NATIONAL QUALITY FORUM

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RENAL STANDING COMMITTEE

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WEDNESDAY
MAY 6, 2015

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The Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:30 a.m., Constance Anderson and Peter Crooks, Co-Chairs, presiding.

PRESENT:

CONSTANCE ANDERSON, BSN, MBA, Northwest Kidney Centers (Co-Chair)
PETER CROOKS, MD, Kaiser Permanente (Co-Chair)
ISHIR BHAN, MD, MPH, Partners Healthcare, Massachusetts General Hospital
LORIEN DALRYMPLE, MD, MPH, University of California Davis
ELIZABETH EVANS, DNP, American Nurses Association
MICHAEL FISCHER, MD, MSPH, University of Illinois and Department of Veterans Affairs
STUART GREENSTEIN, MD, Montefiore Medical Center
DEBRA HAIN, PhD, APRN, ANP-BC, GNP-BC, FAANP, American Nephrology Nurses' Association
LORI HARTWELL, Renal Support Network
FREDERICK KASKEL, MD, PhD, Children's Hospital at Montefiore
MYRA KLEINPETER, MD, MPH, Tulane University School of Medicine
ALAN KLIGER, MD, Yale University School of Medicine

MAHESH KRISHNAN, MD, MPH, MBA, FASN, DaVita Healthcare Partners, Inc.
LISA LATTS, MD, MSPH, MBA, FACP, LML Health Solutions and University of California Health Plan
KARILYNNE LENNING, MHA, LBSW, Telligen
FRANKLIN MADDUX, MD, FACP, Fresenius Medical Care North America
ANDREW NARVA, MD, FACP, FASN, National Institute of Diabetes and Digestive Kidney Diseases - National Institutes of Health
JESSIE PAVLINAC, MS, RD, CSR, LD, Oregon Health & Science University
MICHAEL SOMERS, MD, American Society of Pediatric Nephrology, Harvard Medical School, Boston Children's Hospital
DODIE STEIN, PhD, MSW, LCSW, Indiana University Health Home Dialysis
BOBBI WAGER, MSN, RN, American Association of Kidney Patients
JOHN WAGNER, MD, MBA, Kings County Hospital Center
JOSHUA ZARITSKY, MD, Nemours/Alfred I. duPont Hospital for Children

NQF STAFF:

POONAM BAL, Project Manager
HELEN BURSTIN, MD, MPH, Chief Scientific Officer
ANN HAMMERSMITH, JD, General Counsel
ALEXANDRA OGUNGBEMI, Project Analyst
KATHRYN STREETER, Senior Project Manager
MARCIA WILSON, Senior Vice President for Quality Management

ALSO PRESENT:

JOEL ANDRESS, PhD, Centers for Medicare and Medicaid Services

AMY BECKRICH, Renal Physician's Association

CLAUDIA DAHLERUS, PhD, MA, University of Michigan

LOUIS DIAMOND

JOE MESSANA, MD, University of Michigan

LISA MCGONIGAL, MD, MPH, QMRI

PAUL PALEVSKY, MD, University of Pittsburgh*

SARAH SAMPSEL, NQF Consultant

DALE SINGER, MHA, Renal Physicians Association

*** present by teleconference**

T-A-B-L-E O-F C-O-N-T-E-N-T-S

Consideration of Candidate Concepts/Measures (Continued)

P-R-O-C-E-E-D-I-N-G-S

(8:38 a.m.)

CO-CHAIR CROOKS: Good morning everyone, your co-chair for the Renal Standing Committee for the NQF, measures to consider renal measures.

Welcome everyone. Thank you for making the journey. Thank you for the, all the work, preliminary work that you put into place. And we have quite a challenge today.

And so I thank you for preparing. First rule is jackets can go off if you like it that way. I see most of you do. Ties can be loosened.

It's not going to be overly formal in that sense. Is it a practice to use, Sarah, to use first names, or do we go Doctor, Doctor, Doctor, Nurse?

MS. BAL: It can off of preference, but first names is usually how we do it at NQF.

CO-CHAIR CROOKS: Okay. Very good. My co-chair is Constance from Northwest Kidney

Center.

CO-CHAIR ANDERSON: Welcome everybody, and thank you for coming again. Formal name is Constance, but I go by Connie. So you can use my not so formal name.

I also want to say thank you for coming, for all the hard work that's gone into the four calls that we've had reviewing all the measures.

And I really forward to the work we have to do over the next couple of days. We have a great group, and I think it's going to be a lot of work and a very interesting time as we get through the measures.

And I'd like to thank Peter as my co-chair. This is my first time co-chairing, and so I'm going to learn from the master over here.

And I told him if you see him kicking me under the table, it's okay. He said that he would do that to keep me in line.

CO-CHAIR CROOKS: I won't need to do that.

Okay. Sarah, did you have any introductory comments?

MS. SAMPSEL: I don't other than, I'm sorry. The one thing I'll have to remind everybody. When you're done talking, you always need to turn off your mics because if we have more than two mics on at one time, then the mics don't work.

So that will just be one reminder you'll hear more than once. But good morning, I'm Sarah Sampsel.

I'm a consultant to NQF and have met many of you on other work I've done with renal measurement for other programs and again, look forward to today and tomorrow to, I think, very active discussions and making sure that we go through the process deliberately and purposefully.

And we'll just ask that we turn it over to the staff for introductions.

CO-CHAIR CROOKS: And is this the time to mention that if somebody would like to talk,

is this our custom to put your name tag up this way so we can recognize you?

That will help, so you won't have to get tired of holding your hand up in the air for an hour at a time. Okay. So for introductions - -

MS. BAL: Thank you for that reminder. I'm Poonam Bal. I'm the Project Manager on the Renal Committee. And I believe I've spoken to most of you at this point.

CO-CHAIR CROOKS: Your voice is very familiar.

MS. STREETER: Hi. Good morning. I'm Katie Streeter, and I'm the Senior Project Manager here at NQF. It's nice to meet everyone in person.

MS. OGUNGBEMI: Good morning. I'm Alexandra Ogungbemi, and I am the Project Analyst on the renal project. It's good to see everyone. Good morning.

MS. HARTWELL: Hi. My name's Lori Hartwell. I'm the President and Founder --

CO-CHAIR CROOKS: Yes, I didn't --

MS. HARTWELL: Did I go wrong already?

CO-CHAIR CROOKS: I was to let you know the staff will go first, and I forgot to do that.

MS. HARTWELL: Oh.

CO-CHAIR CROOKS: We'll finish the staff introductions --

MS. HARTWELL: We're not going clockwise?

CO-CHAIR CROOKS: -- and then we'll go clockwise or counterclockwise. I appreciate your enthusiasm though, Lori.

MS. HAMMERSMITH: Good morning everyone. I'm Ann Hammersmith. I'm NQF's General Counsel. To those of you who have been on our committees before, you're familiar with this section of the proceedings.

What we do is we go around. We ask you to tell us who you are, who you are with and then if you have anything you want to disclose. I'll review the disclosures briefly just as a

reminder.

The process is you got a rather long form from us -- sorry about that, but we try to be thorough -- where we ask you about your professional activities.

You also received a form later where we asked you about specific measures that will be considered by this committee.

So for the purposes of this disclosure, we're asking you to tell us if you have something you want to disclose. If you do disclose, it is not necessarily a conflict of interest. Part of the reason we do this is to be open and transparent so that everyone knows where everyone else is coming from.

We are particularly interested in grants, research money, speaking engagements that you have or have had in the last five years but only if it's relevant to the topics before the committee today.

Please don't summarize your resume. Just disclose things that are relevant to the

topics that will be discussed today.

A reminder, you sit as an individual. You don't represent your employer. You don't represent anyone who may have nominated you for service on the committee.

You're here because you're an expert, and you're not representing any particular interest. So with that, I always start with the chairs. So we'll start with Connie.

CO-CHAIR ANDERSON: I'm Connie Anderson. I'm the Vice President of Clinical Operations at the Northwest Kidney Centers in Seattle.

And I have been a member of the Kidney Care Quality Alliance and sat on the steering committee as the lead. So I have a conflict of interest in the two measures that were submitted KCQA.

CO-CHAIR CROOKS: Good morning again. I'm Peter Crooks. I'm a nephrologist with Kaiser Permanente in Southern California.

I have, my career has pretty much been

within Kaiser Permanente although I have been involved with National Quality Forum, the KDOQI Advisory Board in the past.

The only conflict besides measures is I did recently work on an NIH grant on racial disparities, which sort of bumps up against some of the stuff we do in ESRD care.

I have a conflict as a developer on measure 2594: Optimal ESRD Starts and two related measures. Thank you.

And I would like people to maybe mention have you served before. This is my fourth go round just a way to remind us that you participated and who the go-to guys are. Thank you.

MS. HARTWELL: Hi, my name's Lori Hartwell. I'm the President and Founder of Renal Support Network. I'm very happy to be here today. And my only conflicts are with the Kidney Care Quality Alliance fluid management. I was on that workgroup through KCP.

DR. MADDUX: My name's Frank Maddux.

I'm a nephrologist. I'm Executive Vice President for Clinical and Scientific Affairs and Chief Medical Officer for Fresenius Medical Care.

I have no conflicts with regard to grants or speaking. I have affiliations with many of the organizations around, in the renal community including Kidney Care Partners and Renal Physicians Association.

I have not participated actively in any of the measure development for either of those groups as part of that.

I have research relationships that are relatively broad in the industry, including some NIH and PCORI grant affiliations as well as other both privately sponsored and publically sponsored research as well as internally sponsored research. That's my disclosures.

DR. GREENSTEIN: Hi, I'm Stu Greenstein. I'm a transplant surgeon, vascular access surgeon from Montefiore Medical Center in the Bronx.

This is my first time on this

committee, and although it said I had a lot of conflicts, the only conflict I sometimes have is with my wife. So I don't think I have any conflicts. I'm not sure how they got all those conflicts.

And it's a pleasure to be here to see how this place works. Thank you.

DR. KASKEL: Hi. I'm Rick Kaskel, Head of Pediatric Nephrology and Montefiore in the Bronx. This is my second tour on the committee.

I have relationships with a lot of the professional groups here, having been Past President of the American Society of Pediatric Nephrology. Thank you. I have some NIH funding. I'm sorry. Thank you, but no conflicts.

DR. ZARITSKY: Good morning. I'm Josh Zaritsky. I'm a pediatric nephrologist, Head of Pediatric Nephrology at Nemours/A.I. duPont Hospital in Wilmington, Delaware.

No real disclosures or conflicts, and I'd like to thank the group for having the

pediatric representation that's here.

DR. SOMERS: I'm Michael Somers. I'm also a pediatric nephrologist. We think there's safety in numbers. So that's why we're together. I'm from Boston Children's Hospital. I have no conflicts to disclose, and this is my second time being part of this process.

DR. BHAN: I'm Ishir Bhan. I'm a nephrologist and medical informatician at Mass General Hospital. I do adult nephrology. I have no conflicts, and this is my first time. Thank you.

DR. DALRYMPLE: My name is Lorien Dalrymple. I'm a nephrologist and epidemiologist at UC Davis. I receive research funding, pardon me, from the NIH and Dialysis Clinic, Incorporated.

Because there is a measure from Kaiser submitted, I was a pool physician there almost eight years ago.

And my husband is a senior physician and shareholder in the Permanente Medical Group.

I don't have conflicts that directly apply to the measures before us.

MS. PAVLINAC: Good morning, Jesse Pavlinac. I'm a renal dietician and Director of Clinical Nutrition at Oregon Health and Science University in Portland, Oregon.

I was here as steering committee three or four years ago, so my second tour, I guess. I have no conflicts with any of the measures.

I do write for the renal specialty exam for our board certification for renal dieticians, so obviously we talk about PCR and phosphorus and all that stuff.

MS. LENNING: Good morning. I'm Karilynne Lenning, and my background is in social work. I have no conflicts, and this is my first tour.

DR. WAGNER: Good morning. I'm John Wagner. I'm an adult nephrologist based in Brooklyn, New York. I'm Associate Medical Director at King's County Hospital Center there and President-Elect of the Forum of ESRD

Networks.

I've been involved in a variety of organizations that are focused on quality in ESRD care. The Forum of ESRD Networks is a member of KCQA, although I did not participate in the measure development of the activities of the KCQA.

And this is my first tour of duty here at the NQF, and it's my pleasure to be here.

DR. STEIN: I'm Dodie Stein. I work for the Indiana University Health Home Dialysis Program in Indianapolis. I have no conflicts of interest, and this is my first time here and delighted to be here.

MS. WAGER: Hi. My name is Bobbi Wager. I'm a nephrology nurse. I'm on the Board of Directors for the American Association of Kidney Patients, and I'm conflict free. But I haven't talked to my husband this morning, so thank you. My second time around.

DR. HAIN: Hi. I'm Debbie Hain. I'm an Associate Professor at Christine E. Lynn

College of Nursing at Florida Atlantic University in Boca Raton.

And I am also a nurse practitioner at Cleveland Clinic Florida in the Department of Nephrology. I do not have any disclosures, and I had conflicts listed, but I really didn't have any conflicts, so they have been removed by the staff. And this is my first time.

MS. EVANS: Good morning. My name is Beth Evans. I'm a nephrology nurse practitioner out of Albuquerque, New Mexico with a private practice. I have no conflicts to disclose.

DR. FISCHER: My name's Michael Fischer. I'm a nephrologist and health services researcher. I'm currently employed by the University of Illinois and the Department of Veterans Affairs.

I have no conflicts. Disclosures, I have NIH and VA funding in chronic and end stage kidney disease. And more recently, I've been involved in the VA and the reporting of currently NQF-endorsed measures in dialysis patients in VA.

DR. KLIGER: Good morning. I'm Alan Kliger. I'm a nephrologist in New Haven, Connecticut. I'm the Senior Vice President for Medical Affairs and Chief Quality Officer for the Yale/New Haven health system.

This is my second tour of duty, thank you. I was past president of the ESRD Forum of Networks. I was also a past president of the Renal Physicians Association.

And while I was listed as having conflicts here, indeed I do not. And they have been removed and cleared by the staff.

DR. KRISHNAN: My name is Mahesh Krishnan. I am the International Chief Medical Officer for DaVita Healthcare Partners, the Chief Data Officer and the Group Vice President for Research and Development.

My conflicts are that I participated on the, this is my first time here. And my conflicts are that I participated on the workgroup for the ultrafiltration measures, the fluid measures for KCQA.

Just a question I'm still not clear on is I didn't participate on the vascular access measures as a measure development. It seems it's more, it's organizational than individual. So I don't know how you want to deal with that.

MS. HAMMERSMITH: If you personally didn't participate in the development of the measure --

DR. KRISHNAN: Yes.

MS. HAMMERSMITH: -- it's not a conflict.

DR. KRISHNAN: It's the same with others. I just did the fluid --

MS. HAMMERSMITH: Okay.

DR. KRISHNAN: Great. Thank you.

DR. LATTS: Hi. Good morning. I'm Lisa Latts. I'm an internist with a sub-specialty in high risk pregnancy. I am currently working as the Chief Medical Officer for the University of California Health Plans.

And I am also, I work as a consultant based in Colorado. This is my second time

around. I have no conflicts and no disclosures.

DR. KLEINPETER: Hi, I'm Myra Kleinpeter, a nephrologist from Tulane University in New Orleans. I think this is my third time around and have nothing to disclosure, membership in the nephrology societies like many of you. Thank you.

MS. HAMMERSMITH: Okay. Thank you for those disclosures. Do any of you have any questions of each other, comments, questions of me?

Okay. Just one last reminder, and then I'll go away. Part of our conflict of interest process is that we rely on all of you.

We can't know everything, so we really rely on committee members to let us know if during the course of the meeting they think they have a conflict that you didn't disclose or you overlooked, or if you think one of your fellow committee members has a conflict or is acting in a biased manner, we want you to speak up in real time.

We don't want you sitting here thinking, "Hmm, maybe I have a conflict. I'm pretty sure Joe has a conflict." Let us know so that we can do something about it.

If you'd like to bring it up in the meeting itself, you're welcome to do that. If you prefer not to do that, you can go to your co-chairs who will talk to NQF staff. Or you can go directly to any NQF staff member.

Any questions about that? Okay. Thank you.

CO-CHAIR CROOKS: We've been joined by two other, we have two other staff. Helen?

MS. BURSTIN: Good morning everybody, Helen Burstin. I'm the Chief Scientific Officer here at NQF. I guess I've been around for the three tours of duty, as they say.

In my eighth year here at NQF on the, on our renal work, so thanks for so many of you for returning, and thanks for so many of you coming to join us.

The tour of duty makes me worried,

that you're worried this is going to be a really tough, kind of slogging through battle. It won't be.

The beauty of having a standing committee is in fact, the nice thing about having so many of you who've been together before, is that we really have seen that by having a standing committee, a group that stays together, you feel much more comfortable with the process.

You feel more comfortable with the criteria and can actually bring measures back and have a good discussion. So we're really glad to have you back again.

And I'll be popping in and out. But you're in great hands with Sarah and amazing co-chairs. Thanks.

CO-CHAIR CROOKS: And in the back?

MS. WILSON: My name is Marcia Wilson, and I'm the Senior Vice President for Quality Measurement. Thank you.

CO-CHAIR CROOKS: Thank you, Marcia. Okay. Then I think at this time, Sarah's going

to take us through a little more introduction and overview of the evaluation process before we jump in.

MS. SAMPSEL: Sure. Thank you, and are you, actually Poonam's going to make a couple of introductory statements about logistics and the committee overall. And then I'll go.

MS. BAL: Thanks, Sarah. So just a reminder, we did go through this during the orientation call, but we just want to remind everyone that the role of a standing committee is really to act as a proxy for the NQF multi-stakeholder membership.

As you heard Ann say, you're representing yourselves as experts, not your organization. You will be serving two year or three year terms.

And we'll do a random selection after, actually on Day 2, we'll do random selection. You're literally pulling out of a hat or a jar really.

Well, also we want you to work with

NQF staff to achieve the goals of the project, which is to review the measures and provide recommendations for them.

Evaluate the candidate measures against measure evaluation criteria, and Sarah will go into a little more detail about that.

And respond to comments submitted during the review period. So you were informed about pre-meeting comments that you received and will receive even more comments after this meeting on your recommendations.

And we'll have a post-meeting call for you to discuss those. And then respond to any directions from CSAC. This is later down the road.

Once your recommendations are given to the next body, the CSAC, they'll review them. And if they would like you re-review anything or reconsider anything, that would be, we would bring the committee back together for that as well.

So for the measure evaluation duties,

all members review all measures unless you have a conflict. Discussants are assigned each measure. You became familiar with this process during the workgroup calls. We have provided a script for you, in this big pile of papers you've been given, to guide you in your evaluation.

We want to evaluate measures against each criterion. We really try, as you saw in the workgroup, to stay on the criteria that we're on. You discuss evidence at evidence, usability at usability, and so on.

Make recommendations to NQF membership for endorsement. So after commenting, after the post-comment call, we do go to a membership vote. So they need your feedback for that as well.

And then overall see the renal portfolio of measures. We went over this during the orientation call, but we'll let Sarah now start a quick review of the portfolio again for you.

MS. SAMPSEL: Great. Thanks, Poonam. I think one of the first things to remind you all

of, especially those of you who have served before, is the prior iterations of this group had been steering committees.

And one of the differences here is you are now a standing committee, meaning that you really have, I think ownership might be too strong of a word, but management of an entire portfolio of measures.

And so I think we talked about this on your orientation call and the Q&A call, but we want you to all be aware of all of the renal measures that are out there.

Not all of them will be before you today and tomorrow; some of them are delayed. But we'd also like you keep in mind things that go under the Measures Application Partnership and other measures that are out there that might be coming in the future.

And this is basically so you have a more holistic view of the measures but also a longer term view of the measures so that you're not just seated once, get together for two days

and kind of a three month period and we reconvene you in three years.

We really want you to have a more active role on an ongoing basis with this portfolio of measures.

So with that, we're going to walk really quickly through the current renal portfolio. The vast majority of those we'll talk about together over the next couple of days.

I think, as mentioned before, we have a number of maintenance measures, but to the same degree, we have a number of new measures, meaning that they have not been endorsed in the past, even though I do understand some of the measures have been discussed in the past.

But you do need to consider them on the merits that they are being brought to you today and tomorrow and the discussions that have happened so far.

So starting, there's a suite of hemodialysis, pediatric hemodialysis and then some vascular access measures that are before

you.

Then there's some sets of dialysis monitoring, both pediatric and then adult as well as I know there's at least one that covers both peds and adults.

There's the patient safety measure, which is 1460, the blood stream infection hemodialysis patients, and then -- that should say CDC as the measure developer on the measure.

And then peritoneal dialysis, there are a few measures that have been brought forward for peritoneal as well.

And then we have all of the new measures, which are all listed here. And I think for the vast majority of these measures, they fall into some of the groups that I just discussed.

And we will acknowledge, this is a lot of new measures and almost half of the suite that you will be looking at or half the portfolio that you'll be looking at.

And what you really do, and staff will

help you, is to really consider these measures based on the merit of the rationale, the evidence provided on them but also the testing and where there looks to be opportunity for improvement.

And that's why we have such a deliberate structure. Then we have a number of measures that right now, as we did the call for measures, had received indication that the measures need to be retired.

And so there are a couple AMA-PCPI measures, and the rest are CMS measures, and just wanted you all to be aware and have those in front of you, that there are some measures that the developers and the stewards have decided that they no longer want to retain endorsement on those.

We also have two measures where evaluation has been delayed, and we've worked with CMS to understand the reason for delaying those evaluation.

And that did go through a formal, internal process of understanding the reason for

delay and also the work that CMS intends to do over the next year.

And as a standing committee, those measures will eventually come back to you, we think, either later this year or early next year but have to do with some significant revisions to the measures that just don't make, it doesn't make sense to review them now, have revisions to the measures and then bring back to you.

So those are pending maintenance review, and staff will keep an eye on those to make sure that we work with CMS to get those back in within the next year.

And then, finally, there are some measures that cross into other projects, meaning that they've been assigned to other standing committees based on really kind of how the measure is structured or some of the other work that they're doing that you still, we'd still like you to be aware of, specifically looking at things like care coordination and person and family centered care, where we're looking at some

of those cross-cutting issues that may not just be specific to the renal population.

And then, of course, it happens a lot that we have endocrine measures that sometimes cross into this area as well, but we're finishing up an endocrine project. So the measure had actually gone under the endocrine project versus this one.

And then some, again, cross-cutting is all-cause admissions and readmissions. And so what we look for there, and this is one of the staff obligations, is to make sure that if any measures come before this group that have related or competing issues that we would bring those measures to you as well, with overviews of the measures so you can consider that.

And then there's still more with health and well-being, surgery, and cardiovascular. All of these measures are available to you in these slides as well as in previous slides that we've talked on at least the first conference call that we all had.

The other thing we wanted to bring to your attention is the MAP measures, so the Measures Application Partnership. This is also a process between CMS and NQF and specifically the Measurement Application Partnership where works with CMS to assess and determine measures applicable or up and coming for use in CMS programs.

The measures are not evaluated the same way that they are for endorsement projects, but we do -- we did want to bring these to your attention because they, these measures seem to cross into the renal space, some of them very clearly into the renal space.

Many of them are up and coming measures, so they're still being tested. They're still being evaluated. They're not ready for endorsement but thought it would be important for you to also realize there are some measures that are being considered under the Measures Application Partnership that will most likely eventually come to you.

DR. KRISHNAN: Could you speak to that a little more? You said they're evaluated differently because of process?

MS. SAMPSEL: Right. So the Measures Application Partnership is not going through the same NQF consensus development criteria. Do you want more information specifically on their criteria?

DR. KRISHNAN: No.

MS. SAMPSEL: Okay.

DR. KRISHNAN: Just so eventually it will come to us --

MS. SAMPSEL: Correct.

DR. KRISHNAN: --- or what do you think?

MS. SAMPSEL: Yes. That's -- or they could, it could be determined they're not ready for endorsement and stay in testing or wherever they are. Yes.

MS. BAL: So I will go over the time line. So as I mentioned earlier, we have our in-person right now going on right now. And we will

be having, we have a post-meeting webinar scheduled for next week.

However, if we are fortunate enough to finish all the things that we need to do in this meeting, we don't need to have that meeting, and it will be cancelled.

However, if we're not able to get through all the measures or get through all the topics that we need to discuss, that meeting is there as a buffer for us to get through everything we need to get to.

After that point, staff will draft a, will draft the draft report. And we'll post it for NQF member and public comment. The public comment will last until July 13th. After that point, staff will take the comments and kind of consolidate them for you and make a memo from that.

And we'll provide that you in advance of the post-comment call. You will discuss those comments and provide responses as necessary.

And then we'll take that and create

the voting report. The voting report will go out to NQF members. They'll vote on the measures if they would like, if they agree with your recommendation or not.

That will be all taken to the CSAC. Again, they'll review the recommendations, see if they agree or if there's anything else that they feel needs to be discussed.

That will, if all goes well, that'll go to our board who will ratify the measures. And one more step before they're completely endorsed is the appeals process.

For any recommended measures if someone feels that they would be harmful, or if they found a good reason for why they should not be endorsed, there is the appeals process. And there is criteria for that but I won't go into detail.

But that appeals process will happen. After the appeals process, if there are no appeals, measures are considered endorsed. And that will done in about December.

So I did want to just go over ground rules for the meeting today. So NQF continuously strives to improve our committee meetings based on input from a variety of stakeholders.

And we always appreciate getting feedback from our committees and developers and any members of the community. We are constantly trying to improve.

We are fortunate to have the measure developers present at our meeting, and we'll be asking them to briefly introduce their measures as they come up for discussion.

There are two seats over there reserved for developers. Selected committee members will begin the discussion of the measures in relation to the measure evaluation criteria. Again, we did start that in the workgroups, and we'll continue that in the meeting today.

We will provide a designated place for developers, as I mentioned earlier, to do their introduction and also to answer any of the questions that you may have.

They are a resource for you. As I mentioned in the workgroups, we really want the discussion to be among the committee members, but if there's a question that needs to be clarified, or at any point they feel that the, I guess, the path that the committee is going on doesn't really correlate with what they meant for the measure, they can provide clarification.

The developers will put up their card just like committees would, committee members would, to indicate that they would like to make a comment. And then the co-chair would select them to respond.

During the measure evaluation, committee members often offer suggestions for improvement to the measures. These suggestions can be considered by the developer for future improvements.

However, the committee is expected to evaluate and make recommendations on the measure per the submitted sophistications and testing.

Committee members act as a proxy for

NQF membership, as I mentioned earlier. There is a need for respect for differences of opinion and cordial interactions among committee members and measure developers are expected.

Our meeting agendas are typically quite full. We have 25 measures, which is a lot of measures to get through.

All committee members, co-chairs, developers and staff are responsible for ensuring that the work of the meeting is completed during the time allocated.

So during the discussion, committee members should be prepared to, be prepared, having reviewed the measures beforehand and you all have been doing a great job. The workgroup calls have been wonderful. Everyone's been very prepared, and we really appreciate that.

To base their evaluation and recommendations on the measure evaluation criteria and guidance, you'll see that we provided algorithms for you.

It's one of the pile of documents in

that big pile we provided to you. Please remain engaged in the discussion without distractions. We really need everyone to be involved in every measure.

Attend the meeting at all times except for our breaks. We really, obviously, everyone has to go to the bathroom. That's understandable. But I mean if you can avoid not leaving the room discussion, it would be appreciated.

Keep the comments concise and focused. Don't repeat comments that others have made. Again, just trying to keep time in mind and trying to keep the meeting going.

Foster a meaningful participation. Again, avoid downgrading or encouraging, I'm sorry. Prevent dominating the conversation, and always encourage contribution.

And then, again, indicate agreement without repeating what has already been said. So that's generally the ground rules. And with that said, so we've kind of already repeated this, but

I'll say it one more time. For the process for measures discussion, the measure developer will introduce their measure. They'll have about two to three minutes to introduce the measure.

Lead discussants will being the committee discussion by providing a summary of the pre-meeting evaluation comments, so basically what was discussed in the workgroup. And then starting their discussion with evidence and saying their point of view on that and then going to gap and so on.

And again, the script is there for you. It'll provide you guidance on how we'll be discussing the measures and when we'll be voting.

And then, developers will be available to respond to questions at the direction of the committee. And the committee will vote on criteria and sub-criteria when it's that point.

So that is the basic structure. I do want to pause to see if there's any questions before we start our first measure.

Okay. So I'll actually give it to

Alexandra to discuss voting, and the method. Does everyone have a clicker?

