

NATIONAL QUALITY FORUM

Moderator: Lauren Richie
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11:00 am CT

Operator: Thank you for standing by. Welcome to the conference. Please note today's call is being recorded. Please stand by.

Lauren Richie: Okay, thank you everyone for joining the call today. As you know, this is our follow up conference call to our in-person meeting held exactly one month ago today.

So we will just like start a really quick roll call of the Steering Committee members as well as the developers that are on the call today. So I will go through the list as quickly as I can in alpha order, starting with Peter Crooks. I know you're on the line.

Kristine is on the line. Connie Anderson, have you joined us? Sue Barnes I believe is on the line.
Jeff...

Peter Crooks: Sue's here. Okay.

Lauren Richie: I'm sorry?

Peter Crooks: Sue Barnes is here. I heard her say here.

Lauren Richie: Great, and Jeff Berns. I believe Barbara's going to be a few minutes late. Rick Kaskel, has he joined us? And Myra Kleinpeter and Jerry Jackson I believe has called in.

Jerry Jackson: Yes.

Lauren Richie: Alan as well. Lisa Latts, I know she may be a few minutes late. Kathe Lebeau I believe is on the call.

Kathe Lebeau: Yes, I'm here.

Lauren Richie: Joe Nally? Joe Nally not yet, and I believe we have Andrew Narva, Jessie Pavlinac, Robert Provenzano, Joseph Vassalotti, Ruben Velez, (Roberto Wager), are you on the call yet?

No, not yet. Okay and Harvey Wells. And if we could just turn to our developers for - to let us know who we have on the phone, starting with CMS please.

Tom Dudley: Tom Dudley.

Renee Henry: Renee Henry.

Shari Ling: Shari Ling.

Claudia Dahlerus: And then supporting CMS we have Arbor Research U of M Keck. This is Claudia Dahlerus.

Joseph Messana: And Joe Messana.

Lauren Richie: Okay, anyone else from CMS or Arbor? And is someone from CDC on the line yet? And what about Genzyme? Do we have someone from Genzyme?

Jose Menoyo: Hi, this is Jose Menoyo.

Lauren Richie: Okay. Okay, thank you very much. I am going to turn it over to Peter for a quick review of the agenda and we'll get started.

Peter Crooks: Okay, thank you Lauren. I suppose we need to ask for any new disclosures in the - from last month's disclosures that we did at the live meeting. Anybody have any new disclosures they wish to report?

Okay, hearing none I'll go ahead. The only other rule I would ask is that when you speak you say your name. Most voices we can recognize but sometimes we can't so let's try to do that.

The agenda is in four parts. I think we have the review of measures with conditional recommendations, responses by the measure developers to our conditions then we're going to review competing infection measures.

The only area where significant competition overlapping measures is identified is in the infections, then review of related measures from harmonization issues and then some additional questions or clarifications.

So that will be our agenda this - today, and then finally a time for NQF member and also public comment. So if no one sees any additions or corrections to the agenda - okay then let's proceed and I'll turn it back over to Lauren and Karen.

Lauren Richie: Okay, thank you Peter. So we'll get started with the - and let me just reiterate, you may have a different version of the evaluation summary from me this morning.

Just want to remind you that we are referring to the version dated 2/7 of the evaluation summary and not the one that I sent out this morning, so if you do have that, the hard copy or electronic copy, that's the one we will be using today.

And we're going to start with a review of measures with conditional recommendation. I am just going to do a really quick high level summary of the conditions and/or questions that were posed to the developers and then their responses, and then I will it open it up to Peter and the rest of the Committee, the first measure being 1438, Periodic Assessment of Post-Dialysis Weight.

There was actually a question to the Steering Committee, that being, "Why would post-dialysis weight assessment not be appropriate for home hemodialysis patients?"

And then a question and condition to the developer was, one, to include the pediatric population of the condition, and the question was, "Should the word new be removed from the description and simply referred to post-dialysis weight?"

So just to briefly summarize the developer response regarding the condition to include the pediatric population, they did agree that that population should be included and that CTEP also noted that the proposed measure requires reporting and monthly prescription for post-dialysis weight.

This does not denote that actual monthly assessments are performed, however they do believe that this measure encourages good clinical practice. It should also be noted that this measure should be calculated purely for the pediatric population, and then also their fluid weight.

CTEP was in agreement that the implementation of this measure extended to the pediatric population. However they did emphasize that this recommendation was based on the collective clinical experience and is still an opinion-based recommendation at this time.

In regards to the question with removing the word new from the description, the developer was under the impression that that motion was rescinded to remove the word new, so they felt that that should be retained.

Seeing as though it would likely push the requirement for a formal monthly prescription they - their recommendation was to add the phrase, "Irrespective of whether or not a change in post-dialysis weight prescription was made."

So that briefly summarizes Measure 1438 and that's on page 16 of your evaluation summary.

Karen Pace: This is Karen Pace and just one comment about our process that we'll be using today for these conditional recommendations. The measures that were recommended conditionally - the idea is that we got a response from the measure developers.

The Committee will review these - those responses on the call today and we will have to have you vote to either accept, you know, to accept those responses and move forward or, you know, the - potentially not recommend the measures, but we'll do that formal vote after the call.

It's difficult to do those votes on the call and for those that can't join us right away, we want to make the information available and have them also participate.

So at this time what we'd like to do is see if there - if people are - the Steering Committee, if they accept the response from the measure developers or if there are any additional concerns or

questions, and then also I guess to just bring up whether home hemodialysis patients should be considered for inclusion in this measure, so I'll stop there.

Joseph Vassalotti: This is Joe Vassalotti - just one quick question. If I'm interpreting this correctly from the responses that the new part of the question is that the clinician needs to enter the dry weight every month, so whether it's 86 kilograms in January, 86.0 kilograms would have to be reentered as an order every month, whether the 86 increased, decreased or stayed the same. Is that correct?

Karen Pace: Yes, and CMS/Arbor, you want to just confirm that that is the case, correct?

Frederick Kaskel: I believe that's correct.

Karen Pace: Yes, that's what the response said. Okay.

Joseph Vassalotti: Okay, and then with respect to the home patients, so it would be for home hemodialysis and peritoneal dialysis too I guess but - and that would be instead of with the dialysis session with the monthly clinic visit, so that with a monthly clinic visit the - there would be an assessed order for a dry weight.

Karen Pace: So this is just - this is not necessarily some, you know, it was discussed at the Committee meeting at - CMS didn't propose the measure that way. It was just something that when we reviewed the transcripts we wanted to make sure where the Committee was about that, whether it was reasonable to exclude home dialysis patients.

Robert Provenzano: This is Bob Provenzano. I just - I don't know whether it's the purview of the Committee to go down the path of including or excluding anything that the submitters didn't consider.

Although I personally may agree or disagree the process for that, it doesn't rest with the NQF does it?

Karen Pace: No, that would have to be - again that would have to be something that would go back to the measure developers, so it's not something that we can just say has to happen. You're correct.

Robert Provenzano: Okay, but my take on this is that it - certainly conceptually it makes sense that dry weight is important to home patients. It's really a question of stability in data collection so...

Constance Anderson: This is Connie Anderson and I think that'd be very burdensome to try and collect data on a monthly basis when you have a new dry weight prescription every month on the home population of patients.

That - yes, I wouldn't support that at all. I don't disagree with the concept that it's important but the way this measure is written, that just isn't reality.

Karen Pace: Okay.

Robert Provenzano: Yes, this is Bob Provenzano. I respectfully disagree only because all of my home patients will alter their dry weight, and if I don't on a monthly basis really have a in-depth conversation about what they're doing with their dry weights as they manipulate them at home, a patient can get into trouble.

So it seems to me that when you see them for their monthly visit, if you do, that one of the very first things we do focus on is what's going on with your dry weight.

So I would just take the opposite opinion of the importance of that, at least in my clinical arena.

Constance Anderson: I didn't say it wasn't important. I just said it's very burdensome to try and do this.

And yes, we do have some monthly clinics and yes we do assess it, but I think it's overly burdensome.

Karen Pace: Okay, so let me - this is Karen again. Before we discuss that any further, let me just ask if there are - were - if there were - if people are okay with the response to the condition that was put forward initially in terms of this measure, and we'll have to have this as a kind of separate issue.

But before we talk any more about the exclusions or inclusions, was there any other comments or disagreement with CMS' response to the original conditions?

Ruben Velez: Ruben Velez, and it's really a question to clarify something that was said a few minutes ago. Dry weight is mentioned in multiple areas in the patient's chart.

I understand the data source for this measure is going to be CROWNWeb. Did I hear correctly that what we're saying now is that there must be a monthly order of a dry weight in the chart?

Karen Pace: Yes, and that hasn't changed from the original measure that was approved. That was the intent, yes.

Peter Crooks: Karen, your question about the word new, in reading this I don't see them responding directly to that, but you said that they felt they should leave it in with an addition. That's not in writing here is it? Or that was on the other...

Karen Pace: That was in one of the additional responses that we received, so what they propose is to add the phrase, "Irrespective of whether or not a change in post-dialysis weight prescription was made."

Peter Crooks: Okay, so is the Committee - does the Committee have any other questions about that or are they comfortable - uncomfortable with that? Okay, so that takes care of that issue.

And I would like to comment that the way the measure is written, it doesn't say pediatrics are excluded. It doesn't say home dialysis is excluded I don't think.

Karen Pace: Well the condition of the - the condition that the Committee put on this was to include pediatrics and CMS agreed to that.

