

## **NATIONAL QUALITY FORUM**

**Moderator: Lauren Richie**  
**October 4, 2011**  
**2:30 pm CT**

Operator: Welcome to the conference. Please note today's call is being recorded, and at this time I'd like to turn the call over to Lauren Richie. Please go ahead.

Lauren Richie: Thank you. Good afternoon everyone. Welcome to now the fourth Renal Endorsement Maintenance Steering Committee follow-up call. Today we're going to review a couple of the anemia and cardiovascular measures.

These measures were discussed and reviewed at the in-person meeting back in August, but however we do have a few outstanding issues that we will address with the work group members today. Before I turn it over - before I take a brief role call of the work group and committee members on the call, Kristine Schonder, are you on the call?

Kristine Schonder: Yes.

Lauren Richie: Okay. Do you have any opening remarks you'd like to address?

Kristine Schonder: No, I'd just like to welcome everybody to the steering - to this conference call, and we'll have the agenda that we'll be reviewing, the anemia and cardiovascular measures and

trying to work through some of the - my train of thought, I'm sorry - some of the issues with those, so I'll turn it back over to you, Lauren.

Lauren Richie: Okay, thanks, Kristine. And just really briefly, I just want to address those steering committee members that are on the call today, just looking at the attendance. I see that we have Alan Kliger.

Alan Kliger: Yes.

Lauren Richie: Kathe Lebeau.

Kathe Lebeau: Yes.

Lauren Richie: Kristine Schonder, Lauren Dalrymple?

Lauren Dalrymple: Yes.

Lauren Richie: Okay, thank you. Michael Somers?

Michael Somers: Yes.

Lauren Richie: And Myra Kleinpeter?

Myra Kleinpeter: Yes.

Lauren Richie: And are there any other steering committee members that I have not named?

Frederick Kaskel: Yes, Rick Kaskel.

Lauren Richie: I'm sorry, that was Rick Kaskel and who else?

Jeffrey Berns: Jeff Berns.

Lauren Richie: Okay. Anyone else that I missed? Okay, so we don't have as many measures to get through today as we had on the last few calls. The first agenda item is a review of the hemoglobin measure 1667, pediatric ESRD patients receiving dialysis, hemoglobin less than ten. And with that, (Karen)'s going to give us just kind of a background on the measure and where things are, and just wanted to review the status of this measure with the committee to get more of a consensus.

(Karen): Right. And this is (Karen). Thank you all for joining the call today. Before I do that, I just wanted to make one announcement, and that is that it really is primarily related to the measure that this work group reviewed. We did receive a letter from the Renal Physicians Associations, American Society of Pediatric Nephrology, and the Physician Consortium for Performance Improvement, requesting reconsideration of several measures that the committee had not evaluated as meeting the criteria.

We just received this on Friday, and - which was after we had this call already planned. We have not yet had a time to discuss this with the co-chairs, so I just wanted to let the group know that we had received this letter. We will be sharing it with the full steering committee, but we want - we need to have a discussion internally about process and just - we'll let you know that there's more coming on that, and then we'll figure out a way - the best way to handle that.

So the reason we wanted to have this brief discussion with this group on the hemoglobin measures was, if you recall at the in-person meeting, the steering committee evaluated the adult measure of hemoglobin less than ten of not passing the evidence criterion, but ultimately did

evaluate the pediatric measure of hemoglobin less than ten as passing the evidence criterion, and ultimately all the criteria so that it could be recommended for endorsement.

And we wanted to make sure that we had the rationale correct in terms of perhaps on the surface seeming inconsistency, and after that in-person meeting, we had had a smaller call with Rick Kaskel and Mike Somers, and I think Kristine Schonder was on that call.

And I'll just summarize the bottom line from that discussion, and also I guess probably from the steering committee meeting was that the value - or the issues for pediatric patients with hemoglobin less than ten are considerable, and in the absence of pharm data with ESA use that specifically included pediatric patients, they thought that the benefits outweighed potential harm to the pediatric patients.

And just a little bit of context, if you recall, there was a lot of discussion at the committee meeting about the hemoglobin less than ten in light of the recent FDA information that came out again about hemoglobin values and potential harm with use of ESAs, which is one of the factors in not recommending the adult measure.

