ahead.

Lauren Richie: Okay. Thank you. Good afternoon everyone. Welcome to the renal call for the mineral metabolism measures today. We're joined here by Eugene Cunningham and I will be joined by Helen Burstyn, VP of Performance Measures here at NQF and actually Karen Pace could not attend the call today.

So it'll just be Helen and myself. We have a full agenda for two hours today and we have five measures to get through and we will get to those momentarily. But before I do so, I would turn it over to either Dr. Crooks or Dr. Shunder for any opening remarks.

Peter Crooks: I think it's my turn this time, Christine, is that okay?

Christine Shunder: Okay. That's fine.

Peter Crooks: All right. Thank you all for calling in today and welcome. Briefly what we're going to do is go over five measures related to mineral metabolism that we weren't able to do during our live meeting.

And after taking roll call Lauren will briefly introduce each of the measures and try to really highlight areas of disagreement. We want to focus on areas where there may be controversy and not so much on areas where the primary reviewers seem to all be in high agreement. Then the plan will be after - not during the call but after the call to revote on all the measures.

And I think Lauren has sent out a Survey Monkey afterwards and then as time permits we will also try to discuss any related or competing measures at the end of the call. So we did this with hemoglobin anemia measures ten days or so ago and it seemed to work pretty well. So please try to stay on topic and also you may want to mute your phone when you're not speaking. But please don't put us on hold. Okay. Lauren.

Lauren Richie: Thank you Peter. So at this point I'll just take a really quick poll of the committee members and the work group members that we do have on the call. So just to confirm, I see here we have Alan Kleiger, Andy Narva, Jeff Burns, Jesse Pavolnek, Christine Shunder, Peter Crooks, Michael Fischer and Michael Summers.

Alan Kleiger: Yes.

Jesse Pavlonek: Yes.

Lauren Richie: Is there any committee members on the call that I did not name? Okay. Great. Just as a reminder, you may want to maximize your screen in the upper right hand corner as we kind of go through the measure submission forms in the Excel file.

And what we sent out prior to the meeting was a summary of the work group's preliminary evaluations based on your entries before we met at the in person meeting. So it's essentially the same information that was sent out to you in both the Excel and Word versions. And as Peter mentioned, I'll just provide a brief description of the measures and the preliminary evaluations, highlighting any kind of issues or concerns or points of disagreement among the committee and that's when we'll open up for discussion.

We do have measure developers on the call who are available to respond to any questions that may want to direct to them. One thing before we get into the actual measure discussion, so what we did with the vascular access/patient education work group that met a couple of weeks ago, for the criteria of high impact we kind of wanted to address all the measures at once.

And so that work group essentially agreed that the area of vascular access was a high impact area and so we kind of eliminated the need to discuss that particular criteria for each of the measures. So if this committee or if this work group agrees that mineral metabolism in general is a high impact topic, meaning it's an issue that affects a large number of patients, it's a frequently performed procedure, then we will assume so for all of the mineral metabolism measures.

And then we can suspend any discussion of high impact. So I'll just open it up to the work group to see if you all agree or disagree with that suggestion.

Male: I'm okay with that.

Peter Crooks: Lauren, it's Peter Crooks.

Lauren Richie: Yes.

Peter Crooks: I think that actually on a number of these if not all of them there was most of the reviewers felt that there wasn't sufficient importance to measure a report, that the impact was not high.

For instance, the first measure, the sponsors measure, four out of five voted that it was not important a measure or report. So I don't think we're going to be able to do that.

Lauren Richie: Okay. And that's fine.

Peter Crooks: But if you're looking at it a different way than I am but that's what I'm sort of seeing.

Lauren Richie: And that's fine. That was also kind of based on how we looked at the measures during the in-person meeting as well. So that's absolutely fine. We can look at high impact for each of the measures as we go. And then also - I'm sorry.

Peter Crooks: Well, if we find that - this is Peter again. If we find that a measure isn't in this group of high importance to measure and report, we're still going to need to go through the rest, is that correct?

Lauren Richie: That's correct. For these work group calls, yes.

Peter Crooks: Okay.

Lauren Richie: And in fact, for the first two measures that we're going to start with, the serum phosphorus and the calcium measures, there is some additional information that I'll present to the work group that we may want to take a closer look at.

So but yes, we will have to go through each of the criteria as efficiently as we can. So in addition to high impact there are also some issues of evidence and reliability and validity that will probably take up the bulk of the discussion for these measures. So just a little bit of background on that.

Helen Burstyn: And Lauren, this is Helen just to let you know that I'm on if you need me.

Lauren Richie: Okay. Thanks Helen.

Joe Nally: Joe Nally has joined too.

Lauren Richie: Thanks Joe. Okay. So we'll go ahead and get started. Our first measure is 0255, measurement of serum phosphorus concentration.

And as Eugene is going to pull up the measure submission form and I will just give a brief description, this is percentage of all adult peritoneal dialysis and hemodialysis patients included in this same for analysis with serum phosphorus marked at least once within a month, the numerator being number of adult dialysis patients included in the denominator with serum phosphorus measured at least once within the month.

The exclusion are transient dialysis patients, pediatric patients and kidney transplant recipients with a functioning graph. And this is a facility level process measure. So as Peter mentioned, this is one of those measures where we did have some variation on high impact. So if we can pull up the Excel file Eugene, and as you can see there, we've got two lows, two moderates and one high.

So I'll open up the discussion on high impact for this measure and see perhaps maybe for those that rated it low, why you did so or even high. We'll start there.

Jeff Burns: This is Jeff. I rated it low you know and I guess this reflects my sense that process measures alone, measuring something without an attachment to any outcome or response to that measurement, is to me relatively - actually to me is generally quite unimportant.

This is routinely measured. It's always been routinely measured. It will always continue to be routinely measured. What's important is what you do - well, what may be important - this may be an exception. But the importance lies in what you do with it once you (get it).

Male: You caught yourself, didn't you?

Jeff Burns: Say again? I didn't hear that comment. The point here is that when we know that there is something to be done in response to a measurement, it's that response and patient outcome that's important, not the fact that it was measured.

Lauren Richie: Correct. And you're absolutely right. That's something that our CSEC has been putting a lot of emphasis on related to some of these process measures. Go ahead.

Michael Fischer: Lauren, this is Michael Fischer. I may have rated it low. Unfortunately, I'm at the VA and there is security and I cannot pull up the webinar. But I have the materials.

But one of the concerns had been and Karen clarified this is what impact are we rating. Can you maybe clarify again about the - because my sense of walking away from the in-person meeting, that it was the broader impact of kind of the area and less about a specific measure. But I may have had a misunderstanding and it's been several weeks since we met.

Lauren Richie: True.

Helen Burstyn: Lauren, I can help if you'd like.

Lauren Richie: Yes. Go ahead.

Helen Burstyn: Sure. So this is Helen Burstyn. So basically impact really is more so the general area. Is it a high impact area of care, large enough pools affected or severity of the problem?

It really is I think the issues that Jeffrey was just raising are more so about the issue of is it approximate or additional to outcomes in terms of its import. I think 1A is really about truly impact of the condition.

Jeff Burns: Okay. That's helpful.

Helen Burstyn: Okay.

Lauren Richie: Okay. So there - are there any other comments on high impact?

Peter Crooks: Just to clarify, I think mineral and bone disease I think is important. So not to minimize the importance of the general topic area but as opposed to this specific measure.

Helen Burstyn: Right.

Male: Sure. I mean just one quick thing I mean Jeff, whatever the evidence, we know that there is retrospective data that has a strong correlation between phosphorus levels and survival. And given that alone, I would have to say that this has high impact in our population.

Jesse Pavlonek: And this is Jesse. I was the one person that did high impact and for this very reason that was just expressed.

Peter Crooks: Is it the impact though of that measurement only when something useful is done with it?

Male: Well, see, to me that comes more (distant) in the discussion. I mean this says to me that it's an area that deserves - it impacts a large number of our patients - so yes.

Peter Crooks: (I'll branch it out). So in general the issue is important.

Male: Yes.

Peter Crooks: Okay.

Helen Burstyn: All right.