Peter Crooks: Right. Right.

Karen Pace: So that will be made, so what - the exclusion that currently stands is home patients.

Peter Crooks: And in the way it was written initially, I mean, the home patients still, at least in this brief denominator statement it says, "Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis."

That could be taken to include home patients, too. Even though they're not dialyzing in the outpatient facility, that's where they get their support and training.

So from my reading of this, this is not the full denominator statement. It doesn't exclude home patients.

Karen Pace: Right. Okay, so could we ask Arbor or CMS to just clarify and I can pull up the detailed specifications to check, but was the intention that this would include home hemodialysis patients?

Shari Ling: We don't believe so. We do not think it was the intention of the TEP in developing this measure to include home hemo patients.

Karen Pace: All right, and...

Peter Crooks: Was that put down as an exclusion in the original long form of the measure application?

Karen Pace: It - I don't believe it was but let me...

Jeffrey Berns: This is Jeff Berns. Isn't the terminology to just - when something - somebody's referred to as chronic maintenance hemodialysis in an outpatient dialysis facility, I think that's generally taken to assume in-center patient chronic hemodialysis.

And that would - that term alone would be exclusionary of home dialysis therapies I think. That's how I interpret that.

Karen Pace: Right and I believe that's how the - how it is worded.

Kristine Schonder: In the long form under 2A.8 it says, "Denominator details, denominator only includes in-center HD patients."

Peter Crooks: Okay. All right, thank you. So therefore that's what we're - we've approved and unless we are formally asking them to include home patients, it would not include that.

Karen Pace: Right, so currently CMS did accept to include pediatric patients as you all recommended in your condition. They have said they would include some language to make sure there was no ambiguity about new by saying, "Irrespective of whether or not a change in post-dialysis weight was made," so...

Dr. Alan Kliger: Yes, I move we accept their language.

Karen Pace: Okay, and is there any interest then in having further discussions with CMS about the home patients?

Dr. Alan Kliger: This is Alan Kliger. I would suggest we just accept their language as amended.

Jeffrey Berns: Agree.

Karen Pace: Agree.

Peter Crooks: I would agree too.

Robert Provenzano: Sounds good.

Karen Pace: Okay, so what we will do is we'll move on to the next measure, but when we make the voting available to you we'll make it clear that it's voting on it with these - the pediatric and the language about the irrespective of a change. All right, Lauren you want to...?

Lauren Richie: So moving on to the next measure, 1463, Standardized Hospitalization Ratio for Admissions, there were a couple of conditions as well as a clarifying question, the first condition being to remove race and ethnicity from the risk model, and the second condition being to change the time period to one year rather than three.

And the clarifying question was, "What is the data source for this measure?" So CMS did agree to remove race and ethnicity from the risk model. The second condition, it was their intent to have

the admissions measure approved that can be calculated over any given time period within the range of six months to three years.

They then go on to state that the one year SHR is a stable measure as indicated by its high correlation with the three year, and then they clarify that the source is the CMS Medicare claims data.

So they do agree with the first condition and maybe we just may want to have them clarify their range from six months to three years.

Robert Wolf: We have been publish - this is Bob Wolf. We have been publishing on the dialysis facility reports values at three years and have also made available one-year values to the facilities, and those have been proven to be very useful and stable.

The six-month value is also useful for quality improvement in order to be able to provide very current information to a facility and has utility, although it is less stable than the one-year and three-year.

And we seek approval for the entire range with the statistics to be provided to different audiences as appropriate.

Peter Crooks: This is Peter Crooks. Just a question for Karen and Lauren. Is there any problem in terms of consistency with other NQF standards of having different time periods in the same measure?

Karen Pace: Well typically, you know, in our endorsed measures we want things standardized so that everybody that would potentially use the measure would use it the same way.

And the - but the potential exception to that is, you know, if you can really say that it doesn't matter whether you measure it at six months or one year or three years, that you're going to get a comparable result.

But I guess I'm not quite sure on why CMS is asking for such a long range of six months to three years. That seems pretty...

Peter Crooks: This is Peter again. I think that their explanation is reasonable. You get different information by looking at the different time periods and for different uses, and I think that's reasonable.

My only problem was if the National Quality Forum says this is not, you know, consistent with our standards, you know. You need to pick one and stick with it or it's okay to have, you know, I suppose if we picked one they could always report, you know, say we picked one year and said that's the one we're endorsing or we want to endorse, it could - that doesn't mean they couldn't report three years and six months.

Joseph Vassalotti: Yes, this is Joe Vassalotti. What - to me this is sort of similar or harmonious with the mortality ratio. How - what's the interval for the mortality ratio that's currently being reported?

Peter Crooks: Bob?

Karen Pace: Does CMS know? I don't have that.

Robert Wolf: I believe that was approved at three years and the...

Shari Ling: There was no limits on - yes, no time limits were placed on the SMR for time intervals covered.

Robert Provenzano: So let me - this is Bob Provenzano. I guess my concern is I want to make sure I'm understanding this. I understand the statistical analysis of the different time periods, but what is the vintage of this information?

In other words, you know, what data set are we analyzing? Is this two year old data that we're going to be looking at, because if so its value at least in - as I see it in our current environment whether it's with ACOs or whatever, two year old data has almost no immediate meaning as I see it.

So I'm curious, what is the vintage of the data that we will be stratifying to six, one and three years, six months...?

Robert Wolf: The lag in reporting is approximately nine months by the time it gets to the public. That is calendar year is finished on December 31. The data becomes available the following March and it is released essentially in August or September after that.

And then depending upon the duration of the period that is aggregated, it will include years prior to the last time point reported.

Robert Provenzano: Right, to balance it off, to balance those time periods.

Robert Wolf: Yes.

Dr. Alan Kliger: This is Alan Kliger. We talked about the value of this and the timeliness which is wonderful now. My concern about having multiple intervals to look at is that as NQF-approved measures, these are then publicly reportable and presumably useful to patients and doctors to make decisions.

I'm concerned that if there are multiple time intervals that will report the same measure, that it may introduce some real confusion in that reporting. Why should a number be different for a given unit or a different patient?

Would it not be wiser to select one or two rather than a range? And then finally from me, the six month - the relationship of the six months to the stable three year is fine, but looking at the data here, at least the values, is probably not quite as good as the one year I guess.

So I guess I would wonder if it really is valuable to have so many and would it not be wiser to say choose one and three year?

Peter Crooks: Other comments from the Committee?

Robert Provenzano: Yes, can you help me understand again why we pulled race and ethnicity out?

Karen Pace: This is Karen and the NQF criteria really suggests that race and ethnicity not be included in statistical risk models, because they tend to obscure potential disparities in care and that was the discussion at the Committee meeting.

Robert Provenzano: Okay, thank you.

Peter Crooks: Right. So where do we stand with this then? If - do we want to propose to the developer a one and a three - one year and three year denominators in terms of for endorsement?

Dr. Alan Kliger: So - and Bob, can I just ask - it's Alan. I apologize, but is it - was it your strong feeling that it would be wise to have all three of these in here? I'm just concerned about potential confusion.

Robert Wolf: And I do agree that it makes sense to have this specification in the denominator as a particular metric. Our intent was to point out the value of all three intervals, six month for understanding the immediate outcomes of mortality, and then the longer periods to show more of the stable outcomes.

Approving a one year and a three year would be very useful to CMS' purposes.

Dr. Alan Kliger: Thank you.

Peter Crooks: Here again even six months though - the six month - another problem with the six month is that you're looking at data that's now nine months old, so you're looking at data that's approximately 9 to 15 months old.

So maybe it isn't as current as, you know, it might be if for instance they're just doing their own at their own unit, they would know what - could probably get a more up-to-date number, so maybe dropping six months we're not losing that much.

Jeffrey Berns: Jeff Berns.

Karen Pace: So the Committee's original condition was to change the specifications to one year rather than three years, and we asked that they do that or provide some analysis that they could only get stable estimates with the three years is how it was originally proposed. But it sounds like CMS is proposing now one year and three year periods.

Peter Crooks: But I heard Jeffrey Berns in the background trying to say something too.

Karen Pace: Okay.

Jeffrey Berns: I think your question - the - as I read it here these are all very highly correlated, the six month and one year and the three year, which raises the question in my mind, not being a sophisticated statistician, whether there is any increment in value in having more than one of these measures if they're all so highly correlated.

Peter Crooks: I don't think that they're saying they're correlated. I think the...

Jeffrey Berns: It says at the bottom that one year SHR's a stable measure and as indicated by its high correlation with the three year SHR - month SHR is highly correlated with the one year SHR, .88 and .85.

Dr. Alan Kliger: Yes, so Bob, can we ask you that question? Bob, are you still there?

Robert Wolf: The difference between the one year and the three year, they are highly correlated, however they are less correlated for smaller facilities where you see more year to year variation.

And it is useful to be able to present a stable three year estimate or value to certain audiences such as the public, and to present one year values to facilities in their efforts for quality improvement for example, which is also a public kind of reporting.

But the intended audience is different and it's for a somewhat different purpose.

Jeffrey Berns: Do we know that the value of the one year is superior to the three year for any action within the dialysis facility or, you know, is this exact same kind of information or trends in three years have the same information for action within the facility level.

I can understand that there are theoretical reasons why there might be advantages to one or the other in certain circumstances, but is there evidence beyond the theoretical that in fact they are - one or the other is more useful in practice for a certain circumstance?