Oh, Andy's here. Also, Andy Narva has joined us. And once he gets his clicker I'll ask him to do a quick introduction and also disclosures as everyone else did.

DR. NARVA: I'm Andy Narva. I direct the National Kidney Disease Education Program at the NIH. I don't think I have any conflicts. I am on the ABIM sub-specialty board in nephrology.

But I have a Kevlar vest on for you nephrologists in here, so don't throw anything.

MS. BAL: Okay, perfect. Thank you so much. And so now I'll give it to Alexandra to go over voting.

MS. OGUNGBEMI: Good morning again. All committee members have a small blue remote with you at your seat.

Fortunately, all committee members are slated to attend today's meeting and are actually here in person, so there will be no proxy voting necessary.

It is important to note that once ready, I will instruct you that voting has opened. I will read the criteria that we are voting on, and then I will let you know that voting has opened.

Once you make your selection, you may point the remote towards me and press the number of your choosing. After pressing your choice, the display window of the remote will flash the number briefly.

If you would like to change your selection, please do so immediately. You will not duplicate a response by pressing more than one button. The system will only collect the last response received from your remote.

Does anyone have any questions? All right, thank you.

MS. BAL: Okay. And so we'll go ahead and start the first measure. I do want to call the developer up. So if anyone -- let's see here.

We'll be starting with 1454, so I just

wanted to see if the University of Michigan and CMS were ready to present.

MALE PARTICIPANT: Claudia and Joe.

MS. BAL: Yes.

DR. DAHLERUS: Okay. Good morning, and thank you for the opportunity to speak to our measures. So we're going to, first off, I'm Claudia Dahlerus from the University of Michigan Kidney Epidemiology and Cost Center.

So we're going to begin with hypercalcemia, so Measure 1454 is the percentage of patient runs for adult dialysis patients, and this includes hemodialysis, home hemodialysis and peritoneal dialysis patients with a three month rolling average of total, uncorrected serum or plasma calcium greater than 10.2.

The measure was originally developed in 2010 by a mineral and bone disorder TEP and endorsed by NQF in 2011. In 2013, an additional mineral and bone disorder TEP was convened.

They reviewed the measure, and they affirmed the measure, describing it as an

important safety measure as opposed to just a target threshold base measure.

The TEP, in its deliberations, recognized the current body of evidence that warranted monitoring of calcium levels in order to manage elevated calcium and the increased associated potential of adverse events, notably all-cause mortality and cardiovascular events.

In its deliberations, both TEPs also cited the 2003 and 2009 KDIGO guidelines and the 2009 KDOQI guidelines.

We did want to note that in our review of the measure as part of the comprehensive reevaluation, we made a slight revision to the denominator to include patients that had missing calcium values within the three months, in order to discourage gaming of the measure.

So, in other words, a facility could not be included in the measure if they didn't have calcium values, and therefore, they would not be evaluated for hypercalcemia.

Finally, we want to note that in

response to community comments, the measure was expanded to include serum or plasma calcium based on evidence provided to the University of Michigan and CMS, suggesting sufficient equivalence between the two laboratory based values. And I'll stop there.

DR. MESSANA: Well, the only additional comment about the missing is the, I think the TEP in 2013 were considered a hypercalcemia reporting measure for maintenance at that point.

And they felt that if we included missing in the denominator here that would cover, that would be the most parsimonious approach. And so they did not recommend moving forward with the hypercalcemia reporting measure, but one measure that included a reporting component, essentially, in it.

CO-CHAIR CROOKS: Okay. Thank you very much. Our primary reviewers were Joshua and Lisa. Would one of you like to kick off with discussing the evidence?

DR. ZARITSKY: Yes. As a newbie, I'll start off and Lisa's promised to keep me in, step in when I get too far astream.

Basically, this is a rather straightforward intermediate outcome measure. The evidence is largely associative, but it's been reviewed by both the KDIGO, which gave it a 2D recommendation and KDOQI, which again, it was basically expert opinion.

They recommend toward the lower end of the normal, which would get up to 9.5 while the measure does do 10.2.

And I think the measure overall is more of a safety kind of net measure where we're trying to catch patients who are over 10.2 rather than trying to keep people unnecessarily in a specified range.

I don't know if they want more details about the evidence or, it's fairly straightforward.

CO-CHAIR CROOKS: Let's restrict the discussion to the evidence at this point. Lisa,

did you have any other comments about that?

DR. LATTS: No.

CO-CHAIR CROOKS: Okay. Other committee members?

Okay. So I think if there's no other discussions of the evidence, then we're ready to vote on the evidence. Do we need to use that chart to determine --

MS. BAL: So Peter's just asking if we would need to use the algorithm that is a resource for the committee. And we can go over the algorithm for you, if you like.

However, if you feel comfortable with the evidence you reviewed, and you feel that you are prepared to vote on that, we can go to the vote as well. So I guess as a committee --

DR. ZARITSKY: I forgot to comment. I would place this in the moderate degree of evidence.

MS. BAL: Okay. Were there any other comments?

DR. KRISHNAN: When KDIGO or the other

set a specific threshold for greater than or less than, some specific number, how do we account for lab to lab variances?

So, I'm told that if you split a lab sample and you send it to three different labs, you may get slightly different values for that exact same patient.

How do we think about the crispness of that number versus the vagueness of the laboratory science?

DR. ZARITSKY: I think the one thing that kind of helps us out in that aspect is that we're looking at the upper range of normal, and then I think that looking at the actual when we get to the gap, you'll see that the actual rate of average is like 2.1 percent.

DR. KRISHNAN: Small.

DR. ZARITSKY: It's a very small gap, so I'm not too concerned that we're missing. And I think if we're going to go on expert opinion, there's very limited evidence.

Most of the evidence is associative as

well, is that most of us would feel that we want to be on the lower end of normal. So 10.2 as being the upper cut off of the norm, I think, provides enough of a, kind of a wiggle room.

DR. KRISHNAN: I don't know enough about laboratory science or how big the standard deviation is between labs, but I just wonder. I don't know enough to know enough.

I don't know if the developer knows, but I just don't know how big of a spread that is and whether or not if you get sent to one lab versus another lab that helps you with the metric, hurts you with the metric. I --

DR. ZARITSKY: You also have to recognize that the 10.2 is considered the, different labs have different standards of what the upper limit of a normal is. 10.2 is kind of agreed upon.

So even if we looked at the inter-lab variation or intra-lab variation, you also have to recognize that there's probably some labs out there that might consider something over 10.2 --

DR. KRISHNAN: Normal.

DR. ZARITSKY: -- normal.

DR. KRISHNAN: Yes.

DR. ZARITSKY: But I think that because it's expert opinion, and there isn't, we're never going to find a number as a cut off, I think, with that gap that's in place of only 2.1 percent.

It's a fairly safe, and I mention the measure, at least in my opinion, is more of a safety net than anything else rather than necessarily a quality improvement.

DR. SOMERS: Since it's a three month rolling rate, I think that would smooth out the concerns about single laboratory variations as well.

DR. KRISHNAN: I don't follow that because the lab is the question, right. So if the lab, to Josh's point, if the lab was consistently higher or lower, the three month average would still be consistently higher or lower.

DR. SOMERS: But your individual test result will vary from month to month.

DR. KRISHNAN: No, true. That's true.

DR. SOMERS: So it's going to be less common that you'll be right at the edge.

DR. KRISHNAN: Sure.

FEMALE PARTICIPANT: Lorien?

DR. DALRYMPLE: I was hoping to discuss the evidence a little bit more with the primary workgroup. Since this was a KDIGO 2D and a KDOQI opinion and then a TEP, how did the evidence support a moderate rating as compared with perhaps a low rating?

DR. ZARITSKY: I would --

DR. DALRYMPLE: Just so I get your insight from that algorithm.

DR. ZARITSKY: Yes, I was just using the grading. They give us a grading scale of what's moderate and so --

DR. DALRYMPLE: Okay.

DR. ZARITSKY: -- I can find that study. So on Table 2 here from --

CO-CHAIR CROOKS: So I think this is a good opportunity, as long as we have a little more time in this metric, to use this algorithm. And taking it from the top, it's not an outcome measure, although they initially said so. But I think it's really an intermediate outcome.

So to Question Number 1, is it an outcome or a process measure? It goes down to a no. So that brings us to Number 3.

And the question at Number 3 is for measures that assess performance on an intermediate clinical outcome process or structure, is it based on a systematic review and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured.

And so in this case, their evidence is based on KDOQI, four KDOQIs. And usually the KDOQI process includes a systematic review of the body of evidence.

So in my view I think that would be a yes, but I'm just open to other interpretations.

Do others feel differently? I think everybody has this on their, so please pull it out. Follow along with me.

So if the answer's yes, then we go to Number 4. Is the summary of the quality, quantity and consistency of the body of evidence from the systematic review provided in the submission form?

And without opening it up right now, I don't know that they actually provided a, I can open it up and see or maybe somebody else knows. Do you feel that, and these are questions that are asked within the form.

What's the consistency, the quantity, the quality and consistency of the evidence? And so what's the committee's input on that or feedback on that?

DR. DALRYMPLE: Am I correct that KDIGO's recommendation was a 2D, and KDOQI was opinion only?

DR. ZARITSKY: Expert opinion, yes.

DR. DALRYMPLE: Is that correct?

DR. ZARITSKY: Yes.

DR. DALRYMPLE: Okay.

DR. KLIGER: Lorien, it would be helpful for us if you give us the inference of that, why you're pointing that out to us.

DR. DALRYMPLE: My apologies. I was trying to pull up what KDIGO D is. Are others on the committee able to say it off of the top of their head?

I do have it somewhere in my worksheet, or maybe the committee, can you read to us what the D stands for. It's very low or lacking evidence is my -- right?

But if anyone has the exact wording, that would be helpful.

DR. ZARITSKY: I have very low evidence.

DR. DALRYMPLE: And two is also the weaker of the two choices. There's one or there's two.

CO-CHAIR CROOKS: Looking at the application, the section where they are to

discuss the systematic review is 1.7.7, 1A7. And within that are subcategories about the quantity, consistency and quality of the evidence. And those areas are blank.

So I would have to say that they did not address the first question in Number 4. They didn't address and summarize for us the quantity, consistency and quality of the evidence.

So if the answer is no, then it goes down to Box 6. Does the grade for the evidence of recommendation indicate high quality, high certainty or strong recommendations. So I think that's where the conversation you're having about what grades were used from the committee.

DR. ZARITSKY: But then we move to this Table 2 here.

CO-CHAIR CROOKS: Pardon me?

MS. BAL: So there is a secondary table that provides information for you. But the arrows kind of point to you where, what you would rate as what, maybe. I think Connie has additional comments.

CO-CHAIR ANDERSON: Right. So on the table on the algorithm, if the grade does find evidence or recommended high quality evidence, then you can rate it as moderate. But if the answer is no to that, then you rate it as low.

CO-CHAIR CROOKS: My problem with this is that KDOQI does a systematic review, but the developers didn't lay it out for us and really show us how that is done and how it relates to this measure.

So we're kind of left trying to guess. Maybe it did. Maybe it didn't. If you say they didn't, then you go down to Box 6, as you just did. And then we have the option of saying, well, with what we do have, is this high quality evidence, high certainty, strong recommendation by the grading.

And so I guess it's a judgment call. If it is, then we can call it moderate. If it isn't, then it's low. Am I, sorry, Alan?

DR. KLIGER: Peter, I think that KDOQI made clear because it gave a rating and the

rating is low evidence.

CO-CHAIR CROOKS: Okay.

DR. FISCHER: Regardless of whether you go horizontally from Box 4 or down to Box 6, I don't see a scenario where it's not low, either through Box 5c or through Box 6. Seems like it winds up as low.

CO-CHAIR CROOKS: Okay. Is everybody happy with the conclusion on the evidence review? Now does evidence low translate into a no vote on the evidence, or does that mean we can still vote for it?

MS. BAL: So we would still vote. That's just what the verbal discussion would be. That's what you concluded, but everyone does have the right to vote otherwise if they would like.

So due to that, we, since it's an intermediate outcome, we would vote on high, moderate low, insufficient. If it was an outcome, we would just vote yes or no.

So since it's an intermediate outcome, we'll be voting on all three options. And then

there is one additional option that I want to inform everyone. If you so feel, there is additional option with evidence was insufficient evidence but with exception. So you feel that while the evidence may be weak, overall the measure is strong.

And you would like to continue to review and discuss it. That is just an option I wanted to make everyone aware. We would vote on that only if, we voted on these four options first so high, moderate, low, insufficient.

And then if it was low or insufficient, we would then give you the option of voting on exception if you so choose. So we'll go ahead and start this vote, and then based on the result, we can see what option you would like to go with.

CO-CHAIR CROOKS: So we're going to vote.

MS. BAL: Yes, that's correct.

CO-CHAIR CROOKS: Okay. High, medium, low or insufficient. Alexandra?

MS. OGUNGBEMI: Yes, thank you. The committee is now voting on evidence. You may vote high, moderate, low or insufficient evidence. High is one, moderate is two, low is three, and insufficient evidence is four.

CO-CHAIR CROOKS: We need to point to you?

MS. OGUNGBEMI: Yes.

MS. BAL: And I want to just point out, there is no conflicts on this measure, so all 23 committee members should be voting. And so that's the number we're looking for, just so everyone knows.

MS. OGUNGBEMI: Since we have 23 votes, the voting is closed. And we have 4 percent for moderate, 96 percent for low, 0 percent for insufficient and high.

MS. BAL: Okay. So it seems like we don't want to do an exception, but I do want to offer that as an option to the committee. Does anyone feel that we should give the exception, or should we end this measure right now?

DR. KLIGER: I just want to historically remind some of us that the last time we went through this measure, which was several years ago, we found that the evidence was low.

But because it was not a performance measure but considered a safety measure, we continued on with our discussion, even in the face of relatively low evidence.

CO-CHAIR CROOKS: So are you proposing that again?

DR. KLIGER: I'm just pointing out that's what we did the last time.

CO-CHAIR ANDERSON: But I think since then it's become a performance measure, and it's measured through the QIP. And at the 98th percentile, zero percent is the topped out measure.

And so facilities are measuring this, and 98 percent of the nation is at 0 percent with calcium is greater than 10.2. So it leaves little opportunity for improvement.

CO-CHAIR CROOKS: So if we did make an

exception and decided to continue, then we get to gap, which is where it may not pass there.

MS. SAMPSEL: And then you would also, when you get to gap, also have the opportunity to talk about reserve status. And that is when the measure meets the criteria, in this case with exception on the evidence, but has to meet the rest of the criteria but may be topped out but it's still important to monitor, and you want to signal that it's important to monitor.

CO-CHAIR CROOKS: Lisa?

DR. LATTS: I guess I would like to see us get to that gap discussion and discuss the implications of not moving farther with this measure from the safety perspective rather than just stopping right here with no discussion moving faster.

CO-CHAIR CROOKS: Other thoughts? Andrew, if you want to speak, turn your card upward so I can see your name. There you go. Andrew?

DR. NARVA: Thank you. The other

historical fact was this was the only bone and mineral measure that we passed. And there were many others at that time. And it's still the only bone and mineral measure, isn't it?

(Off microphone comments)

CO-CHAIR CROOKS: There is a measure related to phosphorus, but if it's measured it's not --

FEMALE PARTICIPANT: It's a process measure.

CO-CHAIR CROOKS: It's a process measure. I personally am okay with considering an exception for safety.

DR. MESSANA: So I just wanted to raise one question before this gets too far along. Under Section 1.8, we did, under other evidence, we did provide a discussion of more recent literature. And I just wanted to make sure that the committee was aware of that. 1.7 was answered negatively because we didn't do a formal grading of that, of those additional, more recent articles. If, in fact, you all are aware

of that, then that's fine. I just wanted to make sure that that was the case.

MS. BAL: So did we want to go ahead and vote to see if there, the committee would like to give exception to this measure? Okay. So --

MS. OGUNGBEMI: The committee is now voting on evidence, a potential exception to empirical evidence. The choices are one for insufficient evidence with exception, and two is no exception. Voting is now open. We have 83 percent insufficient evidence, and 17 percent no exception.

CO-CHAIR CROOKS: Okay. So we can move on to considering the gap then. Lisa?

DR. LATTS: I think Josh is going to --

CO-CHAIR CROOKS: Okay, Josh.

DR. LATTS: Josh is going to continue, and I'll continue to --

(Simultaneous speaking)

DR. ZARITSKY: -- forge on ahead. As

we've already alluded to that the gap is very low at 2 percent and that this is really more of a sort of a safety gap measure, rather than an improvement, an area for improvement.

As far as the other gap, any data disparities, I mean there's some, with the large numbers that are presented, there are some very, there are some statistically significant differences between some groups, but I think they're largely clinically insignificant.

CO-CHAIR CROOKS: Other comments on opportunity for improvement? Lisa?

DR. LATTS: Yes, I mean as we've sort of discussed, as Alan brought up, with this performance there's very little opportunity for improvement, so this is not an improvement measure. It's more of a safety and a monitoring measure. And so the question that it brings to my mind is what happens if this measure goes away.

Does it mean that facilities will not monitor this anymore? Those of you who are in

the business can speak to it. I think that's probably unlikely because it is a safety measure. On the other hand, if they're going to continue to monitor it because it's a safety measure, why do we think it's not important enough and the evidence is now there?

So it's a little bit of a paradox in that sense. So I'm a little torn on the sense that the performance is high. Do we really need the measure? On the other hand, you know, it's a safety measure.

DR. ZARITSKY: You really want to make it a performance, I mean you'd have to lower that threshold. Then we'd get into, then the evidence isn't there basically. So you're stuck.

CO-CHAIR CROOKS: In terms of process, if we vote the gap is insufficient, we still have to go through the rest of the evaluation, if we're going to consider it for reserve status.

MS. BAL: Yes, so what I would do, I do want to direct everyone to this document, which is inactive endorsement reserve status.

This is an option we have. There are stipulations obviously to reserve status. It needs to be very strong on scientific acceptability, reliability and validity, needs to be very strong.

You do need to see this measure. If you think the gap is low, you need to do, you do need to feel that if we remove this measure, then this will be, it will hurt performance, and performance will go down. So those are some of the things to think about, and we would vote on gap as regular. If it was low or insufficient, we would just do a verbal discussion, if we would like to consider this measure for reserve.

If that was the case, we would go through all the other criteria and vote on them as if this measure was going through, and then vote at the end for reserve status. So that is the process. But we do want this measure to be strong in almost every other aspect to go on reserve status. Were there any questions at this time? Okay.

DR. LATTS: Can I just ask, is it possible to turn up the mics a little bit? I'm finding everybody just a little bit hard to hear.

CO-CHAIR ANDERSON: Yes.

MS. BAL: I can check with IT group but, unfortunately, it is pretty hard to hear people. So we always recommend, as you see, I'm very close to the mic. Please speak close to the mic. Please try to really speak loudly. We have this problem, often, unfortunately. We'll try to get the mics up higher, but I can't guarantee anything. But, please, actually, it's a good reminder. A good reminder, please speak directly at the mic.

CO-CHAIR ANDERSON: So, Mahesh, do you have comments?

DR. KRISHNAN: Yes, just to ask the question, I think, Lisa, you posed, what would happen if this measure goes away. At least, looking at our own data, over the time period pre- and post- when this was actually a measure in the QIP. We didn't see any substantial

differences. So I don't think we would see that.

And then, two, we'll get into this later on, because now of the inclusion of the missing values of the denominator, we will have to talk about the CROWNWeb data issue where we're having data integrity issues in terms of data transmission. Which I just fear, you know, in a measure that only has a 2 percent gap, I suspect that significant amounts of data transmission issues.

The fact that values aren't making it from the clinic into the system may also contribute to that false positive. And I ask myself, well, what is the clinic going to do? They are managing in real time with their data. We don't see any issues. Now, they're being told, potentially a year later, that there was a problem. I don't see that changing too much to answer your question.

CO-CHAIR ANDERSON: Frank?

DR. MADDUX: Yes, I just want to make the point because it came up, I think, in Andy's

comment. I think simply because, with the performance gap being extraordinarily narrow, the evidence being low, the fact that we don't have another bone and marrow measure shouldn't play a role in our assessment of this measure and its value, either as a performance measure or a safety measure for threshold or a reserve measure. We should, in my mind, look at it independently.

CO-CHAIR CROOKS: So I think I'm hearing sentiment that the case, it's a hard case to make that this should even be a reserve measure because of its lack of real importance. And it doesn't seem likely that it's going to deteriorate if it's not an NQF measure. Am I gauging the sentiment correctly? Okay, so I think --

MS. BAL: Before we move forward, I just want to confirm that if there is, this agreement means that if measure goes down in gap, then we're done. We wouldn't continue to discuss it. That's all I wanted to clarify. We can do a

hand vote if everyone --

DR. ZARITSKY: If it comes back as insufficient here, that's it anyway, right?

FEMALE PARTICIPANT: Let's do the vote and then we'll deal with what happens next.

CO-CHAIR CROOKS: We're voting on whether to consider it, oh, we're going to vote the gap first. I'm sorry. Okay.

DR. KRISHNAN: Is this the operating definition between low and insufficient? Can you just review that? Is low, there's too small of a gap, as Connie said. Or is insufficient, there's not a gap, or how does that work?

MS. SAMPSEL: So that would be low. Insufficient is when there wasn't enough information or you don't have enough information, correct?

MS. OGUNGBEMI: The committee is now voting on performance gap for measure 1454. The performance gap is, they have demonstrated considerable variation or overall less than optimal performance across providers and/or

population groups. The options are 1-high, 2-moderate, 3-low, 4-insufficient, and voting has opened. For performance gap on Measure 1454, we have zero for high, zero for moderate, 91 percent for low and 9 percent for insufficient. The measure fails on performance gap.

MS. SAMPSEL: And so the interpretation of this is that the measure failed one of the must-pass criteria, which is performance gap under importance, which means we would not move forward with additional discussions on scientific acceptability, what would go into the report is that you do not recommend this measure for endorsement. Just want to make sure everybody understands that. And to summarize one more time --

CO-CHAIR BROOKS: And there would be an opportunity for an exception but the committee has vocally, sort of vocal consensus, that they don't think that an exception is appropriate. Am I summarizing it correctly?

DR. ZARITSKY: As a newbie, I'm

getting to recognize here that this is -- we're not necessarily considering safety issues here, we're considering a performance measure that we can look in between units, and that there's no difference between, you know, we're all performing at this level. It's like if this measure was a calcium of 15.5, what's the point. If we were going to push the data down and say, hey, I want a lower end of normal calcium to 9.5, obviously, there would be a performance measure there.

But we just don't have the data to back that up. We do have expert opinion to back up, you know, 10.2 as being a higher level of normal what we would think. But that's my feeling, now, of me being the first, a new person at this first. And for this first measure that we're looking for performance measures, obviously, not necessarily something that's going to provide a safety net.

CO-CHAIRMAN BROOKS: Yes, we have some discretion, or have in the past, but in this

particular case, I think we're ready to let this go, unless I'm missing any other procedural points.

MS. SAMPSEL: I just want to make sure that the endorsement isn't for a measure as a performance measure, an accountability measure, a safety measure, et cetera. It's the overall merits of the measure, no matter what its use would be.

So I don't want you to think that you should only be evaluating measures because it has an opportunity to be in a performance measure. I mean, this is an instance where the measure, in a semantics thing, of there's very little opportunity for improvement. Have we already reached that threshold? So that should be the vein that you're looking at.

DR. MADDUX: So, Sarah, can I ask you a question about that, because if a measure is endorsed but would only be appropriate for certain categories where it shouldn't really be a performance measure, but might qualify for safety

uses, how do we address that with regard to our role?

MS. BURSTIN: Yes, this has been a big issue, Frank, you have had for a while. So we actually now have an expert panel convened that's meeting in the next couple of months to potentially move us away from a binary, yes/no endorsement decision, but instead to move towards endorsement for the intended use of the measure, and potentially flexing the criteria to make that more logical to see if that works.

But, at this point in time, it is fair to assume you're using the criteria regardless of the intended use of the measure. I would argue the safety issue is not really an intended use issue. It's really looking at the measure through a different lens.

So we routinely put forward some of the safety indicators that have rates very low, in some instances, as low as this one as almost being sentinel events. So that is appropriate if that is something you think is an important thing

to keep an eye on. But, you know, the question is the measure was framed more so is there a basic rate kind of base measure you would look at in terms of performance.

It's still important to consider the safety measure. It's something you could potentially consider for reserve status just to kind of keep an eye, you know, indicated should at least have somebody keeping an eye on those rates and ensuring that they don't start creeping up, if it's not something that's part of an ongoing monitoring approach.

DR. KASKEL: Did we review, is there any evidence that there's disparities in the data set with this value at all?

CO-CHAIR CROOKS: As part of the gap discussion, yes, that would be appropriate, I think, although we voted already. Did you want to make a point about that?

DR. KASKEL: There is some evidence in the literature that there are some disparities in vitamin D, we know that, and potentially, calcium

and metabolism. Just thought I'd mention that.

DR. ZARITSKY: Yes, when you look at the actual data there, the disparities are, I mean, there are some statistically significant disparities.

But the clinical, you know, you're going from 2.1 to 1.9 percent. So I think what we're facing here is that that cutoff of 10.2, you know, it's at the higher, you know, it's the higher end of normal, like I said, if we wanted to, you know, bring it down without evidence, then there would obviously be a gap. And then some of those disparities might become larger and more clinically significant. But at that upper rate of 10.2, it's very hard to find something clinically significant.

CO-CHAIR BOORKS: Where are we at? So, oh, Lori. Lori has her card up.

MS. HARTWELL: I just want to make a comment, that this is the only measure for bone and mineral metabolism. So I would like it to consider it for reserve or something. I just get

worried, as a patient, that we aren't measuring anything for patients in this area.

CO-CHAIR BROOKS: Alan.

DR. KLIGER: You've got a sense of the group, but there have been about six people who've been vocal and 15 who've not, so the question about reserve status, I suggest you put to a vote. I want to add two things quickly, though. I agree with Frank that the absence of a measure in any particular area shouldn't be our criterion. Our criterion is strictly whether measures measure up to the standards that NQF has established.

And that, in this particular measure, with the evidence being low and the performance gap being very low, I personally don't see the wisdom of putting it into a reserve status. I think that we need to await better evidence before we vote affirmatively for a measure like this.

DR. DALRYMPLE: And I know we voted on performance gap, but since we have the developers

here, one part I'm trying to reconcile is, I think, the 75th percentile was about 3 percent. Yet, in meaningful difference, 15 percent of facilities performed lower than expected. Is that correct?

So as we move forward on some of these measures, in trying to understand gap, I just want to try and reconcile that difference. And I wonder if you can give us insight. I'm not sure if this is a good time to do it. But I think there's a number of measures that appear topped out, you know, a large percentage of facilities are performing worse than expected. So, as we're trying to figure out, moving forward, gaps and performance.

DR. MESSANA: So my interpretation as a clinician, non-epidemiologist, but in talking to our analytic team, is that the measure has topped out for the majority of facilities but there's a skewed distribution. And I think that the meaningful differences come from the tail, right. So there are a relatively small number of

facilities that are relatively far from the high-performing group.

DR. DALRYMPLE: But it's 15 percent that are worse than expected, is that correct? Am I interpreting that correctly?

DR. MESSANA: According, to the analyses that were done, yes.

DR. KRISHNAN: And part of that may be the data issue, right. So CROWNWeb data performance varies by facility, even by chain. So we have a variable data loss of anywhere from 5 to 15 percent of data transmission on a monthly basis. And that also has asymmetrical distribution. So that's why I don't know how to reconcile the data integrity issues, the data quality issues with the gap, because they're both confounded.

CO-CHAIR BROOKS: Dr. Wagner.

DR. WAGNER: Yes. I had a question about the forthcoming NQF focus on safety. If the committee that is looking at safety as a goal of a metric decides to incorporate such a goal,

then would that change the status of this particular metric?

MS. SAMPSEL: No, this is under this committee's purview at this time.

MS. BURSTIN: And this committee is perfectly able to look at safety measures in the KD arena, as well, obviously.

DR. WAGNER: I was just curious, though. If we put it in reserve status, would it then enable us to revisit this at a time when the safety committee has spoken?

MS. BURSTIN: I'm not sure they would add much to the discussion beyond what you've already had. I think the real question for those of you at the table is, is a 2 percent number sufficient such that, particularly if there's a tail, you know, regardless of what it might be, that there should be some ongoing assessment to make sure it's not particularly skewed for some facility rather than others, where they might, in fact, have safety issues.

CO-CHAIR CROOKS: Jessie.