Lauren Richie: Okay. So it sounds like we have some consensus there and that this is a high impact area. Just really quickly then moving on to 1B, opportunity for improvement, there was some variation in responses there.

And as pointed out by one committee member, there was a 77% compliance rate on this measure but there also appears to be a fair amount of variability ranging from 0-100%. So is there any thought about opportunity for improvement? I see we have rated - we have three low, one high, one moderate.

Jeff Burns: I'm just looking through my notes to see why. Looking at the data here, I find it hard to believe that every inpatient dialysis facility doesn't have phosphorus measured on patients who are actually treated in the facility that month or are at least in the facility that day the lab tests are drawn.

So I would have some concerns about the accuracy of that one data point using one source. There is going to be some percentage of patients who are outside the unit the day the lab tests are done. So I'm not convinced that this is hugely supportive of a performance gap.



Lauren Richie: Okay. Others?

Jesse Pavlonek: I'm sorry. On the flip side, we don't know that for sure. And perhaps some people don't draw it as often as we all think they do. But who knows?

Jeff Burns: That was I guess the obligation of the measure developers to convince us that there is a performance gap.

Jesse Pavlonek: Yes. That's true.

Peter Crooks: This is Peter Crooks. I unfortunately got dropped for a couple of minutes and missed some of the discussion. But I wanted to comment that under impact that you know, the criteria have really changed since we voted for this three years ago.

You know, at that point we were rating things differently and that kind of following guidelines and just to measure the frequency of a measurement was not considered less or inferior as it is now. So I really do have trouble with the impact that this is - that there is a link between the evidence and outcomes from doing this.

Male: I guess Peter, while you were gone we thought perhaps that without having a link to outcomes but the fact that the impact on our patient population of high phosphorus, since it's so prevalent, is high and its correlation to outcome is so high, that the impact is high. Whether or not we have a link I think comes more (distant) in our conversation.

Helen Burstyn: Yes. That's really 1B Peter, when we get to evidence. So we probably could move on. I think the impact issue is probably less concerning than I think the mixed ratings you guys have on evidence.

Lauren Richie: Right. And actually, that kind of segues into the evidence for this measure and actually for the following measures. You know, I think we kind of agree that the focus of the measure is distill to the desired outcome but there are a couple of things I want to point out to the work group.

These measures may initially appear to go down on evidence because the evidence submitted is based on observational studies about the relationship between phosphorus level and mortality, which cannot exactly prove causation. And there was no information submitted about any studies that show a decrease in phosphorus levels will lead to better mortality outcomes.

Male: That's right.

Lauren Richie: There is evidence about a relationship between prolonged phosphorus dysregulation and ESRD patient morbidity/mortality and it's based on clinical guidelines and selected studies.

So should it be assumed that increases in phosphorus levels cause mortality or could it be due to just the effects of kidney failure?

Male: Or anything else? I mean multiple other things it could be.

Lauren Richie: Correct. Correct.

Male: We don't know from the evidence.

Lauren Richie: Right. And there was no strong evidence submitted that informs the provider to the best means of achieving appropriate phosphorus levels. However, having said all that, in the measure developer's reliability and testing data there is some critical information that you guys may want to consider.

Specifically in 1C.8 in there on the measure submission form in their results section, amid analysis of the available literature showed an 18% increase in mortality for every one milligram increase in serum phosphorus. Additional reliability data - and this information was submitted after the measure submission from in the addition.

Male: Well, I believe that that is based on the observational studies that you quoted before.

Lauren Richie: Correct.

Male: So this is just a refinement and an aggregation of those same data.

Lauren Richie: Absolutely. Additionally, there was some reliability data that was submitted on a (nova) analysis and that's on Page 26 of that PDF document. There was an interclass correlation of 0.17, an inter-unit reliability of 0.94, which is an indication of how much of difference across facilities is actually true difference.

And that 0.94 is a pretty good number and the results from their validity testing indicated lower performance scores on the testing measure were significantly associated with the SMR, the standardized mortality ratio and the lowest performance measure quintile being 17%. And the validity testing of this process measure is tied to the mortality measure that the committee found suitable for endorsement at the in-person meeting, that dialysis facility, risk adjusted mortality ratio.

So I just wanted to point that out and just kind of highlight those areas that was submitted under their reliability and validity testing but may have some implications for the evidence discussion.

So I'll pause there and see if the group wants to weigh in on evidence.

Joe Nally: Yes. This is Joe and as you recall, last winter I presented the other measure that the enzyme put forward where we set a target for phosphorus.

Lauren Richie: Correct.

Joe Nally: So I think that nobody would argue with the observational data that high phosphorus however you define it is associated with increasing mortality and that this whole issue is an important one.

I think the dichotomy that we're going to struggle with may be that while it'd be good to measure that but the struggle relates to the evidence or the absence of evidence saying that having a high phosphorus that is then treated in any way, shape or fashion since there are no randomized controlled trials that translate into a morbidity mortality advantage with some type of treatment.

I mean that's to me the fundamental struggle here whereby we might be saying it's something to measure because it (tracks) risk from observational data. But I think it's a separate question then about you know, thresholds, targets or treatment. And as I understand it, this measure is only related to you know, the actual measure it or not measure it.

I think there are a lot of assumptions if that is indeed the measure okay so it's either high or low, what should we do with it? But I just - the absence of evidence that we have asked for two decades that I think makes those that look at the subject and come up with a recommendation that I think probably impacted our discussions last January, which was when a (KDGO) or other international group looks at this and says that there are insufficient data for phosphorus and PTH to make a performance measure.

I guess that's what I'm struggling with, with this measure before us as well as the measure we looked at last winter.

Lauren Richie: Okay. Others from the group on evidence? Are we in agreement? I know this is kind of.

Alan Kleiger: Yes, this is Alan. I think that Joe expressed it articulately and correctly.

Lauren Richie: Okay. So just kind of as a general statement, I think this evidence discussion is probably going to be applicable to a few of the measures that we're going to look at today.

So I will just kind of come back to that discussion as we get to the evidence section for the following measures. So I think if the group agrees we can move past evidence to usability. There appeared to be some variation there and maybe we can just have a brief discussion on usability. There were two moderates, two low, one high.

Jeff Burns: I don't have any additional comment. You know, it's measurable and it should be relatively easy to get - to track whether or not it's ordered. It would require some effort but it would be doable.

Lauren Richie: Okay. Anyone else? Okay. So there didn't appear to be any variation on feasibility. So moving right to suitability for endorsement we had two yeses and three nos.

So kind of just considering the discussion we just had on evidence, how does the group feel now about this measure being suitable for endorsement? And I know we had the discussion but I just want to maybe perhaps hear from others on the call.

Peter Crooks: This is Peter Crooks. I think we - I agree with Joe's comments also. I think for us to be asked to re-endorse this measure as a voluntary consensus standard for the country is maybe beyond what our current criteria allow us to do.

I think it's an important measure. I think it's going to be measured as people/practitioners will do what they do with it. But for us to say that this is so important that health plans should be looking at this metric and that it's going to probably improve outcomes if we endorse it, I think is a little hard for me to swallow. What about others?

Jeff Burns: Well, if no one else is talking just ten seconds on sort of what I feel about this - Joe I think outlines the evidence nicely and the absence of not only randomized controlled studies but the absence of any interventional trials, whatever their design, that would lead us to believe that intervening makes a difference to some other outcome.

So I share that skepticism but having said that, I must say that of all of the measures I mean PTH pales besides the correlative data for and calcium both, just pale if you look at all the data behind the correlation for phosphorus and outcomes, hard outcomes and intermediate outcomes as well in terms of bone disease.

And I guess my own feeling is that given absence of randomized controlled trial does not mean indeed that we shouldn't be endorsing measures that there is at least some evidence that we think is important. And for phosphorus the correlative data to survival is so remarkably strong that I believe that measuring it, just saying that it ought to be measured is important.

Why if you can't tie it to something? Well, because people with dramatically high phosphoruses, I know of very few clinicians who would not indeed think that we despite the absence of RCTs that we shouldn't do something to get those down.

Jeff Burns: Alan, doesn't this get to an issue that we've talked about before or questioned and that is where is the line drawn between yes, this is good medical practice, this ought to be done because it's part of what we do in taking care of these patients versus making it a performance measure for public reporting?