Robert Wolf: We do not have that evidence, although it is clear that the feedback that we get from dialysis directors is that the - it is useful to be able to look at the trends in the mortality from year to year, as opposed to just the three year value.

And for smaller facilities it is sometimes useful to be able to look at the stable three-year value.

Jerry Jackson: Jerry Jackson. I was going to say if I were using this for a quality improvement project in a clinic, it would be much harder to interpret or see a change to an intervention with the three year than with the one year.

So if the three year has value for other reasons that maybe - we may need to include it but I would find the one year much more useable for quality improvement purposes.

Dr. Alan Kliger: Yes. So this is Alan Kliger. Let me just again reclarify that in a given measure having two different denominator time definitions is consistent with NQF's policy.

Karen Pace: Generally not. We - I don't believe we usually have measure, and this is something I - I'll have to get some clarification but generally we have measures that are specified a certain way that are being proposed for the purpose of both public reporting and quality improvement, because we - we're, you know, trying to get a standard.

I don't want to say that it's impossible, especially if there's good data that they're essentially providing the same information, but generally we have measures that are specified for a particular time period because of its usefulness in terms of, you know, currency, and then also the issue of

stability of estimates if the occurrences are low or numbers are small, then sometimes the longer time periods are called for.

Dr. Alan Kliger: Because as I hear the description and explanations we just have in the last five minutes, it seems to me that each of these are a measure that has an important use but they're different, that the one year measure would be most useful for quality improvement.

And yet for public reporting the three year measure is likely the one to have the most importance. Would we need two separate measures, one for each of those applications, or could we specify in the denominator one year for quality improvement, three years for public reporting?

Karen Pace: Well typically NQF does not endorse measures that are - whose purpose is only quality improvement. So, you know, we don't really need to endorse measures that are used for quality improvement purposes.

I'm - I wasn't sure about the comment that said that for quality improvement they're also publicly reported. Does that mean that that information is available beyond the individual facility, their one year data?

Robert Wolf: It's - this is Bob Wolf again. Recent experience suggests that it is not feasible to prevent the public from seeing information which is made available to the facilities in certain circumstances.

So it would be somewhat disingenuous to say it would be provided only to the facilities because we - I don't know that that can be guaranteed.

Karen Pace: Okay, so I don't think that there's anything against NQF endorsing a measure that could have two timeframes. Our main concern would be that, you know, if they're comparable results and also the question would come up, you know, can you compare one facility's 12 month rate

against some other facility's, I mean, not one month, one year rate against another facility's three year rate? You know, so that would be the other consideration or at least to specify that.

Dr. Alan Kliger: Right. Well of course that was the reason for my question about confusion.

Karen Pace: Right.

Dr. Alan Kliger: So I - and again this is Alan. I would - after all I've heard I would indeed recommend that we approve this for a single time interval and that that interval be one year.

Peter Crooks: This is Peter. It seems though for public reporting which may be the more important use of it, three years might be the preferable one.

Dr. Alan Kliger: You know, I just - I'm listening to what Bob's last statement was. If this is made - the only way this is useful for quality improvement is if it's a shorter interval than three years.

And if the quality improvement provided to facilities is almost by definition public in any case, then it would seem more prudent to make this a one year measure.

Jeffrey Berns: I agree with Alan. This is Jeff Berns. It's more actionable.

Karen Pace: Are there other comments from the Steering - other Steering Committee members?

Constance Anderson: This is Connie. I agree. I think the one year measure is far more useable for quality and for public reporting. I think it gets confusing if you have two different measures.

Jerry Jackson: Jerry Jackson. I'm - basically agree with Alan but I - I'm going to play devil's advocate and say that if your own dialysis facility compare Web site and I'm a patient and I'm comparing two

dialysis centers in an area and choosing one, and there can be other decision points but the three year would, you know, if you had - just had a bad year one year and then it would make that unit look a lot worse.

You might have a new unstable patient that repeatedly was admitted in a small clinic. There would be a homogenizing effect of the three year for someone in a public reporting sense, but I think it does open the door for a lot of confusion and I'm okay with the one year but I just wanted to throw that out.

Peter Crooks: Yes, that's basically my concern too for smaller units, you know, that - I don't know if this will affect facility compare or not.

Tom Dudley: This is Tom Dudley. Can I just ask a question based on the last comment?

Karen Pace: Okay.

Tom Dudley: As providers what would your thought be for a dialysis facility compare if CMS went to reporting trend data, you know, just - someone made a comment about a bad year.

Jerry Jackson: I made that comment. So you would have - but you'd be using the one year data but reporting it over time.

Tom Dudley: Yes, report several years. Yes.

Jerry Jackson: I like that a lot.

Tom Dudley: It just sparked an interest in my mind. Sorry to interrupt there.

Peter Crooks: And this is Peter. I imagine if you see one year data over several years, you sort of are getting the same information that you'd get from a three year. In other words you could sort of say, "Well that was a bad year but other years they've been doing better," you know, or that kind of interpretation.

Jerry Jackson: Jerry Jackson. I would support that approach.

Peter Crooks: Yes.

Robert Wolf: And there would be more feedback for the facilities.

Peter Crooks: So maybe we had it right the first time, gang. Go back to - so Alan's proposed that we keep it at - that we recommend and keep it just a single measure at one year.

Okay, any more discussion about this right now or - well Karen, we can just vote on that one.

Karen Pace: Okay, and let me just ask CMS/Arbor, do you have any last comments or concerns about that? Okay. All right, well we will - then yes, we'll have you vote on that after the call. Okay, Lauren.

Lauren Richie: Okay, our next measure, 1430, Lower Limit of Hemoglobin for Pediatric Patients. The question to the Steering Committee was, "Is the condition to change from average to each of the three months necessary?"

Then the two conditions posed to the developer, one, to exclude patients with sickle cell anemia; and two, have the numerator the same as the number of patients with hemoglobin less than 10 for each of the three months.

So in regard to the first condition, the developer is in agreement with the Committee that this suggestion include the minimum hemoglobin target and - I'm sorry, duly agrees with this suggestion with the achievement of the minimum hemoglobin target is more difficult in these patients.

And they propose to move forward with the measure, and that exclusion of sickle cell patients be submitted as a measure maintenance step as soon as the data's available.

In regards to the second condition, the developer does not support this proposed revision for the following reasons: the main facility level percent of patients missing this target was 3.3% of facilities, compared to 14.9% with the latter target, suggesting a reduction in the sensitivity of the measure and capturing pediatric patients with anemia.

Additionally, evidence for morbidity and mortality are based on mean values rather than persistently low hemoglobin levels. The existing policy is utilized - currently utilized mean hemoglobin levels.

Requiring a persistently low hemoglobin level to define this measure may lead to substandard care as clinicians may delay appropriate clinical response. And finally, it is more - this measure is more likely to identify patients with ESA resistant anemia rather than identifying patients who would benefit from more aggressive anemia treatment.

Peter Crooks: Okay, let's discuss B. Or no, we were sort of divided among the Committee on this. I don't know if it was this particular measure but this approach. I tend to agree with the submitting body. So - and Alan, were you on the other side of this or Bob Provenzano?

Barbara Fivush: This is Barbara Fivush. I actually agree with you. I think their comments coming back to us of - substantiate why the initial measure was put together the way it was.

And I think that we had lots of conversation at the table and were swayed in this direction, but as I think in - a preliminary...

Peter Crooks: Barbara, you're breaking up a little.

Barbara Fivush: I'm sorry. I think - I don't know who that is but the preliminary measure I would support at this time, the comments that were given to us. And I would support the preliminary measure, because I think the gap changes, the sensitivity changes in a way that we didn't have that data at the table.

Jeffrey Berns: This is Jeff. I took the opposing view and I maintain - and I still take the opposing view. I think that there are risks and benefits to each approach. I think from a management perspective and a quality of care perspective and avoidance of overtreatment, looking at the persistent outlier probably I think provides useful information without providing information about patients for whom no intervention's necessary.

But, you know, I think this is a flaw in how we look at our QA data now that will only be perpetuated. I'm not sure I agree with any of the points that were raised to defend this the way it's written. But, I mean, I don't agree with them but I understand the perspectives.

Barbara Fivush: Okay, why are we - we're talking about lower limits. You're talking about sort of - you had said overuse or overtreated.

Jeffrey Berns: Well, so if you have - if you're looking at the percent of patients who are below target for a single month, that - well it gives you a different bit of information than the percentage of patients who are below target consistently.

Barbara Fivush: Right but...

Jeffrey Berns: That's important because a lot of patients are below target intermittently for a whole variety of different reasons that may or may not happen.

Karen Pace: But the measure is not per month. It's the average over three months.

Jeffrey Berns: Well again - but - I understand that but as we talked about again you can have average that is below target but not have a quality issue that needs to be addressed.

Karen Pace: Okay.

Dr. Alan Klinger: This is Alan. Again I - the answer that the developers gave didn't address my concern, which is that if there's clear evidence that the hemoglobin is rising over the course of those three months and approaching the - or even into a level we'd be happy with, calling it a - basically labeling this as an inadequate treatment or inadequate response because the mean of the three is low makes no sense to me. And I don't see that the response of the developers addressed that concern.

Robert Wolf: Right, and taking off of both what Jeff and Alan said, that would cause physicians to hyperrespond to a level that's less than ten, and get into the issues that Jeff hinted on of higher hemoglobins. I'm - I absolutely agree and this is what we discussed in the last meeting.