MS. PAVLINAC: I just have a process question. So if the measure is retired, it goes into the big black hole and never is seen again versus, if it's a reserve, then periodically, we might look at it to see if that tail has become a significant -- if there's been some change. Is that exactly correct?

MS. BURSTIN: Yes.

MS. PAVLINAC: Thank you.

MS. BURSTIN: So, apparently, there is an expectation that reserve measures come back up for a maintenance review, at least in terms of the gap.

CO-CHAIR CROOKS: If it's not in reserve, it could always be brought again as a new measure with fresh, better data and so on. Lisa.

DR. LATTS: I guess my question is for the developers and for CMS. If this measure goes away or if it is put in reserve status, either way, might there be an appetite to drop the level so that there would be more of a gap. Look at it

as, I mean, it just, you know, what would sort of be your perspective, the CMS perspective, if this actually does go away? I don't know if you guys can speak for CMS.

DR. MESSANA: I generally attempt not to do that. But, you know, this measure was developed, as you all have talked about, with the TEP process. So this was not CMS setting a threshold. This were two subsequent, two TEPs, a couple of years, two, three years apart, setting the measure threshold. When an expert panel suggests, in the future, you know, depending upon what happens here and what happens in the dialysis community down the road is just impossible to answer.

CO-CHAIR ANDERSON: And, again, once again, the QIP measure isn't going away. So it's still a part QIP in pay for performance. So facilities have to meet that 98 percent threshold of zero percent. Calcium's greater than 10.2, so it still has to be monitored by the facilities to meet those target goals as a QIP measure.

DR. LATTS: Although if it goes away, as an NQF endorsed measure, does that affect then the QIP measure down the road?

CO-CHAIR ANDERSON: Yes, I was going to say, go ahead Joel.

DR. ANDRESS: Thank you. My name is Joel Andress. I'm the measure development lead for CMS for dialysis facilities. So to your earlier question, I think Joe's absolutely right. I suppose CMS could arbitrarily reduce the target level. I think we'd have a difficult time justifying that in any venue.

So, you know, if additional evidence comes along which indicated that a lower target was appropriate, say 9.5, as was mentioned earlier, then that's certainly something that we could look into. Until then, I think, 10.2 is the threshold we have available for consideration.

In terms of the question of the measure's implementation, so implementation or retirement of the measure, the QIP is held under

purview of the rule making process. So the decision here has no necessary consequence for that, I think. There are statutory requirements in the QIP for measures of mineral bone disease that we certainly have to consider as we are thinking about the measures that are implemented.

So that would probably factor, that as well as, any decision here at NQF, would factor into our thinking for the measure in the future. But it would be, well, first of all, it would be inappropriate for me to say that we would have a particular response with regard to the QIP, and I would note that any response would be noted in a proposed rule in the future. Does that answer the question?

CO-CHAIR CROOKS: I think the point is, though, that I would emphasize is even if it is continued in the QIP, that has no bearing on our considerations here, it should not. Mehesh.

DR. KRISHNAN: I'm just struck by the history that Andy and Alan provided where we've kicked the can down the road two or three times.

It sounds to me like the answer in this discussion is, we think it's important to have a bone and mineral measure, there are requirements to have a bone and mineral measure, but that this particular measure has had the same discussion twice in the same forum.

And so it may be worthwhile thinking about an alternative measure. I know there's one coming up on phosphorus. But if we desire a safety measure, maybe we need another TEP to talk about that. But it just seems like, it seems to me, and I wasn't -- I'm a newbie here as well. It seems to me like this parallels a discussion that y'all had, you all had, sorry. I'm from West Virginia originally, you had in the past and so it just seems like we're repeating history and it may be time to change that.

CO-CHAIR CROOKS: I'd like to limit the comments. I mean, I want you all to say what you need to say, but please make sure it's something important. Andrew. If you catch my drift.

DR. NARVA: Joel, do you remember when this was developed and considered in 2010, what the gap was at that time? Because this may just be a very successful measure and since there's no additional burden on anybody, everyone's dialysis unit's going to continue to collect calciums, no matter what. I'm just curious.

DR. ANDRESS: Sorry, I do not personally remember. I was not part of the project at the time. I think, so when the measure was originally developed, the denominator was defined slightly differently from what we're talking about now. It was, essentially, a proportion of the data that we received for calcium.

And it was using test data, yes, I know. It was using test data from CROWNWeb as the basis for testing and developing the measure. So I think the data we have now are certainly more complete. Speaking to the issue of the completeness of data and CROWNWeb, certainly, it is true that there are issues that the CROWNWeb

team are working through. I think there're also gaps in the submission of calcium data that also need to be addressed on the provider's side.

And that was one of the reasons that we modified this measure to require more fulsome reporting of the data through CROWNWeb from the facilities. I think that's, you know, part of the rationale for the measure. That there needs to be a, not only a performance assessment, but also a requirement for reporting and so that was part of the rationale in moving forward.

I also want to speak to the issue of holding another TEP to review a potential alternate measure. So, we've done that, and we've held three TEPs on this topic. I think that's the most TEPs we've had on any topic and this is the most soundly supported measure that has come out of those deliberations.

So I just want to make it clear there's not a measure we're hiding in our back pocket with evidence demonstrating, you know, that it is the performance measure and that's

what we should be using. We have, in fact, been pushed to develop additional measures in mineral bone disease and we have attempted to do so.

Speaking to the issue of reviewing the issue on its own merits, I think that's absolutely correct. I just want to be clear. We're not going to be able to pop out a new measure of mineral bone disease next year as a consequence of this measure not being endorsed. And I want that to be clear when you're considering your vote.

CO-CHAIR CROOKS: Okay. We'll soon be voting on whether to consider this for reserve status. Frank.

DR. MADDUX: Sure. So I appreciate the comments that John, Claudia and Joel have made. But it strikes me that we do, although, we need to truly vote on each individual measure, we need to also think of what I would call, the unintended consequences, of something like reserve status.

And, the unintended consequences that,

despite there being three prior TEPs, I think the three prior TEPs having difficulty coming up with a measure is indicative of the complexity of this part of the associated condition for end stage renal disease patients.

And my concern would be is that reserve status might actually limit the ability of developers, whether it's CMS or other developers at really working hard at trying to figure out what an appropriate measure for bone marrow metabolism should be.

CO-CHAIR CROOKS: Thank you. Dr. Zaritsky.

DR. ZARITSKY: Just one last comment. Because, you know, with this measure. I mean, obviously, we're talking about things that we're going apply to subsequent measures. And I just wanted to just touch upon the patient's safety aspect.

To look, let's say the measure before, even if only 50 percent of the facilities were making this measure ten years ago, you know,

because the gap has narrowed or come down, that doesn't necessarily reflect the ruling here, but rather also the general consensus in what the expert opinion is.

So we've gone, you know, I'm rather junior, but we've gone from, you know, this idea of, okay, high calciums are okay, et cetera, to this recognition now that, you know, there's too much calcium out there in a general thing. So I'm not worried that by, at least in a pediatric setting, the units that I know and the people that I talk to that if this measure is, you know, dropped from that perspective that we're going to adversely affect patient outcomes.

And then the final thing is lowering, I think part of the, and I'll use the word weakness, that the 10.2 is, is that you recognize if we tried to move that measure down, you know, which I think we would have -- you know, some of us might have an argument, I could make an argument to bring it down to 9.5. The evidence that I would use it is largely associative and

it's very weak from that, you know, from a very, very high standard that you'd want to go to.

So I think that, there's that idea that 10.2 well, because it's upper level of normal and we all kind of agree with that. But, you know, if I thought about bringing it down, we'd have even more problems.

CO-CHAIR CROOKS: Right, and just as a passing note. We generally aren't going to be rewriting or changing metrics here. We take the metric and the information as it's presented. Okay. I see no other, I see one other card up, that's Josh. Put your card down, Josh. All right, anybody else?

I think we can now vote on whether to -- this isn't whether, if it's going to be a reserve, it's just whether to even consider this because of there would be a whole process after that. Am I right? A hand vote, this will be a hand vote. So those in favor of continuing of exploring making this a reserve measure, raise your hands. And keep them up, raise them high.

One, two, three, four, five, six. I'm counting six.

CO-CHAIR ANDERSON: One, two, three, four, five, six. I have six.

CO-CHAIR CROOKS: Sort of up and down, there's three there and three here. Okay. And those not in favor of exploring it as a reserve, raise your hands. So I would say this vote has it. So we're going to not consider it further as a reserve measure. Okay. That concludes our business on this particular metric. I think we get to the bio break, or our break a little early. The 4 percent --

(Laughter.)

MS. BAL: So before everyone leaves though, we will be taking our break early. About ten minutes. So we'll ask everyone to come back ten minutes early. So, please, by 10:20 be ready to review our next measure. Thank you.

(Whereupon, the above-entitled matter went off the record at 10:05 a.m. and resumed at 10:20 a.m.)

CO-CHAIR ANDERSON: All right. We're going to move to measure 2594, and -- which is the Optimal End-Stage Renal Disease Starts, and Peter is here as the developer.

MS. BAL: Actually, sorry, Peter --

CO-CHAIR ANDERSON: Oh, I am sorry.

MS. BAL: It's okay. Before you start, I forgot to mention related and competing before, and this is the first one we'll be having those kinds of measures, so I did want to bring that to everyone's attention.

So before -- prior to the in-person meeting, we did notify developers if there was a related or competing measure identified there for their measure. They were asked to respond, and they have provided responses to all the measures listed on the annotated agenda.

You can find that on the link I sent to you on, I believe it was, Monday. There was a link filled -- it was a folder filled with all the different documents. If you want to open that up, you can. We'll have it open -- we'll

open it up for you as well when we talk about it.

Again, the procedure is that we talk about each measure individually as they are, and then if they are chosen to be recommended for endorsement, we would consider if they were related or competing to other endorsed -- recommended for endorsement measures.

So that's not a factor we take into consideration until the end, because we do want to make sure that these measures pass endorsement on their own, and then at that point. And so, again, it's the same procedure. You'll be asked to consider if these are related and competing measures, do you think there is a best in class? You can ask the measure developer clarification.

Were there any questions about that? And that -- we'll do our first round of related and competing after the -- these next four measures. Any question before we start?

(No audible response.)

MS. BAL: Okay. So now I'll give it to Peter.

CO-CHAIR CROOKS: Okay, and before you start my two to three minutes, I am -- just to let the Committee know, I am now a developer. I won't be able to vote. I won't be able to say anything unless asked, so please feel free to ask if you have any questions. Okay. So this is -- okay.

Measures that matter: I have been told that this is the new NQF motto, measures that matter. Well, I believe Optimal ESRD Starts is a measure that matters, and it's a measure that works.

By now, I hope you have had time to become familiar with this measure. Optimal ESRD Starts is a process metric. The focus is on pre-emptive kidney transplant, starting ESRD on a home dialysis modality, or starting in-center hemodialysis with a fistula or graft.

The process measured is the success at identifying high-risk CKD patients, educating them about modality choices, and helping them make those choices, and then once they have

selected that, see that they have prepared before they reach ESRD. The better those processes perform, the higher the optimal ESRD starts.

Now, this measure is not intended for dialysis facilities. This measure is intended for the broader U.S. healthcare system, CMS and health insurance companies, ACOs and other integrated care delivery systems, and nephrology groups and organizations. But while not intended for the dialysis facility use, it will deliver better patients: prepared, educated, with a fistula and a graft, so the dialysis industry will benefit.

The data elements are very simple, and the calculation is back-of-the-envelope easy. Date of ESRD, the modality, be it transplant, home dialysis, in-center hemodialysis, and if in center, what is the vascular access used at the very first treatment? If a patient recovers GFR, they did not have ESRD, and they are not included.

Now, to clarify the ten percent limit

on grafts, let's think about what that means. Let's say a large nephrology group or insurance company has 100 patients that start hemodialysis in a year. 10 percent of those patients, or 10 of them, may have grafts and meet the definition.

So, typically, 70 percent start hemodialysis with a catheter in their neck, unfortunately, and 30 have prepared -- surgically-prepared accesses. That means 1 in 3, 10 of the 30, could be grafts, and it would be acceptable.

So 1 in 3 is not really that encumbersome, and we've found in practice that it does allow for choice in individual patient decisions, yet it is consistent with the Fistula First Initiative, which we I think all have to recognize has done a lot to improve dialysis care in this country. So does this measure pass the NQF criteria? Let's run it down.

Evidence: multiple guidelines, and more importantly, systematic evidence reviews support the following conclusions: one, a pre-

emptive kidney transplant has better health outcomes than starting hemodialysis with a catheter; two, starting from home dialysis modality has better outcomes than starting in-center hemo with a catheter; three, starting hemodialysis in center with a surgically-prepared fistula or graft is better than starting with a hemodialysis catheter.

The evidence is strong: Optimal ESRD Starts reduces mortality, reduces bloodstream infections, reduces hospital days, while improving quality of life. I hope you agree that the evidence is strong.

Gap: extracted data from USRDS and Fistula First shows that optimal ESRD starts in the U.S. in 2012 was 35.5 percent. For KP nationally in 2012, it was 51 percent, and since then, it was increased to 58 percent in mid-year 2014.

What is the upper limit? I suspect that using urgent-start PD and the new immediate-use grafts, the level may be able to reach as

high as 80 percent or even higher. So there is a gap, and that gap can be closed.

Reliability and validity: the testing of critical data element accuracy showed the measure to be both reliable and valid to a high degree of certainty, and while we did not specifically utilize phase validity argument, I think the medical evidence provides that. It does link optimal ESRD starts to improved health outcomes.

Now feasability and usability and use: well, it is feasible, as KP has been doing it across the U.S. It is usable, and it is improving outcomes. Now, I have heard concern that this may only be usable within Kaiser, and that the data elements are not easily electronically accessible. Well, I hold in my hand CMS Form 2728, and as you all know, this form is filled out for every patient who starts dialysis in the United States, whether they have Medicare insurance or not.

Let's see if it contains the data

elements necessary for calculating optimal ESRD starts: date of ESRD, check; ESRD modality, check; and if they start in-center hemo, item 18(d), what access was used on first outpatient dialysis, AVF, graft, catheter? It's all there. CMS has the data, and they can start calculating optimal ESRD starts today.

The Permanente Federation, the measure steward, looks forward to working with CMS to put this measure on the PQRS Reporting System, to work with RPA to put it on their registry, and to work with any other groups that would like to implement this measure.

So there it is. All the criteria seem to be fulfilled. And to repeat, this measure is not intended for the dialysis facility, but is aimed at the broader U.S. healthcare delivery system, but it will deliver better, healthier, educated patients into the dialysis facility with a usable AVF or AVG. Optimal ESRD Starts: it's a measure that matters, and it's a measure that works. Thank you.

CO-CHAIR ANDERSON: Thank you, Peter. All right. And so we have our -- our two reviewers, who are Beth Evans and Lori Hartwell. Beth, are you going to start, or Lori?

MS. EVANS: Yes, I am. All right.

CO-CHAIR ANDERSON: So we'll start with the --

MS. EVANS: Right. So the evidence is based on four clinical practice guidelines, KDOQI 2006 grade a and b; U.K. Renal Association 2008, 2011, grade 1b, which was strong opinion and moderate evidence; and Vascular Access Society, unknown date, and it's not defined what their level III evidence is; and the Canadian Society of Nephrology, 2006, grades C and D, which C is not defined and D is opinion.

It was also based on a systematic review of 62 studies of over 500,000 patients. It was not graded, but a retrospective study. Moderate evidence per the NQF algorithm based on retrospective patients.

Pre-emptive kidney transplant was one

clinical practice guideline of the U.K. Renal Association rated 1a, which was strong opinion and high evidence. Systemic review and a meta-analysis was also retrospective study with low to moderate quality, moderate evidence per NQF algorithm.

New recent studies, all with positive outcomes, with transplant, which was a cohort retrospective study, and a 2007 article evaluating lifelong cost for transplant. So the process of care is directly related to improved health outcomes with improved cost effectiveness. So it's a process measure. Okay.

CO-CHAIR ANDERSON: Lori? Do you have anything to add, Lori?

MS. HARTWELL: To what -- could you briefly -- I couldn't hear you.

CO-CHAIR ANDERSON: The evidence, do you have anything to add to --

MS. HARTWELL: You know, the only thing I would add is that, you know, in reading this, and I'm reading this from the patient's

perspective, this seems like a very meaningful measure, and the evidence is there of pre-emptive transplant, of starting home dialysis, I mean, just in the community.

And so I think this is a -- an excellent measure that would help patients, and especially push the grid in pre-emptive transplant, so it was a very easy measure to understand. I just had one question for you, though. When it said -- is it okay to ask a question -- home dialysis starts, was it PD and home hemo? Was there -- what were the percentages in starts?

CO-CHAIR CROOKS: Yes, any home -- either home modality is an optimal start, and, you know, in terms of percentages, within Kaiser, actually, since we started this initiative, we're up to 30 percent incidence rates in Northern California, one of our larger regions, and home -- home hemo is, as many know, there are -- we have maybe 1 percent of our patients on home hemodialysis.

MS. HARTWELL: 1 percent?

CO-CHAIR CROOKS: About 1, yeah, roughly.

CO-CHAIR ANDERSON: Andy?

DR. NARVA: Sure. I like this measure a lot, and I think one of the reasons is that it's a way of driving improvements in care prior to initiation of dialysis, which -- which I think is really important.

I was just wondering, since I think you started -- this started -- this measure was first implemented in Kaiser Permanente Southern California, it's been implemented across the country, do you have data to show how formal adaptation of this as a measure changed care in other facilities as well?

CO-CHAIR CROOKS: Is that a question? Do I --

DR. NARVA: Yes.

CO-CHAIR CROOKS: Yes, in the appendix is all the results for the last -- since we started measuring it nationally, and there's been

improvement in all of our regions. Some go up -- some of the small regions may go up and down a little bit because they have smaller numbers of patients, but overall, the trend has been upwards, and there has been a great growth in home peritoneal dialysis during that time as well. Does that answer your question?

DR. NARVA: Yeah, it confirms my bias, I like it.

CO-CHAIR ANDERSON: And we would like the committees to discuss the measure within the Committee and ask Peter the questions after there has been discussion. Okay. Stuart?

DR. GREENSTEIN: I am just curious about Kaiser Permanente, what is your pre-emptive rate, what is your rate of fistulas at beginning, and also grafts, graft rate? Do you know -- do you know what the numbers are?

CO-CHAIR CROOKS: If I -- I guess I am the one that has the answer. We average 2.5 to 3 percent pre-emptive transplants, which is what you see, I think, in most any health care system,

showing that pre-emptive transplant is largely a family endeavor, and -- and we should be able to do better, and we're thinking hard about how can we improve pre-emptive transplants, but we're stuck below 5 percent. You know, sometimes we've seen 5 percent in a region temporarily.

For our -- our fistula and grafts, I can tell you that the graft -- the fistula prevalence is over 80 percent, and incidence rates I can't quote you right off the top of my head.

DR. GREENSTEIN: Another question, how soon from the time of initiation of dialysis to referral for transplant? I ask that because now they've changed it in terms of waiting times, that you get your waiting time starts from start of dialysis.

Which, you know, is a way of preventing patients from being penalized from not being referred, but at the same time, what happens is patients then say oh, I'll wait five years before I go for transplant. I'm wondering

if you have any numbers along that line of where -- how long after they start dialysis do they get referred?

CO-CHAIR CROOKS: Well, one -- while not relevant to the measure per se, we do -- I believe we do a very good job screening patients, getting them in early, and whatever the sorting system is, that they should be out early, and a hard search for living donors.

CO-CHAIR ANDERSON: All right. Just a reminder to the Committee that we really do need to look and keep our comments related to the evidence based on this measure. So Frank?

DR. MADDUX: Sure. So a couple of comments and one question for Beth and Lori. First of all, I think this is an unbelievably important area of measurement that we need to develop, and -- and I am pleased this was brought forward, and I think measures go through a maturity cycle, and even if this one has some immature elements, I think, nationally, we need to consider it very strongly.

I have a couple of questions about the fact that if we extrapolate the Kaiser experience, we all believe Fistula First has been a success in most ways, but I am concerned about the elderly patient that is getting fistula after fistula after fistula that will never mature.

And I am a little bit concerned about the 10 percent graft, sort of, hurdle here, and I can see how it kind of fits into the existing numbers, but I don't want to create targets by saying well 10 percent should be your overall global target for a graft. I think that this is permanent access or non-permanent access, and I see this as a catheter avoidance strategy measure.

But one question that I have, which I don't -- either didn't read it well enough, or I don't understand the measure quite well enough is does home hemodialysis trump the vascular access type for that population of patients, or is it home hemodialysis and catheter avoidance, or home hemodialysis in spite of catheters?

MS. EVANS: I'll answer that because actually Peter answered that for us at the -- in the conference call. And it has to be home hemo with fistula or graft. Catheters are not acceptable at any times in that as an optimal start.

Okay. I do want to add one thing. I think he clarified nicely that 10 percent of grafts is really based on their entire new starting dialysis population or transplants, so of 100 patients, 10. So that does give a bit more of a liberal amount. I didn't understand that initially, so that makes it a little more achievable, based on this measure.

CO-CHAIR ANDERSON: Alan?

DR. KLIGER: I wonder then based on the discussion we just had what your assessment of the strength of the evidence is?

MS. EVANS: The only, to me, weakness is that it was retrospective studies for the systematic review. I don't think it's possible at this level right now to do a prospective

study, so using what we have for the NQF, I had to rate it moderate, but I still feel if we could maybe even put it tiered in there between moderate and high, it would be a moderately high evidence, as kind of a modifier with that.

CO-CHAIR ANDERSON: Bobbi?

MS. WAGER: I have to agree with Dr. Greenstein. I think this -- and Lori, this measure is very important because of the new kidney allocation policy that I feel does not promote pre-emptive transplants, which I think pre-emptive is -- as we all know, it's a gold standard of care for ESRD, but this -- this measure will help keep the pre-emptive transplants out there for the patients.

CO-CHAIR ANDERSON: All right. Are we ready to vote on the evidence?

MS. OGUNGBEMI: The Committee is now voting on evidence for measure 2594. The options are 1 for high, 2 for moderate, 3 for low, and 4 for insufficient. Voting is now open.

(Pause.)

We have 6 votes for high, 2 votes for moderate, 0 for low, and 0 for insufficient for evidence for measure 2594. The measure passes on evidence.

CO-CHAIR ANDERSON: All right. Let's move on to performance gap. Okay. Kaiser data suggests a performance gap and supports the need for a national performance measure. The gap is apparent in evaluating new starts to a therapy to replace the usual function.

This optimal start process has been in place for ten years with KP in California and five years nationally, and using abstracted data, has calculated the U.S. national 2012 AVF rate as 35.5 percent. The KP data for June 2014 is approximately 58 percent for AVF and optimal starts total. So it's a significant performance gap between the U.S. and the Kaiser Permanente performance.

Disparities, do I cover that also at this time? Disparities in care has very little evidence regarding fistula, with just one article

suggesting arm vein differences resulting in lower fistula creation in Caucasian versus African Americans with private insurance. No recent articles found comparing PD to hemodialysis disparities except higher utilization of PD in other countries. I think we all know that.

One article that suggested zip codes with higher African American population are associated with lower nephrology care, and unclear evidence of disparities with this process in the literature. So the -- and the USRDS Fistula First data shows a significant gap in performance of pre-dialysis education, and certainly an opportunity for improvement. And this is also considered a high priority -- I am sorry, next one, left, so. Lori, any comments?

MS. HARTWELL: I think you summed that up really well.

CO-CHAIR ANDERSON: Any other comments from the Committee, or discussion?

(No audible response.)

CO-CHAIR ANDERSON: Are we ready to vote? All right.

MS. OGUNGBEMI: The Committee is now voting on performance gap for measure 2594. The options are 1 for high, 2 moderate, 3 low, and 4 for insufficient. Voting is now open.

MS. BAL: As a reminder, since Peter is the only one with a conflict, we are looking for 22 votes.

MS. OGUNGBEMI: We have 18 votes for high, 4 votes for moderate, 0 for low, and 0 for insufficient. The measure passes on performance gap, for measure 2594.

CO-CHAIR ANDERSON: All right, Beth, high priority?

MS. EVANS: That --

CO-CHAIR ANDERSON: Okay, that -- now that was brought up as a question. We do or do not discuss priority?

MS. EVANS: We do not, we do not.

CO-CHAIR ANDERSON: We do not. Okay.

MS. SAMPSEL: So just -- and let me

just clarify, technically, with high priority, while it's not -- no longer a voting criteria, that would be something that you would want to discuss as part of evidence and part of gap, and certainly if folks -- and I think it did come out quite a bit with some of the comments, so just, it's not a clear not discuss, but more of a let's encompass it in the other important criteria.

CO-CHAIR ANDERSON: Thanks, Sarah. Okay, moving on to validity. Okay.

MS. SAMPSEL: Actually, generally, on scientific acceptability and any -- this is the first part of reliability would be a discussion of the measure specifications.

CO-CHAIR ANDERSON: Okay.

MS. SAMPSEL: And any questions anybody might have on the specifications or comments on the specifications, to make it clear.

CO-CHAIR ANDERSON: Okay, Beth?

MS. EVANS: The numerator is the number of new ESRD patients who initiate renal replacement therapy in the 12 month measurement

period with an optimal ESRD start, which is defined as fistula, graft, pre-emptive transplant, or home dialysis without a catheter, home hemo.

Denominator is the number of patients who receive a pre-emptive kidney transplant or initiate long-term dialysis therapy and do not recover kidney function by 90 days for the first time in the 12-month measurement period, and there are no exclusions to the denominator.

CO-CHAIR ANDERSON: Lori? Okay.

MS. HARTWELL: I don't have anything to add.

CO-CHAIR ANDERSON: Any further discussion on the part of the Committee? Questions? Alan?

DR. KLIGER: Yeah, I want to raise the question about the specification that Frank mentioned, that is, home hemo patients and their vascular access.

I am unaware of any studies showing for home hemodialysis patients that catheters

afforded a higher risk to them than do fistulas or grafts, and I say that in the setting of speaking to some of the zealots for home hemodialysis who have at least anecdotally, but also reported in the literature their experience that catheters, when handled by patients rather than by staff, have a far better outcome than in the hands of our staff in dialysis units.

Only to say I don't know of any evidence that would say for the home hemo patient that an optimal start is necessarily with a graft or a fistula, and so I have just some concern, in the absence of that evidence, for that part of this measure, that we really don't know that.

CO-CHAIR ANDERSON: Mahesh?

DR. KRISHNAN: Question for Peter, do we -- have you considered as an exclusion some patients who may have a limited life expectancy, or are coming on to dialysis for a transient period of time where converting from a temporary access to a permanent access may not be consistent with the general plan? How would you

handle that, or should that be an exclusion? I don't know how you would quantify that, but just a question.

CO-CHAIR CROOKS: Okay, two questions. Taking the last first, the -- if a patient chooses not to start dialysis, then they are not ever in the denominator, and in fact, if you think about it, having a good, active palliative care -- you know, palliative care program improves your optimal starts, because you don't get elderly patients who shouldn't be starting dialysis in the unit with a catheter, so that actually helps optimal starts improve.

I do believe that we need a new paradigm for looking at elderly, fragile patients. The concept of a trial of hemodialysis, which I have always kind of shied away from, but I think is a viable consideration in some cases with a catheter. And there's some data that elderly patients with catheters may not have as many bloodstream infections. Right now, though, they would be treated as a non-optimal

start.

DR. KRISHNAN: Right.

CO-CHAIR CROOKS: You know, measures can change as time goes along, and we will be re-endorsing. Maybe there will be new paradigms and better strategies for handling elderly, frail patients.

As to Alan's remark about the home hemodialysis with a catheter, this was a debate that went on back and forth among the measure developers. For years, we've been talking about that. And I favored Bob Lockridge's strategy, and I was outvoted. But I think this is something that we could, you know, if this was a measure-buster, that we could really take back and re-discuss.

My sympathies are with Alan's position. The data that we do have shows that catheters are worse than fistulas and grafts, you know, and that's sort of where they went back to. But I think that that's worthy of consideration for tweaking in the future.

CO-CHAIR ANDERSON: Ishir?

DR. BHAN: Yes, so this is probably an issue that would come up on many measures, but one question relates to how we deal with the implications for patient selection.

So, for example, I think these are certainly worthwhile goals for patients who are being followed pre-dialysis to try to achieve, you know, better access before initiation. But there are also patients, particularly at sort of tertiary care institutions, who show up, often from other countries, with no pre-dialysis care and therefore would end up with a catheter.