Alan Kleiger: Yes, I agree with you Jeff. I do think it's part of that discussion. In the continuum of that discussion this is just one that just to me jumps out and says in the year 2011 I still think that clinicians should be following the phosphorus levels.

Male: I would agree with Alan. I can sleep at night sending out the message that serum phosphorus particularly its elevation, is important and somebody ought to be measuring it on a regular basis.

I have a level of comfort with that because it has us addressing this issue as opposed to the other side where you're setting its target and an inferring treatment is good that I was not comfortable at all with. I think having a measure without any say, anything more than saying you should measure it is an important message to be heard.

Jeff Burns: If I could just also point out - not to belabor the point - that this measure specifically requires phosphorus measurement at least once per month.

Male: Yes, good point. I guess whether it's monthly, quarterly.

Jeff Burns: Annually.

Male: Jeff, are you going to measure phosphoruses just once a year in your patients?

Jeff Burns: No but again, we're talking about a performance measure, you know?

Male: That's right.

Jeff Burns: I always think it's the best thing for medical practice and I think it's easy to make a case that just with monthly measurements, it's not necessary. I think it's hard to make a case that it is necessary. I'll rephrase that.

Male: Let me play the devil's advocate for a minute. Let's say for the sake of discussion we took the approach of not passing this measure, having you know, the same discussion and outcome as we did last winter.

My concern would be there might be a message sent that we don't view this entire area as important and that we do not recognize that observational data. I understand Jeff, one month or three months but I don't know - mixed feelings about this one. But it seems to me that there should be some general recommendation out there at least measuring.

Lisa Letz: Guys, this is Lisa Letz. I apologize. I just joined. Which measure are we talking about?

Male: Hi Lisa.

Lisa Letz: Hi.

Male: We're talking about what number is this guys, I can't remember - the phosphorus.

Lauren Richie: Hi Lisa. It's Lauren. It's 255, measurement of serum phosphorus.

Lisa Letz: Okay.

Lauren Richie: Okay. So I think just kind of given this discussion here about suitability for endorsement and the need to in fact have some kind of process in place for monitoring it, I think what we'll do is



kind of capture all of your comments and concerns and then we'll just see what happens when the work group formally kind of votes on the measures.

And we'll see what comes out in the wash under the major criteria and the sub-criteria. But in the interest of time I want to get to the other measures as well but definitely take into concern your issues about this measure because I'm sure we're going to revisit and have the same conversations again. So if there aren't any - yes.

Peter Crooks: Lauren, this is Peter. I'd just like to kind of revise my sentiment a little bit. I think if you compare phosphorus to PTH and calcium measures there is a stronger linkage to mortality as Alan pointed out.

And I think if we were to say you know, we need to have - we'd really like to have something on mineral metabolism for dialysis patients, this probably makes more sense than perhaps the others and we'll be talking about those shortly.

Lauren Richie: Okay. Absolutely. And that also may just be something you want to include in your notes when you submit your Survey Monkey and that, kind of expressing these concerns but perhaps still considering the importance of the measure.

So with that I think I'm going to move on to the next measure, that being 261, measurement of serum calcium. Again, this is essentially the same measure except we're looking at calcium. 77% compliance rate with this measure, the same as for phosphorus. So much of the same discussion is true or I'm assuming would be for this measure - the monthly measurement of calcium and it is a facility level process measure.

I just want to point out that the committee recently recommended a measure - the ESRD committee recommended a measure about hypocalcaemia and that was proportion of patients

with hypocalcaemia. So again, the evidence applies, the discussion about evidence applies, the discussion about reliability/validity.

Male: Yes but if I may, there is a real difference in the discussion here than the phosphorus that has to do with the safety signal.

Lauren Richie: Okay. Okay.

Male: As we discussed because patients, particularly those that are on medicines that increase calcium, are critical to monitor. So monitoring calcium is not just following the course of chronic kidney disease.

But an opportunity to pick up patients that are being over treated and are developed threatening hypocalcaemia. So I would look at this a bit differently as a safety signal rather than sort of a pure quality signal.

Lauren Richie: Okay. Then with that then - point well taken. Why don't we just start with the criteria and go through? We'll start with high impact and then move on to opportunity for improvement.

So we do have some variation again in the responses here across the board with low, moderate and high. So is there any discussion on high impact? Okay. Or is there any discussion on opportunity for improvement? I mean Helen?

Peter Crooks: Lauren, this is Peter. I wanted to point out that as opposed to the phosphorus measure where a few people voted for high or moderate impact, we had only one vote for high impact here. So that is different.

Lauren Richie: Yes, you're right. Correct. There's just one. So any other comments?

Jesse Pavlonek: This is Jesse. I think it's the same as it was. I think I was the only high last time too and there were a couple mediums and a couple lows.

Lauren Richie: Okay. So it looks like things haven't changed from there.

Peter Crooks: So does the committee still or the people on the call generally feel that this does not provide a high impact metric? In Alan's point/comments about the hypocalcaemia being a signal that we need to attend to is important, I don't think that the submitters made that point because I don't have the full application in front of me. And we do know that we have to pass the metric along those lines. So I'm inclined to vote that this is not impactful.

Male: I agree.

Lisa Letz: This is Lisa. Can I just ask a question and I missed the previous discussion so I feel like I'm a little handicapped here. But I guess the question is maybe it's not the most important measure in the world but it is - what I'm hearing is that A, it's important and B, what other measures are out there that are more important?

I guess I'm thinking of sort of the quality world where a lot of times we measure things that maybe aren't the most important but they're a start. And this is something that's measurable. Clearly people - you know, the results are not 100% so it's not a reason for not doing it. So I guess I'm wondering what the harm is even if it's not the most impactful measure.

Alan Kleiger: My inclination again - I think in the absence of some other performance measure that doesn't already get at what we're concerned about, which is the safety signal, I would be inclined to agree that there may be some more value to this.

But we have endorsed a measure or recommended for endorsement a measure that really gets to the heart of the matter, which is safety related hypocalcaemia. So that's closer to the desired outcome. This is further away. It seems like it's that much.

Lisa Letz: That's true.

Alan Kleiger: And I guess the other comment I'd make rather than looking at what harm does it cause, I would ask what benefit it does in addition to/additive to what we already have going?

Lisa Letz: Well and then maybe a quick process question - should we consider the other measure now or do we consider this measure on its own and then harmonize after?

Peter Crooks: Well, technically you're correct. Our job is to see this measure without looking at competing or similar measures.

Lauren Richie: That's correct, yes. Okay. So are there any other?

Alan Kleiger: Yes. The only thing I'd say I guess cutting to the chase, I think if there were no measures of calcium at all I would personally be concerned about the safety signal and want to pass this one.

We have one as Jeff points out that is much closer to it, which at the point of harmonization, we can get to and harmonize the measures. So my only take would be that I would say this still deserves to be endorsed and with a recommendation that it be - and this is a facility level measure, correct?

Lauren Richie: That's correct.

Alan Kleiger: And that we harmonize this facility level measure with the clinician level measure that we passed already.

Jeff Burns: I'll just make the same comment about this that I made before is to stipulate monthly.

Lauren Richie: I'm sorry. Can you repeat that last comment?

Jeff Burns: Yes. For phosphorus this measure again specifies monthly monitoring as a requirement.

Lauren Richie: Okay.

Lisa Letz: I'm sorry. I still didn't hear that.

Jeff Burns: This measure is based upon or the performance on this measure is related to monthly monitoring of calcium as opposed to some other frequency, which I think just leaves open a question of if we're going to endorse the measure around simply measurement there ought to be some justification for the frequency of measurement and there is none here.

Lisa Letz: Okay.

Lauren Richie: Okay. So I think we kind of want to try to at least hit on each of the criteria if we can. So moving from high impact to opportunity for improvement, again some variation there between low and moderate responses.

Is there anything under opportunity for improvement that the work group wants to address that we haven't already discussed? I know. If not then I think we want to spend a little bit more time talking about evidence for this measure. And Alan, you mentioned that this has some difference between the last measure we just looked at.