So I'll stop there and ask if Rick or Michael Somers want to make a few comments, and then we'd like to hear from the rest of the steering committee.

Frederick Kaskel: Right, well I can go first, and then if Michael wants to add something.

Lauren Richie: And just one other thing. Would you all please - we often forget to do this, but on the conference call would you identify yourself when you make a comment? It just helps for people when we just hear the voices. Thank you.

Frederick Kaskel: Right. So, Rick Kaskel from Children's Hospital ((inaudible)), and I've been on the committee now for - since last - a year ago summer. So we presented this measure, and we presented a rationale for this based on the fact that there's very little data in the pediatric literature in terms of identifying the gap and that we wanted to bring as much to the table as we could.

We showed some recent data that was not initially reviewed prior to August with two new papers that did show data regarding quality of life and cardiovascular risk factors, regarding in hospitalizations, regarding pediatric patients on dialysis with hemoglobins below ten.

We also had the most recent pediatric dialysis data that we could get from the ELAB project, which was given to us nicely at that meeting, which shows about 20% of the patients over that course of 2010 that for the period - project period, had hemoglobins less than 10. And we also had recent data from the chronic kidney disease in children study showing that almost 40% of patients entering into this study, level two through four CKD, level two through three CKD, were anemic.

So a lot of data from our population in only two or three publications indicating that potential risk for children who have hemoglobins less than ten. Michael, did we cover that - everything there?

Michael Somers: This is Michael Somers. Yes, I think Rick summarized it nicely. I think the key points are that the literature is very much different in children than adults, in that we have this target of ten that shows below ten there's significantly increased morbidity along a whole set of clinical parameters; whereas we do not have the same data that exists in adults, that there are disadvantages to being greater than ten. And in fact there's no pediatric data that suggests that there's detriments even as the hemoglobins continue to go higher.

We - at the meeting, as Rick said, you know, one of the big points was that we didn't have data for performance gap. But I think that that ELAB data that he just alluded to and that Lauren sent around as an email about half an hour ago on page - I think it's page...

Frederick Kaskel: 28 and 29.

Michael Somers: Sorry - has the data that shows 20% of patients are not meeting the goal of 20 - of ten. So I think that that shows that there's a performance gap as well.

Lauren Richie: Okay, so I think the main question - we just want to make sure that the steering committee feels that there are differences that justify moving forward a pediatric measure, but not the adult measure, and basically on the rationale that Rick and Michael were just mentioning. So we'll stop there and ask if the other steering committee members have any questions or comments about that.

Kristine Schonder: This is Kristine. I think I'll just kind of echo what Michael and Rick were saying, is that the pediatric data is very different from the adult data, and the fact that there are some - there is evidence in the pediatric population of harm with a hemoglobin less than ten. In the adult population, we don't have that same evidence of harm, per se, until the hemoglobins drop much, much lower.

There is the quality of life information in the adults, but that's - there's not evidence of true harm in the adults, and so that makes a difference when you're looking at the two different populations for measures development.

Frederick Kaskel: Again, I make a case that, you know, if we're going to move ahead with limited data in pediatrics regarding this issue as well as some of the other measures, we have to have a start. We have to have a go ahead. We have to accumulate the data to build the data base, like

anything else. And if we don't get that opportunity, then we'll come up to the plate again less prepared.

Alan Kliger: Yes. Well, this is Alan. I think that the data as was presented and we discussed last time for harm for hemoglobins less than ten in children satisfies the criteria that we discussed and justifies the decision we came to. In adults, the - there are data for harm at hemoglobins between six and eight, and eight and ten. If you look at strength, vitality, and fatigue, which are patient-derived outcomes that are very important to patients, so I wouldn't discount those as saying they're not really harm. They are harm.

But no data that I'm aware of using ten as a cut off, and indeed that quality of life data showed that at levels of hemoglobin about ten, there's really little evidence that - or no evidence I'm aware of that giving - that changing or taking steps to increase hemoglobin resulted improvement in those outcomes. At much lower hemoglobins, there is evidence that that's the case.

So I think we made the right decision, to recognize the data for children and recognize the absence of data for adults for this measure.