And so my question is regarding how that might influence, you know, selecting certain patient populations to focus on, sort of unintended consequences of this type of measure. I'd love to hear from people who have been around for a couple cycles to hear how that would affect things, or how those factors are considered.

CO-CHAIR ANDERSON: Well, I think also with the new starts, new to dialysis, and the

evidence of 2728, they do ask how long patients have been under the care of a nephrologist prior to the start. And if you look at that data, about I think it's 62 percent -- is that right -- I think it's 62 percent are under the care of a nephrologist for at least a period of six months. But there is some where they're going to be urgent starts that come in --

DR. BHAN: And that would probably vary by institution or region.

CO-CHAIR ANDERSON: Right.

DR. BHAN: And my concern is the exclusion criteria don't have any of that baked into it. It's just anyone starting dialysis, not anyone starting dialysis who has had pre-dialysis care.

CO-CHAIR ANDERSON: Under a nephrologist, yeah. Lorien?

DR. DALRYMPLE: And I actually have a similar concern and was hoping as a Committee we could discuss it and then ask Peter questions. But there are institutions where 50 percent of

your incident patients present to the ED. So in this specification of the measure, if it's at a physician level, and your quality is reflected, I think the question is, should the specifications take into account that a lot of this depends on access to care? And depending on where you practice, access to care will be very different. So I share that concern in terms of specification.

I also had a question for the pediatric nephrologists in our group. My understanding is because children are often going to transplant or hoping to get transplanted, we don't often put fistulas or grafts in them. I hope you guys can weigh in on that a little bit more, but it seems, at our institution at least, they often start with catheters, and mom is going to be their donor in two months, and no one attempts to put access in.

And do you feel this measure, as I understand it, and Peter will clarify for us if I'm wrong, pediatric patients are included in

this measure?

DR. SOMERS: Well, you know, happily, a good proportion of pediatric patients are going to be covered by PD, so that takes them off the table, and there's a growing number having pre-emptive transplants.

I think it is true that, especially in the U.S., a large number of kids who we think who are going to go to transplant quickly will be dialyzed by catheters, but I am not sure that there's actually evidence to -- when you look at practices in other parts of the world, there is actually more of a push to put in fistulae, for all the reasons that have been shown that fistulae are better.

But I do think that, you know, as a practice, that it would be difficult for pediatric nephrologists to have a high degree of performance on this because of current practice.

CO-CHAIR ANDERSON: Josh, go ahead.

DR. ZARITSKY: Just also answering to the pediatric is, if you looked at any individual

unit, the numbers are so small that, you know, if you had two or three children who are, you know, under age five or something, it's just not practical to put a fistula or a graft in, that we'd have to deal with it.

But I think it's still, you know, from a pediatric standpoint, it's still an interesting thing for us to have on the table.

CO-CHAIR ANDERSON: Frank?

DR. MADDUX: So, two thoughts. When I think about what the potential intended or unintended consequences might be, is this would drive programs with a lot of urgent starts to doing urgent start PD, which may or may not be clinically appropriate, and the measure could drive certain clinical behaviors that we don't really know what the result would be of that. We need to be aware of that.

The other which concerns me about this is the rapidity with which our delivery systems are moving towards risk-based models for end stage renal disease care. And it strikes me that

the re-evaluation of this measure in the context of palliative care, and potentially palliative dialysis for somebody that really just wants to get to the wedding in three months or the graduation in six months or something as a primary goal for therapy could also create some fairly unintended behavior that it would be nice to see that considered within the measure on the front end. Because three years from now, if we're reassessing a measure that's beginning to get into the system, our delivery system could be fundamentally different.

CO-CHAIR ANDERSON: And I think going back to the whole Fistula First Initiative, it was all surrounding vein mapping for AVFs and AVGs, and we still had the unintended consequences of these little old ladies getting multiple, multiple, multiple attempts at fistulas because AVGs weren't included in the Fistula First Initiative.

And so I am really pleased that, at least with this, there is AVGs considered. And I

am concerned about the elderly, and also our cancer patients that, you know, catheters may be the best alternative for them, and those that are at end of life. John?

DR. WAGNER: Thank you. I guess in talking about measure specifications, it really raises in my mind the question as to, to what audience is this measure targeted? Is this a measure to assess the quality of integrated care delivery systems? Is this a measure that targets hospitals? Is this a measure that targets physicians?

And it's important to understand who the audience is because then we can tailor the specifications, perhaps, in a more measured manner.

CO-CHAIR ANDERSON: John, can we hold that to the feasability/usability, because that's exactly where that discussion would go?

DR. WAGNER: I mean, I think it drives the specifications discussion as well.

CO-CHAIR ANDERSON: Yeah.

Sorry, Lorien?

DR. DALRYMPLE: And is this a time where we can ask Peter questions about some of the things the Committee has brought up, or would you --

CO-CHAIR ANDERSON: Yes.

DR. DALRYMPLE: So I was wondering, Peter, do you have any data, at least within Kaiser, about how this measure performs when patients have only been under a Kaiser nephrologist's care for, let's say, two months versus a year?

And I am sorry if I missed that in the submission. Or if you're knowledgeable of does this have vastly different performance? I would assume so, but you may have actual numbers on that.

CO-CHAIR CROOKS: Okay, well, I've got a couple remarks related to specifications. And to start with that one, when we initially developed the measure, we limited the denominator to patients who had been under a nephrologist's

care, or who had at least been identified in our data system as having CKD Stage 4 for three months or longer. So, we felt that was a group the nephrologists felt comfortable, they had control.

As we expanded the measure, we made the decision to go with all ESRD patients, in part because of the data systems problems. It's easy to say, "this patient started dialysis, they're in," as opposed to, you know, putting some qualifications on them.

I will say that if you're limited to patients who have been under the care of nephrologists, the numbers bump up about 10 percent. And the discussion about what about these patients who just walk in the door, you know, well, first of all, this will never be 100 percent because there will be those patients that walk in the door and they end up in a hemodialysis center with a catheter in their neck.

But this is a healthcare system

measure, so it's not only up to the nephrologist to find these patients. If there's patients walking around with a high risk for ESRD, we should be finding them. And this measure encourages early identification, and then referral, appropriate referral and education of patients.

So it's broader than just the nephorologist's practice, and it's broader than a hospital. It's the healthcare system's responsibility to find these patients and then have a process. It's measuring their process. Did you find the patients? Did you educate the patients? Did you take them step-by-step until they're ready for ESRD?

Peds. I don't have the measure in front of me. I don't think the pediatric population was included in the specs. I could find out in just a minute, but I think it says adults. But it doesn't --

CO-CHAIR ANDERSON: It says "all new," yeah.

CO-CHAIR CROOKS: It's been a few months since I looked at that particular -- you're right. It doesn't eliminate -- what do you think? It's the standard for pediatrics, too. Not being a pediatric nephrologist, should they be excluded?

DR. KASKEL: I would think they should be excluded, I would think so. We don't have enough information. There's lots of variation here, and geographic distribution too. PD is the recommended treatment, not only because of age, but because they're far from any center and they do better on PD, so there's lots of factors that need to be addressed.

CO-CHAIR ANDERSON: And the population numbers are so small, especially as you get into the littler kids and pre-emptive transplants.

DR. KASKEL: And as Michael said, our goal is to transplant, not to dialyze.

CO-CHAIR ANDERSON: Right.

DR. KASKEL: The time on dialysis is minimal, and that sets us apart.

DR. GREENSTEIN: Maybe that's what it should be, pre-emptive transplant. You should be looking at it for the pediatric patients rather than the fistula rates or graft rates.

First of all, doing the surgery, I can tell you right now, I have never put a graft into a little kid. It's just technically impossible. The vessels are just too small, and it never would work. Fistulas are even difficult to do on the kids sometimes.

CO-CHAIR CROOKS: I presume that we can modify it, if the Committee suggests, and the developer -- no?

MS. SAMPSEL: No, what we would have to do is vote on it as it has been presented. And so if the peds population and their inclusion presents a significant concern, you would actually vote the measure down. You could make the changes during the comment period, and the Committee would then make a decision if they want to re-vote with the changes to the measure.

CO-CHAIR ANDERSON: At the return

conference call next week, or later?

MS. SAMPSEL: No, thank God, it wouldn't be next week.

(Laughter.)

MS. SAMPSEL: Basically, it would go through the -- and it could go either -- you know, if your vote is gray zone, meaning you don't have 60 percent criteria to pass, or if it is voted down as low because of that ped population, you would then make that recommendation to say, you know, if the measure did not include peds, you know, we might be more favorable towards the measure.

Then we, as staff, have about a month to prepare a report. That goes out for public comment for another month, and during that public comment period is when Kaiser or any developer could come back and say we would make these following adjustments. And with those adjustments and public comment, you would have the opportunity to re-vote. But it's a couple months away.

CO-CHAIR ANDERSON: Mahesh?

DR. KRISHNAN: I mean, I think on this issue, the number of pediatric patients at any given facility is so small that, on aggregate -- I know we're talking about it because we're thinking of it specifically in our context -- but realistically, for the vast majority of the 6,000 dialysis units with the limited number of health systems, it seems like that is less of an issue.

CO-CHAIR ANDERSON: Lorien?

DR. DALRYMPLE: And I was just hoping for a clarification to follow up Mahesh's question. So, perhaps we want to discuss pediatrics, but we don't think it's significant enough to say it's not going to pass on this criterion. Do the developers, though, then have the opportunity to revise a measure that has passed if they think, after further comment -- this might save the developers -- if comments come up today that afterwards the measure would be stronger with that modification, but the measure passed today, could it be modified in one

to two months and then brought back to the Committee?

MS. SAMPSEL: That would be through the annual review -- you can do it? Okay.

DR. DALRYMPLE: Because these issues come up that perhaps aren't significant enough for us to say, "this measure doesn't warrant it, but it could be optimized."

MS. BAL: So, it would be the same procedure. So, if you endorse it or if you do not endorse it, they have the opportunity to make changes based on what you stated.

So, if you want to move forward with this measure but you have provided this recommendation, the developer can choose if they would like to do that and then present that information to you at the post-comment call.

What Sarah was also referring to was that if they weren't able to make the changes by the post-comment call, and the measure is endorsed, there's an annual review process. So in a year from now, the measure developer would

basically say there's minor changes, or there's this major change that's been added, and then at that point, staff would decide if it needs to be reviewed again.

So, with something small like this, we would probably just, you know, say, include it in the description of the measure. So during the annual review, they could provide new information, say this is a minor change, but this is something the Committee asked for, and then we would just basically add a little asterisk, I guess, to the measure.

Does that answer your question?

CO-CHAIR ANDERSON: Ishir?

DR. BHAN: So, just with regards to the sentiment that, as a healthcare system, we should be trying to capture patients who are sort of underserved pre-dialysis, I wholeheartedly agree with that.

My question is regarding the level of analysis that is specified here. It says the first item is clinician, which would effectively

-- I don't know, penalize isn't the right word -- but disproportionately affect clinicians who take care of an underserved population that may not have access to care pre-dialysis. And I wonder how much are we taking into account this level of analysis specification here?

CO-CHAIR ANDERSON: Any comments from the Committee? I mean, there are certainly -- yes, Frank?

DR. MADDUX: I would just say I think, for all of these new measures, there's a period of needed benchmarking across a broader audience than maybe just one integrated system like Kaiser. And it strikes me that a lot of these questions are really valid, I think, that you brought up.

And the measure is attractive. There are these features that need a better sense of how they'll play and what influences they'll have on the delivery of care and the outcomes for patients. And it strikes me that that can't -- it's a little bit of a chicken-and-an-egg. We

advance the measure and the measure moves into a realm that it might get used in a way that isn't what we intended, or isn't what the measure intended. Or we don't endorse the measure, and there is not really the capacity to go out and do national benchmarking, for example, from a single organization that has proposed the measure.

So I struggle with the choice that's sort of black or white with regard to this particular measure.

DR. ZARITSKY: I think probably the inclusion of pediatrics might have just been an oversight, that all patients here, but I think when you look at the denominator, that, yes, there's large units out there that have one or two pediatric patients, but there's also units out there that are exclusively pediatric.

In fact, we would argue that's probably the best model of care. And in some senses, that would hurt those specific units.

DR. NARVA: It's kind of hard to imagine any quality measure which isn't going to,

you know, penalize providers who are taking care of people who have decreased access to care and have poor socioeconomic status. And is that normally something that's taken into account when we consider measures?

MS. SAMPSEL: I'm going to ask you to repeat it and rephrase it because I'm not sure I understand the question.

DR. NARVA: Sure. I guess it's hard to imagine any quality measure that wouldn't penalize providers who take care of disadvantaged populations with decreased access to care. And I think there are other reasons to implement quality measures, in part to lift all boats.

And I am wondering, is that generally a factor in assessing quality measures through NQF?

MS. SAMPSEL: So, this is another example of, if Helen were here, she'd say it's one of those areas that NQF is constantly dealing with, is how to deal with some of those issues with the measures, and especially, you know,

socioeconomic status, access to care, et cetera, and putting those criteria and those components in to have clearer guidance for the committees.

So, you know, I think, in this case, it's something you have to consider, you know, based on your knowledge and expertise as a committee for this specific measure. But more globally, it is something that NQF is dealing with, and I don't know if you guys have more information on that.

MS. BAL: There is going to be a trial for SDS that will focus on that topic and how to incorporate that into measures. It's currently underway. And so we'll have more information for that.

But as Sarah said, it is something to consider, but the guidelines are being worked on, and we're really testing how, at NQF, best to use that.

DR. DALRYMPLE: So, I think, at least my take on that question, is a number of the measures we're reviewing, for example the

dialysis facility-level, require that patients are on dialysis more than 90 days. And I interpret that as a build-in to allow facilities to assume responsibility of care for the patient.

And so that's my only caveat about this measure, which is heavily linked to access to care. And if it was only at the integrated health system level, I think that would be one issue, because you could identify patients who belong to a health system and make them accountable. But as clinicians who never had an opportunity to provide an optimal start, how do you make them accountable?

If you're at a hospital where 50 percent of your patients present at the ED, how do I as an individual clinician become accountable that they did not start optimally when there was no opportunity?

So, that's what I find challenging, because I think all of us believe optimal starts are needed, necessary, and we don't do a good job. At least that's my bias. We underperform

in this. So I think we need a metric. The question is how do you make it that the people who are accountable were given the opportunity to be accountable?

So, that's my only comment. The dialysis facilities often get these 90-day periods. Now, they might tell us that's actually not enough time, but it is something. It's three months.

CO-CHAIR ANDERSON: We are really going to have to wrap up the reliability section. And so if there are some new comments or additional comments -- Mahesh?

DR. KRISHNAN: Yeah, I think we've got to keep in mind what Peter said, right? This is an integrated health system view of the world, right?

And so I think, Lorien, to your point, if we think about that, in this context, there's a lot an integrated health system could do. You know, there's great integrated health systems across the country that do community outreach to

try to get pre-dialysis.

I just think it aligns people's incentives, where we think about it from our own perspectives, whether it's the dialysis facility or the physician. But in reality, we're incentivizing the Geisingers and the Kaisers of the world to do the right thing.

So, for me, it's an aligned incentive. I just think we have to be careful about how we vote. We need to vote for the right perspective for which the measure is being construed, rather than applying our own -- because what you're describing is, if your sphere of influence is far smaller than your sphere of responsibility, how the heck do you fix that? But if you're an integrated health system, which is the nature of the measure, your sphere of influence and your sphere of responsibility are much more aligned.

CO-CHAIR ANDERSON: Okay. Lori?

MS. HARTWELL: Just to clarify, this is a process measure. So, one of the things that I believe is good about a process measure is it

helps people see who is doing well and then helps people understand that and perform.

Does a process measure always become a performance measure? Because I see right now this is just a process measure, and I think this may give the community or the healthcare systems ability to look at the leaders and say, oh wow, this is what they're doing. And I think that was the purpose, if I am not mistaken. Is that right, Dr. Crooks?

CO-CHAIR ANDERSON: Peter, I think what she was getting at is, this is a process measure, this isn't a performance outcome measure, and so --

CO-CHAIR CROOKS: Right, it measures the outcome of the process --

CO-CHAIR ANDERSON: Right, of the process, so you're right, Lori, that is what it is.

CO-CHAIR CROOKS: May I just make one other comment on specs, that it is suggested that there should be at least 50 patients within a

year's period in order to do the metric.

So, for small pediatric units and for an individual practitioner, it's not appropriate to say, you know, this year, you had 80 percent and last year you had 20 percent. There is going to be a lot of variability. So you needed a large enough denominator, and that is in the specifications.

CO-CHAIR ANDERSON: All right. I think we're going to need to look at voting on the reliability.

MS. BAL: Sorry, actually, before we start, let's discuss reliability testing, that was specifications, and then we'll vote on reliability as a whole.

CO-CHAIR ANDERSON: Okay.

MS. EVANS: So, at the performance metric level, accuracy is very good. The positive predictive value is excellent, at 0.94, and the negative predictive value is good at 0.79. So that region correctly identified true optimal ESRD starts at 11.6 times more often than

it incorrectly identified a non-optimal ESRD start as optimal, which is a very good ratio.

2,681 patients were scored for this measure from July to June of 2014, which is an adequate sample size to generate the results for widespread implementation. So it's demonstrated sufficient validity as an indicator of quality. I think that was kind of short, to the point.

CO-CHAIR ANDERSON: Any other comments on reliability testing?

(No response.)

CO-CHAIR ANDERSON: All right. Are we ready to vote?

MS. OGUNGBEMI: The Committee is now voting on reliability for Measure 2594. Reliability includes precise specifications and testing. The options are 1 for high, 2 for moderate, 3 for low, and 4 for insufficient. Voting is now open.

(Pause.)

MS. OGUNGBEMI: The results are 10 high, 10 for moderate, 1 for low, and zero for

insufficient. The measure passes on reliability. Thank you. For Measure 2594.

CO-CHAIR ANDERSON: All right. Moving on to validity. Beth?

MS. EVANS: Okay. So, there was no risk adjustment. Meaningful differences: regional rates compared to national rates show meaningful differences. Missing data rate is low.

Statistically, the calculated statistic is 29.73 with 5 degrees of freedom. This is statistically significant.

Region differences demonstrated that performance differences can be identified within the optimal ESRD start metric, and the region's results were also statistically significant from the national rate of optimal ESRD starts.

So missing data was very low. It was less than 3 percent, posed no statistically significant effect on the results. So, one interesting thing on the missing data was non-KP clinics. They did not obtain the data from them,

so that was the difference with that.

CO-CHAIR ANDERSON: Lori? Oh, sorry.

MS. EVANS: My assessment of validity was it was very good.

CO-CHAIR ANDERSON: Lori, any additional comments?

(No response.)

CO-CHAIR ANDERSON: Discussion by the Committee on the validity? Any comments, questions? Frank?

DR. MADDUX: Peter, I have a question. You, in your preface, held up the 2728 Form. At Kaiser, did you use the 2728 Form for your data, or did you use internal sources?

CO-CHAIR CROOKS: We did not use the 2728. And that has not been validated per se, but the validity check and data element check was to take what was submitted by case managers through our electronic system. And then we faxed dialysis units and said, what was the access used? And then we matched that.

So it was a more authoritative source

going right to the dialysis unit. But we didn't use 2728, and that would need to be validated, you know, going forward, if that source is going to be used.

CO-CHAIR ANDERSON: Any other comments? Questions by the Committee?

(No response.)

CO-CHAIR ANDERSON: Are we ready to vote?

MS. OGUNGBEMI: The Committee is now voting on validity for Measure 2594. Validity includes specifications consistent with evidence, testing, and threats addressed, exclusions, risk adjustment/stratification, meaningful differences, comparability, multiple specifications, and missing data. The options are 1 for high, 2 for moderate, 3 for low, and 4 for insufficient. Voting is now open.

(Pause.)

MS. OGUNGBEMI: The results are 6 for high, 13 for moderate, 2 for low, and zero for insufficient. The measure passes on validity for

Measure 2594.

CO-CHAIR ANDERSON: All right. Moving on to feasability.

MS. EVANS: Recent data has described, regarding AV graft versus fistula placement in the elderly, might recognize that the presence of a permanent vascular access versus an ideal vascular access is preferred. A catheter is preferred in certain sub-populations of all patients. This may invalidate some of the detailed criteria in this measure, with the 10 percent AV graft placement based on a single organization's results.

Also, this measure has been tracked with the regional coordinator within the Kaiser Permanente system that uses part of their connected system. With a national measure, there are hundreds of different electronic sources, and of course there is the 2728 for tracking access start, date of start, type of modality, but does not track transplant, pre-emptive transplant, and would require a definite coding system to be

identified across many dialysis centers, transplant centers, and offices.

This measure is important and could promote better health outcomes, so it's really the tracking consistency and compiling that data into that requiring more burden on the staff to collect that, and of course, not counting the 2728 Form.

CO-CHAIR ANDERSON: Lori, any comments?

(No response.)

CO-CHAIR ANDERSON: Peter, can I ask you a question? Why are you not using the CROWNWeb data? Because the 2728s are a part of the CROWNWeb, and it has all of that information. It would be very easy to extract the data from CROWNWeb, except for pre-emptive transplant, that would be the only one that wouldn't be there.

CO-CHAIR CROOKS: Right. We just haven't tried it yet. We have been put off -- I don't know if you've ever opened up the CROWNWeb site and tried to get data out of it. I don't

know that -- you know, you'd have to do a special project with Medicare, I guess, to do that.

But that's what we look forward to doing. We really do. I think once Medicare adopts this, they will be able to slice and dice it and look at it from all sorts of perspectives, including racial disparities, income groups, health plans, and so on.

CO-CHAIR ANDERSON: Because otherwise, the burden of getting the data is going to be pretty significant.

CO-CHAIR CROOKS: Right. I think that's the ultimate way to go.

CO-CHAIR ANDERSON: Okay. Other comments? Mahesh?

DR. KRISHNAN: An alternative, I don't know if you considered this, Peter, would be to use a combination of 2728 and the SRTR, the transplant registry.

I mean, as long as you can do the attribution for a population of patients, you should be able to pull that data on the back-end

from pre-existing submission systems so that the data collection burden would be almost zero.

CO-CHAIR ANDERSON: Yes?

DR. FISCHER: Just about feasability, I mean, I guess what I am struggling with, and I think this will come up with other measures, is this appears to be feasible in Kaiser, but already, you know, we have no idea about how it will be for places outside of a vertically integrated system like that. So, while the feasability at face value in Kaiser seems fine, to me, it's difficult to evaluate that in terms of endorsing a measure, considering that that will be something that will be used elsewhere.

And I am not saying that that's negative, it's just I think this comes up with other measures, and I don't know if others have a way of perhaps framing that in a way that we can make an informed evaluation of the feasability.

CO-CHAIR ANDERSON: Mahesh?

DR. KRISHNAN: I think it's a good question. I mean, if I look at some of these

similar measures in our Medicare Advantage data, for example, where it is an integrated system and all the claims are going to one place, it's definitely doable, right? I mean, anyone that takes risk should have all the claims data to substantiate this, and then you'd have to get some of the dialysis data.

But in my opinion, while it was tested in Kaiser Permanente, it would be feasible because there's other, similar measures that are used in Medicare Advantage for star ratings, et cetera.

CO-CHAIR ANDERSON: Any other comments, questions for Peter?

(No response.)

CO-CHAIR ANDERSON: Are we ready to vote for feasability?

MS. OGUNGBEMI: The Committee is now voting on feasability. This includes data generated during care, electronic sources, and data collection which can be implemented. This is for Measure 2594, and the options are high 1,

moderate 2, low 3, and insufficient 4. Voting is now open.

(Pause.)

MS. OGUNGBEMI: Results for feasability are 4 for high, 15 votes for moderate, 3 votes for low, and 0 for insufficient. The measure passes for feasability for Measure 2594.

CO-CHAIR ANDERSON: All right, moving on to usability and use.

MS. EVANS: So, the usability is reported for Kaiser in six regions. No data for wider usability. So, this rating is uncertain, unknown.

The denominator must be careful to include only new starts and not modality shifts, as that could obviously impact the results.

Potential for this to be submitted to CMS as a potential PQRS measure. Within Kaiser, it has not yet been tied to a payment program, and it's not being used by any entity for licensing or certification. Obviously, it could

be as a public reporting measure.

In Kaiser, they actually evaluate every six months, and there has been a steady trend of improvement. 47 percent increased to 57.7 percent, compared to the U.S. estimate of 35.5.

Unintended consequences is unsure, not tested, but there potentially could be surgical complications from AV fistula or AV graft surgeries, or creating an AV fistula or graft and it never being used.

And the benefits of the measure outweigh the potential negative consequences are yes. So it's not currently publicly reported, and we do know that patient education leads to informed decision-making and patient empowerment.

CO-CHAIR ANDERSON: So Peter, can I ask you a question? In terms of the patient education, how are you going to capture the data that patients are being educated as part of the optimal starts? Is there a mechanism that will be in place for capturing that data, and is that

part of the measure?

CO-CHAIR CROOKS: No, it isn't per se, but it's the result of that process.

So we set the bar and say this is what your goal is, and every other health care system is not Kaiser, and every other health system that adopts the metric will then have to figure out how do we do these processes? How do we find the patients, how do we educate the patients, how do we then taken them from making a choice to being ready? Three, I think, distinct steps.

And it's not a patient satisfaction measure, it's not a tracking their education, it's really the end stage of all of that, but then it expects -- the implication is that systems that adopt this measure will then go back and work on those processes that will improve the metric.

CO-CHAIR ANDERSON: Oh, sorry, Frank?

DR. MADDUX: I had a question, Peter, about is your intention that the measure would in a person's lifetime only be -- have one instance

of that measure? So returning from transplant back to renal replacement therapy via dialysis would be excluded?

CO-CHAIR CROOKS: Yes, at this time, it's a once-in-a-lifetime, you're only -- you only reach ESRD one time.

CO-CHAIR ANDERSON: Lorien?

CO-CHAIR CROOKS: Unless you're Lori, whose hit five times now, I think.

MS. HARTWELL: I'm an overachiever.

CO-CHAIR ANDERSON: Lorien?

DR. DALRYMPLE: And this is a question for Peter. So currently within Kaiser, is this reported more at the regional level or at the center level?

Because I know earlier you mentioned there were going to be recommendations for usability, how this gets implemented into other systems. So at Kaiser, is it currently reported regionally? Is that the level?

PARTICIPANT: Could you make your mic a little louder?

DR. DALRYMPLE: Oh, sorry.

Currently within Kaiser, is this metric reported at a regional or network level? How do you use it currently for internal QI?

CO-CHAIR CROOKS: We're using it in six different regions across the country, and the data is submitted to our Federation office, and -- and we've -- and they do the calculation and disseminate the reports.

DR. DALRYMPLE: Because I was thinking of something earlier, you said -- and I just wanted to clarify before we discuss usability, is the recommendation that this is more at -- used at a regional level or a center level or a larger health center?

Because I think some of the issues that were coming up earlier is at the very top of the measure, where it says level, it includes clinician and a number of other things. So I'm trying to reconcile that very first page with what you envision --

CO-CHAIR CROOKS: The --

DR. DALRYMPLE: -- as the best usability of this measure.

CO-CHAIR CROOKS: So you're -- you're addressing the level that this measure intended to be used at?

DR. DALRYMPLE: Yes.

CO-CHAIR CROOKS: And, you know, when you're clicking -- when you're doing these forms, there's check boxes for some of these, and so they come out in the order they come out in.

You know, my preference would have been that the top level, this is oriented towards the large payers: CMS, large insurance companies, integrated health care systems.

Now large nephrology groups will want to look at their optimal starts. FMC has a very creative program where they put a case manager in with a large nephrology practice, and in fact, they're measuring a metric that is almost identical to this optimal starts. I am just glad I got it here before you guys did because -- you know.

So nephrologists will want to know how they're doing and how they're participating in the system. So I think it is a clinician level, but not the single clinician, not -- if you only start 30 patients on dialysis in a year, it doesn't mean -- but it's within the larger health care system that it matters the most.

CO-CHAIR ANDERSON: Dodie?

DR. STEIN: Thank you. I am going to bring up this education issue again because it bothers me.

It seems to me that this is the assumption underlying whether this measure is going to be effective or not, and I understand that Kaiser is its own system and can build that in and build it in effectively, but I am concerned about the rest of us and the rest of the world.

And especially because you can deal with education, and then there's effective education, and the kinds of emotionality that we see with patients during education, and that's

going to affect when they get to dialysis and how they get to dialysis.

I am -- I am just concerned that there is not that component that's specified and clarified on this.

CO-CHAIR ANDERSON: Yes, it -- this is more for Committee discussion, so Michael?