Alan Kleiger: Yes. I mean if you're talking about correlating calcium alone to survival like we talked about, the data are far less convincing for that for calcium.

Lauren Richie: Others in the group, thoughts on evidence?

Jeff Burns: I think most of what they have cited here is tangential to the specific question about benefit of measuring monthly calcium. You know, associations aside, vascular calcification aside again, it gets to the point that Alan made that the link between hypo and hypocalcaemia and outcome is less strong.

The occurrence of that is less common and its relationship to any of these outcomes is much less clear.

Lauren Richie: Okay. And any others? Okay. So if we can just for a few minutes talk again about scientific acceptability for this measure, reliability and validity, the relative risk of mortality for this performance measure quintile for this performance measure was 16%.

So are there any thoughts or any discussion that differs from our previous discussion on reliability and validity for this measure? Okay. I'm taking that's a no then.

Male: The only thing I'll add is I thought that the section on reliability and validity was a little bit confusing.

They have numerous DPT and ISV9 codes undefined and they also keep talking about which kind of kidney disease and then parenthetically stage greater than or equal to three. So maybe refine this corrected but I think that's an error - they meant three or less - but I don't know. But anyways, it was tough to read and I thought there were some inconsistencies.

Lauren Richie: Well, if you want to ask the measure developer if they want to clarify we can do so. Do we have someone from Arbor or CMS on the call?

Male: I'll take that as a no.

Male: Yes.

Lauren Richie: Okay. So I'll just quickly touch on usability and feasibility. Is there any discussion under usability? Again, we're kind of across the board with a couple of low responses, one high, one moderate.

Is there anything different from the previous discussion on usability that we want to point out here?

Alan Kleiger: I guess I'm a little confused why would anyone call usability low here, those or all of you who said low? Why would this not be a usable if we judge that it were scientifically important? Why would it not be usable?

Male: I don't remember - I can't see what I rated this.

Alan Kleiger: We have lows from Jeff, Constance, Lisa and Peter.

Jeff Burns: I have a comment there for usability. Can somebody open that and show me what I wrote?

Peter Crooks: I can comment Alan, that in my usability for public reporting, I'm sort of thinking of sitting on a quality board of a health plan and interested as we need to look at if calcium is being measured in dialysis patients monthly. And from that perspective I don't think it's that usable.

Jeff Burns: Alan, my comment there was understandable but not useful or meaningful.

Alan Kleiger: That's right but is that what usable means?

Jeff Burns: ((inaudible))

Alan Kleiger: Okay.

Helen Burstyn: It's supposed to be a measure you'd think would be especially useful for both quality improvement and public accountability.

Lauren Richie: I see. I've got it. Okay. Thank you.

Jeff Burns: In other words, you can measure it and it's feasible but it's not I didn't think useful.

Alan Kleiger: Got it. Thank you.

Lauren Richie: Okay. So looking at feasibility then, there appears to be general consensus there on feasibility with most responses being high. So again, we'll look at suitability for endorsement again with two yeses and three nos.

And given the discussion we just had on the phosphorus measure, does the group feel the same way in that perhaps this is still an important area to measure and what does the group feel about this measure being endorsed, being suitable for endorsement?

Alan Kleiger: Again, I guess I would say I would not look at it the same way I look at the phosphorus measure. I think you have to look at it as a potential safety signal measure and would want to see it harmonized with the one that we passed for the physician level measure.



Lisa Letz: This is Lisa. I would agree.

Male: I'm sorry. I didn't mean to.

Lauren Richie: I'm sorry. Go ahead.

Joe Nally: The only kind of interesting catch 22 there, I think we wanted to have the hypocalcaemia as a safety issue but in order to be able to detect that signal as a safety issue I think it infers that you are measuring serum calcium.

Alan Kleiger: Yes. That's my point Joe. I think that's why the harmonization would be important.

Joe Nally: Harmonized some way.

Alan Kleiger: Yes.

Jeff Burns: Does anybody recall what the frequency of monitoring was for that measure?

Lauren Richie: I think I have it here. Proportion of patients with a three-month rolling average of total uncorrected serum calcium greater than 10.2.

Jeff Burns: Okay. Thank you.

Lauren Richie: Okay. So then for this measure we will make a note that the work group would want to see this measure perhaps harmonized with the previous hypocalcaemia measure.

We will get back to the measure developers on that and then perhaps turn around something back to the work group to then take a look at for potential harmonization. That's assuming that through your votes this measure will move forward as suitable for endorsement. And again, you may just want to make note of that in your online surveys that you do after the call.

Okay. I think we're moving on. The next three measures again, another phosphorus, calcium, PTH measure. Again considering the same discussion about evidence, the same topic areas except for these measures encompass CKD and not just ESRD. So starting with 0570, CKD monitoring phosphorus - these are members with phosphorus levels blood test during the measurement year.

And this is a clinician and health plan level process measure. You may want to take into consideration the previous conversation on phosphorus but we'll perhaps maybe start with high impact again for this measure specifically because we're now encompassing CKD and not just ESRD. So maybe we'll open up the discussion on high impact for this measure and see what the group thinks.

Jeff Burns: Can I ask a question first? I'm sorry. What is IMS health?

Lauren Richie: IMS health is the measure developer. Are you asking the acronym?

Jeff Burns: Yes. Who are they?

Lauren Richie: Do we have someone from IMS on the call?

Helen Burstyn: I believe Judy is on. Basically they are one of many measure developers out there primarily using claims based data for measurement. This is Helen.

Jeff Burns: Looks like they're a consulting firm or something like that.

Helen Burstyn: I think they had another name before. They were bought by a big consulting firm so adopted their name. I forgot what it was before. They've changed names in the last year or so.

Lauren Richie: Yes they have.

Jeff Burns: Okay.

Alan Kleiger: Do we know what their funding source was to examine this question?

Jeff Burns: Or what their stand - sort of why they're involved in this at all?

Helen Burstyn: They are I believe a measure developer that primarily focuses on claims based measures not specific to renal at all. They have a wide variety of measures across all conditions. And I believe they are a proprietary vendor of measurements.

Jeff Burns: Go ahead.

Peter Crooks: So they're for profit, right?

Jeff Burns: Who funded this? Was it the pharma people who are selling drugs that are funding this? I just wonder who funded it.

Helen Burstyn: No, I don't believe so. I think as Peter points out, it's a for profit measure development company.

Jeff Burns: I know that but they have to be making profit by getting funding from somebody.

Helen Burstyn: I believe they sell the measures and the use of the measures.

Lisa Letz: Yes. I don't know who they are but it's probably like RHR where they - Resolution Health.

Helen Burstyn: Yes.

Lisa Letz: They sell their services to health plans and to systems to measure quality.

Jeff Burns: I see.

Lauren Richie: And hi, this is Lauren. (Corrine), operator, are you there?

Operator: Yes.

Lauren Richie: Can you open the line please to Judy Chen from Woodland Hills? She is the measure developer. Perhaps she can shed some light.

Operator: And her line is open.

Judy Chen: Hi. This is Judy. Can you guys hear me?

Jeff Burns: Yes indeed.

Judy Chen: Hi. Okay. I just want to explain IMS Health a little bit. I think was it Helen that was explaining it?

Helen Burstyn: Yes.

Judy Chen: I think it's exactly right. We are a consultant to the healthcare companies. We help them implement P4P programs that we develop measures that would be in line for their - that would be useful for P4P measurements.

And these measures are not funded by a pharma company per se or what happens - I'm an MD, I'm an internist and I do some training in health services research. So I just looked at what would be useful and what would be useful for the quality measurement domain. And my team, we develop the measures. So we're not paid for to develop these measures by specific entities.

Joe Nally: This is Joe Nally. I remember looking at one of these and I don't know if it was your company but are you the company that was originally started out of New York City by some cardiologists?

Judy Chen: No. the company was originally started by Antonio Lagoretta. I don't know if you're familiar with his name. He was into health benchmarks. He did come from New York but he moved to California soon after. But he was not a cardiologist.

Joe Nally: Thank you.

Jeff Burns: If I could ask one additional question - so then your use of this if it is endorsed by the NQF would be what?