(Karen): Okay. Any other comments? We just wanted to make sure that we had the right rationale that we could present when these go out for comments. So we appreciate you taking a look at this again. Okay.

So given that, moving forward in terms of harmonization related to the anemia measures, we really - we have these two, the less than ten for pediatric, and the greater than twelve for the - for anyone on ESAs. I had - need to double check. Maybe that's on the adults. 1666. Oh, yes. 1666 is adults. So, and these are both by the same measurement group.

We - Lauren provided a side-by-side of the specifications, so I guess the question is whether the steering committee or the work group members and the other committee members on the phone see any harmonization issues that we should bring up to the measure developer. Obviously the numerator is different, and the denominator is somewhat different as well, because one's pediatric and then the other one is adult patients on ESAs. But any issues that we should bring back to the developers?

Frederick Kaskel: Help me understand what your question is.

(Karen): Well...

Frederick Kaskel: We do have different definitions, as you just described.

(Karen): Right.

Frederick Kaskel: So what beyond that - what in harmonization beyond that do you - are you asking about?

(Karen): I think you're right. I don't think we have any harmonization issues. I just wanted to ask the group. So I will - I think we don't really need to go any further with that. Okay.

So the next issue that we had was on measure 626, and this measure was not passed at the steering committee meeting. The developer had asked if they could submit some additional evidence, and we wanted to just see if you had any thoughts about whether this measure should have any further consideration. So Lauren, do you want to...

Lauren Richie: Sure.



(Karen): ...say anymore about that?

Lauren Richie: Just in a subsequent conversation with the measure developers, they wanted to provide the committee with - provide it some additional information on their summary of evidence of high impact as well as performance gaps as well as some additional testing data. So we did give them an opportunity to do so.

And I don't know if you had a chance to go through the measure submission in detail, but I'll just quickly highlight where the additional information was submitted. And that's first under 183, the developer provides some additional information on the prevalence of - some additional information on the prevalence of diabetes and the relation with hypertension and CVD, and additional information on the pediatric data as well.

So I think maybe what we should do is perhaps look at evidence of high impact and performance gaps for the new information that they submitted, and kind of go from there. And we will review the measures as though we would in person.

(Karen): Well, yes. I mean, maybe we should - well, why don't you go ahead, Lauren? Yes.

Lauren Richie: So I'm just going to pull this up briefly here. So I'd like to ask the work group, is there any information here that would sway your opinion from what was discussed at the in-person meeting?

(Karen): And maybe we should review what the issues were at the in-person meeting. In your memo for this conference call, I think we put a summary from the in-person meeting in there.

Lauren Richie: Basically this measure does not pass ((inaudible)).

(Karen): What page was that on?

Lauren Richie: Page 12.

(Karen): Okay, so it was page 12 of your memo for this conference call. Page 12? Okay. So Lauren, you want to just say what the...

Lauren Richie: So under the importance, the rationale was that lipids are a national health priority. No performance data on this previously endorsed measure even though indicated measures in use. The performance gap data for all adults, but measure also includes children.

In the latter ((inaudible)) in the measure, kids and adults on/off dialysis, and preexisting cardiovascular disease, post, primary, and secondary prevention, and the evidence there. So basically the performance gap data did not - the committee felt that it did not meet the NQF criteria for that, and additionally thought measure developers submitted really - okay.

(Karen): So let's just ask the steering committee. I know you didn't have a lot of time to look at this, but is there any questions or comments that you have about the additional information that the measure developer thought you should see?

Alan Kliger: This is Alan. I mean, the developer did provide evidence of a performance gap in adults, unless I'm misreading the additional information. I didn't see children in the additional information. Did I miss that?

Michael Somers: Yes. He talks about pediatric dialysis as being a thing.

Lauren Richie: Yes. It's actually on the screen now, so approximately 29 to 87% of pediatric peritoneal dialysis patients had elevated cholesterol levels with LDL greater than 100, and then from additional 72 to 84% of pediatric kidney transplant patients had LDLs greater than 100.

(Karen): But that's impact, right?

Lauren Richie: Yes.

(Karen): Did they provide any data on this measure, because it would be measure maintenance. What did they put under 1B?