Frederick Kaskel: This is Rick Kaskel. I agree with the prior two speakers on this, because they could have been in some intercurrent illness, any number of things that would have caused periodic fluctuation below the norm and will respond without the appropriate - without increasing the dose too high, which would give you a hyperresponse, so I agree with his comment.

Peter Crooks: This is Peter Crooks. I would like to just kind of make a distinction between the way you manage a patient, individual patients, versus public reporting of quality, you know, to others.

And I think these are all valid points when it comes to managing individual patients, but in terms of looking at, you know, comparing facilities or comparing healthcare systems, I think that the mean is the better one to use.

There'll be some as Alan said maybe coming up and looking better, but there'll also be some that are just going down and they wouldn't get caught in that metric.

So, I mean, that stuff averages out when you're starting to look at populations and I would argue that this is, you know, not meant to be a guideline for how you treat individual patients. It's meant to be a standard for public reporting more than a quality metric.

Jeffrey Berns: If the intent of this...

Lisa Latts: And this is Lisa Latts. I would totally agree with that, that this is, you know, when you look at the population it's very different than the overall individual patient.

And if the overall population is being managed adequately, you know, you shouldn't see overall a low number because of an individual patient or two.

Jeffrey Berns: Again I think that it - we're looking at quality and I think that if you look at an average over three months you're going to get a mix of good quality and bad quality.

It's not pure. I think looking at it the other way is more - is a more pure reflection of quality - former...

Dr. Alan Klinger: This is Alan. I - one thing - I really do agree with the developers and I'm not sure how to factor this in, is that for many patients finding persistently low hemoglobins likely does reflect those with ESA resistance rather than people who would benefit.

So I do think that that is generally right but, you know, maybe right among those conscientiously treating or trying to treat patients. I will bet that places where quality is not quite focused well enough, that finding persistently low hemoglobins may reflect inadequate treatment rather than resistance to ESA.

So, you know, and one other quick thing for me which is that yes, while there surely is value in public reporting of populations of patients, this is more than that.

These measures guide clinicians in what they're going to be doing with individual patients and the concerns that what it's going to look like in the aggregate.

So I believe it would be a mistake to look at this as only a public health measure, but indeed will be an individual guiding measure for treating physicians.

Peter Crooks: I don't think that these are - should be viewed as guidelines. I mean, I don't know if Karen would like to comment on that perspective.

Karen Pace: Well I think you're right. I mean, quality performance measures should be based on the evidence, but they aren't to the level of detail and nuance in terms of individual - management of individual patients as guidelines try to do.

So, you know, you are looking at across the population and I assume that this measure of the mean is - the intent is that overall how is the facility managing their patients in terms of achieving, you know, minimal hemoglobin levels.

Dr. Alan Kliger: So Karen, this is Alan. Of course I think that's right, but I believe it would be naïve to believe that that would not in turn guide clinicians and patients in making individual choices about therapy.

Karen Pace: Sure. Now let's - yes, that's valid that people are concerned about their performance measures, right.

Dr. Alan Kliger: Correct.

Barbara Fivush: I just want to go -- this is Barbara again -- back on the record and say that I understand the concept of overuse of ESAs, overreaction, but we're talking about low, very low hemoglobins in a pediatric population.

And these - we don't have lots of studies in peds but we do know that under 10 there are some substantive issues that arise that may be different than in the adult world.

And I think actually a reaction - an aggressive plan would be indicated for someone who has maintained a hemoglobin less than 10. So I...

Dr. Alan Kliger: This isn't maintained though. That's the point. Three successive months is they're maintained that way. That would be right but what it's being compared to is a mean of the three. That doesn't say maintained at low. It well could be changing and rising.

Barbara Fivush: I understand that but I still feel that in that range, that's still - if the mean is still less than 10, even if it's going up, inching up, that still tells me that there's a substantive issue over a three month period that needs to be addressed.

So I'm not - I personally, you know, I'm not worried about overuse at this level in these patients, and I know we talk about ESA resistance. It's something of great interest and we talk about how much we know about it in peds yet, so I understand.

I guess what - to me again is the change in the number of patients we'll identify when we think there's a tremendous gap in care, you know, by changing the measure we will really pick up less patients.

And I actually think this is an area where we don't do well in pediatrics, so that's why I'm kind of interested in identifying this is more of an issue I guess than less of an issue.

And I - although I appreciate all the other comments and I will certainly go with the decision of the group, I just wanted to put that out there again that this is a tremendous - I really think this is a tremendous issue in pediatrics.

And I don't think this is one of the areas unlike adequacy where we really do have a gap in care, and I think we can impact a difference.

Peter Crooks: Okay, as we are nearing the end of our first hour and I don't know how - if these - if this is where we would expect to spend the bulk of our time we'll kind of pass it.

So maybe we're not going to get consensus on this right now and we need to vote again or Karen, do you - can you suggest a way forward?

Karen Pace: I think what we'll need to do is have you vote on it again, and we'll make sure it's clear what you're voting on. Basically, you know, the developer is - presented a rationale to leave the measure as originally proposed, and we'll be asking you to vote on whether you accept that and

move forward with the measure as originally proposed, and we'll see where that vote comes out to determine what our next step would be.

Peter Crooks: Okay.

Joe Nally: Peter?

Peter Crooks: Would that be okay? Yes.

Joe Nally: Before you vote - this is Joe Nally. I had joined you late. I had a problem that I emailed Lauren about. And I've heard this entire discussion but I just realized I have a Webinar and a telephone but I do not know how to vote. Could you tell me that before...?

Peter Crooks: We're - yes, we explained earlier before you were able to join us that we're not going to vote today. We're going to discuss things but the voting is too difficult from Karen's experience to try to vote on the phone for these things.

So we'll still be sending out a summary with an opportunity for us to vote later.

Joe Nally: Thank you.

Lauren Richie: Okay, for the last one in this group, 1454, Proportion of Patients with Hypercalcemia, the question to the Steering Committee was, "Is the condition to change from the average to each of the three months necessary?"

And then the condition to the developer was to change the number of patient's total uncorrected calcium greater than 10.2 for each of the three months.

The developer response was in summary there are published studies that were largely based on single calcium levels and not on persistently high calcium levels.

The approach was chosen to identify a patient who may be more likely to experience poor clinical outcomes due to the prolonged exposure to elevated serum calcium levels over time.

The proposed revision would identify patients who are consistently exposed to very high calcium levels over the prior three months. Then they go on to give an example, for example 780 facilities had 5% or more of patients meeting the proposed criteria, while only 113 had greater than or equal to 5% of patients meeting the revised criteria.

The developer proposed change may negatively - they believe that this change may negatively impact the quality of care delivered, since only very few patients with persistently high calcium over a three month period would be included. I'll turn it over to the Committee.

Peter Crooks: Right. This is similar of course to the last discussion and I agree with the developers that we're look - this is not a clinical guideline but it's a public - it's a measure to compare overall how facilities are doing in this metric.

Joe Nally: Peter, again it's Joe Nally. I had presented this originally. I share your thought there. Is it possible - what I have in front of me on the Webinar, the page ends as they start talking about some of that data?

Karen Pace: Right. I'll move it down. Do you see the table now with the data or...?

Joe Nally: Yes I do. Would you repeat that statement then about the data, about how the numbers will go down dramatically?

Karen Pace: Okay, maybe we'll ask CMS/Arbor to just briefly review your comment about the - what will be picked up in the measure by changing it to the persistent.

Peter Crooks: Joe, can you handle that?

Karen Pace: Francesca, are you on the line?

Joe Nally: I think that while Francesca is or someone else may too, I think the tenure of this measure was say in contrast to the setting a level for phosphorous, that this level was trying really to pick up a toxicity of therapy such as calcium supplements, vitamin D, other things.

And it was my understanding that the group wanted to have a measure in place, i.e., hypercalcemia monitoring that would exist as a monitor of toxicity of therapy.

So if there was indeed a dramatic cut back as I understand this data, the difference between three month versus all three going from 23 to 3%, I understand the concern of the response.

Francesca Tentori: Yes, can I just say that the number of patients - using current Web data the number of patients who would meet the original criteria were 6200, 6284, and if we accepted the suggestion that would drop down to roughly 1500 patients.

Dr. Alan Kliger: Yes so - this is Alan Kliger. So my question is, is it the 1600 that we have clinical concerns about or the 1500? If somebody has a single value of 10.2 but then dropped it down, are those people in danger compared to people who have persistent hypercalcemia? Does the developer know the answer to that?

Francesca Tentori: In order to have an average over three months of 10.2, that would be either one single very high value or a couple of persistently value above 10.2. And personally - and the TEP members felt that that would be a risk factor for various patients.

Dr. Alan Kliger: So somebody who has a value of 13 where the clinician appropriately makes changes and it comes down from 13 to 10 to 8, they'll still be over 10.2 average of the three. Is that patient indeed at risk?

Francesca Tentori: That specific patient's - well for sure he was at risk when he was at 13.

Peter Crooks: Right. He was at risk when he was at 13. Alan, this is Peter.

Dr. Alan Kliger: Of course. My question is you're capturing him after he's out of the risk area though. Is that indeed what we should be reporting?

Peter Crooks: So there was a quality problem before that let the patient get to 13 perhaps, and so to say that that unit had a patient that had gone high, even though it was corrected is not inaccurate.

Dr. Alan Kliger: No I would - well you and I disagree about that. I would call that inaccurate because there will be times with good quality care that patients will get high and have an appropriate and timely response to that.

Peter Crooks: Sure. And that should average out between different facilities and, you know, and no one's expecting this should be zero, you know, that it would be zero patients that are ever high.