Judy Chen: We'd like when we go to health plans to sell our services, we would like to say - we would like as much of our measures to be you know, endorsed by a national entity, that they are valid measures. Because a lot of health plans use pay for performance and even public reporting. And we definitely want these measures to be reviewed by NQF.

Lauren Richie: Okay. Thank you.

Judy Chen: Sure.

Lisa Letz: And this is Lisa. I can just add that when we're looking at pay for performance programs we try to develop broad programs across a variety of specialties. And unfortunately for many specialties there are not decent measures. So what companies like this are trying to do is find measures that cross the specialty spectrum.

Alan Kleiger: Yes. Thanks Lisa.

Lauren Richie: Okay then. So we'll get into discussion then on high impact for this measure. Again, we're kind of spread across the board here with low, high and moderate responses. Is there any discussion or is there anything under high impact that the group wants to address?

Jeff Burns: I guess I didn't vote on this one.

Alan Kleiger: I apologize, but could you show us the numerator and denominator again for this measure?

Lauren Richie: Sure and I'll also read it. Numerator is numbers with phosphorus level blood test during the measurement year, the denominator, members with at least one inpatient diagnosis of CKD during the year prior to measurement year or members with at least two diagnoses of CKD in an outpatient setting during the measurement year or year prior, at least one of which must be during the year prior to the measurement year.

Alan Kleiger: So I don't know - this is more of a validity and reliability thing. I'd be very curious if maybe they replied to the measure developer as to why they're defining CKD with codes in that way.

And this is one that has a long list of codes and there are inconsistencies about what they're defining as CKD.

Lauren Richie: Okay. Well, yes, that is.

Alan Kleiger: We can table that until we get to reliability/validity. I actually Lauren, as you know, I have to leave the phone conference unfortunately. I just wanted to mention that now.

Lauren Richie: Okay.

Alan Kleiger: But I think that it's unclear to me. I've used administrative data extensively in VA and Medicare, why they're using certain numbers of codes, inpatient, outpatient - I don't know. Maybe I missed it. But it's not clear. And then it gets at the heart and integrity of the measure if you're really identifying appropriate individuals with CKD or not.

Lauren Richie: Okay. We will certainly bring that to the attention of the measure developer once we get on the evidence criteria. Perhaps we can move to evidence if there isn't anything under high impact or opportunity for improvement that the group wants to discuss.

There does appear to be some optimal performance overall and variation by provider in this measure. So if there aren't any other comments perhaps we can look at evidence now.

Peter Crooks: This is Peter Crooks. I'd just say that as opposed to doing a monthly phosphorus in dialysis patients to impact mortality, which you know we talked about at length, here we're talking about an annual measurement and that the focus is I think really to detect and see early bone disease. And I think from my view this is easier to vote that this is impactful, reasonable to do and there is probably a performance gap here where there isn't so much a performance gap in the dialysis population.

Lauren Richie: Okay. And operator again, (Corrine), if you could open the line to Irina from IMS.

Operator: And her line is open.

Lauren Richie: Okay. Thank you. Given - is there anyone on that wants to address Peter's point?

Joe Nally: I'll make a comment - it's Joe - because I'm tuned into this issue with our CKD registry with 70,000 people in it. One - and I'm not sure if this is the appropriate point that Michael started making.

One is about who gets labeled with CKD particular as an inpatient diagnosis. But the other question that relates to Peter's point and Peter having Kaiser data may be a great source of information here. But I think there is tremendous opportunity for improvement here because many people within a healthcare system who happen to have different degrees of CKD.

Particularly early on, the suspicion is that fairly low numbers of them actually have serum phosphorus measured annually. You're going to have to have a defined population here if we could get to the definition of CKD. But the real question across the nation of all these millions of people, these 16 million of GFRs less than 60, how many of those do we think could actually be collecting on that are in healthcare systems keeping track of this information?

Alan Kleiger: That gets down to the reliability and validity - really reliability or usability and feasibility.

Joe Nally: Right. So Peter, do you have a sense having made your comments about tracking it once a year within a closed system like Kaiser, what kind of numbers you're looking at and how big of an issue this is?



Peter Crooks: I wish I could pull out that data for you. I don't think we've looked at that in that way as far as what percentage of CKD patients have phosphorus tracked. You know, so and we haven't really approached that in a systematic way and that might be a good thing to do. But I'm afraid I can't answer the question.

Lisa Letz: So again this is Lisa - so I think it's a bigger, a much bigger issue than just the closed health systems. You know, just the little bigger issue is the new rise of ACOs and those systems.

So that's just one issue. The other issue is you know, as the developer said, just pay for performance for nephrologists. You have the whole attribution issue there. But if this is indeed a quality problem and there is a gap, which there appears to be, then you know, we need to improve it. And without a measure you can't start to improve it.

Now who we is, whether it's the physician, whether it's the system, whether it's a health plan, whether it's an ACO, that is all to be defined down the way but without a measure there is no hope of even doing any of that.

Joe Nally: Yes. No Lisa, it's Joe. I agree with you 100%. And again, there is a little bit of a catch 22. If your group happens to be one of those forward thinking groups in a closed healthcare system or ACO or something then you are being kind of held accountable to a measure.

My suspicion is right now that the average free ranging patient out there and their doctor who may or may not be doing a decent job are not held accountable because they're not in a system that can measure it. That's a little bit of a conundrum.

Lisa Letz: Yes. I agree. I think that is a problem.

Lauren Richie: Okay. Taking into account I think again this may be an issue that we'll just have to see what happens at the results of the outcome of the voting after the call.

But I do want to spend some time looking at evidence and reliability and validity testing. So is there anything under evidence again? There is variation in the responses here. Is there anything under evidence that we have not already discussed as it relates to the other phosphorus measure that we talked about?

Okay. So then if not there are a couple things under reliability and validity. This is a provider level measure but the reliability and validity testing was conducted using a large, aggregated data set. And they don't compute the scores at the level for which they say it's going to be used to assess performance. The other thing is that the measure is reported clinician level but no clinician level data were provided in the results for the testing.

And generally reliability should not be rated high unless data is provided for both the data element and the score. And they compared scores over time compared to lost data sets and the literature but is that really an appropriate test of reliability? In their supplement responses the measure development did provide a rationale for using correlation of facility scores in two time periods as a demonstration of reliability.

They conducted a test/retest of the provider scores between two years and two plans. It found the retest reliability high based on a person's correlation coefficient but this is not considered an appropriate test of reliability to test/retest because it's not the same patient.

Jeff Burns: Doesn't it also - all this tells us is that whatever they did the first year and did again, have similar results.

But it doesn't tell us at all what the accuracy was of their first year tests. But if they were grossly inaccurate in both years but the methodology remained the same then they would have similar outcomes but both would be grossly inaccurate. Is that correct?

Lauren Richie: Correct. Correct.

Jeff Burns: What they didn't do was go into their 43.6% and confirm that that was true, correct, an accurate representation of performance if I understand this correctly.

Lauren Richie: Is that something you want to address to the developer?

Lisa Letz: (She's) on the line.

Lauren Richie: Sorry?

Lisa Letz: I think it would be a good question to ask Judy, Lauren.

Lauren Richie: Judy, are you still there?

Irina: I don't - I think Judy is here. This is Irina from IMS. One reason - as we mentioned before, we are a firm that does create indicators for our clients. And the clients do have the data.

We don't have access to electronic medical records or charts to be able to perform any sort of reliability testing in that way. And that is why we did do the correlation coefficients instead.

Additionally, we do have - one thing we do offer our clients is a product called HBI online where they are able to take a look at their results.

And if a test was done they're able to create a flag showing that the test was done and we go ahead and go over those flags.

Lauren Richie: Does that answer your question somewhat Jeff?

Jeff Burns: It doesn't change the fact that what was tested was not reliability.

Alan Kleiger: So let me just ask a technical question. If we don't have adequate reliability testing does that stop us at that point?

Lauren Richie: Well, for the purpose of this call we would kind of go through the rest of the criteria. But correct, if it did not pass on scientific acceptability then we would not move further on the measure.

Helen Burstyn: Yes. And this is Helen. For many of these claims based measures we for the most part expect signal to noise analyses for these large, claims based measures. And the question is is this adequate? I'd be curious of Karen's take on this, Lauren. Did she indicate? I know she's not available today.