Lauren Richie: Under 1B-2 - I don't think there's anything in there about pediatric.

Frederick Kaskel: Right, not in terms of the levels, but in terms of the measurement.

Lauren Richie: Right. Right. So what they provided in 1B-2, I don't know that this is any different, was the, again, population data from their data, but it was at the aggregate level of - 84% were found to be compliant for lipid panel monitoring, and people with chronic kidney disease, across the patient population, across all providers.

Michael Somers: And it was all adults.

Lauren Richie: Correct.

Alan Kliger: Yes, I just go back again to what I think we said when we talked about this, which is that either the measure has to be adopted to deal with the data we have, so call it adults, or provide the data on performance gap in this measure for the children.

(Karen): And the other thing is, we still don't have, even for the adults - this is being put forward as a measure for clinician level - let's see, process - clinician or physician level performance, and we just have one large 84% out of all the data, so it's hard to know what the distribution, or the physician level performance is. So is the developer on the line?

Lauren Richie: Do we have someone from IMSL? I'm sorry, from Active Health Management? Sorry.

(Karen): Okay. And they also provided additional evidence, right?

Lauren Richie: Yes. So in section 74, they provided some additional information there. They referenced the Sharpe trials, and that was - lipid profile monitoring while supported by the American Academy of Pediatrics.

(Karen): Okay. All right. So any other questions or comments from the steering committee?

Lauren Dalrymple: Hi, (Karen). This is Lauren Dalrymple. So just to clarify, the new paragraph from our data of a population of over 13 million, 96,000 is still the denominator, the work doing that does include the adolescents and adults? We just don't know the...

(Karen): Are you - under 1B2?

Lauren Dalrymple: Yes. It doesn't - let's see. What did they say about the data? Right. It says out of their field there, defined denominator, so we're presuming that's a mixture of adolescents and adults.

(Karen): Right. Right. That's what I would assume as well.

Alan Klinger: This is specific to the population that we've defined in this group, that million? I doubt it, right? There aren't a million people on dialysis.

(Karen): I think - no, 90,000 fulfill their denominator. I think they're saying they have a million that they have data access...

Alan Kliger: Sure.

(Karen): 90 of them - of whom meet their denominator criterion.

Alan Kliger: Sure.

Lauren Richie: And that's chronic kidney disease, not just dialysis.

Alan Kliger: Right. Right, sorry. Sorry, that's right. So this is 13 million and your denominator of CKD three or higher. Is that correct?

Lauren Richie: 96000 is the denominator.

(Karen): So I think as Lauren's saying, whether - what they are saying, that they have 13 million patient records in their database, and of those, 96,000 met the denominator, which their denominator is defined as males greater than ten and females greater than 13 diagnosed with chronic kidney disease.

Lauren Richie: And I'll just ask again, is someone from Active Health on the call? Dr. Vir? Okay. Or if you can't get into the speaker line, you can just send me a message on the chat box.

(Karen): Yes, Operator, how would the person signal to you that they're on the participant line?

Operator: If someone's on the participant line right now and they need the line open, hit star zero. Also please make sure your phone is not on mute.

(Karen): Okay. All right. All right. So if we had that clarified, does that - I think the other issue with the measure was under evidence. This is the same - I mean, in terms of the evidence, it would not be direct, because this is about assessing, which is not real proximal to the desired outcome, and there were questions about this lipid monitoring - obviously that in itself does not affect outcome.

Observational study links CKD to hyperlipidemia, and some volume studies that statins reduce micro-inflammation. So they were submitting some additional evidence information if you look at what items did they change, one...

Lauren Richie: 1C. ((Inaudible)) And then ((inaudible)) but it's the same information.

(Karen): Okay. All right. So, does the committee feel they need to have more time to look at this? How would - does anyone have a suggestion of how to proceed with this particular measure, if there's any interest in reconsidering it by the steering committee, or should we kind of poll you after the call to get the sense of the members on the call?

Lauren Dalrymple: (Karen), this is Lauren again.

(Karen): Yes.

Lauren Dalrymple: I only had time to briefly review the measure, and others may have had more time. I think even if we were willing to accept new evidence and all agree that there probably is room for improvement, and that this is a moderate to high impact, I think this measure would still run into significant difficulties as to reliability and validity.