DR. FISCHER: I just wanted to go back to the level of analysis because philosophically -- and perhaps I'm incorrect, that you choose the analysis about how you want to incentivize quality.

Meaning some things probably require a facility-level policies to improve performance in an area, others perhaps it's individual provider/physician performance.

So going back to this measure, that's why ---- maybe I just wanted to ask Peter, I guess, in terms of envisioning it, I thought when I read this that this was a provider physician-level measure. It seems like in the preceding discussions, that's not as clear, but I wanted to

ask him, you know, in terms of using this measure to promote quality, is it really targeting physician-level practice, facility-level practice, and if so, what -- what really is the -- the level of analysis that it's targeting?

CO-CHAIR CROOKS: Yes, as I mentioned twice in my presentation, this is not intended for dialysis facility use, and it's aimed at the broader health care system, and you know, it takes a village sort of thing, you know.

This -- we, in our practices, think so much on the ground and what we're doing today, but there is a whole health care system around us that we are part of -- we respond to, and the responsibility for this is shared between all the -- all the entities: the payer, the providers, et cetera. Keeping my answer brief. Thank you.

CO-CHAIR ANDERSON: All right. Ishir?

DR. BHAN: So I very much agree with that sentiment.

I guess the question is when we're voting on this, are we voting taking in -- that

into account, or are we voting based on what's listed in the documents here? That's what's unclear to me.

CO-CHAIR ANDERSON: You should be voting what's on -- what's listed in the documents. This is -- and actually we have too many mics on -- but we, I mean, the measure -- your vote is on, you know, the current usability and use, how it has been presented in the documents versus how it might be used in the future.

DR. BHAN: Okay. And the sponsor has the opportunity to revise the -- this.

So I guess my -- my comment would be that if we feel that the individual clinician level feels out of place to us, then my suggestion would be to give that feedback and allow the revision of the document.

CO-CHAIR ANDERSON: Yes, in that case, what we would do as staff is we'd make sure that that's one of the notes in the overall report.

Not necessarily that the measure would

need to be revised, because again, the other thing that the developers have to do is bring in front of you, through these forms and their presentations and responses to questions, the actual level of analysis that they used in the testing and the development of the measure.

So you know, even though, you know, there's a form or we know that the data is in CROWNWeb, et cetera, that's not -- we're not -- you're not endorsing it for use in a specific area.

DR. GREENSTEIN: I'm just curious, how do you handle those patients who are in your data analysis who are -- you know, when you capture the data, there are patients who adamantly refuse fistulas and grafts and only want a hemo catheter.

CO-CHAIR CROOKS: They're non-optimal starts, and, you know, we refuse to believe that no is really no.

You have to kind of -- if you're having a high rate of denial, then, you know, you

need to think about, you know, is there other ways to get at that? Patient advocates and so on.

CO-CHAIR ANDERSON: Frank?

DR. MADDUX: I'd like to just make a comment to Dodie's question and comment.

And I think ---- the way I look at it, my perspective is that the education aspect is -- is one subsystem process that this particular measure, in my mind, is above that level, because not only do you have to educate people, but you then have to have action after that that leads towards some decision or some surgery or some other preparation.

And so it's, you know, as a -- as a process measure, it's really a system process assessment and outcome. And education is certainly a part of that, but I don't think inside the measure you need to get the sub-components sub-measured. If we need a separate measure for education itself, I would say we -- that's a different question.

CO-CHAIR ANDERSON: All right. I think we're running out of time, and so if -- sure, John?

DR. WAGNER: Sorry, I just -- I want to clarify something.

So is it not our concern that this measure could be applied to other-than-integrated health care delivery systems because the data are presented in terms of usability with respect to an integrated health care delivery system, so we don't need to get involved in those kinds of details?

MS. SAMPSEL: Correct. I mean, really, this measure is coming before you as endorsed as the way that it was presented, and should somebody else want to use it in another way, we don't control that. NQF doesn't control the use of the measure.

CO-CHAIR ANDERSON: Okay. We will be voting on usability and use.

MS. OGUNGBEMI: The Committee is now voting on usability and use for measure 2594.

That includes accountability, transparency, reporting within six years or, if new, a credible plan, and improvement, as well as benefits outweigh evidence of unintended negative consequences.

The options are 1 for high, 2 for moderate, 3 for low, and 4 for insufficient information, and voting has now opened.

(Pause.)

The results are: four votes for high, 11 votes for moderate, three votes for -- six votes for low, and zero for insufficient. The measure passes on usability and use for 2594.

CO-CHAIR ANDERSON: We do have some related and competing measures which will follow later, after we do the final vote on this measure.

Any other general comments, discussion by the Committee?

Yes, Alan.

DR. KLIGER: I just want to remind all of us that we're voting on all of the

specifications the way they're written on the sheet.

CO-CHAIR ANDERSON: That is correct.

All right. I think we are ready to vote on whether to recommend the measure as suitable for endorsement.

MS. OGUNGBEMI: The Committee is now voting on overall suitability for endorsement: does the measure meet NQF criteria for endorsement?

Voting is now opened. The options are 1 yes, 2 no.

(Pause.)

The results are 17 votes for yes, three votes for no. The measure passes for endorsement, that's measure 2594.

MS. BAL: Okay, so we'll move on to the next measure, but I just wanted to call the developer, they'll be on the phone.

See if the developer could -- not the developer, Cathy, could you make sure that Robyn Nishimi is on the phone?

THE OPERATOR: She has disconnected.

MS. BAL: Oh okay, never mind, actually, she is not going to be on the line.

CO-CHAIR ANDERSON: Oh, okay. So the next -- next measure is 0251, the vascular access measure, and it's Lisa, and Robyn dropped off.

DR. MCGONIGALIGAL: Okay, I am Lisa McGonigal with the Kidney Care Quality Alliance, which is a coalition of patient groups, providers, health care professionals, and suppliers working together in kidney care, trying to improve quality.

We are very pleased to be here to discuss our vascular access measure with the Standing Committee. Thanks for having us.

The measure is NQF 0251. This is a clinician-level measure. It was first endorsed in 2007, re-endorsed in 2011, and now it's -- it's up for consideration again.

The measure assess the percentage of adult ESRD patients on chronic hemodialysis who have either a functional AVF or an AV graft, or

they have a catheter but were evaluated for a permanent access at least once during the 12-month reporting period of the measure.

So the intent of the measure is to reduce the frequency of vascular access-related complications and to improve patient survival by promoting AVF and/or AV graft placement.

Supporting evidence for the measure. As we noted in the documents, the measure stems from KDOQI's 2006 guideline update for vascular access. We note that in addition to recommending fistulas as the preferred access, the guideline also specifically notes that the Fistula First's at-all-costs approach may not be the most cost effective or optimal for each individual patient and that an AV graft is an acceptable alternative to fistulas in some patients.

So the KCQA vascular access measure is unique and advantageous in two regards. First of all, as I just mentioned, the measure recognizes the fact elucidated in the KDOQI guideline that AV grafts are the more appropriate permanent

access in certain patients, and so the measure gives credit for both AVFs and AV grafts.

Second, the measure recognizes that clinical circumstances can and sometimes do change over time, and that some patients who were previously not candidates for permanent access may be able to support a fistula or a graft at a later date.

The measure thus encourages an annual evaluation by a vascular access specialist as defined in the measure specifications, and the specialist is to reassess patient status so as to further maximize permanent access placement and to minimize catheter use.

So we do acknowledge, as pointed out in a pre-meeting comment that we received, that the evidence supporting the measure doesn't specifically address the inclusion of this evaluation component of the measure. There is no published literature addressing this issue that we can turn to in this instance.

However, the process does have face

validity. It was the consensus that both our clinical experts and patient representatives within KCQA that this aspect of the measure is of vital importance for the reason that I just stated, to assess and reassess the patient appropriateness and readiness for permanent access so as to minimize catheter use, and to use AVFs and AVGs to the greatest degree possible.

As noted in the documents that were submitted to NQF, the measure has been tested in both dialysis facilities and nephrology offices, and it was found to be both highly reliable and valid in both settings.

And finally, I would like to address one additional issue that was brought up in pre-meeting comments that we received that the measure has not yet been in use since it was first endorsed. We do acknowledge that this is a weakness, and we note that at the time the measure was tested, it did rely on CPT codes to capture the surgical evaluation component.

However, there has been subsequent

release of vascular access G-codes that are now included in the measure's microspecifications, and this data element can be more easily captured, and it significantly increases measure feasability.

Secondly, CVS -- or CMS, I am sorry, convened an ESRD Vascular Access Technical Expert Panel just late last month to evaluate the existing NQF-endorsed vascular access measures that CMS uses in its programs, the QIP and the DFC 5-Star Program.

The KCQA vascular access measure was included in the TEP's deliberations, and the output of these deliberations are anticipated in the fall of this year, so we should have information on that before too long.

And I'll stop there to try to keep it close to the three minutes.

CO-CHAIR ANDERSON: Thanks, Lisa.

All right. Our two discussants are Karilynne and Jessie, and we'll start with evidence, and --

MS. LENNING: Okay, we're going to tag-team this here, the dietitian and the social worker doing vascular access.

So we are thrilled to be part of the Committee, and thank you very much to the developer for doing a nice, thorough introduction of your measure as well.

The evidence you speak to -- KDOQI being the basis of your evidence, is there -- I don't have anything in addition. Jessie, do you, regarding the evidence?

MS. PAVLINAC: Only that they did describe, unlike some other ones, that the KDOQI grade was grade B, and went through that process pretty thoroughly.

CO-CHAIR ANDERSON: Can you turn your mic on?

MS. PAVLINAC: Sorry. Okay. Don't mind us.

Because it is KDOQI, it is -- their process does lead down the path to moderate based on the algorithm.

And we're trying to keep it quick. If you want us to be more specific, we can, but given the hour, we thought we'd do this quickly.

CO-CHAIR ANDERSON: Well, I think the KDOQI has been the evidence, and also all of the Fistula First initiatives, and they are at a grade B, right? Any discussion, comments?

Stuart?

DR. GREENSTEIN: I just have a question: how do you define vascular access complication? Are you just referring to hemo catheters and infections, or complications relating to fistulas and grafts, which can be also present, and how do you follow them/track them?

DR. MCGONIGAL: Well, the measure actually doesn't follow complications. We are just looking at the degree of placement, so we don't specifically define that.

DR. GREENSTEIN: But the rationale is because you want to decrease the complications, so --

DR. MCGONIGAL: Yes, yes, absolutely, so infections --

DR. GREENSTEIN: -- if you can't track them, how do you know if you were truly doing that?

DR. MCGONIGAL: Based on the evidence that currently exists that catheter placement is associated with a high degree of complications, infections --

DR. GREENSTEIN: Right, so --

DR. MCGONIGAL: -- is the one that comes to mind.

DR. GREENSTEIN: -- you're looking only at the complications related to catheters, not related to fistulas and grafts, which can also be --

DR. MCGONIGAL: Absolutely.

DR. GREENSTEIN: -- fairly common, given that, you know, you can put a fistula in somebody and it will take them nine months before it can be used and they're getting ballooned constantly or thrombosed and things like that,

and the same thing for grafts.

DR. MCGONIGAL: Right, right, right --

DR. GREENSTEIN: I just bring that up because I think one of the problems that we have in a lot of the things that are being developed is that we don't -- we don't look at the other side of the coin, and that is that there are complications in fistulas and grafts, and we don't track them well at all.

DR. MCGONIGAL: Absolutely, and so the issue is the -- the evidence that exists right now ---- basically there is the tiered preference: the fistulas are the primary choice, followed by grafts, then catheters. Catheters are still known to have the highest complication rate.

The beauty of the measure is that it does allow grafts as well. So if someone is unable to support a fistula, there is that. You could have a graft as you're maturing your fistula, and we do have the re-evaluation component.

So there is there the rare patient that was mentioned in the last discussion who maybe can't support either, or your patients who are in hospice, or your patients who have cancer, elderly patients who really can't support them. So in those instances, they may actually need a catheter, but as long as they're reassessed and that is determined to be the case, you get credit for the measure.

CO-CHAIR ANDERSON: And also from a provider's standpoint, you are looking at thrombotic episodes for AVF/AVG, you're looking at infection rates for AVF/AVG, and you do also report that through the NHSN Safety Network. So those are part of the MAT that are required to be reviewed through QAPI, at least at the provider level, so the data is there.

DR. GREENSTEIN: Do you know if they tracked at all the stenting? Many times, fistulas or grafts will get stented higher up.

And actually, having been doing this for 25 plus years already, from the transplant

side, I am seeing more and more patients who have central vein occlusions, and that's because they are getting constantly manipulated up there and stented, and I think that kind of complication is worse than some of these other complications we tracked.

CO-CHAIR ANDERSON: Right, yeah, I don't think -- I don't think they are. I am sure they're not.

MS. LENNING: I have a comment from a social work perspective.

The one piece that I really picked up on in this measure is that it did allow the flexibility, it seemed to meet the numerator based on what was best for the patient.

DR. DALRYMPLE: So I was hoping just for broader Committee discussion on the issue of the numerator as it relates to the evidence and this issue of does evaluation by a vascular surgeon or other qualified surgeon in the last 12 months deserve equal weighting to having a fistula or a graft, and does the Committee think

evidence supports the numerator as specified that way?

I think the intent is clear, I am just curious about the Committee's view on the evidence before we vote.

CO-CHAIR ANDERSON: Alan?

DR. KLIGER: Before going to my question, I thought it might be more appropriate to seek responses to Lorien's question.

DR. DALRYMPLE: So I'm just curious, the Committee at large, how people perceive that with respect to evidence in its current state.

I think the intent is understandable. My question is more the evidence --

CO-CHAIR ANDERSON: Michael, do you have -- ?

DR. SOMERS: I agree with what you just said.

I think, you know, the evidence that is presented for -- for this measure supports AVF, but really, it doesn't address all the complex factors that may go into the impact why

you may end up with an AVF or not with an AVF, so I don't think the evidence necessarily supports, you know, what they're trying to get at here.

DR. LATTS: So I'm -- I don't know the clinical evidence beyond what's presented here, but I guess my take on it is that in an era where we're trying to get to more shared decision-making and more weight on patient choice, the ability to have met with a vascular surgeon, discussed the pros and cons of a particular approach, and then taking the patient preference into account, because I think that's what this represents, is incredibly important.

DR. DALRYMPLE: Do you think it's potentially an easy out?

DR. LATTS: I think it's appropriate, and I think to take it out would be to disregard patient preference to some degree.

CO-CHAIR ANDERSON: Alan?

DR. KLIGER: So I want to respond but also ask my question.

Just a point of clarification: is this

measure identical to the last, or were there any adjustments or changes made from the last version that was passed three -- or whatever, four years ago?

DR. MCGONIGAL: The change -- from when it was initially endorsed in 2007, there were actually two separate measures. There was an AV fistula and an AV graft measure.

The NQF Standing Committee at that time actually advised that we put them together and make it into a compound measure. They also advised that we change the -- it was initially a referral measure, and they recommended that it be a seen evaluation measure as well.

And since the last re-endorsement, we have included in the G-codes because they do sort of help capture that evaluation component a little more clearly.

DR. KLIGER: So -- so that's helpful.

Last time around, again, we were really concerned, as I remember, with making sure that patient choice and patient-informed choice

was part of the measure, and having clear evidence, not only of a referral to a vascular surgeon, but an assessment and discussion with the patient by a vascular surgeon was the component that we felt helped in -- in the pursuit of endorsing patient choice.

So my own opinion is that yes, in one sense, it's an easy out if you look at it from the standpoint of ways of accommodating that need, but from the standpoint of the patient, I think that this is an appropriate measure.

CO-CHAIR ANDERSON: John?

DR. WAGNER: So I'm just curious, if one sees an interventional nephrologist to have one's catheter replaced in the prior year, does that count as within the measure specification as being someone who has now seen an interventional nephrologist?

DR. MCGONIGAL: Yes, it counts. There should be an accompanying reason why they cannot support it, the patient needs to be documented as not being able to support a permanent access.

I'd also like to also note that the easy out part of the discussion, we -- we like to think that the measures that are being used right now sort of do complement each other, and so some of the outcome measures out there will -- if someone is taking a constant easy out to just keep catheters in, their mortality and their hospitalization rates are going to be higher, so we like to think of the measures as complementing each other as well. So I just wanted to bring that up.

CO-CHAIR ANDERSON: Frank?

DR. MADDUX: To Lorien's comment and question about evidence, I think when you have these composite measures that have really been combinations of narrow things you could do, it's going to be very hard to have a uniform body of evidence across that, and I certainly think the evidence on the -- on the vascular side for AV fistulas and grafts is stronger than the evidence on the impact on quality from a referred and assumed visit with the -- with the vascular

surgeon for reassessment.

But I think if we don't allow there to be some variability of evidence in these composite measures, we'll never get composite measures, and so that is one of the challenges we have to just make individual decisions on.

CO-CHAIR ANDERSON: Lorien?

DR. DALRYMPLE: Quick clarification though, we are allowed to vote insufficient evidence with exception, correct? So it doesn't stop a measure if there is insufficient evidence, it's just a way of appraising it, is that correct?

MS. SAMPSEL: Correct.

DR. DALRYMPLE: Okay.

CO-CHAIR ANDERSON: Okay. I think we are ready to vote on evidence.

MS. OGUNGBEMI: The Committee is now voting on evidence: structure, process, and intermediate outcome measures.

The options are 1 for high, 2 for moderate, 3 for low, and 4 for insufficient, and

this is for measure 0251. Voting is now open.

Results for evidence are 2 votes for high, 14 votes for moderate, 1 vote for low, and 5 votes for insufficient evidence. The measure passes, measure 0251 passes for evidence.

CO-CHAIR ANDERSON: All right, moving on to performance gap.

In relation to performance gap, on our evaluation forms, there were numerous notations regarding gap in performance with fistulas, grafts, and catheters. In part of our discussion this morning, we have already brought that up as well.

MS. PAVLINAC: So this was interesting that it was -- in 53 dialysis units, they did for-profit and not-for-profit, they had 1057 dialysis patients in their sample size and showed a significant performance gap.

I rated it moderate.

CO-CHAIR ANDERSON: Any further discussion, comments?

All right. We're ready to vote on

performance gap.

MS. OGUNGBEMI: The Committee is now voting on performance gap for measure 0251. The options are 1 high, 2 moderate, 3 low, and 4 insufficient. Voting is now open.

The results are 3 votes for high, 18 votes for moderate, 1 vote for low, and 0 votes for insufficient. Measure 0251 passes on performance gap.

CO-CHAIR ANDERSON: All right, moving on to reliability.

MS. PAVLINAC: So under -- excuse me -- specifications, it is a process measure, and it is not risk-adjusted or -stratified.

The difference between the two previous times this measure, in various forms, was presented is the availability of the G-codes.

MS. LENNING: I don't have anything to add to that.

CO-CHAIR ANDERSON: Any comments by the Committee, any further discussion or questions?

All right --

DR. DALRYMPLE: Can --

CO-CHAIR ANDERSON: -- we are ready to vote.

DR. DALRYMPLE: -- I have a quick clarification?

CO-CHAIR ANDERSON: Oh, sorry.

DR. DALRYMPLE: Is there any intent to use CROWNWeb for this? Can you remind us on that issue please?

DR. MCGONIGAL: Yes, the -- the measure is actually a clinician-level measure, but it was specified and it was tested such that it could be used within CROWNWeb or either data collected administratively or --

DR. DALRYMPLE: But does CROWNWeb have a field that captures the vascular surgeon evaluation within the last 12 months?

DR. MCGONIGAL: I am not entirely clear on that. I understand that they can capture the G-codes, but I am not sure right now if they have that incorporated in or not.

CO-CHAIR ANDERSON: They don't. To my knowledge, CROWNWeb does not have that field in there.

DR. KRISHNAN: With that being said, in the CROWNWeb users group, we are always -- CMS and us are always thinking about what measures need to be put in, so for example, we're now doing the microspecifications for the depression and pain screening which were not there in the past, but the data collection system could support that as long as it was collected in the dialysis unit.

MS. LENNING: All right. Are we ready -- do we also need to discuss reliability testing, do we talk about that now too or not?

This measure also did have reliability testing within the physician office groups, inter-rater reliability as well.

CO-CHAIR ANDERSON: Josh?

DR. ZARITSKY: So I am sorry if I missed this, but just remind me, for that numerator, for the patients that go to the

referral, what is your proposed mechanism of tracking that?

DR. MCGONIGAL: When we tested it, we used CPT codes. Now, there are G-codes available that capture whether the fistula was placed, an alternative access was placed, and a rationale for why a fistula was not placed.

DR. DALRYMPLE: So there is a G-code, sorry, that captures that an evaluation occurred even in the absence of access being placed, is that correct, that --

DR. MCGONIGAL: That is my understanding, yes.

DR. ZARITSKY: So how frequently -- how -- I just have no, you know, I have never filled out the G-code there because I am not a vascular surgeon, how frequently are these utilized, these G-codes, what is the evidence for them being used? I am just addressing this numerator, because this is an important part of your proposal is including this group of patients, and I just want to make sure that they

are somehow captured in a meaningful way.

DR. MCGONIGAL: Yeah, my understanding is within -- particularly within PQRS, they are now turning almost exclusively to G-codes to capture their numerators. I am not sure exactly -- they're working this in right now, so I am not sure how far along they are.

And again, as Mahesh pointed out, if it's determined to be appropriate, it is something that could be worked into CROWNWeb as well.

DR. GREENSTEIN: Doing this procedure for the last 27 years, I don't even know what the G-code is. I don't think they track it in my place, so I wonder if -- and I'm at an academic institution, I wonder how many other places have the same problem, that they don't track that, because I don't know what it is even.

DR. MCGONIGAL: And I'm assuming you do use the CPT codes to capture the -- ?

DR. GREENSTEIN: The biller does, yeah. I mean, I just mark down office visit and

x, y, z, and that's it, you know.

DR. MCGONIGAL: Yeah, that's with the administrative data, the CPT codes are included in there as well. So any way that we can capture it, it's been included into the specifications so there are multiple roots that get at the information.

CO-CHAIR ANDERSON: All right, I think we're ready to vote on reliability.

MS. OGUNGBEMI: The Committee is now voting on reliability.

The options are 1 high, 2 moderate, 3 low, 4 insufficient. This is for measure 0251. Voting is now open.

The results are as follows: 2 votes for high, 14 votes for moderate, 5 votes for low, and 1 vote insufficient. This is for measure 0251. The measure passes for reliability.

CO-CHAIR ANDERSON: All right. Moving on to validity and validity testing.

MS. PAVLINAC: Yes, validity. Chart validation results showed high validity for

sensitivity, specificity, positive predictive value, and negative predictive value. There were no exclusions to this measure, and there is no risk adjustment.

There was a meaningful difference that was defined as a significant spread of greater than 20 percent between minimum and maximum scores. The performance for each individual facility in the pilot ranged from 41 to 100 percent, with a mean of 93.8 percent in those 53 facilities.

CO-CHAIR ANDERSON: Karilynne, any other comments?

MS. LENNING: It just seemed like on our work group call, this was also where the G-code discussion came up again, where we had a lack of any evidence or data, you know, because they are so new, I just remember that discussion as well.

MS. SAMPSEL: So let me just comment on that because staff was doing some research on this as well, and so basically, the way that

these measures can currently be reported are through PQRS, and so PQRS is well-established, and physicians are able to report CPT and G-codes based on once they're in the system.

As already mentioned, those measures -- you know, the G-codes are -- they morph as the PQRS measures get developed, get added into PQRS, but they have been tested and are well-utilized.

When we looked at the last year of kind of summary reports for PQRS and ability of nephrologists to report on the measures, only about 20 percent of qualified nephrologists are reporting on PQRS.

You know, that's not necessarily an indication of able-to-report or not, that's more of an indication are they reporting or not, but you see that number coming up. They're just not really in the -- nephrologists really just aren't in the top 10 of those participating in PQRS right now.

So, you know, I guess just really kind of talking about capturing of the data and able

to capture the data, it's institutionalized now across PQRS measures.

CO-CHAIR ANDERSON: John?

DR. WAGNER: It's talking about nephrologists or vascular surgeons with respect to that?

MS. SAMPSEL: I mean, so vascular surgeons didn't show up anywhere in PQRS in the top 20, so all I can tell you is when talking about renal specifically and looking for these measures, you know, there are a number of renal measures in PQRS. Only 20 percent of nephrologists are, so you have to make some conclusions.

CO-CHAIR ANDERSON: Lorien?

DR. DALRYMPLE: So with respect to the PQRS issue, those that are reporting, do we know the accuracy of that reporting around these new G-codes, I guess is my question? Just because they exist doesn't mean they are being used correctly.

MS. SAMPSEL: I don't think that we

know about specifically these codes other than the fact that, you know, it's the same process used to develop any G-code and test it for any G-code when it goes through those AMA committees in establishing the coding structure.

DR. DALRYMPLE: So just so that we have a good understanding, at least that process ensures some testing to make --

MS. SAMPSEL: There is some very rigorous standards codes have to go through to be approved by something called -- I think it's called the PUG, and don't ask me what the PUG stands for, but, you know, it's another acronym that goes through an entire clinical review as well as coding review.

CO-CHAIR ANDERSON: We would like to try and get through this measure before the public comment period, which is in a couple of minutes, so I would like to call for the vote on the validity testing.

MS. OGUNGBEMI: The Committee is now voting on validity. This is for measure 0251.

The options are 1 high, 2 moderate, 3 low, and 4 insufficient. Voting is now open.

The results are 1 vote for high, 15 votes moderate, 3 votes low, and 3 votes for insufficient. Measure 0251 passes on validity.

CO-CHAIR ANDERSON: All right, moving on to feasibility. Jessie or Karilynne?

MS. LENNING: Feasibility we've talked a lot about already and being able to capture those data elements through CROWNWeb or using the G-codes --- excuse me --- or the CPT codes. So it appears feasibility would be high.

CO-CHAIR ANDERSON: Jessie, any comments?

Any questions or comments on the part of the committee? Can we vote on feasibility?

MS. OGUNGBEMI: The committee is now voting on feasibility for measure 0251. The options are 1 high, 2 moderate, 3 low, and 4 insufficient. The voting is now open.

The results are 6 votes for high, 15 votes for moderate, 1 vote low, and zero votes

insufficient. Measure 0251 passes on feasibility.

CO-CHAIR ANDERSON: All right, moving on to usability and use.

MS. LENNING: This particular measure currently is not being used, but there are plans for it to be used in public reporting and payment program, and also planned for use in quality improvement with benchmarking -- with external benchmarking to multiple organizations and planned for use in quality improvement as well.

CO-CHAIR ANDERSON: Andy?

DR. NARVA: Yes, I just wanted to ask Lisa a question.

You envisioned this being most useful in combination with other outcome measures, so if we have those outcome measures, what do you see this adds to them?

So, I mean, it sounds like an outcome measure is --

DR. MCGONIGAL: Yes, that -- oh, I am sorry -- that is not exactly what I -- I meant or said --

DR. NARVA: Okay.

DR. MCGONIGAL: -- basically, I am saying that when the measures are used in tandem, as they are a lot in the QIP, that they do provide a nice balance for each other, so it helps prevent that gaming the system, which is a word I hate to use, but it does help prevent that, as someone suggested that perhaps someone could just always check the box and say that catheters were done.

So I am not saying to envision it in tandem with any particular outcome measure, I am just saying that that's sort of a way of preventing the gaming.

CO-CHAIR ANDERSON: All right, are we ready for the vote for usability and use?

MS. OGUNGBEMI: The Committee is now voting on usability and use for measure 0251.

The options are 1 high, 2 moderate, 3 low, 4 insufficient. Voting is now open.

The results are 4 votes for high, 16 votes for moderate, 0 votes low, and 2 votes

insufficient. The measure 0251 passes on usability and use.

CO-CHAIR ANDERSON: All right. So now, we will be voting on whether to recommend the measure as suitable for endorsement.

MS. OGUNGBEMI: The Committee is now voting on measure 0251, overall suitability for endorsement.

The options are 1 yes, 2 no. Voting is open.

The results are 19 votes yes, 2 votes no. The measure passes suitability for endorsement.

DR. MCGONIGAL: Thank you.

CO-CHAIR ANDERSON: All right. We will now open up for public comment.

THE OPERATOR: At this time, if you would like to make a comment, please press star, then the number 1.

At this time, there are no public comments.

CO-CHAIR ANDERSON: Is there anyone --

anyone in the room that has comments?

MR. DIAMOND: So I am Lou Diamond, speaking for myself.

Just a couple of comments. I obviously stand between you and lunch, which is probably better than standing between you and a -- laid off and a gin and tonic, so I am in good shape.