Lauren Richie: She did not. But -

Helen Burstyn: Okay. We can clarify that with her (and Paton).

Jeff Burns: Can I ask also a question regarding reliability and validity testing? I think I know the answer to this but was there any analysis done using that measure or was this just looking to see whether phosphorus was obtained on a patient population? Did they use the measure's CKD definition or some other measure, some other definition to determine the tested patient population?

Lauren Richie: Operator, could you please open the line again for Judy Chen as well as Irina?

Operator: Their lines are now open.

Lauren Richie: Thank you. Did either of you want to respond to that question?

Judy Chen: I would like to - this is Judy. Can you guys hear me now?

Jeff Burns: Yes.

Lauren Richie: Yes.

Judy Chen: Okay. Good. I first want to address the way we defined the CKD denominator because I'm sure that has a lot to do with the validity, whether we can accurately capture the denominator population.

The reason we have such an algorithm because we're following methodology used, there is literature - I mean the validity, the sensitivity and specificity of claims data in capturing the CKD population. There are actually at least three papers and I can't recall off hand but I'll be happy to forward after the call. They tracked it either with the laboratory data or they checked it with patient interview.

It depends on what - mostly it was laboratory data for CKD. And they did find a methodology using specific codes, the number of instances in which in a period an outpatient/inpatient setting, how specific it was and to define the population. Now the algorithm we chose was very much in line with the literature that shows the specificity of capturing the CKD population up to the 98%.

That is very specific. It's not as sensitive - I mean (being they're) CKD patients, we want to make sure that whoever we capture at least has CKD when we're measuring. And we also check in the numerator whether phosphorus was done. As you know, in this measure we excluded the dialysis patients because dialysis is by bundled coding.

We were unable to capture whether they were done during the dialysis session. But for everybody else we captured whether there was phosphorus. And I have to look in the literature for that but I believe that in order to get paid for the phosphorus measurement to be paid that you did the flag, you had to have billed it to the health plans.

So I think it's reasonably reliable to capture that the phosphorus measurement was done.

Lauren Richie: Okay. Did that answer your question? Should we perhaps maybe have the developer submit additional information to get back to the work group on this on their reliability and validity?

Jeff Burns: I think that'd be helpful.

Lisa Letz: Yes, I agree.

Lauren Richie: Okay. So then we will stop there on reliability and validity and we'll get something back to the work group. Irina and Judy, I will work with you offline.

Looking at usability for the measure, across the board there seems to be mostly moderate responses under usability. But is there any other discussion here that the group wants to address on usability? And actually the same for feasibility as well. Most of the responses were moderate as well. So there seems to be general consensus there so unless there are other comments.

Alan Kleiger: There is really no consensus. Both of them have lows, mediums, moderates and highs.

Lauren Richie: Under?

Alan Kleiger: Feasibility.

Lauren Richie: Yes. You're right. I picked the wrong one. So we have three moderates, two highs - (I can't see) exactly.

Alan Kleiger: And one low.

Lauren Richie: On feasibility. So okay, is there any - I mean given the variation there do we want to discuss a little bit about feasibility for the measure?

Jeff Burns: Maybe I can just ask.

Joe Nally: And are we looking at the same one? Under feasibility I see two rated high and four rated moderate on feasibility.

Lauren Richie: Correct. Correct.

Alan Kleiger: That's under 4D on the data. I'm just going 4A is across the board on feasibility.

Joe Nally: You're looking at the more detailed one.

Jeff Burns: Can I ask just a general question, that is when we're talking about feasibility and usability, it would vary I guess depending upon who was using it, right?

So one of these big - a company or a health plan that has access to huge numbers of claims and it's all internal and particularly if it's universal, they have every lab test inside that system, its usability and feasibility are different than if a less confined health system or plan, multiple outside labs were going to try to use this. Does that weigh into our decision making at all?

Jesse Pavlonek: I would think that's more implementation than the feasibility of the measure itself. I mean if it's feasible, it's feasible.

Lauren Richie: Right. And Helen mentioned for us feasibility typically you know, is looking at quality improvement or public reporting uses.

Joe Nally: This is the issue that I was bringing up before in terms of say a closed system that's well done in identifying their CKD patients and knowing what in this case laboratory studies are monitored.

That may be very feasible for them and I think it's the right thing to do. I think the struggle is that the majority of patients in America with this diagnosis are not in such a system. So in my judgment this is the right thing to be doing. And how do you going to brow beat the rest of the world into complying with this processes of care if you've got a measure based upon a minority optimal care group?

I mean to me that's the primary struggle, the fact that say this group or Kaiser knew other patients and could give you this answer is probably the right way to go and this is how we ought to point people. I'm just concerned about if we set a measure for the country how it's going to be assessed and monitored in kind of a wide open system.

Jeff Burns: I guess the gist of my question is that just up to each health plan or insurance company to decide whether or not they want to use this measure?



Lisa Letz: Yes. And I mean I think that's what all of NQF measures that are just out there in the world and then those who want to measure performance in one way or another just pick the measures that are applicable to their situation.

Lauren Richie: That's correct.

Joe Nally: So in a way this is very, very different than an ESRD measure where you have this closed system with the federal program you know, monitoring process.

Lisa Letz: Well, it's actually not because in the ESRD measures, those measures are also out there. So health plans and anybody else could use them as well. Now because we don't have the data source, it's more difficult. But like a Kaiser that has the data could absolutely use all those measures.

Joe Nally: No but I'm saying if I'm an ESRD provider and say it's hemoglobin greater than 12, that is not only being monitored by the ESRD program but it now has what we might have thought as some time ago as an unintended consequence.

That particular measure is now under kind of a quip kind of pay for performance. So in that sense it's different in that it's a more structured system. Whatever individual plan happens to pick up one of these pre-dialysis ones, they have a lot of leeway as how they apply criteria and lots of other perturbations on the theme I guess.

Lisa Letz: I guess I'm - this is Lisa - coming from sort of a different place. So that's how I think about measurement overall. So I'm not quite understanding the difference because that's to me what measurement is.

Lauren Richie: Helen, did you want to weigh in?

Helen Burstyn: I agree with what Lisa just said, yes. I don't think it's actually that different.

Joe Nally: Okay.

Lauren Richie: All right. So moving on, I know we're kind of getting close in time and we still have a couple more measures to look at, suitability for endorsement for this measure we're kind of split right down the middle - three yes, three no. What's the group's thoughts on suitability for endorsement?

Peter Crooks: This is Peter. My main concern is the reliability and validity factor. Otherwise you know, I think it's important, I think it's usable and presumably feasible. But I do have concerns about reliability. And as we asked the measure developer may have a chance to make their case on that.

Lauren Richie: Okay. So does the group agree that perhaps we'll just wait to see what additional information the developer can get to us and then look at suitability for endorsement after receiving that information?

Joe Nally: Yes.

Jeff Burns: That's fine.

Lisa Letz: Good idea.

Peter Crooks: Good.

Lauren Richie: Okay. Moving on then to measure 0574, CKD monitoring calcium - again, the numerator members who received a calcium level blood test during the measurement year, denominator is the same as the previous measure.

The exclusions are members who are on dialysis or in hospice during the measurement year, also members who are hospitalized during the numerator timeframe and did not fulfill the numerator criteria. Again, the clinician health plan process measure based on administrative claims - again, this is very similar to the previous measure.

But I know Alan, you did mention some with the other two. The first two measures we looked at, some concerns and differences between the calcium and phosphorus measures. Would you say that you have the same concerns here with this calcium measure?

Alan Kleiger: Not the same degree because CKD patients and again, I'm concerned about the definition of CKD. I'm not only concerned about reliability and feasibility but I'm also concerned about how it was defined by this developer.

But the relatively early stages or mild stages of CKD are unlikely to carry with it the risk of use of high calcium medicines causing hypocalcaemia, much less likely than in ESRD. So it would not carry that same safety concern for me.

Lauren Richie: Okay.

Jeff Burns: May I ask another question, which I guess I should have asked in the prior measure as well? I looked closely at the ITD9 folks - this isn't for CKD at all stages. So somebody with normal GFR ((inaudible)).