Karen Pace: The - just to - I don't know if it factors into your discussion, but the other component of this is that it's a rolling average, correct, so that that older high level in the next reporting period, the next three month will no longer be factored in for that patient so...

Dr. Alan Kliger: Right. Right.

Karen Pace: I don't know if that affects any of your discussion but just wanted to clarify that.

Robert Wolf: I guess it just depends on your point of perspective and I think that's where Alan is going. I mean, in the world where you find a value and you respond to it, you try not to hyperrespond.

There's going to be this ebb and flow. We've seen it in every aspect of what we monitor and I also agree with Alan. There are going to be clinical situations, who knows, but they occur where boom, somebody's calcium jumps off the scale.

So even though this is a rolling average, it sets the perception that care is not being addressed when in fact it probably is.

Jeffrey Berns: This is Jeff Berns, if I could just make another comment. I think that there seems to be a prevailing view in the mind of the creators of this I guess that 23% is closer to the right number.

Dr. Alan Kliger: Yes, that's my - too.

Jeffrey Berns: And I'm not sure that there - that that's the case.

Dr. Alan Kliger: Right. Correct.

Jeffrey Berns: I mean, .4% is a reasonable identifier of quality. We have to recognize that 10.2 is not particularly hypercalcemic. It's actually normal for many labs.

Dr. Alan Kliger: That's right.

Jeffrey Berns: So, you know, if, you know, if we ran these numbers with 10.8 then probably would have even smaller numbers. So I think the 10.2 is a very, very conservative measure.

It's normal calcemic in fact and identifying 3% of dialysis units that have patients above 10.2 one could even argue is excessive, because 10.2 is not such a bad number.

If you wanted to redo this measure as the percent of patients with a rolling average above 12 or a single value above 13, you'd get very different numbers and it would have a different use.

I'm not saying - it maybe have more use but as it is, I think there's an - the notion that we have to identify 23% of facilities as being outliers on this I think is mistaken.

Francesca Tentori: If I can just say, the TEP did not have any preformed notion on what was the proportion of facilities that should be identified, but they did feel that using a rolling average over time would be the best indicator in terms of overall exposure of patients to a certain level of calcium.

Whether a 10.2 is adequate or not I think it's an open debate. The literature does suggest and the TEP members felt that 10.2 was an adequate target for hemo patients.

Robert Wolf: But time averaged calcium over a period of time I don't think can - again we're - what we're attempting to do is develop quality indicators that suggest whether or not a physician is responding to an alarming value.

So their response is what we're looking for, so I agree with Jeff and Alan and, you know, I just think we are going to have to agree to disagree on this.

Helen Burstin: Hi Peter, this is Helen Burstin, if I could just make one comment. I've been listening in as well. I just want to again remind people these are facility level measures.

There's always going to be the risk of one patient and any person who's given ((inaudible)) one day for example. I think the issue we really need to consider is whether at that facility level this rolling average would give you the appropriate information, that there may be something people should be looking into more closely, that there may be a quality problem.

It's not an individual patient, individual clinician measure. I just want to remind folks about that, because I think it does tend to change the review of these measures.

It really is the group of patients in - at a given facility. I would argue if you look at many of the other measures involved in primary care and other areas, there's really level measures like this that would actually be pretty much the norm.

Joe Nally: What - it's Joe again. I - there are two issues at play. One relates to a threshold of 10.2, which I think most of us think is kind of upper limit of normal.

And then the second issue is the rolling average or not under the whole umbrella of trying to monitor for hypercalcemia as a toxicity of therapy. Any measure that includes 10.2 and the rolling average to identify one out of four facilities as failing a quality measure, particularly when that threshold of 10.2 is in such a gray area, I think is the concern of many of us in addition to things that Alan has outlined in terms of one value being up and off the charts and then coming back after appropriate therapy.

I - anything that targets one out of four facilities I think has to be thought very carefully about.

Joseph Messana: Excuse me.

Helen Burstin: It's not one out of four facilities as we think.

Karen Pace: Yes, I don't know what you're...

Joseph Messana: This is Joe Messana from Arbor Keck. I'd like to clarify.

Joe Nally: Okay Joe.

Joseph Messana: This table is a descriptor to help you all understand the relative proportion of facilities that have a certain threshold, be it 5%, 10%, 15%. It doesn't define the differences between facilities.

It doesn't define which facilities would we - considered outliers. It's information to give you background about the sensitivity of the two alternative proposed numerator definitions.

Peter Crooks: The - this is Peter. I think, you know, one - another thought about this with the rolling average is there's probably some percentage of patients that it's normal.

In other words just in the normal business of doing dialysis that maybe, you know, at any given time 10% of patients would hit and maybe that's okay, you know.

There's a - we don't really have a baseline to say this is - the right value is 10%. Fifteen percent is too high and so that makes interpretation somewhat difficult.

Lisa Latts: Well this is Lisa. I, you know, I'm just struck again by the need to have measures that will tell us on a population level how different facilities perform.

And I think we've been thinking about individual patient scenarios as opposed to the overall patient population where a facility that's doing well on an overall basis, the patient population is going to be performing well.

So yes, there will be some patients that are flip-flopping or up and down, but I think, you know, it's a population level measure that we're concerned about.

Dr. Alan Kliger: Yes, and Lisa this is Alan. I agree with you and I propose that the best population-based measure is one that captures those that show inadequate response of the care team to an issue.

And I think that population to be looked at are those with persistent abnormalities such as the calcium here.

Peter Crooks: Okay, I think we're at the same place as the last measure. We should probably - unless there's other compelling comments we can let this go to vote.

Karen Pace: Okay. All right, so the next topic that we wanted to discuss was the competing measures, the competing infection measures. And before we get into those I just want to recap that during the meeting the Committee actually approved two measures.

One was the CDC measure of bacteremia rate. That was Measure 1460 called Bloodstream Infection Measure. The CMS Measure 1456 I believe, so let me just double check my notes here so...

Sue Barnes: Fourteen fifty-seven.

Karen Pace: Fourteen fifty-seven, I'm sorry. That was the CMS measure of access related bacteremia, and when we reviewed the results and the discussions, it raised - the question for staff that we presented to you was about CMS Measure 1456, which was just the bacteremia rates.

So let me just make a couple of comments or at least summarize the discussion that we saw reflected in the transcript. A lot of the discussion was about the vagueness of definitions for how and - who first of all and how a determination would be made that it was access related.

And therefore the Committee approved the CDC measure that was just the straight bloodstream infection rate, which all of these would be stratified by type of access.

However when it came to the CMS measures the vote on those two measures was quite close, but it was kind of the opposite. The access related one was approved but not the straight bacteremia without making that distinction.

So I think we need to kind of clarify where the Committee is with that issue first to make sure that we have the right measures identified, and then I just wanted to lay out NQF's approach that we really do not want to endorse multiple measures of the same topic for the same target population that are, you know, slightly different.

And so our process is to the best of our ability to try to select the best measure for a particular topic. In this case whichever way we go we'll end up with some competing measures that we would want the Committee to select the best measure.

The other issue that I'll bring in is that the CMS measures are currently untested, so that when we would go to do any comparisons it would be unlikely to find them superior because we don't know anything about reliability and validity as we have some data presented for the CDC measure.

However given that the - and this was expressed at the Committee meeting, a strong desire to have information that's applicable for both CDC and CMS, and basically that ESRD facilities would be reporting the same information that would result in reportable information for both CDC and CMS.

You know, we have that consideration and Helen's on the line so Helen, do you want to make some comments there?

Helen Burstin: Yes, I'll just make the point that I think, you know, as we were talking about it, it seems that - highly unlikely that both of those measures would get through the rest of the process.

They've gotten a lot of pushback from public comments, the Consensus Standards Approval Committee and increasingly the Board that competing measures like that are just not going to make it through the process.

So I guess what we're faced with right now is we have one, you know, the CMS measures are untested. The CDC measure is tested although there are some feasibility concerns, so we'd really like to get a sense from the Committee of what's the most logical approach, which we would actually hope would be potentially that CDC and CMS could actually work together to come up with a measure or a set of measures that actually would really add value here.

Dr. Alan Kliger: I sure would endorse that.

Sue Barnes: Yes, this is Sue Barnes. I certainly endorse it as well and as - and would restate as I did during the face-to-face meeting that this - from the perspective of infection prevention, 1460 from NHSN is the best measure in terms of reflecting infection in this population.

It is tested, it is already in use in some states and likely will be used in others, and it just - and it is the gold standard destination for mandated public reporting of healthcare associated infections of all types.

And it would be great if there could be health information exchange built between NHSN and CROWNWeb.

Dr. Alan Kliger: So can - this is Alan. Can we suggest a harmonization of the measures by the two developers?

Sue Barnes: Well I - sorry.

Karen Pace: This is Karen and I, you know, what we would probably ask them to do is to come to agreement on what the measure should be, and also who would be the steward because we still would want to endorse one measure, whether it's, you know, if they agree that, you know, CDC is going to be the steward or CMS is going to be the steward or if they're going to be called jointly the steward.

But we still wouldn't want to endorse two measures. Even if they were exactly the same that also is kind of confusing for people, so we need one measure.

But that is certainly something that we could ask the developers to at least try to do, but before we did that we'd want to also clarify from the Committee's standpoint are we talking about as a lot of the discussion went a bacteremia rate that is stratified by access type, or whether you want to try to get to the level of also saying that in addition they have to, you know, it has to be identified that the suspected source or the likely source of the infection is the access so...