And some of that would be related to some of our prior concerns that this is actually a measure that includes a very diverse population, adolescents, adults, all ranges of CKD, transplants, dialysis, with and without cardiovascular disease, and I don't know if we want to discuss the reliability and validity, but my general sense is I don't think it would pass on those issues, even though the developers have submitted some new evidence and data. I think those two areas would still be very difficult for this measure.

Kristine Schonder: This is Kristine. I would agree with Lauren on that comment. As well as the reliability and validity testing, from what I can tell, it's still not done on the clinician level. And since this is a clinician level measure, it doesn't appear that they've met that criteria either.

(Karen): Okay. Okay. So we can follow up with you more formally after the call just to make sure that we are - you know, get everyone's input on this to - on not moving forward with this measure, but we'll follow up with you after the call on that.

Dr. Bani Vir: Hello?

(Karen): Yes?

Dr. Bani Vir: This is Dr. Vir with Active Health Management.

(Karen): Oh, okay.

Dr. Bani Vir: We didn't know if you were discussing our measure because we were not on the agenda until 4:30.

(Karen): Right. Sorry, we're moving faster. So the question was just a clarification for the data that you provided on performance gaps. The question - you identified that out of a population of 13 million,

we assume that's all of the patient records that you have? That you say 96,482 met the denominator, so that would include the children, the - as defined in your denominator, males greater than ten and females greater than 13?

Dr. Bani Vir: That's right. Typically with this measure, the pediatric population that falls into this denominator is quite small, but at this time it does include the pediatric population, yes.

(Karen): Okay. And do you - we still don't have, you know, performance results at a clinician level.

Dr. Bani Vir: I did explain that in my resubmission, that our performance gap is measured at a provider - at the provider level across the entire patient population. If it needs to be broken down further per provider, provider-specific, that would be done on a client-specific request. We wouldn't make that information public knowledge without a client request. But these numbers are based on a provider ((inaudible)) option.

(Karen): And we would not be asking for identification of the providers, but some idea of the distribution of scores across the providers, but...

Dr. Bani Vir: Okay.

(Karen): Steering committee, do you have any other question for the developer from Active Health Management?

Lauren Dalrymple: This is Lauren. I did have a question about the numerator. Ready?

(Karen): Okay, go ahead.



Lauren Dalrymple: The numerator appears to include hyperlipidemia diagnoses that won't - wouldn't necessary actually represent lipid profile testing. I was just hoping to clarify if I'm interpreting that correctly, that the numerator might actually just include the diagnosis.

Dr. Bani Vir: I'm sorry. Could you point out to me which section you're reading, if it's A1.3?

Lauren Dalrymple: Sure. If I go to Section 2A, 1.3, lipid panel monitoring 15 months, one of the following is correct. It's number 5, presence of at least one to - the way I read this is one of the following is correct. So technically, if number 5 was correct, meaning the patient received a hyperlipidemia diagnosis in the past 15 months, they would be counted in the numerator. But that's not the same as having a lipid panel performed.

So I just wanted to clarify, because I also noticed a lot of - I believe these are ICD9 codes for diagnoses of hyperlipidemia, as opposed to actual lipid profile testing.

Dr. Bani Vir: Correct. So the hyperlipidemia diagnosis the last 15 months - we, in that particular element in our rule, it would require that they actually had a lipid panel in order to receive that diagnosis.

Lauren Dalrymple: I see, so somehow in your data, diagnosis would be linked to a true lipid panel being drawn.

Dr. Bani Vir: Exactly, and if you would like further breakdown of that particular breakdown, we can certainly provide the datum.

(Karen): Okay. Any other questions for the developer while we have her on the line?

Lauren Dalrymple: This is Lauren. Can I just clarify one last issue?

(Karen): Yes.

Lauren Dalrymple: Since it's come up, with the - since this is such a broad population, meaning adolescents, adults, all stages of CKD, dialysis, and renal transplant, my recollection is that the results weren't going to be presented separately for these different groups. Is that correct, or was that changed in the revision?

For example, would these - you know, would the results for the adolescents be mixed with the adults, and the results for nephritic syndrome be mixed with dialysis and renal transplant on lipid profile monitoring?