So first, just three quick comments, if I could. One is, as an outside observer sitting at the back here, the structured process that you used for voting was in fact very helpful. I am not sure whether this has been used before, but it was very helpful.

I do observe that it appeared to me at least that you -- you should have been voting, or you are voting, on the measures as submitted and specified in the documents before you, and I think Alan made that comment, and I observe anecdotally that the -- in my own opinion that some of the voting was not congruent with some of the discussion you had about some of the concerns

with the measures, so it might be kind of helpful to look at that because the distinction between voting on what you think the measure should look like based on your discussion is different from voting on the actual measure as specified.

I am aware that we are at the beginning of a process, so the measure can be modified by the developer going forward, which obviously will occur based on the discussion and the personal comments.

The second comment I wanted to make is I thought that, Sarah, the -- the summary you provided at the beginning of the meeting, and I am not -- it was very helpful.

I am not sure what the full scope of the Committee is in terms of what you can or cannot do, but you spoke there about urging the Committee to take a "holistic" approach to the overarching issue that is on the table, which is measures for the end stage renal disease patient population and -- and the providers.

I do think it would be helpful in the

future, and you may have already done this, and maybe in your briefing books, to display -- display the measures against the -- the national priority strategy domains so you can get a sense of which measures are in fact mapped to those domains.

It would also be helpful to be able to map the measures that you're looking at against the measures that are currently in use in various programs.

And thirdly, and I think very importantly, and this Committee could play a role in that, map the measures in terms of facility-level versus physician measures in terms of the domains that they are actually tackling, because the ESRD program is in very -- in some respects very unique in terms of physicians and facilities working so closely together, and yet having distinctly different -- well, not distinctly different measures, but they have different measures, certainly differently specified and sometimes in different domains. And some kind of

alignment and harmonization of that would be helpful if the Committee could actually tackle, that to kind of figure out how you would do that.

My last comment, and I did speak offline to Peter on that, I thought the discussion on the -- what is it, the Optimal End Stage Renal Disease Starts was a fascinating discussion.

Let me say up front, this is an incredibly important measure. There is no debate about that.

I came away, as an outsider, totally unclear about what the level of analysis was for this measure. There was a lot of discussion about this being a PQRS measure, which is a physician-level measure, and then there was a discussion -- and in fact some discussion that it was going to be loaded into perhaps in the future in the RPA Registry, which is in fact a physician-level registry at the moment. Hopefully it will be changing in the future.

And then there was discussion that

this was at the -- at the organizational level, and those are two distinctly different kind of levels of analysis.

And then there was a lot of discussion about feasability, and yet you guys -- and some concerns about the feasability, and yet you guys voted in favor of -- of feasability.

And finally, relating to that, it does seem to me that the question of optimal starts, end stage renal disease starts, really has to deal fundamentally with looking at some measures of shared decision-making in addition to the outcome because that's going to be kind of important going forward.

So thank you for allowing me to comment.

CO-CHAIR ANDERSON: Any other comments?

Well, do you want the good news or the bad news?

The bad news is our lunches are stuck downstairs because the elevators are out, so what

we'd like to do -- which Poonam just informed us -- so what we'd like to do is keep going on the measures until the elevators work and we can get our lunch up here.

So if you don't mind, we'll just move on to the next measure, which is 0256, and it's Claudia and Joel for the developers.

DR. DAHLERUS: All right. Okay. So we're going to start.

We have two paired vascular access measures for CMS.

So the first one is measure 0256. It is a facility-level intermediate outcome measure which reports the percentage of adult patient months on maintenance hemodialysis for patients on maintenance hemodialysis during the last treatment of the month, and that have a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session.

Catheter rates have been decreasing since the Fistula First Initiative launched in 2003. Based upon data from the CMS Fistula First

breakthrough initiative, a gradual trend has been observed towards lower catheter use among prevalent maintenance hemodialysis patients in the United States, declining from approximately 28 percent in 2006 to 24 percent by May of 2007.

Furthermore, the percentage of maintenance hemodialysis patients using a catheter for greater than 90 days has declined over this time from 12 percent to approximately 9.5 to 10 percent, which is something that we reported in our testing in our submission.

Lower mortality has been observed in many studies, with reduction in catheter use and an increase in fistula use in facility- and patient-level studies.

The goal of the catheter measure as paired with the fistula measure is to continue encouraging further reduction in chronic catheter use.

The measure was originally developed in 2006 by a clinical TEP, citing among the evidence and guidelines the 2006 update of the

KDOQI Vascular Access Clinical Practice Guidelines. It was originally endorsed in 2007 and retained endorsement in 2011.

In response to community concerns about unintended consequences of promoting fistula use over catheter use and relative to graft use, and that there may be circumstances when facilities should not be penalized for prolonged catheter use, we on behalf of CMS convened a Vascular Access Technical Expert Panel that just met late last month to consider these two paired measures in order to recommend potential revisions to the measures that would address these concerns.

As was noted earlier, the TEP recently met, and we are currently working on the report of the TEP deliberations, which will be released later this summer, so we really cannot go into specific recommendations.

However, the general consensus among the TEP members was that chronic catheter use should continue to be discouraged.

We tested the catheter measure using calendar year 2013 CROWNWeb data. We are also able to calculate the measure using Medicare claims. And the testing involved approximately between 5600 and 5900 facilities.

And so I think we'll just end our opening statement there.

CO-CHAIR ANDERSON: All right. We have Stuart and Jessie as reviewers of the measure. I don't know of Jessie or Stuart, who would like to go first?

DR. GREENSTEIN: Sure, I'll take it. So in terms of the evidence, there were numerous articles that -- since the last few, that support the concept that decreasing use of catheters leads to improved survival rates for hemodialysis patients, and it's a direct measure. It's an outcome measure that shows that you have improved survival rates, and there's evidence to that. It's important.

CO-CHAIR ANDERSON: Jessie? No comments?

All right. Any further discussion on the part of the Committee? Alan?

DR. KLIGER: I guess I am just a little confused in that the measure is being asked to be re-upped again, but we have no data since 2007. Is that correct?

DR. DAHLERUS: No, that's not correct. We were just citing the trend, the decreasing trend which had included data up to 2007. When we did our testing, we used calendar year 2013 CROWNWeb data.

DR. KLIGER: What's been the trend since the last eight years?

DR. DAHLERUS: So the current national performance rate is at approximately 10 percent.

DR. KRISHNAN: Ten percent catheters?

DR. DAHLERUS: Yes, 10 percent catheter rate.

DR. KRISHNAN: I'm looking at Frank, Frank is looking at me --

DR. DAHLERUS: Greater than 90 days.

DR. KRISHNAN: It's a little low. I

mean, between Frank and I, that's two-thirds of the country. We're not at 10 percent. We're at 13 percent.

DR. DAHLERUS: Well, that's -- again, that's what we're reporting with the CROWNWeb data. We can -- we can look it up again.

DR. MADDUX: Either way, though, I think it's representative that there has been a vast improvement, as is described, and there is still room for improvement.

But there's probably a limit to the level --

CO-CHAIR ANDERSON: It could be a problem with CROWNWeb data too, in terms of especially with access, and so it could be with the extraction of the data, that's why there is a discrepancy. I mean, I agree with you. Our data doesn't show that either, so --

DR. MADDUX: So it strikes me there are a couple of things here that I think are really important as this remarkable reduction that has occurred since the mid-2000 period, the

rate of that reduction is clearly going to hit some asymptotic level, and nobody knows exactly where the delimiter is on that, so -- .

DR. GREENSTEIN: Well, I think that what is going to happen is that as these patients get dialyzed, go for transplant, come back on dialysis, you are going to see that they will end up with more and more catheters and that we will reach a bottom where we won't be able to go below that number. I would think 10 percent is not bad, actually.

CO-CHAIR ANDERSON: Any other discussion or comments or questions?

Yes, Claudia?

DR. DAHLERUS: So I just wanted to sort of clarify a response to you, Dr. Krishnan.

So the calculation of the national rate is defined, and it's reported in the DFR, and it's using the definition based on -- it matches Fistula First, so the percent of catheter that we report in the DFRs as well as what we report for the DFC, using Medicare claims, is

just about between 10 and 11 percent, and similarly in CROWNWeb.

When we remove -- so for the -- when we calculate the fistula measure, we also include cases where the patient has a catheter present. If we revise that definition and only report -- and report the percentage of catheter which also could include the presence of a fistula, then the rate goes up to 14 percent.

And so some of this is a function of how the data definitions are in both sources.

DR. KRISHNAN: And Claudia, what -- just so I understand that, I mean, we consider a catheter as a risk as long as it's there, right, because they're a wick for infection --

DR. DAHLERUS: Correct.

DR. KRISHNAN: -- and that definition of catheter with fistula still has a risk for catheter? Is that --

DR. DAHLERUS: So, and that is an artifact of the data elements as defined in CROWNWeb, and this is actually something that was

discussed at length by the recent vascular access TEP who were equally uncomfortable with the fact that you get credit for a fistula if a catheter is present.

DR. KRISHNAN: Yes, that makes sense. So just so I am clear, we talked about the data issues with CROWNWeb perform, specifically around vascular access, and I know the ESRD networks have been very vocal around this issue because of how they're incentivized. How do you think that the data errors are affecting the gap analysis and the other analyses? Do you have a sense of what that would be?

DR. DAHLERUS: So I am not sure we would characterize it as data errors. Are you referring to missing data?

DR. KRISHNAN: Sure.

DR. DAHLERUS: Well, I guess we don't feel entirely comfortable saying that there are data errors in the CROWNWeb because when we calculate the measure in claims, the percentages are pretty comparable.

DR. KRISHNAN: Yes, the -- we can talk about this later on. The trick there is not to say what's the correlation between data that makes it into CROWNWeb to claims, the data there is to say what's the percentage of patients who don't have data in CROWNWeb who have claims data for a dialysis session? It's a slightly different nuance.

DR. ANDRESS: I think it's also a question of what you're defining as a data error.

I mean, I think -- I think, you know, data error, I think, implies that there is an issue with the system that's collecting the data. I think there are cases where we have incomplete data for patients through the CROWNWeb system. I think it would be inappropriate to attribute all -- all of that to issues within the system, and it's something that can be addressed at the submitter level, and in fact, a number of those issues are -- you know, vary by the submitter, and we've seen evidence that they can in fact reduce the rates of errors with some investment

of their own time.

So I think, you know, pushing for better submission of data is certainly within the purview of a quality measure and a quality program.

I think the point to be made is that, one, performance using common definitions for the measures yields similar results; two, direct comparisons are not feasible in the entire population because of course the claims data yield only data for Medicare patients, and so there's going to be some degree to which we don't know the entire picture, comparing the two data sources.

But based on the best data that we have available, we seem to get comparable results using two different data sources, and that seems to us to be a good indication that we're getting close to the correct story for the catheter measure.

DR. KRISHNAN: Sure.

CO-CHAIR ANDERSON: Any other comments

or questions for the developer on evidence?

If not, again, this is an outcome measure, and so we will be voting.

MS. OGUNGBEMI: The Committee is now voting on evidence for an outcome measure, 0256.

The options are yes, 1, 2, no. Voting is up.

For health outcome measures, the rationale supports the relationship of the health outcome to at least one health care structure, process, intervention, or service. Voting is now open.

The results for evidence for measure 0256 are 21 votes yes, 0 votes no. The measure passes on evidence, measure 0256 passes on evidence.

CO-CHAIR ANDERSON: All right, moving on to performance gap.

DR. GREENSTEIN: So in terms of the data that was presented, there clearly was disparities in care being measured based upon an analysis both for between sex or age,

ethnicity/age, and diabetes, and the same was true for gap performance, that there was clear cut disparities.

CO-CHAIR ANDERSON: Lorien?

DR. DALRYMPLE: Just one comment on disparities that came up on our work call.

This was one of the measures where there were statistically significant differences but the Committee may want to discuss whether they were clinically meaningful differences.

There are very large sample sizes, so the power to detect very small differences was present, so there was some discussion on our call as to whether people felt this was clinically meaningful, differences by disparities, so if other Committee members have thoughts on that?

CO-CHAIR ANDERSON: Alan?

DR. KLIGER: Just a question: what was the year that these were carried out? Was this in the '07 period or something more contemporary?

DR. DALRYMPLE: Can we actually pull

up the page so we can all look at it together with the disparities testing? Is that possible?

CO-CHAIR ANDERSON: And it says that the data was January 13th through December 13th.

DR. DALRYMPLE: I think this is all CROWNWeb 2013.

So yeah, it's just -- just -- we'll have to capture the two there.

So I think on the work group call, maybe you're all driving this for yourselves, is for example if you look at quintiles for females, between quintile one and quintile five, it's 9.5 percent versus 9.2 percent, so yes, the P value is statistically significant, but most of us would not necessarily consider a 0.3 percent absolute difference to be clinically meaningful.

I think on age greater than or equal to 75, perhaps there's a little bit more spread, 9.1 percent versus 10.7, but I think this issue is going to come up again and again when we're reviewing disparities for any measures with such large sample sizes, so it might be worthwhile as

a group to discuss it now if we are being asked to decide whether these are disparity-sensitive conditions by NQF, the statistical significance versus clinically meaningful.

CO-CHAIR ANDERSON: Jessie?

MS. PAVLINAC: I may be wrong, but four years ago, didn't we have the whole big discussion about we don't talk about clinical relevance with this, that it's all -- I am looking at Alan because I thought you were the impassioned one about we're talking about quality and not clinical, or maybe it was NQF staff, because -- like I said, I may be totally wrong.

CO-CHAIR ANDERSON: Go ahead, Alan.

DR. KLIGER: No, I mean, I -- again, Lorien's question I think is exactly the right question.

When we look at this, we have to talk about what's clinically important, and the data we look at here shows a very small difference.

CO-CHAIR ANDERSON: Frank?

DR. MADDUX: So I -- I have a question

for the developers and the group that analyzed this in detail, is other data has shown substantial socioeconomic and geographic disparity, and yet it's never included in this data, and it just strikes me that we know that it exists to some degree, and yet we don't speak to it when we're looking at these measures, and I just would like some conversation about that.

DR. ANDRESS: Fantastic. So I think there are -- as has been mentioned, this is a fairly dynamic circumstance anytime we're talking about SES.

The measures were developed of course at a time when NQF guidance was pretty clear that we should not be risk adjusting for socioeconomic status, and I think while the question has certainly become more prominent in recent years, the matter itself is not entirely settled, hence the purpose of the trial.

This was an issue that I believe came up during the TEP's discussions as well, although I think it was more driven in the fistula measure

discussion than the catheter measure discussion.

I think, you know, there's relatively little to be gained by arguing the point for or against risk adjustment for SES here. I think the ground is well-trod. The measure as it is currently specified does not adjust for SES.

We are certainly capable of providing supplementary analyses to allow this Committee to look at variation by SES within the constraints of indicators that are currently available to us. And I suspect that this is something that when we have final recommendations out of the Technical Expert Panel that met last month, this will be something that we will again be addressing, at least in part, because we will have passed the NQF's own timeline for -- submission timeline for when the trial becomes active.

I think when we submitted these measures, it was prior to their deadline for including that kind of information.

So we can certainly provide supplementary information on an ad hoc basis if

that would be of interest to the Committee to look at, but that was not a focus of our analyses in preparation for the submission here.

DR. KRISHNAN: Do you think, though, Joel and Claudia, that that would play a role here? Do you think that there is variance where facilities could be inadvertently penalized because of the patients they serve?

DR. ANDRESS: I think that we probably don't have time to discuss my opinion on SES risk adjustments in general.

It's a fairly complex issue. I think that it is possible that facilities are assessed on measures that may vary by SES. I think it's an open question as to whether or not we can truly disentangle what is actually the responsibility of the facility and what is outside of the facility's control.

Most indicators of SES that I have seen proposed include a little bit of both, and at that point, I think it becomes a value judgment. Do you value more holding a facility

harmless for matters that are outside of its control, or do you value more holding facilities responsible for variations in care that may be due in part to factors that are inside of its control, including how its treatment varies for patients of different categories, resources, you know, language proficiency and so on?

That is an open question. I think it's a difficult one to answer, and again, I suspect that the answer is -- the answer ultimately is going to be a little bit of both, and then what do we do about it from there? And I think that's what the trial is actually intended to help us disentangle.

CO-CHAIR ANDERSON: Alan?

DR. MADDUX: I was just going to say, we've talked a -- the responses and conversation was a lot about SES. What about geography?

DR. ANDRESS: So the -- I mean, you know, we've talked about geography.

I think the focus in talking about geographic differences in care has been,

historically, it was in my experience about differences in standards of practice, patterns of practice in the United States and for the -- for CMS, for its quality program purposes, we have a standing policy to not risk adjust for that, and that's been true of quality measures that have been implemented well beyond the dialysis facility programs.

And I think that that is, you know, not something that I would be able to address on my own. It's a much larger policy issue at CMS. So no, we have not accounted for geographical variation. We do typically have the capacity to look at it, but it was not, again, a focus of the analyses that we have provided here.

And I think the other point to make is that catheters are bad, and it doesn't much matter where you are, catheters are still going to be bad for you. So I think the question then becomes, you know, a little bit of, you know, is it okay if catheters are more prevalent in one area or another, and again, I am not sure that's

a question we have the data to answer definitively.

DR. KLIGER: So I want to just go back to is there a performance gap or not?

We talked about the limitations of the data, and particularly large data sets, so among ourselves, can I ask those of us that are exposed to large groups of patients on dialysis, and I am looking at Frank and Mahesh I guess, what's your opinion about is there a performance gap?

DR. MADDUX: I'll answer first.

I think there is a performance gap still. I don't think we've hit that sort of delimiting area where you've got all the patients. I think there are some moving parts.

I do have a sense that Fistula First, despite all of its good results, which I don't want to minimize, has had some unintended results in some people with perpetual inability to get fistula placed by the lack of recognition, so I, in my own mind, divide the world up into permanent access/non-permanent access

predominantly and recognize that fistulas are better than grafts, but grafts are a whole lot better than catheters.

I also think that in this measure, and certainly for others, the gap should be looked at based on a number of factors like vintage, which this one does to some degree. The vintage of the patient is really fundamentally different, and I think the outcomes are fundamentally different in the long-term survivor and the brand new patient to dialysis.

So from my perspective, I still see performance gaps, but I do see differential performance gaps not just based on practice patterns, but actually populations of people for all of those reasons that exist in different areas when I see more gaps in some places than others, let's put it that way, and some of that is process and culture, and some of that could be demographics and background. It's not clear to me what those are.

DR. KRISHNAN: Yes, I think there is

still a gap.

We think about an intractable catheter rate. There's always going to be a floor where you're going to have patients, either because they're new to dialysis or between accessees or whatever, are going to have that number, and we look at within our integrated care setting where we have a ton of resources to pour into this what the lowest number should be. It's about 8 percent.

So there are some clinics that hit that. No matter what you try to do, they're not going to get any better. There are other clinics, as Frank said, that have a high proportion of incident patients just from where they are, but no matter what you try to do, no matter how many resources you pour in, it doesn't change, so there is still a gap, and we could debate how reasonable it is to try to modify some of those things or not, but there is still a gap, I think.

CO-CHAIR ANDERSON: Our lunches are

here, but what we'd like to try and do is finish this measure and then take lunch, so we'd like to try and wrap this up by one o'clock so that people can get some lunch.

So are we ready to vote on -- oh, sorry.

MS. HARTWELL: Just for information purposes, I had a question.

Do you see a performance gap in areas where the clinics do not have access to good vascular surgeons? And I was just curious for that. I mean, is that the reason? Because --

DR. KRISHNAN: Yes, I mean definitely, right?

MS. HARTWELL: -- it's just not more patient-driven, it's more vascular-access-surgeon-driven --

DR. KRISHNAN: I mean, any outcome in medicine is due to one of three factors: the patient, the provider, and the disease, right? So as it relates to the surgeon and the availability and, sorry Stuart, the quality of

the surgeon, we see that, right? We see certain markets where even though the patients can't get access to surgery, so it takes a while, we see other markets where the patients get access to the surgeons and they never mature, and so it doesn't really help you because you still have those catheter days coming on, so yes, definitely.

DR. MADDUX: Lori, I see the root causes as being really multi-factorial, and surgeons may be one of those root causes, but coordinating the entire process and creating actionable elements that decrease the time to a surgical visit, the time to an assessment, the time to surgery, the time to maturation, the time to cannulation. If we begin looking at how you look at those durations and say what could you do from a root cause standpoint to squeeze those down, that's the kind of granularity we have to get to.

So I don't think we can lay it just in the hands of the surgeons. It's the whole

system.

CO-CHAIR ANDERSON: All right. Are we ready to vote on performance gap?

MS. OGUNGBEMI: Measure 0256 is open for performance gap. The options are 1 high, 2 moderate, 3 low, 4 insufficient.

This is data demonstrative of considerable variation or overall less than optimal performance across providers and/or populations groups.

The results are 5 for high, 17 votes for moderate, 0 votes low, and 0 insufficient. Measure 0256 passes on performance gap.

CO-CHAIR ANDERSON: All right.

We'd like to do both the reliability specifications and the reliability testing together.

DR. GREENSTEIN: So the measure is well-defined, numerator and denominator clearly defined, and the data form is from claims and also CROWNWeb data, so from a specification point of view, there was no concerns.

In terms of reliability, again, it appeared to be very reliable in terms of data, and there were no exclusions, so the patient population does not include pediatrics, and this was appropriate also.

CO-CHAIR ANDERSON: Jessie, anything further? Nothing? Mahesh?

DR. KRISHNAN: I guess I'd just be interested, on the data, Joel, you mentioned that there were some correlations done. I haven't seen those, so it would be helpful just to understand that because clearly we have a disconnect between what we perceive as data -- how much data is there and how much you perceive the data is there, so it would be helpful to see that validation of the CROWNWeb data.

DR. DALRYMPLE: So on our work call, a similar question came up. So would it be possible to show the table to the Committee to discuss comparing claims to CROWNWeb? Because there actually is an absolute difference of 3 percent, which on a performance measure where

it's 8 versus 11 percent seems relevant, and the developers, you know, we could get a response, but I think it's worth the Committee being able to see, that's the table 2 facility-level measure mean percent, page 30 on my version, but these versions have changed.

And the correlation data is presented, and the correlations were strong, but on the work group call, one of our concerns was the absolute difference was large, and is this because it's medical claims versus CROWNWeb all payers, or is there some other explanation? And given the transition to CROWNWeb, we thought it was valuable to understand why those differences were observed.

So keep -- it will be a table. Are you guys to your page 30? Keep going. If there's other members from the work group, you guys can help us find this table. Okay, just a little bit lower. This one.

It's a facility-level measure, so you can see catheter greater than or equal to 90 days

in CROWNWeb, 8.5, this is from 2012-2013, versus claims, 11.4 percent overall, so the correlation is high, but the absolute difference seems very real to me on a measure with 11.5 percent performance to have a 3 percent difference.

So I don't know if other Committee members had thoughts, or if we should go ahead and then, because of time, go to developers, but I think this is one of the questions Mahesh and also the work group had concerns about.

DR. DAHLERUS: Yeah, so this did come up as an issue during the work group call, and as a result of that, we actually reran the analysis using much more current data, so we used calendar year 2013 data, and we did the analysis to compare agreement using Medicare claims and CROWNWeb.

And the difference, the absolute difference, goes away. So again, both sources report very similar mean -- facility-level means, 10.8 percent, in claims, 10.3 percent, and the correlation was 0.8, so moderate to strong, and

it was statistically significant, and then the kappa was 0.81, and again, statistically significant.

DR. KRISHNAN: So this was -- just for clarity, this was a number of patients who had data from claims compared to the number of patients who had data from CROWNWeb for the same facilities, or across the entire population.

DR. DAHLERUS: No, they were matched, patients were matched in both sources.

DR. KRISHNAN: And the percentages you gave are for the entire aggregate population, or is there a variance by facility at -- if you did it by facility, or did you do it by facility, or did you do it at the universal level?

DR. DAHLERUS: This is facility-level.

DR. KRISHNAN: So the -- but if you did the measure by claims, and if you did the measure by CROWNWeb, the kappa at the -- you're looking at the kappa per facility across all the different facilities, right? Great, yes, I'd love to see that.

CO-CHAIR ANDERSON: Any other comments or questions? Yes, Frank.

DR. MADDUX: Just a clarification, Claudia. How do you handle missing data on this measure, or unknown?

DR. DAHLERUS: So for the catheter measure, if there is missing data, I believe those patients are still included in the numerator, and so that would count against the facility, and if they are missing -- so this is for catheter, and then if they're missing for fistula, they are not given credit.

DR. KRISHNAN: Well you may know this, but I wasn't at the CROWNWeb users' group, because I know the networks track this, do you know what the percentage of -- I think the networks are incentivized to have a zero percent, or some really low, vascular access failure rate. Do you know what the current rate is? Did they say in the meeting?

DR. ANDRESS: I'm sorry, the current vascular access failure rate?

DR. KRISHNAN: The missing data, right? So the networks, that is the metric they track. Did they say -- I wasn't in the meeting last week -- did they say what their current, most recent percentages of --

DR. ANDRESS: I am not sure -- I am not sure what it is specific to the fistula data, no.

DR. KRISHNAN: Or the vascular access in general, they didn't say?

DR. ANDRESS: I -- I don't recall from the meeting. I am sure we can probably ask them and follow up, but I don't have that information right now.

CO-CHAIR ANDERSON: All right. Let's go ahead and vote on reliability, both the specifications and the testing.

MS. OGUNGBEMI: For measure 0256, the Committee is now voting on reliability. This includes precise specifications and testing.

The options are 1 high, 2 moderate, 3 low, 4 insufficient, and voting is open.

The results are 4 votes high, 16 votes moderate, 2 votes low, and 0 votes for insufficient. Measure 0256 passes on reliability.

CO-CHAIR ANDERSON: All right. Let's go ahead and move on to validity and validity testing, or validity.

DR. GREENSTEIN: So there were no exclusions, and the patient population does not include pediatrics, and it was felt to be appropriate, and there was no risk adjustment either, so we all thought there was -- the consensus was that it was fine from a validity testing point of view.

CO-CHAIR ANDERSON: Jessie, any additional comments?

MS. PAVLINAC: Just that they looked at both SMR and SHR measures there to get the data, to do the --

CO-CHAIR ANDERSON: Any comments or discussion or questions on the part of the Committee?

DR. KLIGER: Just quickly. So Stuart and Jess, what was your opinion of the validity?

DR. GREENSTEIN: I thought it demonstrated good validity. We didn't have a problem with it, actually.

DR. KLIGER: You would say high?

DR. GREENSTEIN: Yes.

MS. PAVLINAC: I'd say moderate.

CO-CHAIR ANDERSON: We're ready for the vote for validity.

DR. KRISHNAN: Just curious, why is there such a difference between you two, Jessie and Stuart?

MS. PAVLINAC: Yeah, I would say personality. On a Likert scale, I am never a one or a five, so it's really hard for me to get to it being perfect. Sorry.

MS. OGUNGBEMI: The Committee is now voting on validity for measure 0256. This includes specifications consistent with the evidence, testing and threats addressed, exclusions, risk adjustments and stratifications,

meaningful differences, comparability, multiple specifications, and missing data.

The options are 1 high, 2 moderate, 3 low, 4 insufficient, and the voting has opened.

The results are 8 votes high, 14 votes moderate, 0 votes low, 0 votes insufficient. Measure 0256 passes on validity.

CO-CHAIR ANDERSON: All right, moving on to feasability.

DR. GREENSTEIN: So the data is actually collected already via CROWNWeb and Medicare claim forms, so it was felt to be quite feasible in terms of data collection.

CO-CHAIR ANDERSON: Jessie?

MS. PAVLINAC: I agree, and I even think it's high. I'm sorry.

(Laughter.)

MS. PAVLINAC: You've got those two, those two -- the only things we've got, right guys?

CO-CHAIR ANDERSON: Any further discussion or comments? Yes, Mahesh.

DR. KRISHNAN: Is -- so is the intent, maybe for the developer, is the intent to migrate from claims to CROWNWeb for these and the other measures? Is that true?

DR. ANDRESS: Are you referring specifically to the QIP, or --

DR. KRISHNAN: Yes.

DR. ANDRESS: So, you know, again, with the proviso that we can never truly say what we are going to do in the future with regard to the QIP, I think our -- you know, we implemented the collection through claims data because the CROWNWeb system was delayed several years ago. We now have the CROWNWeb system live. We are, as you are well aware, you know, working through the -- working through the, sort of the startup bugs.