Sue Barnes: You know, I think it's really important to consider the impact and the feasibility - the impact on the facility is the feasibility of collecting the data and that is another reason why I was speaking in favor of 1460, which is the NHSN positive blood cultures per 100 hemodialysis patient months as the least impactful to the facilities.

The CMS - and I believe the CMS measures were also offered as a package. Did I misunderstand when one of the individuals representing CMS spoke up and said that they withdrew their measures because they wanted them as a package or not at all?

Karen Pace: No. That was just three measures Sue. That was the three measures that had the clinical confirmation aspect.

Sue Barnes: Okay.

Karen Pace: So CMS had ten measures altogether. The - what you're referring to was just the three that had clinical confirmation.

Sue Barnes: Okay.

Peter Crooks: This is Peter. Let me just - it looks like we have two tasks that we have to take care of.

One is the issue that you stated Karen of do we want to have not only a bacteremia measure as approved, but also one that also says beyond that the - somebody has to designate this as not an access related bacteremia.

So that's one issue. The second is if we had passed 1456 instead of 1457, in other words we had two bacteremia measures and we just had to delete one or the other, the CMS one would lose out because they haven't been tested and the CDC one has then.

So I think in terms of that question in my mind that's not really an issue, that if we had in fact passed bacteremia instead of access related bacteremia, we would be saying at this point the CMS one is out and the CDC one is in.

Jerry Jackson: This is Jerry. Go ahead.

Peter Crooks: So if we could say - if we can agree that that's not an issue anymore, then I think the discussion's really should we have two measures, one that's bloodstream infection and one that's access related bacteremia.

Jerry Jackson: This is Jerry Jackson. I disagree to some degree with that perspective. I want to explain why. In respect to what Sue is saying that this has been tested for reliability and validity, 1460, but had we passed 1456 I think it would harmonize better with 1457 than 1460 would do so, and the reason being that we don't want to have a situation of having two separate data collection systems.

I think that adds a great deal of burden. We're going to have CROWNWeb for sure and 1456 provides bacteremia data through the CROWNWeb environment, and it's bacteremia with antibiotic therapy.

Fourteen sixty could potentially include false positive blood cultures and I'd like to see what you guys think about that, but it's probably a low percentage. But 1456 is going to pick up just the ones that the caregivers feel are valid and needing antibiotic therapy.

Fourteen fifty-seven gives a slightly different perspective in that one could compare the rates of bacteremia alone versus those that are felt to be access related.

They're also stratified I believe by type of access and over a year's period of time during the time that the measure is provisional, we could then determine if both are needed or one should be dropped. So I actually personally favor 1456 over 1460 for those reasons.

Sue Barnes: I would just strongly remind the group that the 1460 is already in place, so that would require the more than 150 facilities that are currently reporting 1460 to either duplicate their efforts or change their process.

And again NHSN is the gold standard destination for infection reporting. CROWNWeb is not. I think that the priority should be an interface which certainly we have the capability to do from a technology perspective, connecting the two databases.

I think that would be where it would - our efforts would be more productively focused. The 1460 metric provides a measure that is perfectly sufficient in terms of accuracy for public reporting and performance improvement.

We're not talking about it has to be perfect. It's not a scientific study. It's not going to be, you know, this is not a publication. It's for performance improvement and public reporting.

So again I would just suggest that this is most definitely the superior metric because for those reasons and also it does stratify based on the type of access.

Jerry Jackson: I believe there are over 4000 dialysis facilities in the U.S. and so all of those are going to have to in a sense do duplicate data entry unless this linkage can be guaranteed, unless the data sharing...

Karen Pace: So I think maybe what we could do is ask briefly if CDC and CMS could comment, but I think the ideal situation would be that there's one measure and the information - the same

information that's going to, you know, be mandated for CMS and CDC be consistent or exactly the same so that people are collecting one set of data, whether it's going into CROWNWeb which all of them I understand are going to be required to do, but that same information could also be exactly what CDC needs.

So I guess the question is do people first agree with that basic premise that, you know, certainly we want, you know, as Sue's pointed out CDC is, you know, predominant in dealing with infection and infection data and needs that to be consistent and we understand CMS need, but from the facility perspective they want to collect data once and be able to use it for both purposes.

Sue Barnes: Yes, absolutely.

Karen Pace: Okay, so could we hear from CMS about - and, you know, I know that you may need to think about this but is it possible for you to have some discussions with CDC about coming together with a measure that would be brought back to us?

Tom Dudley: This is Tom Dudley. And certainly yes, and actually there have been communication there. We've been having communication with CDC on a number of different elements and trying to figure out the way that data can be shared between different databases.

We're just not there yet, but there is active discussion. There are active discussions going on and not just with the ESRD data sharing with NHSN, but with other care settings, long-term care and so forth.

Karen Pace: And did - was Dr. Patel, was she able to join the call?

Dr. Priti Patel: Yes, I'm on.

Karen Pace: Okay and what about your perspective from CDC?

Dr. Priti Patel: Yes, I would agree that what's been described in terms of having a technology interface is certainly what we were striving for, so that's definitely something that is of interest.

Karen Pace: But I think even before the technology solution is possible that the starting point would be one measure that serves both CDC and CMS so that the facility is collecting data for one measure that could be provided to both entities, even before we get to the technology solution which is the ultimate goal.

Sue Barnes: So then I would respectfully suggest that we defer to the experts on infection measurement for the metric that's been proposed - 1460.

Peter Crooks: Well maybe as a Steering Committee we should, and I would propose that we continue with our endorsement of 1460 with a strong recommendation that CMS work with CDC to - for their measure to be the same and to work together to have a seamless data sharing in this area of infection going forward.

Sue Barnes: Sounds great.

Joe Nally: And Peter, when a recommendation like that comes from the Steering Committee, what about expected timelines?

Peter Crooks: Well we don't have enforcement power or, you know, our hammers is a - is basically this is what the National Steering Committee for NQF would like to see.

And having said that, we've said it and I don't know that we can enforce it in any way.

Joe Nally: No, I understand that part of it or maybe Karen would - better to ask. Is there any - does history teach us anything? Is this something they could do in one year, three years or...?

Karen Pace: Do you mean in terms of agreeing on...?

Helen Burstin: Sometimes I think we - yes. This is Helen. I mean, I'll give you an indication that there has been the times that we haven't been in fact actively engaged with two stewards to try to harmonize and at best combine into a single measure.

It does then take a while. My guess is it's probably three to six months, and I think the advantage of this is we do still have a fairly long process to the end till we get to endorsement, so again we could put this report out for public comment and we could see public comment as well specifically on this issue of feasibility and, you know, ways they could potentially work best together.

And again for those, you know, Tom and - that's - I would be happy to help facilitate that in any way we can - see what needs to happen to make this work.

Joe Nally: Thank you.

Tom Dudley: Can I - this is Tom Dudley again. Can I interject one other thing?

Peter Crooks: Go ahead.

Tom Dudley: Yes, with regards to a measure aren't we - would we be focused more on the elements of the measure, what needs to be measured and the numerator, denominator rather than the database to collect it?

And I appreciate the whole burden and CMS and CDC need to figure out a way to avoid redundancy data collection, but - and just trying to not lose sight of the fact that we're looking at measuring not necessarily the tool or data collection tool.

Karen Pace: Right. Right. Right. So the thing would be the actual measure specifications, the data elements. Obviously they're, you know, they would come from certain fields in your CROWNWeb and - but we'd want those aligned, yes, the technical...

Helen Burstin: And there has been some history here. For example there was an ACC-based registry measure last year regarding PCI which CMS was going to build a special Web-based collection forums port to allow the same data elements to be submitted.

So I think there is some history here we can build on Tom, to think through how to ensure that you're in fact getting the same data collected the same way.

How they actually get shared I think is something that might need to be, you know, take a bit more time.

Tom Dudley: Yes.

Karen Pace: Right. So I guess where things stand right now is, you know, as Peter was saying 1460, the CDC measure, was recommended. The CMS measures are untested so I guess the question really is whether CMS can implement 1460, or if there's any big objections, if those are issues that those can be worked out with CDC so that we actually end up with one measure that both groups will find acceptable for their programs.

Peter Crooks: And if that's the case then we can - we would be dropping 1457.

Karen Pace: Right. Well potentially, yes. That...

Peter Crooks: Well that's a second issue. I think we need to resolve that. Do you view - you wrote - you view 1457 as competing plus the - it would be a whole different data collection system, although I suppose ultimately if - worked together to have uniform collection system, 1457 could be tested and be used.

Tom Dudley: Just to interject one other thing, this is Tom Dudley. I apologize to keep interjecting things. CDC and CMS did work together with the elements that are being incorporated into CROWNWeb.

Dr. Patel and I have active communications. We need to make sure that the elements are defined the same way, which has not been done yet. But we have collaborated on trying to capture the same elements regardless if whether it's NHSN or CROWNWeb in anticipation of being able to have some sort of a data exchange to avoid the redundancy.

Dr. Alan Kliger: This is Alan Kliger. Tom, don't you think it's possible to talk to them and come up with a single measure that both of you would agree to?

Tom Dudley: I think so, yes.

Dr. Alan Kliger: Good.

Jerry Jackson: This is Jerry Jackson. Could we bring to that conversation the issue over only including patients the first two days of the month versus patients who are present throughout the month?

Or the patient there is for the incident patient who comes into the unit on day three and beyond, brand new patient, they often have a catheter and have probably the highest incidence of bacteremia, so we're missing a certain number of high risk patients.