Lauren Richie: Judy or Irina, could you clarify?

Jeff Burns: There's three - I see 583.XX but I mean.

Judy Chen: I'm sorry. What was the question? Whether it includes?

Alan Kleiger: All stages of CKD, CKD stage one, two, three.

Judy Chen: Only includes stage three and above and excludes dialysis.

Alan Kleiger: Thank you.

Lauren Richie: Okay. So are there any other thoughts here? Should we look at high impact for monitoring calcium? Are there any differences and thoughts from the previous measure looking at phosphorus?

Alan Kleiger: Just quickly, this is Alan again. I would find it much less convincing that there is a rationale for monthly measure - sorry, yearly measurements of calcium in the wide population base of people with CKD stage three for example. I just don't see it.

Lauren Richie: Okay. Others from the group?

Jeff Burns: This gets back in my view - this again may be on an individual patient basis something that's important to do as part of good medical care. But I don't see it being a valuable performance measure.

Jesse Pavlonek: And this is Jesse. After the discussion I certainly would drop my high down to at least a medium or low even.

Lauren Richie: Okay. Yes ((inaudible)) so then looking at opportunity for improvement, here we have all lows and just one moderate. Are we of the same thought here that as we are?

Does everyone agree here that this is a low rating for opportunity for improvement? Are there other thoughts? Okay. I mean I know there is not much difference between this measure and the previous one - we're just looking at calcium. But just want to make sure we touch on all the criteria. So moving on to evidence, under reliability and validity in general, again this measure is currently endorsed.

And it has 100% physician compliance in both the first and third quartile, perhaps suggesting room for improvement. So are there any thoughts there under reliability or validity? Again, I know it's not much different from the previous one but just want to make sure.

Joe Nally: Yes. It's Joe and again, I'm kind of echoing what Alan said. This may be less than important in the stage threes but when you actually look at the evidence I've gone from middle of the road to kind of low across the board. And I'm just not a high degree of enthusiasm to make it a measure on the evidence that's there.

Jesse Pavlonek: And this is Jesse and in light of what we've discussed I would certainly change my final vote to no on this one.

Lauren Richie: Okay. Thanks. So given that we'll just really quickly under usability, are there any thoughts on usability different from the previous measure? We had two lows, two moderate, one high? Jesse, I'm assuming your response again as well?

Jesse Pavlonek: Well, it can - it's usable. So I don't know that it matters at this level.

Lauren Richie: Okay.

Jesse Pavlonek: But there certainly is a lot of variation because of the various clinical impacts on calcium.

Lauren Richie: Okay. Others? Okay. Feasibility, it looks like we have all moderate responses there. So I guess we'll go ahead on feasibility. We can look at suitability for endorsement and there we have two yeses and three nos.

And not to kind of rehash the same discussion but I just want to offer the opportunity for those to weigh in with their thoughts on endorsement for this measure. Okay. So then we will capture your formal responses on your recommendations for endorsement in the survey. And then the final measure of the day is 0571 and that is PTH measure.

Again, the same measure developer and this is members who received their PTH level during the measurement year, same denominator. Exclusions are members who are in hospice during the measurement year and this is a clinician health plan process measure again based on administrative claims specific to CKD.

Just as a reminder, the two PTH measures that were discussed at the in-person meeting were the intermediate clinical outcome measures with specific high and low PTH values. And those measures were not considered suitable for endorsement because basically there is not sufficient evidence that altering PTH levels affects outcomes.

Measure implies that two drugs with the right intervention and there is evidence they will lower PTH but no evidence of improved outcome. So just wanted to remind the work group of that.

Again, this is another assessment measure and we've been talking about assessment measures so far and I think we have a pretty good understanding of the group's thoughts on that.

So we have talked about calcium and phosphorus measures but we haven't talked about monitoring PTH in CKD. So with that I'll start with high impact and see what the group thinks. And there was some variation there and one high and three moderate and two lows. So what are the group's thoughts on high impact for this measure?

Alan Kleiger: Low. I just - you know, the thought of having a performance measure in CKD stage three that asks for PTH measurements year after year for the 75-year-old with CKD 3 seems to me to be incredible. I think that the impact is a negative impact.

Peter Crooks: Yes. This is a metric to measure once maybe. You know, you could be active to say in this patient has (to be within a year) to be in good care (simply is fine).

Joe Nally: Yes. I just think to stall here I tried to muster up a near medium in the first column and then everything as we head to the right quickly falls off to lows as we start looking at any degree of evidence.

Lauren Richie: Okay. Then if there aren't any other high impact, looking at opportunity for improvement, again variation there in responses. A couple comments by the work group members who evaluate these measures, maybe we can put the comments there Gene.

So although there are no time frequency evidence based guidelines, there are clinical guidelines that show evidence of a need to monitor PTH. And there may be a gap in measuring PTH but given absence of evidence based guidelines for frequency of measuring in management of abnormal values, it's hard to argue a need for this measure.

So just wanted to again offer the opportunity for folks to weigh in on opportunity for improvement.

Alan Kleiger: Depends on how you define improvement. I don't see that it's an improvement to increase the frequency of measurement of PTH for CKD.

Peter Crooks: But if there is a performance gap I think that's probably as easy to swallow. But again, if the impact isn't high then I think there is a performance gap.

Lauren Richie: Okay. Any other thoughts there either on impact or opportunity for improvement? All right. I think we're doing good here. Really quickly, evidence - as you Joe, I think as you mentioned we're kind of seeing more lows here as we get further into the evaluation.

But much of the evidence is only about the levels of PTH and no evidence was cited to indicate that patient outcomes are improved by annual PTH testing. So as has already been mentioned on the call, any other thoughts about evidence knowing that assessing the lab value is not proximal to the desired outcome?

And also the measure developer did not really provide performance results on the measure. So I know that was a concern as well but any other thoughts on evidence? Okay. So then I think perhaps just for the rest of this measure reliability - is there anything under scientific acceptability or any other key points on either usability or feasibility on this measure that we haven't discussed with the prior two CKD calcium and phosphorus measures?

And again, under suitability for endorsement we have three yeses and three nos. So perhaps maybe the group can just weigh in on their overall thoughts on that again.

Jeff Burns: I'll maintain my no.

Joe Nally: I see that I'm a yes but that I would make that a no.



Lauren Richie: Okay.

Jesse Pavlonek: And this is Jesse, as would I.

Alan Kleiger: Constance, where are you?

Lauren Richie: I don't think she's on the call. Okay then. So I think what we'll do is as I mentioned, we'll send out a - I'll try to send out a survey like as soon as this call is over so that hopefully while the discussion is fresh in our minds we can get your votes submitted online.

And then we will take the recommendations from this work group and then forward to the full committee.

Joe Nally: Lauren, can I ask a question before we leave this area, a question of the measure developers?

Lauren Richie: Sure, absolutely.

Joe Nally: I mean in general I believe you're going in the right direction here trying to you know, measure or maybe even set up targets in certain areas related to CKD. And I'm presuming we're only seeing part of your package as it relates to calcium, phosphorus, PTH. Do the measure developers actually have data as to a patient with CKD in their recommendations for measuring say serum creatinine or some marker of proteinuria or albuminuria? Is that part of your CKD package?

Peter Crooks: And possibly blood pressure, Joe.

Joe Nally: Well, I'm just looking at laboratory things, right?

Peter Crooks: Okay.

Joe Nally: And creatinine and protenaria would be you know, two things that the CKS consortium would look at to try to predict risk, risk being all cause mortality or a renal outcome.

Lauren Richie: Either Judy or Irina, did you want to respond?

Judy Chen: I'm on the line. Can you still hear me?

(Crosstalk)

Judy Chen: Okay. Yes. We don't have a creatinine one but (given like) yearly measures to check creatinine just to check whether it was done, creatinine was checked.

Peter Crooks: So the idea is to see if the disease is progressing or any indications of this towards dialysis and so on?

Judy Chen: Yes. Thank you for that suggestion. We will definitely pursue that. I know there is a measure out there to look at protenaria for the diabetic population but I don't know specifically for CKD. So thank you for that suggestion.