I think we have not yet decided upon a process for making the decision for a transition. I think we find CROWNWeb to be ultimately a preferable data source because it is not limited only to Medicare patients.

What that portends for the, you know,

for the QIP, one can only imagine.

CO-CHAIR ANDERSON: Okay. Ready to vote for feasability.

MS. OGUNGBEMI: The Committee is now voting on feasability for measure 0256. This includes data generated during care, electronic sources, data collection that can be implemented.

The options are 1 high, 2 moderate, 3 low, and 4 insufficient. Voting has opened.

The results are 21 votes high, 1 vote moderate, 0 votes low, and 0 votes insufficient. Measure 0256 passes on feasability.

CO-CHAIR ANDERSON: All right, moving on to usability and use.

DR. GREENSTEIN: So the measure is publicly reported, and there is an accountable application, both via the Dialysis Facility Compare and also ESRD QIP so that clearly, there is a usability element to this, and I thought it was fine. I don't know what Jessie thought.

MS. PAVLINAC: Yes.

CO-CHAIR ANDERSON: Any comments or

questions, further discussion?

All right, we are ready to vote on usability and use.

MS. OGUNGBEMI: The Committee is now voting on usability and use for measure 0256. This includes accountability and transparency, improvement, and if benefits outweigh evidence of unintended negative consequences.

The options are 1 high, 2 moderate, 3 low, 4 insufficient. Voting is now open.

The results are unanimous: 22 votes high, 0 votes moderate, 0 low, and 0 insufficient. The measure 0256 passes on usability and use.

CO-CHAIR ANDERSON: All right. We will now be voting on whether or not to recommend the measure as a suitable measure for endorsement.

MS. OGUNGBEMI: The Committee is now voting on overall suitability for endorsement for measure 0256, answering the question does the measure meet NQF criteria for endorsement?

The options are 1 yes, 2 no. Voting is open.

Again, unanimous decision. For overall suitability for endorsement, the measure passes. There are 22 votes and 0 votes no, for measure 0256.

MS. BAL: All right. So that does conclude this measure, and lunch is here now. We will grab food and come back at the scheduled time, which is 1:15. We were going to do a working lunch anyway, we just did it backwards.

We did have to get through one more measure in this selection and do related and competing for that, and then continue on our schedule, so please go ahead and grab food and whatever else you need and be back by 1:15.

(Whereupon, the above-entitled matter went off the record at 1:03 p.m. and resumed at 1:16 p.m.)

CO-CHAIR ANDERSON: Okay, so the next measure is 0257 hemodialysis vascular access. The developers are Claudia and Joel and the

discussants are Stuart and Lorien. Are Claudia and Joel here?

DR. DAHLERUS: I'm sorry. So this is the paired measure to the catheter measure that was just reviewed. This is measure 0257. It's a facility level intermediate outcome measure that reports the percentage of adult patient month for patients on maintenance hemodialysis during the last treatment of the month using an endogenous AV fistula with two needles.

The intent of the measure, as paired with the catheter measure, was to recognize facility efforts to increase fistula use as the primary vascular access. This measure treats fistula as a positive outcome in prolonged use of channel catheter as a negative outcome and treats AV graft use as neutral. AV fistula has a longer median survival time, required less costly and invasive intervention to maintain patency and are less likely to become infected.

As we mentioned in our response on the April 23rd work group call of us and just

recently in the last session, a TEP was recently convened to review both measures. And there was a lot of discussion at the TEP about the current specifications to the fistula measure that, as currently defined, allows a facility to get credit for fistula even in the presence of a catheter. And this again has to do with the function of the data elements as defined in CROWNWeb which is used to calculate the measure for the testing.

The measure is going to be undergoing further revision as a result of the TEP deliberations, so obviously no revisions were made to the measure that was submitted at this time. And the TEP is currently, we're currently summarizing the recommendations that were made by the vascular access TEP. One of the concerns that was discussed by the TEP during the deliberations was cases where a fistula may not be appropriate for a patient due to multiple failed attempts at having fistula mature and this could be the case, for example, in older, infirm

patients and therefore a graft may be more appropriate and currently there is no way that the fistula measure would account for that and give credit to that for facilities. I think I will just end there.

CO-CHAIR ANDERSON: All right, Stuart, Lorien.

DR. GREENSTEIN: So, this is really part two of the previous one, my online. It's an intermediate outcome which correlates AV fistula impact on mortality. The evidence does support that AV fistula is the primary choice. But again as was mentioned, it doesn't really address the complexity of the issue of decisionmaking of whether or not you should go for fistula versus whether or not you should have a graft put in and minimize the torture to the patient over time. But overall, it was felt to be a good measure.

DR. DALRYMPLE: So as part of the evidence KDOQI guidelines were submitted that fistula preferred access type with a grade B. The quantity quality consistency were not

directly presented in the measure. However, there was a summary of a literature review. There was not a systematic review of the body of evidence presented within the measure. However, there was a literature review since the last maintenance cycle. And there were 52 articles listed. However, there were not summaries for each of the cited articles, so we could not access the findings from that. So based on the algorithm and the materials as submitted in the measure, I gave the evidence rating as moderate.

CO-CHAIR ANDERSON: Discussions or comments?

Mahesh.

DR. KRISHNAN: We've mentioned the unintended consequences of fistula first multiple times, how do we think about this measure based on the discussion we had. I know we've talked a few times about little old ladies getting multiple fistulas placed, never maturing, how do we balance this out in terms of the evidence?

DR. GREENSTEIN: I agree with you.

There's definitely an outcome that can be very negative to the patient and that is they keep trying to do a fistula and you keep doing balloonings, angioplasties, whatever. The problem is you don't collect that data and I would maintain that that's something that's just as critically important because without that data we have no way of really knowing whether or not we should go the fistula route versus the graft. I have my own preferences when I evaluate a patient and that's in clinical practice. I know because I have somebody who's, let's say, 75 or 80 years of age, there's no point for me to torture them to try to do a fistula if their veins really are plus minus. But not everybody goes that route. There's no doubt about it.

DR. DALRYMPLE: So, I think in terms of unintended consequences, that will also come up in usability and there was some discussion of that. In terms of the evidence helping us understand the complexity of vascular access decision making, I don't think it's there. We

have guidelines and again, it comes out as what was this KDOQI these are your preferred sites and order, but that really doesn't get at those of us who have patients we know are not fistula candidates who go straight to graft because it's medically appropriate.

I guess the counter balance would be this ends up being combined with catheter plus fistula, but I think this issue, I don't know if the committee wants to discuss an evidence or usability, but there was concern about unintended consequences. I think as many of us have come to realize with fistula first that perhaps catheter last is the better emphasis.

CO-CHAIR ANDERSON: Alan?

DR. KLIGER: Can I ask the developer, please? You said that you have a committee that has looked at this and has some suggestions or changes they intend to make, but are not ready to make yet. Were any of them driven by the evidence? Can you help us with the evidence and what your committee thought about the evidence?

DR. ANDRESS: So any summary I provide you is going to be my impressions during the discussion. I think we're working on getting the formal report together and that will be available publicly at a later date.

The kinds of things that we were looking at, as I recall, tended to focus on circumstance, tended to focus on looking at strategies for risk adjustment or exclusion in circumstances where a patient is potentially a poor candidate for fistula use where, for instance, where conditions are in place or conditions are present where fistula failure is deemed to be a substantial risk. These were the kinds of things that were considered by the TEP in modifying the measure. I think that's about as much detail as we can get into that.

DR. DAHLERUS: And I just wanted to provide a little bit of clarification in terms of the sequence of events. So we did our initial reliability and validity testing and assessment of both the measures late last fall in order to

have the forms ready to submit to NQF in February.

The TEP only convened at the very end of April and considered the evidence, as well as later preliminary analyses, that we conducted in preparation for the TEP. So what you have reviewed on the form is not as current as some of the later analyses and summary of the literature that was discussed with the TEP.

DR. KLIGER: Right, just quickly in follow up. So I get that, but did the TEP identify new or additional evidence that would be helpful for this committee to hear?

DR. DAHLERUS: So at this time I think it's a little premature to discuss TEP recommendations as we are still preparing the final report which needs to be reviewed by the TEP. They did recommend additional analyses, but I don't think we would feel comfortable presenting anything as final recommendations since they just met two weeks ago and haven't had an opportunity to review our draft summary

report.

DR. KLIGER: Yes, I'm just disappointed, I must admit. We rarely -- we consider these measures twice a decade and so it's a shame not to have the most current data available to us for that.

MR. MESSANA: Can I just follow up on that comment? Alan, I agree with you as a general statement. The compact that we make with a TEP is that it's our job to try to record their opinions and their statements. Part of that compact, part of making sure we get it right because these are publicly-available opinions is that we write a draft. They review and edit it and then sign off that it fulfills their -- it accurately represents their opinions and their statements and their ideas about this.

What I will say, as an observer there, I wasn't a facilitator at that TEP, but what I will say as an observer is that much of the discussion focused around whether the equipoise about fistula and graft and catheter, that is,

that we talked about three years ago at this meeting, where you have an implied mid portion, kind of a mathematically equivalent difference between a catheter and a fistula when you have two linked measures that excludes graft, whether that general relationship is correct or whether fistula and graft are closer together as some members of this group have stated and whether that's true for all or whether that's true for some populations. That's the general discussion that went on, but until the TEP has an opportunity to actually review what we think we recorded, it would be unfair for us to characterize it further out of respect to them.

MS. BAL: And just a quick question, when would that be available in case we could bring it to the committee for the post-comment call?

DR. ANDRESS: I'm sorry, can you repeat the question?

MS. BAL: So my question was when that would be available, if it's going to be available

as a post-meeting comment call, we could provide it to the committee at that point, but if it's not going to be available --

DR. ANDRESS: I want to be clear on something. When we discussed this with NQF in a previous state, I mean there's an understanding I thought that we'd be submitting the measures as they currently exist for the review for this committee.

We are certainly considering the changes that can be made to the measure in the future and those changes we anticipate will be submitted to this committee for its discussion at that point. I think we have a time line for when we think the draft will be ready. That is, of course, subject to change depending on the TEP's feedback and it would be irresponsible to try to provide you with a specific date by which we'll have everything hammered out.

We expect, we've been talking generally about having a project early next year. We expect this measure will probably be available

for submission at that time and I think we'll be in a position to be able to speak more fulsomely about what recommendations came out of the street.

I thank you, Joe, for recentering the discussion on this point. It got a little lost in the weeds out of desire to be helpful, but I want to make clear, the measure is submitted as it is. We are asking for continued endorsement of this measure as it is. This measure is implemented in the Quality Incentive Program. Any alterations to that would require rulemaking and would require time, certainly. And as such, the consideration of endorsement of this measure, as it is currently specified remains relevant even in the face of a TEP that's meeting to address some of the concerns that you have raised here and that I suspect will continue to be raised in this discussion.

But we don't have any particular intention to modify the measure as we go through the process here. I think that would be one,

incredibly difficult to do, and two, I think it would be inappropriate and well outside the scope of this group.

That being said, I think you all have ample opportunity to review the measure when we do submit and to make a decision about whether or not we have addressed many of the concerns that you may have for the measure. And we'd certainly welcome the raising of those concerns here or during public comment. I don't mean to shut off discussion, but on the issue, if we try to fix the measure, if it can be termed that, while going through this process and while going through the development process, we are going to have chaos. And I think that's not particularly helpful to anyone's purposes here.

CO-CHAIR ANDERSON: All right, Frank.

DR. MADDUX: Knowing that there are a number of vascular access related measures and there's new information that we'll have at some point in the not too distant future, it seems to me one of the questions that we have is whether

we re-endorse an existing measure for a length of time that's going to cross over that period where we have new information to base it on.

I guess I'm asking Poonam and Sarah and others is there any guidance with regard to the fact that we anticipate we're trying to make a decision knowing that there's additional information that should be considered in front of us. So is it strictly a yes or no on what exists today or is there some way to recognize the fact that we anticipate the decision might be substantially different once there's new information?

MS. BAL: Right now, your decision will be only based on what you have in front of you. However, as you mentioned earlier, there is the annual review at which point the developers give it an opportunity to supply any new information. As it seems they supply something that requires additional review, we would bring it back to this committee and do a different review.

And so it wouldn't be that it would just be waiting or that changes would be made and they wouldn't come to your attention. If a major change is made, it will come back to the committee.

MS. SAMPSEL: Let me just add and because this is something that's happened in other -- for other measures, other topic areas as well. That's one of the reasons that this is a standing committee so that as changes to the measures, you will have those come before you. There will be identification is this a substantial change for measure that could warrant a revote or reconsideration of the endorsement or is it just a minor -- they've added a code or something which we would not bring back.

But we can also put in the report and also signal to Joel and the developers that this is something that you want to monitor. A similar situation has to do with there are behavioral health measures that kind of reimbursement for certain types of behavioral health services is

changing. And so the committee strongly advised the developers for that project that we want to know in a year where you are in changing your codes on getting this measure up to standard and up to evidence. And so absolutely, that can be a clause put in, we approve as it's specified right now or we recommend it or we don't recommend it as is specified right now, but developer, we want to see this back and we do want updates on it.

DR. KLIGER: I apologize, but just one last piece which is it surely would use this committee's time much more effectively if we didn't go through this whole process now only to look at it again in the near future because there's a simultaneous look at the measure. Wouldn't it be wiser to wait until that's in before we spend our time doing this?

MS. SAMPSEL: I would say the other thing that NQF is in the process of is identifying a more streamlined review process when there are just minor changes to the measure so that in the event that it does come back with

minor changes, it may not be all the criteria that you're going through and voting on, but just for whatever specific portion of that measure. And it's hard to say without an assumption of what's being changed in the measure, but that is part of the process that's being looked at. And we do understand, but at the same time the way that this measure is submitted right now and the interest in keeping it endorsed as it's specified, the process sits.

CO-CHAIR ANDERSON: Yes, Josh.

DR. ZARITSKY: Just a technical note here. This is a clinical outcome we're looking at evidence for, not as the analysis as an intermediate clinical outcome, right, the preliminary analysis?

DR. DALRYMPLE: I believe during some of the work group pre-evaluation, it was listed as an intermediate clinical outcome, but I guess we as a group can -- if that's how it was initially specified, but clearly here it's being weighted as an outcome.

MS. SAMPSEL: So I'll just have to -- I need to comment on that, too. So right now and we just ask that you all not hold the developers accountable for this, but the way that you fill out the forms in the NQF system right now in that very front part of the form that identifies if it is a process and outcome, et cetera, they don't have a choice of intermediate outcome which is why all of them either say process or outcome. We don't have any of the other types of measures.

It's when you get into the evidence portion of the measure that you can identify if it's an intermediate outcome or not. And for the most part, staff caught those before they came to you. Sometimes it happened in the work group. I think there was only one or two that we didn't catch it, but then the developer did make those changes subsequent to coming to this meeting today. So that's -- unfortunately, it's the way that the information is collected through the NQF system right now.

DR. ZARITSKY: We need to vote on the

high, moderate, right?

MS. BAL: Ignore the voting slides right now, those aren't actually what's up. Those are just a place holder for now.

We'll make sure to keep the correct ones up. Thank you.

CO-CHAIR ANDERSON: John.

DR. WAGNER: I would just like to clarify. On the annual review, is the measure developer obligated to incorporate the new information that we're discussing here into the view that they then present about the necessity to change the measure?

MS. SAMPSEL: Let me make sure I understand. So based on the information that we've provided here during their annual review, are they required to respond to that?

DR. WAGNER: We've said that we believe there will be new information forthcoming that may influence -- if that information was present today that might influence our decision making today. But we're not privy to that

information or we're to take that information into account because we're supposed to take the information as presented to us today into account.

If there is new information, does the measure developer -- must that measure developer take that information into account in their annual review so that we know that that information is incorporated into whatever decision is made with respect to changing the measure?

MS. SAMPSEL: So that's part of the documentation and reporting process in that we do -- we will have continual conversations with the developers to make sure that the changes -- although we don't know what they are, but one that they're substantial and then two, that they would come back as substantial for consideration.

DR. KRISHNAN: Just so I'm clear, we'll vote on this measure now as we did the prior one, the TEP will report out. That may result in additional measures being developed or

current measures being tweaked. Then it will come back to this committee at some point in the future to reconcile. Is that the way I should think about it?

MS. SAMPSEL: I would say it's not necessarily -- I'm having a little bit of a problem with the reconcile part of it. But yes, I mean so basically --

DR. KRISHNAN: Wrong word.

MS. SAMPSEL: No, no, no, that's right. What I would see would happen here is that whatever decision comes out of this, but let's say that the measure is recommended as it's currently endorsed. So it stays with this in its current recommendation. And then apart from this NQF process, CMS and University of Michigan are reacting to their TEP maybe making changes to that specification.

While it's required during the annual review that they then provide us any changes to the measure, in the meantime we're having ongoing discussions with CMS and University of Michigan

to know where they are in their TEP cycle, understanding measures, and this has implications otherwise as well. So yes, it will then come back to you as a standing committee.

DR. KRISHNAN: Thank you.

CO-CHAIR ANDERSON: Any further comments or discussions on the evidence of the measure? We are ready to vote.

MS. OGUNGBEMI: The committee is now voting on evidence for measure 0257. The options are one, high; two, moderate; three, low; and four, insufficient. Voting is now open.

MS. BAL: And also just to comment, you can start voting once the slide is up, so you don't have to wait for Alexandra to finish. We're going to try one more time. Give us a second.

Go ahead and try one more time for us. Are you still getting error message? Okay. So we're going to have to go old school for a second. And start voting with hands until we can get this technology problem fixed.

So I'll go ahead and ask for a hand vote. So if you vote high, please raise your hand. I count two. So moderate. Okay, so low. And insufficient.

Okay, so the total is 2, high; 19, moderate; 0, low; 0, insufficient. And we'll move -- for evidence, 0257, and we'll work on technology while you guys discuss gap.

CO-CHAIR ANDERSON: All right. We're moving on to performance gap.

DR. GREENSTEIN: So similar to the other one, we did recognize that there was a disparity in performance gap although not that large. Again, just like the other one, we felt that it should be listed as a disparity-sensitive gap.

DR. DALRYMPLE: So in terms of opportunity for improvement, CROWNWeb data from 2013 presented. The mean percentage of patient months with AV fistula was 67 percent. The first quartile was 60 percent and the third quartile was 75 percent. No national goal rate is stated,

but I think you could infer from the bottom quartile that there is room for improvement.

In terms of disparities, can you pull that up first? I believe it's page 16. So this is one where I think as a work group we were more impressed by the differences, by -- pull it up so everyone can see it.

So as you can see here in females, for example, patients who are black, white, Hispanic, in some of these groups, bigger spreads between the first quartile and the fifth quartile such as 71 percent versus 60 percent. So I don't know if you all want us to go through each disparity listed as a committee or if you just want us to acknowledge disparities were present and it depends on -- is that what you would like? Disparities were present on our assessment.

CO-CHAIR ANDERSON: Any comments or discussions regarding performance gaps and Lorien's comment about the disparity issues?

MS. BAL: We're going to try the software again.

CO-CHAIR ANDERSON: We are ready to vote on performance gap.

MS. OGUNGBEMI: For measure 0257 the committee is now open for voting on performance gap. The options are one, high; two, moderate; three, low; and four, insufficient.

MS. BAL: We're still short a couple. If everybody could put their -- we need 22.

MS. OGUNGBEMI: The results are 24 percent high; 76 percent moderate; 0 low; and 0 insufficient. The measure 0257 passes on performance gap.

CO-CHAIR ANDERSON: Moving on to reliability and reliability testing. Stuart or Lorien.

DR. GREENSTEIN: Let me just get to -- so again similar to the other measure, the data elements were clearly defined and we felt that the measure was primarily designed for collection via CROWNWeb and Medicare forms and that there was good specification and reliability. We had no concerns.

DR. DALRYMPLE: I think we had one concern, Stuart, if you don't mind me weighing in.

DR. GREENSTEIN: Sure.

DR. DALRYMPLE: On the specification and I think the developers may want to respond because this came up on the work call and may be relevant to the TEP, although they may be able to give us limited information.

So if you look at the specification in CROWNWeb, you're counted as having an AV fistula with two needles if you "have an AVF combined with a catheter." And also from the claims data, if you have vascular cath. which I think is vascular catheter, yes, or a fistula, yes.

So one of the issues that came up is that actually appears what's being captured are people who have catheters plus fistulas and do we think this is consistent with the title of the measure that specifies fistula with two needles in place because we took this to mean potentially those patients who have developing fistulas and

are either still relying on their catheter or doing one-to-one needles for example. So that came up with a concern about specification being consistent with what the title implies of this measure. So I think the developers were going to give us more feedback here today.

DR. DAHLERUS: So again this is something that got a lot of discussion at the vascular access TEP about the fistula measure. And the way the measure is currently scored, yes, facilities will get credit for having a fistula even if a catheter is present. This is going to likely be one of the recommended changes to the fistula measure, but again we haven't revised the measure yet to reflect such a change. And again, this is also attributed to how the different data fields are defined in the respective Medicare as well as CROWNWeb data sources.

CO-CHAIR ANDERSON: I think I'm a little confused here because I thought what's in the CROWNWeb data is two needles with a fistula. If you still had a catheter in place, catheter

still is what's actually recorded, even though you have a fistula with two needles. As long as the catheter is remaining in place, it still counts as a catheter versus as the fistula.

DR. KRISHNAN: So let me try to help. We've gone through this with CMS and CMS actually recognizes this issue starting with what happened with the KQRV on the claims in 2010 or 2011. The microspecifications of exactly what people want as it relates to what we map from our EMR are being defined specifically for the fistula first initiatives and some of these other things.

So it will clarify it because right now there is some component of subjective interpretation on the part of the person making the link up between what's in the EMR and what gets submitted. And the goal is to provide sufficiently granular microspecifications to minimize that variability. So even though I harp on this, it is definitely something that we're working with CMS. CMS recognizes that we recognize it because if we're just told

"fistula", there's a lot of variance of fistulas, right? So it was very eye opening when we had this discussion amongst four major batch providers that control 90 percent of the submissions for U.S. We all had slightly different definitions and so our mapping was slightly off, but there is a macro initiative for everything data to specify that in a microspecification manual.

So I'm confident we'll solve it by the time this gets there, but the operating definitions aren't as smooth because we don't get to that level of detail necessarily when we specify measures, but you need to when you do the implementation.

CO-CHAIR ANDERSON: Lorien?

DR. DALRYMPLE: And so I think perhaps one of our recommendations would be simply that if we correctly understand the specification that you can have a fistula and a catheter and be counted in the numerator and that the brief description of the measure is perhaps not as

accurate as it could be because it states using an AV fistula with two needles which we don't think these specifications are per se consistent with.

DR. DAHLERUS: We'd actually like to speak to this issue, but I'm going to defer to Dr. Messana.

MR. MESSANA: So in preparation for the vascular access TEP and at the vascular access TEP and this wasn't an opinion from the TEP members, but we did work with someone who was on the TEP who has high level working knowledge from the network perspective. If you look at the CROWNWeb definitions, there is a separate definition in CROWNWeb for one lumen or one needle in the fistula and blood flow through one lumen. So there is that level of granularity in the CROWNWeb data.

The problem that the networks identified as being particularly relevant here is that if you have a fistula and a catheter is still in place, but you use the fistula and a

catheter is still in place, but you use the fistula with two needles, it still counts -- it counts in CROWNWeb as the numerator is the fistula. So there's the potential to hide a catheter if you use a fistula early.

The claims definition is different, but has been developed to be consistent with or attempt to be consistent with the CROWNWeb definition. Under the Medicare claims right now you use V modifiers, right? And you are instructed to if a catheter is present at all, whether it's being used or not, you have to report V5.

If a fistula is present, okay, you are instructed to report -- and a catheter, you are instructed to report both. And so a claims-based metric could be defined either way, the complete absence of a catheter or the presence of a catheter and a fistula with the fistula being used.

Right now, the claims definition is being -- has been defined to be consistent with

the CROWNWeb reporting instructions. So for clarity, it raises all the sediment in the pond for everybody, but the fact of the matter is the specific thing that you raise as an issue shouldn't be happening in CROWNWeb if people are interpreting the instructions correctly.

There is a difference between one lumen and one needle versus fistula with two needles, but a catheter is still hiding in the background.

DR. DALRYMPLE: So in CROWNWeb, when the numerator is counted then should this field, AV fistula combined with a catheter be included in the numerator for this measure or should it only be those who have AVF with two needles checked? I don't know what CROWNWeb looks -- so I'm just looking at what fields were quoted to us in the specifications.

MR. MESSANA: So I guess the numerator right now means from CROWNWeb that fistula was used with two needles, whether or not a catheter was present. And that's because that's the

current instructions for reporting in CROWNWeb.

DR. DALRYMPLE: So in the specifications for this measure, where it says the numerator counts if the following is checked AVF combined with a catheter in CROWNWeb is what shows up in our measure specifications for review of the numerator. It says if this or this is checked, then they get counted as a yes and one of those is AVF combined with a catheter, the specifications that were submitted to us for review. But if we're misunderstanding, please clarify it because this was one of the struggles on our work call to understand these specifications.

MR. MESSANA: Apparently it's a struggle on my work call as well. But the definitions are in CROWNWeb whether they've been applied as you think is appropriate or not is a reasonable question. The definitions in CROWNWeb are clear. You can specify two needles and a fistula, one needle and a fistula with one needle in a lumen or using two lumens from a catheter.

So that granularity is available. So I'll stop there.

DR. KRISHNAN: The definition in the specification, not the data definition?

DR. DAHLERUS: So you're talking about the measure description is misleading, yes, yes. And that is something that we plan to revise when we resubmit a potentially revised measure.

DR. GREENSTEIN: So how will you revise it to say that it's fistula hemo catheter equals hemo catheter? Will it be revised that you have a fistula hemo catheter it will be considered a hemo catheter or will it be considered a fistula?

DR. DAHLERUS: So I think the more fundamental revision would be a more conservative measure for fistula that only gives credit for fistula if that is the only access present. If there is a catheter still present, they would not be given credit for fistula, but that we would count as part of the more comprehensive revision.

I think it is probably possible to

revise the title of the current measure because I think that requires a minimal change to the measure title for the measure that's up for endorsement maintenance.

CO-CHAIR ANDERSON: Any further comments, discussion on the part of the committee? All right, seeing none, I guess we're ready to vote on reliability and reliability testing.

MS. OGUNGBEMI: The committee is now voting on reliability for measure 0257. The options are one, high; two, moderate; three, low; and four, insufficient. Voting is now open.

There are still more votes that we are missing. Could we just try and get those two in, please.

Pardon me. The results are 0 votes for high; 17 votes moderate; 1 vote low; and 2 insufficient. The measure passes on reliability. This is measure 0257.

CO-CHAIR ANDERSON: All right, moving on to validity and validity testing.

Stuart or Lorien?

DR. GREENSTEIN: So there were no exclusions and no risk -- I'm sorry, the exclusions were consistent and there was no risk adjustment supplied and there seemed to be meaningful difference between in terms of quality by looking at fistulas and catheters.

Lorien?

DR. DALRYMPLE: We got hung up on specifications so just so the whole group is aware as we're about to hit validity, they did do IUR. It was 0.76 CROWNWeb versus claims had a kappa of .91. In terms of validity, it was done at the performance measure level. And divided into quintiles and then AV fistula -- percent of patients stylizing with an AV fistula was associated with both the SMR and SHR. I'm not sure that you all want me to read these to you, but that was the process for validity. If some measurers want to weigh in, there also was data provided on CROWNWeb versus claim. My assessment of validity was that it was moderate.

DR. GREENSTEIN: Is there an updated analysis, Claudia, for this as well as there was for the catheters?

DR. DAHLERUS: Yes. I can't walk and speak at the same time. Yes, so we recalculated the fistula measure using Medicare claims calendar year 2013 as well as CROWNWeb data calendar year 2013. And the agreement for the fistula measure in both sources, the kappa was .92 and it was statistically significant and the correlation between the measure in both sources was .869.

DR. KRISHNAN: Just so I understood this, I wasn't clear on this before, so that means for the same patients if you ran them in claims versus CROWNWeb you got that correlation?

DR. DAHLERUS: Yes, for patients that were in both sources.

DR. KRISHNAN: In both sources. But you don't necessarily know how many patients, you don't know the delta between the number of patients you had a claim in the dialysis unit for

that period of time versus the number of patients whose CROWNWeb data made it for that facility?

DR. DAHLERUS: No, we do not. Not today.

CO-CHAIR ANDERSON: Any further discussions?

DR. DALRYMPLE: I just had one more comment that we didn't get to address --

CO-CHAIR ANDERSON: Sorry, Lorien.