Peter Crooks: Jerry, the explanation I - as I understand that is the first two days is just to make the denominator number, but that the new infection, new patient coming in on day three with a sepsis would get captured. Is that...?

Karen Pace: Right, and that was - that clarification was provided by Dr. Patel and was in the materials.

But all the infections are counted in the numerator and it - the first two days was simply to minimize the burden of identifying the number of patients, so that some patients come and go in the month but they discovered that if they count everyone on the first two days, that that gives them a pretty stable estimate of denominator number. But Dr. Patel, do you want to comment further?

Dr. Priti Patel: That's correct. I don't know if it's necessary to go through the whole...

Karen Pace: Okay. All right.

Tom Dudley: Thank you. I'm satisfied with that.

Karen Pace: Okay, so we'll get back to - if anyone has any objection to this I guess speak up now, but what I'm hearing is that we will ask the CDC and CMS to get together and that - and see if they can agree on one of the measures or I guess probably starting with the measure that you approved and has been tested, but to make sure that we - to see if they can make the decision about which measure is the best measure to go forward for endorsement.

And if they can't then it will be up to this Committee to just make your selection.

Lisa Latts: This is Lisa Latts. Can I just ask a quick question about timing? What sort of timing would the CDC and the - and CMS have to come to to make it to this round of measure development?

Karen Pace: That's a good question. We're going to have to look at the timeline again to determine that and so that is a good point. If it's something that cannot happen within the time parameters of this project, then obviously this Committee will need to move forward with, you know, a tested measure.

But we'll need to examine that and get back to you about that. I'm sorry I can't...

Peter Crooks: I think we could set up a - in other words we could pass it in this fashion. If the Steering Committee's preference is for CMS and CDC to work together to repropose 1460 as a joint, you know, one they can both agree on although there will only be one steward, but - and they have six months to do so.

If they don't then we're going to endorse 14 - we'll - we will endorse 1460 as it stands. I suppose that doesn't motivate CDC as much as it does CMS.

Dr. Alan Kliger: That's like the Sword of Damocles. I'm not sure that that's a wise way to do harmonization.

Peter Crooks: Yes, I saw that as I was saying it that was a problem.

Karen Pace: So why don't we do this? We'll start with, you know, getting a formal response from CMS and CDC, because we just sprung the - this on them today.

And then we'll see what's possible and look at that within our timelines and we will keep the Committee apprised of what direction we have to go.

Myra Kleinpeter: And Karen, this is Myra. I think the small dialysis organizations that have to manually input all their data, you know, do a data dump of almost everything that they have so they need to define those fields in CROWNWeb where additional data will need to be supplied by the independents to make sure that all of - all data is available for - across all dialysis providers.

Karen Pace: Right. My understanding is though that CROWNWeb and the conditions of requiring facilities to submit CROWNWeb data applies to all facilities regardless of...

Myra Kleinpeter: Right, but what is the - so some of these other calculations that are being done at the facility level requires some additional data input. Right now those strings are not defined.

We've done testing at one of the independents that I was working at. When we would put in a lot of the data, the information was different there compared to what was being fed from the - all the other that I do most of my work at.

Tom Dudley: The - this is Tom again. The infection information hasn't been fully incorporated into CROWNWeb at this point, and it's not expected to be available for even testing till some time this summer, kind of - to say the capabilities.

Karen Pace: Okay, so we will communicate with CDC, CMS, get a quick - initial response so that we can figure out the timelines and what is really possible within the constraints of this project and get back to the Committee as quickly as possible.

Okay, we will I guess move on to - there were some measures that we wanted to take a look at regarding whether there were any harmonization issues to consider, and those start with frequency of adequacy of measurement for pediatric hemodialysis.

And I'm going to move to that - 22 - page 22 in the comparison table. Okay, thank you. So one of the I guess main issues regarding these two measures is - and something that we're being asked often is whether two measures are even - oh, let's see.

Oh okay, so for all of these dialysis adequacy measures where we have an adult measure and a pediatric measure, I think the question is going to be for you to consider whether they really need to be two separate measures.

Are the, you know, right now they may be worded slightly different because they were developed by two different groups, but if their content is really essentially the same does it necessitate having two measures or should it be one measure that applies to all patients, unless there's evidence that there's something different and that if it's desirable such a measure could be stratified?

So that's probably one of the biggest questions when we're talking about pediatric versus adults' measures. So the first two were frequency of adequacy of measurement and for - 1418 was pediatric, a measure that you recommended, but 0247 was the prior endorsed adult measure.

Barbara Fivush: This is Barbara. I would just say to the group that at the time that 0247 was developed, and that was several years ago, correct?

Karen Pace: Yes.

Barbara Fivush: We were not ready in pediatrics to move forth with measure development. We didn't have a substantive evidence base, so many of the measures that you saw that were developed now for this go around by the CTEP were in fact with knowledge of what was needed just when you develop that.

So again I think the reason that the measures were not harmonized initially was that we weren't ready to come forth with measures then, and the measure already existed which doesn't mean it can't be harmonized.

So there was no real reason for them to ever be - there was no purpose for them to be separated except for just timelines, different timelines.

Peter Crooks: Looking at the - looking at them side by side there isn't a lot of difference. The denominator in ones is facility specific and the other one doesn't say, just in the sample.

That's one difference I see, you know, other than the ages and the numerator statement is virtually identical.

Barbara Fivush: Well is 0247 a physician level measure because one...?

Karen Pace: No, it's facility level.

Barbara Fivush: Right.

Peter Crooks: It does say setting, dialysis facility, so even though it doesn't say facility in the denominator statement I think it is implied. So as I read it I don't see that there's any harmonization problem.

In other words they seem to be basically identical except one denominator's 18 years and older and one is less than 18. Does anybody see it differently or have different information?

Jeffrey Berns: I agree.

Barbara Fivush: Now - and again the intent was not to separate them. It was just when this one was developed there was not enough evidence.

Lisa Latts: Yes, I would agree.

Constance Anderson: I would agree.

Peter Crooks: So they are harmonized is what we're - I think we're saying Karen.

Karen Pace: Right. They're harmonized and I guess one of the things that - and this isn't anything that would need to be done immediately but eventually, I mean, the question is whether since they're essentially asking the same thing, you know, do we really need separate measures or is it a measure that applies to both adults and pediatric patients, anyone getting hemodialysis?

Lisa Latts: Do we have to go through a formal process to change the older one to remove the age limitation?

Karen Pace: Well the - that's - and this is an interesting timing thing. That measure is going to be reviewed in the upcoming continuation of this project, the next phase, so that can be addressed at that time.

But I just wanted to see - get the feeling from this Steering Committee, I mean, it doesn't - first of all the question was whether there were any harmonization issues and I'm hearing that there really isn't, that they seem to be consistent.

And then the second issue is this may be something that we make as a recommendation that eventually, you know, one measure if it applies equally to all people getting hemodialysis that we would only need one measure.

Dr. Alan Kliger: Yes.

Peter Crooks: As long as there's a - pediatric colleagues agree that the metric is equally applicable, and this isn't even saying the adequacy or say this is just that it's being measured.

Karen Pace: Right. Right.

Barbara Fivush: Right, so I think this is an easy one to harmonize, you know, again getting over the timeline, time limitations of one being considered for one thing and the other for - I think if we can get through those I don't see why they wouldn't be one measure.

And I think in the future because patients are not dialyzed at units by the breakdown point of the team, because there are certainly 19 year olds done in pediatric or 16 year olds being done in adult facilities, it - when there was no reason to make them different measures to harmonize them because the patients really are spread over all types of units.

Karen Pace: Right, okay. So the next ones were about the minimum spKt/V and that is related to two prior measures. Again the 0249 and 0250 are up for review in just a few months, and again it - I'll just leave it there.

It seems that they ended up with the same threshold value for pediatric as we had for the adults, but just wanted to review that with you as well.

Barbara Fivush: This was - I just want to point that this was one of the measures discussed, because in the pediatric measure it says three or four.

Karen Pace: Oh yes.

Barbara Fivush: The week - the adults, that's not a standard practice.

Karen Pace: Right.

Barbara Fivush: And in looking at the numbers about 5% of children under the age of 18 are dialyzed four times a week, so it's not a large number but it's a number. I just want to point that out as...

Karen Pace: Right. Yes.

Peter Crooks: That's an issue and also I don't know what's going to happen when we review this measure again, but there may be or should be some thought about moving to a more - to a standard - standardized Kt/V, in other words it can be calculated in a standardized way so no matter how many days a week you're dialyzing you can still compare to the same target.

Barbara Fivush: Right, and we had - and that - we discussed that in length at the meeting and I don't think - we don't have a lot of experience using standardized Kt/...

Dr. Alan Kliger: It's actually standard.

Barbara Fivush: Standard. Alan, do you have experience using that now?

Dr. Alan Kliger: Yes.

Barbara Fivush: I mean, evidence-based?

Robert Wolf: I mean, that's all we use in adult measures now.

Dr. Alan Kliger: Yes. It's really something or something like it to - it needs to be used if you're not looking at the same number of treatments a week.

Barbara Fivush: Right and we talked about this. This is an unusual - this is something that is a different practice pattern. And it's something I don't think the adults traditionally will ever use four times a week, or at least stated it's chronically used four times a week unless there was a problem.

Dr. Alan Kliger: Well as you know we have a growing number of people across the country that are getting done three times, four times, five times, six times a week.