Peter Crooks: And I hope that blood pressure - I think most people would on the face of it say this patient should have their blood pressure checked at least once a year and maybe that to try to look at ((inaudible)) - to a specific level. So that's another thing to consider.

Judy Chen: Thank you.

Jeff Burns: Just I would be careful not to take this as a recommendation of the NQF. You're hearing some thoughts from some committee members here.

Judy Chen: Right. So thank you nevertheless.

Joe Nally: But putting life in perspective, if you're concerned about the health and outcomes of the CKD patient whether their disease is progressing related to a creatinine or an EJFR and whether they have a little protenaria, no protenaria or a lot of protenaria would be again, personal opinion, looking at the literature, more important things to be following than say a PTH value.

Judy Chen: Okay. Thank you.

Alan Kleiger: Of course the conundrum is that their denominator includes by definition a creatinine.

Joe Nally: Correct. The question is, is it getting worse with time?

Alan Kleiger: Right.

Judy Chen: Yes. I think our denominator doesn't include the creatinine value. So I think that would be okay. It just includes diagnoses (to follow) creatinine.

Alan Kleiger: Well, but the diagnosis - that's true. It doesn't contain the value. But it has to be of a value sufficient to define CKD stage three, four or five.

Judy Chen: Right.

Jeff Burns: Could I - would it be possible to ask a question without any of the developers on the line?

Lauren Richie: Sure.

Judy Chen: We can.

Jeff Burns: Once we're done?

Peter Crooks: We're open but we can keep them from responding but I don't know if we can keep them from hearing.

Lauren Richie: Correct.

Jeff Burns: Okay. Never mind.

Lauren Richie: But if there is something you want to forward via email to the group then we can get that to the measure developers.

Jeff Burns: It's not a question for the measure developers. It's a question for the group.

Helen Burstyn: Yes. That's fine. Just send it along to Lauren and we can take care of that.

Lauren Richie: Okay. So with the few minutes we have left we've gone through all the measures and there was a section on the agenda for review of related and competing.

And we're not going to go through that entire table in detail especially considering the discussion we've had on the CKD measures for phosphorus and calcium. From our previous discussions, you know, we're going to take a look at harmonization with these previous hypocalcaemia measure proportion of patients with hypocalcaemia and the ones that we're looking at today, 0261 for calcium.

But were there any other either harmonization or competing issues that the members of the work group want to address or discuss either with the phosphorus or the calcium measures if you take a look at that table of related or competing measures? What I think we would do is we'll look at these more closely.

We'll ask our measure developers to come back with a plan for harmonization if need be and then we'll have the steering committee recommend something and then that way it kind of saves everyone some time there. But I just wanted to check in with the group to see if there are any other harmonization issues that you want the developers to consider.

Peter Crooks: Laruen, not shown on your table is the competing calcium measure that - or complementary set of serum calcium measure that we passed, is that right?

Lauren Richie: Right. Correct.

Peter Crooks: So this table shows 261 and 574.

Lauren Richie: Right.

Peter Crooks: I don't know those numbers.

Lauren Richie: Yes. And I think what we discussed is that we will look at what's not on the table is measure 1454, proportion of patients with hypocalcaemia.

Peter Crooks: Right.

Lauren Richie: For potential harmonization with the 0261.

Peter Crooks: Right. So that needs to be added. And it's interesting to note the frequency and the method that kind of - those differences with the running three-month average versus a monthly measure. So whether they're combinable or we can look at.

Lauren Richie: Yes. And like I said, that's something that we'll certainly have the developers look at and let us know how feasible that is for them to do and then get that back to the work group and the full committee.

So if there aren't any other critical issues around harmonization or any other burning issues or discussion points that we want the full steering committee to consider as it relates to the mineral metabolism measures, if not then I think we will open the call to our...

Peter Crooks: Lauren, this is Peter. I was muted and I was trying.

Lauren Richie: I'm sorry.

Peter Crooks: I just wanted to ask the question of you. When we do the Survey Monkey now and we write in rationale, I'm sort of concerned about what the full steering committee is going to see.

Are they going to - because we've already written those comments in before and so we're looking at now we're going to do Survey Monkey and they're going to be other space for us to include rationale and when we get around to doing the full steering committee meeting is all of that going to be visible or just the more condensed stuff?

This time I think it's important because I'd like to ask the work group to be it compulsive or to put in a lot of rationale or maybe not depending on how (those) will be forwarded.

Lauren Richie: Yes. I think the original thought was to just send the full committee the results from this second call today they were having after the work group had had a chance to discuss and kind of hash these issues out.

But we can certainly maybe provide a maybe side by side analysis of what the committee members thought prior to the discussion and then after the discussion and then maybe compare the votes or their final thoughts on recommendation. Is that what you're asking?

Peter Crooks: I'm thinking it through as I'm asking the question. I think that to send all of this to them would be you know, a bit redundant and overwhelming and they do have access right, to this voting material that was sent out to them.

Lauren Richie: Correct.

Peter Crooks: So I guess I'm thinking that it may just be most reasonable to send them the new stuff. And in that case I would ask the committee, those on the call who are going to be doing the survey to be sure to simply sum up their concerns and their rationale.

Alan Kleiger: We can do that but I would hope that we've captured some of the key points, right? I've heard the comments made that many of the key points have been captured, right Lauren or others?

Lauren Richie: Yes. That's correct.

Alan Kleiger: Yes. Okay.

Lauren Richie: That's correct. And we'll also provide a summary of today's call with some of the key points for the full committee.

Alan Kleiger: Good. Yes. I mean Peter, all I'm saying is of course we should each write that but I'm hope - I heard lots of very good points made and rather than relying on our memories we'll put it in but I know that the NQF folks have been taking notes and will include the high points of the discussion.

Lauren Richie: Absolutely. And that summary as well as the results from the voting both will go out to the full committee.

Peter Crooks: But we're going to see the summary of this call before we get to do any votes, correct to make sure our memory and the written document remember the same thing?

Lauren Richie: Well, that was part of the reason why I wanted to have you all complete this survey perhaps today or tomorrow so that while the discussion is kind of fresh in your minds you can complete the survey. Otherwise we can certainly leave the survey open until after we complete a summary if that will help you.

Peter Crooks: I think every member on the call should endeavor to try to do the survey within a day or two rather than - while it's fresh in our minds.

Alan Kleiger: Yes. Yes.

Peter Crooks: And I know we're supposed to be on the call tomorrow and these things. So it's really an advantage to do it while it's fresh in your mind. And I would agree with Alan, we don't need to write volumes about to rationalize our votes.

But I think I kind of - I believe that when we really get around to the final steering committee not everybody will be able to read every note from everyone in these meetings. And they'll be looking



at this as a high level voting and these particular comments. So I think this is an opportunity particularly if you have a competing point of view.

But also maybe to illustrate what the majority of us thought as we went through these measures.

Christine Shunder: This is Christine. If I could just add, I think it would be good to especially for those who changed their vote from the preliminary to this vote, it might be good to put that in for the rest of the steering committee to see why you may have changed your vote.

Lauren Richie: Yes. Thanks Christine.

Peter Crooks: ((inaudible))

Lauren Richie: Yes. And as Peter mentioned, we do have another call tomorrow from 2:00 to 4:00 and that's Eastern Time. That's for the dialysis adequacy group of measures. So if you can attend that call, great even if you weren't in the primary group.

So we'll have lots of summaries coming your way to look at hopefully everyone will kind of be on one page by the time the committee meets again by mid-October. So if there are any other questions, comments, concerns? You'll be getting a link from me for the survey shortly after the call. If not, we can - Peter, do you want to open the call for the NQF comment period?

Peter Crooks: Yes. Let's go ahead and open the call for member/public comment.

Lauren Richie: And operator, if you can open all the lines please.

Operator: All right. It'll be just one moment. All lines are open.

Peter Crooks: Okay. We're open now to other comments from members and public on the line. Anyone care to comment?

Lauren Richie: Or any of the measure developers?

Peter Crooks: Okay. Hearing none, I will assume the public approves of our work and I think we can adjourn unless there are any other questions from the committee.

Lauren Richie: I just want to thank everyone again for your time today and hopefully we can speak with some or all of you all tomorrow.

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