Dr. Bani Vir: They would be mixed, and the - we were under the understanding that that - that we were not asked to separate them at this time.

Lauren Dalrymple: Okay, thank you. I just wanted to clarify that the revision - that that was still the case. Thank you.

(Karen): Right. And if the - you know, if the guideline or recommendation evidence are the same, it wouldn't be necessarily required to break that out separately.

Dr. Bani Vir: That's correct, since - because this is a - simply a screening and not a treatment measure - type of measure, the requirements are the same.

Lauren Dalrymple: Okay. Thank you.

(Karen): And Lauren, what do you think about that? I mean, I think that was the basis of having them combined.

Lauren Dalrymple: Well I think that the guideline is generally being followed, but I think it just gets to interpretability, I think.

(Karen): Right. Okay.

Lauren Dalrymple: And so that's my concern, is if these numbers are collected, how will clinicians, pediatric nephrologists, adult nephrologists, be able to use them in a meaningful way and interpret them? In my recollection, when this measure was presented at the original meeting is there was a lot of concern about the diversity of the population and interpretation.

Dr. Bani Vir: Okay. All right, so just to point out that the pediatric nephrologists would be measuring only pediatric patients. You know, that's - that would be tied into our provider assignment rules.

Lauren Dalrymple: Right. So - yes. So it would obviously be their patients if it was a pediatric nephrologist.

Dr. Bani Vir: Correct.

(Karen): Okay. All right. Any other questions for the developer? And so what we'll do is follow up with the committee about the thoughts about reconsidering this measure.

So until that would be settled, we really don't have a harmonization issue. And I'll just ask if the steering committee has any other issues they want to bring up before we open up for questions or comments. And then we'll do that.

So are there any other measures? And as I said, you know, we just didn't have enough time to turn around that other letter for you to consider on this call, unfortunately. So we will follow up

with you specifically about those measures separately and decide what the best process will be to move forward. Steering committee, comments, questions, issues?

Frederick Kaskel: Kind of quiet.

(Karen): Yes.

Frederick Kaskel: Uncharacteristic of us.

Lauren Richie: And with that, I think we will just go ahead and do our formal NQF member and public comment period. So Operator, if you can, open all of the lines, please, speaker and participant lines.

Operator: Absolutely. And lines are open.

(Karen): Okay. So are there any NQF member and/or public comments, or comments from the measure developers at this time? Okay. With that, I will assume that there are none.

So let me just tell you what our next steps are going to be then. As I said, we'll follow up with you specifically on whether you want to recommend pursuing 626 any further. But in general, and we've kind of been in flux about this a bit, how to handle the full steering committee meeting, which is scheduled for October 13th.

And I think at this point we've decided that we will be getting out to the full steering committee all of the summaries from the work group calls, so you can see what their deliberations were, and in some cases they revoted on some of the measures. So you can see that information.

We've decided that we'll hold off on the full steering committee voting until after that October 13th call. So on that call we will try to organize it so that we can spend the time on measures where there still seems to be difference of opinions; but also, you know, identify those measures that seem to be, you know, clearly recommended or clearly not recommended so that the full steering committee can raise any questions or issues before we do any voting.

So - and we will focus that on the measures that were discussed on these work group calls. We may need to schedule another conference call after that, if we still have any outstanding issues. And we'll probably get out a scheduler to you just to have a potential date in case we need it. But I'll stop there and see if anyone has any questions or other suggestions regarding the next step.

Dr. Bani Vir: This is Dr. Vir again from Active Health. Just to clarify, you - would you - is the October 13th meeting - will we be able to attend that meeting, and did I understand there will be an agenda sent out, or is that an internal meeting only for the NQF?

(Karen): No, it'll be an open meeting, and there will be an agenda posted, and call in information.

Dr. Bani Vir: Okay, great thank you.

(Karen): Any other questions or suggestions from the steering committee? Okay, well we won't hold you any longer. We just had a few items that we wanted to review with you, so appreciate you getting on, and we'll follow up with an email and go from there.

Male: Thank you.

Male: Thank you.

Female: Thank you.

Male: Thank you all so much. Bye.

END