Karen Pace: Right, so I guess at this juncture because of the differences in those two measures, we would need two measures but I - what I'm hearing is that when these adult measures come up for review in a few months there'll be much more discussion about continuing with the single-pool Kt/V versus a standard Kt/V.

Dr. Alan Kliger: Yes, I think that's right.

Barbara Fivush: So Alan - so clarifying, you think that the old measure will switch or stay as a single-pool?

Dr. Alan Kliger: Well I can't predict it but I think that people familiar with this stuff would suggest that we need to go to standard.

Barbara Fivush: So then I think that it's probably not the right time to try and harmonize these two because of that difference and because of our lack of evidence in that area.

Peter Crooks: Right. And this measure Karen, 0323, which is - was I guess adopted by another group, not the ESRD.

Karen Pace: That also was endorsed by NQF remember? That's the physician level measure.

Peter Crooks: Was that in our project or was that in...?

Karen Pace: Yes it was.

Peter Crooks: Oh it was. Okay.

Karen Pace: Yes, it was at the individual clinician level so it also will be coming up for review in the next phase.

Peter Crooks: Okay.

Karen Pace: Okay, and then I guess the only issue - or with the hypercalcemia measure just...

Peter Crooks: Well we have two different metrics now. Well we don't know what the hypercalcemia metric is going to be for sure, and in the adults I presume it's just a mean, not the three months.

Karen Pace: Yes, the adult measure was a means.

Peter Crooks: Yes.

Karen Pace: Okay and that one will be coming up for review. I know that in this project a revised adult measure - was that the one that was put forward? Anyway I'm sorry, I'll...

Peter Crooks: Well it looks like, you know, if I can comment it looks like the 261 is about that the calcium is being measured, not a target.

Karen Pace: Yes. Yes, you're right. You're right. These are just - the only issue of harmonization - well there was just a question - they're kind of on the same topic if there were any concerns, but I don't think there were really any issues that we needed to specifically address.

Peter Crooks: And this measurement of certain calcium for adults will be coming up again...

Karen Pace: Right.

Peter Crooks: ...soon. Okay.

Robert Wolf: Could I ask a point of - this is Bob Wolf. Could I ask a question about NQF?

Karen Pace: Yes.

Robert Wolf: And when a standard of measurement is changing and Dr. Kliger is exactly right, the community - several people in the community understand the benefits of using the standard Kt/V as opposed to the single-pool.

Much of the community is not there yet. Is there a standard way to have an overlap period where one is phased out and another is phased in?

Karen Pace: Well we don't typically do that, though that was really the reason we had 0249 and 0250, because one was supposed to sunset and I, you know, that's something we'll have to find out from CMS whether they actually did that.

And that had to do with - let me see if I can go back to that for just a second. But typically we don't but we have considered that in the past. Oh sorry, I passed it up.

Lisa Latts: Isn't that part of what measurement can do is accelerate the adaptability or adoption of a better measure or better...?

Dr. Alan Kliger: Yes, great comment.

Karen Pace: Yes, so I guess, you know, typically NQF wants to endorse the best measure that's based on the best evidence. And so, you know, if there are certain considerations we can certainly look at those but not, you know, that's our usual approach.

And then if there are exceptional circumstances certainly those would be brought out in the project and we'd have to think about what could actually be done in the interim.

Robert Wolf: Thank you.

Karen Pace: All right, I think - well we're - I think maybe we're about out of time and we need to see if we have any comments. We may have to follow up on these last measure items by email.

The Standardized Hospitalization Ratio for Admissions - we do have another hospitalization measure in another setting, and again it's just to look at whether there are kind of opportunities for harmonization.

So we'll be more directive in a follow up email if there are any issues we want you to consider. The items for additional questions or clarification were things that we again had sent some questions to the developers for some clarification.

We'll just follow up with you on those specifically. You have all those materials but we'll just focus on those specifically in a follow up email to see if there are any issues.

So before we open the lines for public comment, are there any concerns or issues the Steering Committee wants us to be sure to address in follow up or follow up communication?

Joseph Vassalotti: This is Joe Vassalotti. I have a question for CMS.

Karen Pace: Okay.

Joseph Vassalotti: I mean, I understand the - this process is going to lead to this - the CMS QIP, the Quality Improvement Program, and also there's going to be public reporting.

In what format will the public reporting take place? Do we know about that? Is that going to be public - dialysis facility compare Web site or something else?

Tom Dudley: It's most likely that the reporting would be incorporated into the existing dialysis facility.

Joseph Vassalotti: Thank you.

Tom Dudley: But as far as use with the QIP it - we - we're required to go through the rule making process before adding any new measures to the QIP program.

Barbara Fivush: So - and I'm sorry. This is Barbara. To follow up on that and just so I understand it, the three measures that have been identified - these will stay in existence through dialysis facility compare collection for an undetermined period of time? Is that...?

Tom Dudley: For the purpose of QIP the three measures that have been identified will be used for the upcoming payment year.

We're currently working on the rules for upcoming years in which case not any new measures or any change in the measure source would be indicated.

Barbara Fivush: Okay and then - I'm sorry again. I just - is the public reporting piece going to be through dialysis facility compare or...?

Tom Dudley: Yes. Yes.

Barbara Fivush: Yes.

Tom Dudley: Through dialysis facility compare. Sorry about that.

Barbara Fivush: That could change but at this point it is what is in place and we're not sure when any of that will change.

Tom Dudley: That's correct. Sorry for being vague but we're just not there yet.

Barbara Fivush: No, thank you for that information.

Karen Pace: Operator, will you see if there are any people on the public line that would like to make any comments? Operator?

Operator: Would you like me to just open all lines, ma'am?

Karen Pace: Yes.

Operator: Okay, all lines are now open. Please go ahead.

Peter Crooks: Any public comments - people who have been listening in who would like to make some comments? I guess there are none then Karen.

Karen Pace: Okay. So Lauren, do you have any - I guess the - we'll just recap here. We'll be sending out a survey to vote on the things regarding the conditional recommendations.

We will be communicating with CMS and CDC about the infection measures to see if we can make some progress there. And then the last thing is on these final items regarding additional questions or clarification we will communicate with you by - via email to get some response.

But I think I'm going to ask for just a few comments about - the first two issues were about recommending use of iron therapy for pediatric patients but not for the adult measure.

And when I reviewed the transcript it seemed to be related - the difference in your decision related a lot to thinking that the definition of when patients need iron therapy was much more definitive specific in the pediatric measure.

But I just wanted to bring that up to see if there was any interest in revisiting that or if there were other rationale to support recommending the pediatric but not the adult measure.

So maybe what I'll - we'll do that in a follow up as well to make sure that we have the Committee's will about that. And I know that our time is about out and we probably have lost some people on the call, but any last comments?

Dr. Alan Kliger: Nice discussion. Thank you.

Frederick Kaskel: Thanks everybody.

Karen Pace: And Peter and Kristine.

Jeffrey Berns: Bye-bye.

Tom Dudley: Thank you.

Joe Nally: Thank you.

Peter Crooks: I'll stay on a minute Karen if...

Kristine Schonder: Hello?

Karen Pace: Okay thanks. Stay on.

Kristine Schonder: I'm still here too as well Karen.

Karen Pace: Okay thanks. Okay, so we'll try to get things pulled together as quickly as possible, but if you - do either of you have any suggestions for us of things we need to be sure to address?

Peter Crooks: One thing I thought about suggesting near the end was, you know, we have like five or six bullet points to go over, and maybe you should focus, you know, ask some people to respond specifically, you know.

You could divide it up into little groups and say, you know, would you think about it and give us a response on the use of, you know, should we be revisiting the iron therapy for pediatric patients or on the...

Karen Pace: Okay.

Peter Crooks: And that way maybe that forces some people to think a little more deeply about it and then provide their thoughts back to the group.

Karen Pace: Okay, that's a good idea.

Kristine Schonder: Yes, I didn't have any other suggestions that came to mind right away.

Peter Crooks: I'm kind of perplexed that we were unable to really make much movement on getting, you know, the three in a row versus a mean and, you know, my feeling that people truly are thinking of and Alan is - has really worked on dozens of these types of committees and guideline groups and so on.

And I think he really does think it's a better quality measure for public reporting and so on, but I think what health plans are used to and, you know, is the mean. So I'm sorry. We really seem to have a divide on that and that...

Karen Pace: Yes. Yes.

Peter Crooks: ...can work through that but...

Karen Pace: And, you know, it was a pretty close vote at the Committee meeting and I - if the conversation that we could hear was any indication it seems like it might be close again on the follow up vote, but I guess we'll see what happens and what we can do.

And what we'll also do, because if it will still be a close vote when we put it out for comment, when we put out the draft report for comment, we'll kind of highlight the, you know, the majority position and the minority position because it, you know, I think, you know, it was maybe a vote of 11 to 9 or something like that. So it's not like an overwhelming - and specifically ask for comments on it.

Peter Crooks: Yes.

Kristine Schonder: That's a good idea.

Peter Crooks: I think that might be a good way to deal with that.

Karen Pace: Okay, well thank you both again and we will be communicating as always. If you think of anything else feel free to get in touch with Lauren or myself and suggestions are always welcome.

Peter Crooks: We'll do that.

Kristine Schonder: Okay.

Peter Crooks: Okay.

Karen Pace: Okay, thanks a lot.

Kristine Schonder: All right, thank you. You too. Bye-bye.

Peter Crooks: Bye-bye.

Operator: That does conclude today's call. Thank you for your participation.

END