DR. DALRYMPLE: -- which was exclusions. There were none other than the denominator, but I didn't know if the committee wanted to discuss whether there actually should be exclusions in circumstances where an AV fistula would be deemed to be medically inappropriate. And that's come up with other measures and just in general consensus, but it's one of the things we're asked to assess in terms of threats to validity are exclusions or the lack thereof appropriate.

CO-CHAIR ANDERSON: And I think this is part of the difficulty because as the TEP met,

there may be additional revisions to the measure based on whatever the discussions for the TEP were, so it makes it kind of difficult to know. We're really voting on the measure as the measure is presented and whether or not we want to move it forward with or without the exclusions that are currently in place.

DR. DALRYMPLE: And I think we'll be reconciling competing measures, but it's just that discussion of does the committee think there are threats to validity if, for example, patients with a life expectancy less than six months are not excluded from an AV fistula measure or if you can think of other circumstances. The ones that I can think of are, you know, scheduled living donor plan, but need an approximate mixture of ADPKD so we're not going to use a fistula.

So I'm just bringing this up as part of our script that was sent out if committee members think there are threats to validity by the lack of exclusions.

CO-CHAIR ANDERSON: So Lisa?

DR. LATTS: I guess my only comment on that and a very thorough review, outstanding, would be that I think those are all probably true, but I wouldn't expect any systematic bias by any one facility to have any more than any place else. So it's just one of these many measures where you just wouldn't expect the rate to be 100 percent. You expect it to be something less because of all those exclusionary circumstances.

DR. WAGNER: Do we collect data on that though? It seems reasonable to say that, but since this is an important question, if the facility is of small size and there are a significant number of patients who either have a lower than expected life expectancy or are old and have frail veins, isn't that something that would be important to collect information about?

DR. DAHLERUS: I'm sorry, could you repeat the question?

DR. WAGNER: We are deciding that we don't have data on exclusions, but wouldn't that

be important to collect such data to see if there are facilities that would particularly be at risk for being judged to have lesser quality because they have patients with limited life expectancy for whom they're not placing fistulas or facilities that have a particularly older population that might have difficulty in having access placed by fistula.

DR. DAHLERUS: So that's a great question and actually these were analyses that were recently recommended by the vascular access TEP to look at those factors, those patient characteristics as potential exclusions or for consideration for risk adjustment, but we did not submit these analyses as part of the current measure under consideration.

DR. WAGNER: And similarly would there be a role for querying facilities regarding patient preference since there are patients who prefer not to have anything but a catheter? So again, we're assuming that this gets smoothed out in the aggregate, but an individual facility may

be particularly affected by these kinds of patients.

DR. ANDRESS: So something that's worth -- what I hear is that patient preference is not something that's currently collected through the existing data sources. So the capacity to capture something like that would be extremely limited. I think certainly it would be something that would be of interest to us, but it's not something that we could capture or provide analysis on at this time.

DR. WAGNER: We're in the era of patient centeredness, so I think this is an extremely important area to explore and we need to develop information about this because we're in a vacuum when we're talking about this.

CO-CHAIR ANDERSON: Any further discussion before we vote on validity? All right.

MS. OGUNGBEMI: The committee is now voting on validity for measure 0257. The options are one, high; two, moderate; three, low; four,

insufficient. Voting is open.

Results are 2 votes for high; 12 votes for moderate; 4 votes low, and 4 votes insufficient. Measure 0257 passes on validity.

CO-CHAIR ANDERSON: Okay, moving on to feasibility.

DR. GREENSTEIN: So these measures are routinely generated via CROWNWeb and Medicare forms so the consensus was that there essentially was no concerns in the feasibility of this.

CO-CHAIR ANDERSON: Lorien. Any discussion on the feasibility? All right, let's go ahead and vote.

MS. OGUNGBEMI: The committee is now voting on feasibility for measure 0257. The options are one, high; two, moderate; three, low; four, insufficient. Voting is open.

The results are for feasibility 14 votes high, 8 votes moderate, 0 votes low, and 0 votes insufficient. Measure 0257 passes on feasibility.

CO-CHAIR ANDERSON: All right,

usability and use.

DR. GREENSTEIN: So the measure is commonly used by the ESRD QIP and also from the dialysis facility compared, so these are used for public reporting and payment programs. So we're using it. Not much we can say.

DR. DALRYMPLE: So again, sticking to the script, to the best of my ability I thought it would be valuable as the committee to discuss unintended consequences of just measuring pure fistula rates because I think in the last five years this has rapidly evolved. Obviously, we've changed our language a lot realizing that sometimes intentions can do undue harm.

So because usability and use includes unintended consequences, I didn't know if the committee at large wanted to discuss the measure that only includes fistula rates.

CO-CHAIR ANDERSON: Frank.

DR. MADDUX: I think it's obvious because we brought it up so many times that just the fact that there's another TEP having these

discussions sort of begs the question that there are issues beyond simply fistulas alone. Again, I'd reiterate I think my biggest concern here with this measure is the duration by which our endorsement applies before we get to the next iteration and that's really my only concern of this measure from a usability standpoint.

CO-CHAIR ANDERSON: Any other comments or questions? Are we ready for voting for usability and use?

DR. KRISHNAN: Let me just pick up on Lorien's part. Is there an exclusion criteria that we would consider to avoid the unintended consequence? And I don't know how you track that. Just from speculation, I'm sure you've probably put more of these in than any of us. If you had to come up with trying to avoid the little old lady getting five of these and at the same time accruing many catheter days because we're still using the catheter, right, when we're trying to get a fistula, is there something that you would suggest as the exclusion criteria or

how does one do that?

DR. GREENSTEIN: I don't think you can because you're going to find that there's judgment and that's so variable, you know. So many access surgeons all around the country -- I'm not sure how we can ever do that.

DR. KLIGER: Now Mahesh, though I guess from my standpoint that's the reason why you need a mature group discussing a measure from the beginning because the facts around constructing the measure change as our experience and as the evidence changes. So asking that question sort of separately, you know, is hard, but that's the whole reason that we hope that a developer puts that together, puts evidence together, assembles their team in adequate time so that we have that information to use to make a decision about that. So it's a very important question. It's not something we can decide today, but that is something the developer needs to address.

CO-CHAIR ANDERSON: Any other

questions for the developers, comments? All right, let's vote on usability and use.

MS. OGUNGBEMI: The committee is now voting for measure 0257 on usability and use. The options are one, high; two, moderate; three, low; and four, insufficient. Voting is open.

The results for usability and use for measure 0257 are 5 votes high, 10 votes moderate, 4 votes low, and 4 votes insufficient.

CO-CHAIR ANDERSON: Okay. Before we vote on recommendation whether to submit this for endorsement, is there any other issue? I think we want to recognize that we are hearing what the concerns are and what the issues have been raised through the committee and we are -- the time line for when the new measure and the changes to this measure based on the TEP outcomes will just be moving forward and at this point we are voting on the measure as the measure is presented as to whether we want to continue to move it forward for endorsement.

DR. KRISHNAN: Just to be provocative

because I'm thinking of the question I posed to Stuart. It has been proposed by some that in lieu of a fistula and a catheter metric, one only has a catheter measure, right? So you don't have the unintended consequence. I don't know if that's something to debate or talk about, but I don't know what you guys think or not. Poonam says no, so I'll shut up.

MS. BAL: Just for the sake of time if it's not relevant to the vote, we would say to continue that conversation at a different point.

DR. KRISHNAN: I think it is relevant because we're going to vote on endorsing it or not. If you endorse it, you'll perpetuate what we've had going on. I don't know if there's a solution for it, but -- or if people have any comments. If not, we'll just vote.

DR. DALRYMPLE: Can I just ask a general question?

CO-CHAIR ANDERSON: Yes.

DR. DALRYMPLE: Because I noticed after this we're going to discuss the relation of

competing measures. So then do we have an opportunity to try and reconcile -- can you help us with the process so we know the right time to discuss issues like this such as maybe catheter last is really the only needed metric. I think that will come up during competing or in the face of individual measure review.

CO-CHAIR ANDERSON: I think we'll be giving you instructions and it will come up in the review of the competing measures.

So are we ready to vote for endorsement or not?

MS. OGUNGBEMI: I need to first say that the measure passes on usability and use. That's measure 0257.

CO-CHAIR ANDERSON: Sorry. For the record. Thanks, Alexandra.

All right, now I guess we're ready to vote on whether or not to endorse this measure.

MS. OGUNGBEMI: The committee is voting for overall suitability for endorsement for measure 0257. The options are one, yes; two,

no. Voting is open.

The results are 17 votes yes, 5 votes no. The measure passes for suitability for endorsement.

CO-CHAIR ANDERSON: All right, now we're going to move into the related or competing measures and Poonam is going to explain the process.

MS. BAL: So, yes. So this is our first grouping related and competing measures. You were sent a form on Monday, and also it's in your group of papers, which give you the decision logic to identify related and competing. So this was identified by staff as somewhat related. And all the developers have given responses about the measures. And now it's up to you to, one, decide do you agree that these measures are related or competing; and then, two, if so, what result do you want from that? Is there just them harmonizing and changing a couple specs to correlate better, or is it that one measure is better than the other and it should be stated as

the best in class? So that's the general process.

I will go over quickly what the developers have said about these measures. Okay. So KCQA felt that 0256 and 0257 focus on reducing catheter use exclusively in favor of AVF use. And they're seeing that as the main difference between the two -- or I'm sorry, all these. And then CMS referred that Measure 0257 is a referral process measure and that the most basic requirement to get into a numerator is referral, and that 0256 and 0257 are paired intermediate outcome measures which report to the percentage of patients with current AVA. So basically they're saying the difference is not treating AVA -- sorry, I can't see these words properly, but fistula and AV graft as equivalent outcomes.

And then there's other things, but I'm not going to read the whole thing to us in the standard time. And then Kaiser also said that 0256 and 0257 are related but not competing and that they have generally a different focus.

So I'll start off with the Committee looking at the decision logic. And if you start, the first question is does the measure address the same target population or the same measure focus as another endorsed or new measure? So that would be your first question to answer. And we can move forward with that thought. So I'll open up to the Committee. Do you feel that these measures address the same target population or same measure focus?

DR. KLIGER: Yes.

MS. BAL: And would you say that for all measures or --

CO-CHAIR CROOKS: Target population or --

MS. BAL: Yes.

CO-CHAIR CROOKS: -- focus?

DR. DALRYMPLE: I would argue that Kaiser Measure 2594 is not the same as 251, 256, and 257.

MS. BAL: So would the Committee generally agree that we should take that measure

out of the equation and just focus on the other three?

DR. DALRYMPLE: Yes.

MS. BAL: I'm seeing nods all around. Okay. Perfect. So that one's out of the running now.

So now, of the three measures you said yes. Did you mean because it was the same target population or the same measure focus?

DR. DALRYMPLE: Both.

MS. BAL: Both? Okay. So in that case, we will go to step 2. Do the measures address both the same target population and the same measure focus? So is it both, basically the question is.

(No response.)

MS. BAL: Yes. Okay. So then do the measures address -- I'm sorry. Determine whether or not the measures are specified for at least one of the same care settings. So would you say that these measures have the same care setting?

(No response.)

MS. BAL: Yes. Okay. So then the last question is, does the measure as specified for at least one of the same levels of analysis? So do you think they have the same level of analysis?

(No response.)

MS. BAL: So then --

DR. DALRYMPLE: What's the level of analysis for the KCQA? Because the other two are dialysis facility level, but is the KCQA physician level reporting?

MS. SAMPSEL: It's a clinician level.

DR. DALRYMPLE: It's a clinician level.

MS. SAMPSEL: Correct.

DR. DALRYMPLE: And the other two are dialysis --

MS. SAMPSEL: Correct.

DR. DALRYMPLE: -- facility level, correct?

MS. SAMPSEL: Correct.

DR. DALRYMPLE: So this is Number 5,

Poonam?

MS. BAL: So then, if the answer is no, then you would put it as competing with the rational different levels of analysis, and then it would be up to you to determine if you feel components need to be harmonized or if they're fine as they are for the measure that you said no for. So the KCQA measure. And then for the measures -- the other two measures, as competing, you would determine again the same thing. Do you feel like these measures need to be harmonized or if they can stay together as paired measures as they currently are.

So no more algorithm and more just your opinion. I guess I should say the question is, do you feel that any specifications for these measures need to be changed for them to work together, or do you feel that these measures as are already -- are fine the way that they are, basically?

DR. KLIGER: Well, maybe I can wade in. The two that are designed to be paired

measures are indeed paired measures. The third has a different level of analysis at the physician level rather than at the unit level. And none of them are incompatible with one another. So I guess my own view would be that these are fine to be working together.

DR. KRISHNAN: Let me offer a slightly different opinion, because I think we'll get to these when we get to the other adequacy measures as well. Should the math that's used to calculate the facility level outcomes be the same math that's used to calculate the clinician level outcomes? In other words, if you were to add up all the clinicians in the facility, should that equal the facility? But if the math is different, they won't because they're two different comparisons.

MS. BAL: I just ask that everyone speak a little bit louder. It's been hard to hear everyone. And I agree, I also need to work on being louder. So, let's all. And then I believe --

CO-CHAIR CROOKS: So I'm speaking as a Committee member again. So we have two that by this algorithm are competing, but they're paired. They have the same denominator and they work together. The one that has the clinician level, the question is, can it be harmonized? And it seems to me that I don't see any reason why the one that looks at the clinician level couldn't also look at facilities and vice-versa. So could they be harmonized? Are the data sources different or the same? If the data sources are similar, then it seems to me they could and should be harmonized perhaps. I don't see an advantage to having two different ones.

DR. MADDUX: It seems like one of the questions we should try to address is the fact that whether it's the clinician or the facility level measures, we've got one that's measuring a more holistic view and the two paired ones that are measuring the two isolated components: the most optimal, the non-optimal. To me the question is whether we harmonize to try to get

measures that are measuring the full set. In my view we should be measuring permanent versus non-permanent access and trying to harmonize towards that, whether it's through the recognition of the KCQA measure of recognizing some proportion of catheters and reassessment or whether it's through saying an AV fistula is not always the most appropriate graft, or the most appropriate permanent vascular access for a patient.

CO-CHAIR CROOKS: So, Frank, you're saying that you would hold the KCQA one out as a separate and non-competing, or no need to harmonize, or you lose something of value if you tried to harmonize it?

DR. MADDUX: I do think if you look conceptually at where the distinctions are, you've got one that's looking at this essentially catheter avoidance measure in totality. And then the others you've got where you're looking at the two ends of the spectrum, the very best to the very worst, and not sort of this middle ground. And so you could decide that you wanted to make

directionally everything consistent or recognize that they're just two separate things. They're really measuring in a different perspective, which I think they are right now.

DR. KRISHNAN: Frank, what do you think are the denominators between them? Should the denominators be the same?

DR. MADDUX: I think the denominators can clearly be harmonized probably easiest. It's the selection of what you want in the numerator where you got to make a judgment decision. I mean, what do we actually think is driving what would be believed to be better care?

CO-CHAIR CROOKS: So does that clarify it for the staff? Have we finished this job, this chore?

MS. BAL: That sounds good. That's exactly what we need to know to how to -- oh, I believe Andy had a question, though. A statement.

DR. NARVA: Well, the two are outcome measures and one is a process measure. So

there's a bias in favor of an outcome measure, isn't there, in general, in terms of quality of measures?

MS. SAMPSEL: Yes, I mean, I would say if you were choosing best in class, that might be a consideration, but if you're not choosing best in class and have just decided -- from what I've heard from the discussion is these three measures are recognized as competing by going through the NQF algorithm and decision tool for related and competing, however, this Committee has chosen there's no need to further harmonize. But then there are comments heard that perhaps a better measure in the future would be permanent access as well as focusing on outcomes measures. Because I would say, yes, overall everybody would like to see more outcomes measures versus process measures no matter what the content area is.

DR. KLIGER: Just one other comment, which is I think that Frank's comment really makes sense to me and I wonder if again we would be better informed by knowing what the TEP is

thinking. Because if indeed they're moving in that direction, then we might well have recommended the kind of harmonization that Frank suggested.

DR. ANDRESS: So I think there wasn't a great deal of discussion of harmonizing with the KCQA measure. First to clarify a point, and I think this is worth clarifying. It's not just a case of the two ends points being measured. I mean, the way that the measures function together as a pair, the catheter and the fistula measures function as a pair, there is an explicit assessment of the use of grafts within a facility. The consequence of using a graft is that you get a score that is mid-range between using a catheter or a fistula. But the consequence and certainly the way it's used in the QIP but also in pairing the measures together in a measure program is the same. I think the question that's been raised is that tiered process always appropriate, or is that tiered setup always appropriate? But it's wrong I think

to say that it ignores the midpoint of the use of a graft.

In terms of the recommendations of the TEP, I think there was some interest certainly in keeping the measures capable of functioning together as a paired set. There was some value in that. There was some discussion about having a distinct graft measure that combined with the other two, but if I recall correctly, that was not something that was discussed at terrible length in the TEP. It was raised, but not expounded upon a great deal.

In terms of harmonization, I think of course the fact that we're using the measures paired, we want them to be harmonized certainly with each other. It has not been a part of our efforts in the past I think to necessarily harmonize with measures across settings. So I think the extent to which that would be feasible or desirable is something that we would want to look at before we made a final determination of what our position would be.

MS. BAL: So that's all we need from staff. And obviously this was the long version of doing related and competing, but we wanted to give you one -- something to do so the work call -- we wanted to go through the algorithm, but it will be a much quicker discussion moving forward because you'll know what you're looking for.

And so --

DR. KRISHNAN: What was the end conclusion, Poonam, that we decided?

MS. BAL: That the measures would remain as they are and they will be classified as competing though but, from what I understood, the Committee did not ask for any changes.

CO-CHAIR CROOKS: Right, we're not asking for further harmonization.

MS. BAL: Yes, harmonization.

CO-CHAIR CROOKS: Recognize them competing, but we don't see value in them necessarily trying to harmonize them at this point.

DR. KRISHNAN: Did we say the

denominator should be harmonized or not?

MS. BAL: Yes, that can be a recommendation that you make to the developer.

CO-CHAIR CROOKS: Well, because it's clinician versus facility, you can define the patients the same, but you're not going to get the same patient in the denominators.

DR. KRISHNAN: Right, it's just the math. Yes, the math should be the same, I think. The numerator would change and the number of patients in the denominator would change, but the math should be the same, I would think, between measures.

CO-CHAIR CROOKS: Well, a clinician measure could cross facilities, right? Is that --

DR. ANDRESS: And depending on the physician involved could cross settings --

CO-CHAIR CROOKS: Yes, settings and --

DR. ANDRESS: -- and, as I think Mahesh would appreciate, potentially areas of responsibility. So I don't know how that would

fall out in a vascular access measure, but it would certainly need to be considered for the purposes of harmonization if they were undertaken.

DR. KRISHNAN: I guess my question is for the -- even if they across multiple facilities, the business rule is to determine which patients go in --

(Simultaneous speaking.)

CO-CHAIR CROOKS: Right, so it would be worthwhile to look at the denominator definition.

DR. KRISHNAN: Right.

CO-CHAIR CROOKS: Adult over age 18, dialyzing for so many months.

DR. KRISHNAN: Right. That's what I mean. Yes.

CO-CHAIR CROOKS: That type of stuff would be --

DR. KRISHNAN: That type of stuff.

CO-CHAIR CROOKS: -- approved by the Committee, or encouraged by the Committee. So

take a look at how they define their denominator. Then you should take a look at how you define your denominator patients and see if they're the same.

DR. KRISHNAN: Right.

CO-CHAIR CROOKS: Okay. I think that concludes that.

So before our next break, which is scheduled in 45 minutes, we're going to start on the peritoneal dialysis measures. And I'm going to give Connie a break and -- for carrying the load all morning.

CO-CHAIR ANDERSON: We're going to do this one first.

CO-CHAIR CROOKS: Right, and I've been told that in order to keep the CMS measures together, we're going to move the measure 321 first, which is the RPA measure. And so we welcome the developers back and Mahesh and I are the reviewers. And I'm going to take the lead on this one. Is that what we decided?

(No response.)

CO-CHAIR CROOKS: Okay.

MS. BAL: And I'm just going to ask if Paul Palevsky is on the phone from --

MR. PALEVSKY: Yes, I am.

MS. BAL: Okay.

CO-CHAIR CROOKS: Okay. Welcome. You have the floor.

MS. SINGER: So, thank you very much. I'm Dale Singer. I'm the Executive Director of the Renal Physicians Association. And I'm going to let Paul Palevsky, who was a member of our Measure Developer Group, take the lead on summarizing this measure.

CO-CHAIR CROOKS: Thank you.

MR. PALEVSKY: Thank you, Dale.

So this is actually a measure that has previously been endorsed by NQF. It's a physician-level measure. Percentage of patients aged 18 years and older with a diagnosis of end-stage renal disease receiving peritoneal dialysis who have a total Kt/V greater than or equal to 1.7 per week measured once every four months. So

total meaning both residual kidney function and dialysis clearance. The rationale for this is that adequacy of dialysis is strongly associated with better outcomes including decreased mortality, fewer hospitalizations, fewer days in the hospital and decreased hospital costs.

This is an intermediate outcome measure. It is currently in PQRS and it is included in the RPA kidney quality improvement registry for 2015.

This measure is based on the KDOQI Clinical Practice Guidelines that we acknowledge are a bit dated, but they have not been updated. Guideline 2 from those CPGs state that for a patient with residual kidney function, the minimal delivered dose of total small solute clearance should be the total of peritoneal and kidney clearance of at least 1.7 per week. And for patients without residual kidney function, the minimal delivered dose of total small solute clearance should be a peritoneal Kt/V urea of at least 1.7 per week measured within the first

month after starting dialysis therapy and at least once every four months thereafter.

There was concern previously regarding performance gap. When we went back -- and whether there was a performance gap -- per the last USRDS annual data report this target is being met by 87 percent of patients. So there's still a gap. We do not have disparities data.

So I will leave it at that point unless you have additional questions for me.

CO-CHAIR CROOKS: Okay. Please stick around. There will likely --

MR. PALEVSKY: I will.

CO-CHAIR CROOKS: -- be questions. Okay.

Okay. So Measure 321, re-endorsement, adult kidney disease, PD, adequacy, solute. Outcome measure, intermediate. And in the evidence they did use primarily KDOQI. They did provide a systematic review of the evidence and did include the ADEMEX study. And I thought ADEMEX was post-2006. Am I wrong about that? Am

I getting -- is it earlier?

PARTICIPANT: (Off microphone)

CO-CHAIR CROOKS: Yes, okay. So it does include ADEMEX in the analysis.

So I felt that given that, nephrology has -- at least has a couple clinical trials in this that the evidence is sufficient and actually strong.

Mahesh, did you have any thoughts about the evidence that --

DR. KRISHNAN: Yes, I thought there was sufficient evidence. I don't have anything else to add.

CO-CHAIR CROOKS: Let's open it up then. Who would like to make comments on the evidence? Alan?

DR. KLIGER: Only to add, although it's not analyzed here that the international PD Group reviewed the evidence as well. When they revised this number down to 1.7, they were the first one to do that because KDOQI originally was 2.0. And the evidence that they cited was

convincing.

CO-CHAIR CROOKS: Good. Other comments on the evidence?

(No response.)

CO-CHAIR CROOKS: Okay. Am I seeing any cards? No. Okay. Then I think we're ready to vote on the evidence.

MS. OGUNGBEMI: The Committee is now voting on evidence for Measure 0321. The options are: one, high; two, moderate; three, low; and four, insufficient. Voting is open.

(Voting.)

MS. OGUNGBEMI: Results are 11 votes high, 11 votes moderate, 0 votes low and 0 insufficient. The measure passes on evidence. And that's Measure 0321.

CO-CHAIR CROOKS: Okay. Performance gap. I think they make the case. Mahesh?

DR. KRISHNAN: Yes, I agree. I just had a question for Paul.

When you said 87 percent of patients, since this is a clinician-level measure, we don't

have any inter-clinician variation in that, right? It's just the national data?

MR. PALEVSKY: No. No, and I'm just -- that's just the most recent data on a patient level. And I don't have clinician-level data.

DR. KRISHNAN: Yes. So I know there's a gap because we still see this, but -- that's not supported by the data, but I believe there is a gap.

CO-CHAIR CROOKS: Okay. Other comments about the performance gap? Alan?

DR. KLIGER: Well, this is a question I'm going to raise related to this and other of our adequacy measures when we talk about performance gap because it really gets to be very subjective, right? If the performance gap were that 98 percent of patients are there and 2 percent don't, we might have some agreement that there's not a performance gap. And if it was 50 percent of patients that got there and 50 percent who didn't, we might have general agreement that there was a significant performance gap.

But when we're talking now about 14 percent that don't get there, or 10 percent that don't get there, or later on 6 percent that don't get there, some of the other measures, I think it's worthwhile just discussing for a moment what we as a group think of as a significant performance gap.

CO-CHAIR CROOKS: Do you look at the standard deviation? If the standard deviation goes over 100 percent or under 0 percent, that might be another measure of how close they are. When you get to 95 percent in Kt/V, there's always going to be 5 percent who have malfunctioning catheter or a half-obstructed fistula. And I don't think 100 percent is possible. And that might be -- in my mind that's topped out. But at 80 -- what is this, 86 percent? Seventy-six percent.

MR. PALEVSKY: Eighty-seven percent.

DR. KLIGER: And just asking a general -- I'd like to just address our general sense of this.

CO-CHAIR ANDERSON: Okay. Josh first.

DR. ZARITSKY: As a relative newbie again, when something like this is topped out, I mean, then there's always room for like a backslide or something like that. This still remains a performance measure, so I would be reticent to see -- we're not dealing with one percent or zero -- I mean, that there's -- that it would seem to me that this still needs to be continued.

CO-CHAIR CROOKS: There is an option for that. And we're going to be talking about that quite a bit this afternoon, I think, as many of these measures are threatening to be topped out. And that is called reserve status where if all the other criteria are met but the performance gap is low, endorsement can be considered but in reserve, which is saying to the healthcare world that keep an eye on it, but this is not -- don't spend a lot of your resources on it right now. But we're going to continue to keep it on because it is important.

DR. KRISHNAN: And there's a mathematical definition. I don't know, Joel, if you have it, but I think in last year's final rule, or it was the year before, CMS actually published a mathematical definition of what they consider topped out. So I think there is -- I think it's interquartile range. I don't remember.

I know, Joel or Joe, if you guys remember that. But there is a mathematical definition, at least for public measures that was used which seemed to make a lot of sense. I think we used it for the pediatric measure. I don't remember. Joel, do you remember? You know what I'm talking about?

DR. ANDRESS: So there are actually two partner criteria for it being topped out. One is the interquartile range.

DR. KRISHNAN: Right.

DR. ANDRESS: And I am completely blanking on what the other one is, but we could probably look into it and get that to you in

fairly short order.

DR. KRISHNAN: Yes, but that's what I use when I think about this. And I think the KECC Group did a really good job when they looked at this for one of the previous measures in terms of the -- is there a clinically meaningful difference amongst the interquartile or interquintile, whatever you want to use, range so you can apply it, to answer your question, Alan, is what that is.

DR. ZARITSKY: But philosophically when you mentioned, do organizations spend time and energy -- so but, I know we're not making that assumption, but by taking something and putting in reserve status or taking it off the table, then that energy still needs to be -- we all agree the energy still needs to be made to make sure that people are measuring Kt/Vs and ensuring it's a good level.

DR. KRISHNAN: Yes, I mean, I'll tell you what we do. When we hit -- internally when we hit a metric that's topped out, we fix it. We

tell the facilities they have to stay there. And then we give them something new to play with, right, whether it's these complicated other measures or something like that. So that's what we do operationally. Because it's sort of like Six Sigma, right? Once you get to a certain level, to get from the fourth to the fifth Sigma takes so much effort you might -- and if it's not clinically meaningful, go play with something else.

DR. SOMERS: And just going back to what was asked, I think in my mind very much it depends on the measure itself. And part of it and how I look at it is the evidence that's been given for the importance of that measure itself. So I mean, if there are profound ramifications to the patient for not meeting that measure, then I would want a very, very tiny performance gap, almost what Sarah mentioned earlier today in terms of you know sentinel events, maybe something that you'd still -- if there's a very tiny gap, you'd still want to have that as a

measure in place.

DR. KLEINPETER: I know that looking at it from some of the networks, the number of units that have 11 patients to report has been a lot of the problem. And so a lot of the units don't feel that they don't have that number of patients. Because it's not going to be a clinically significant number, they aren't significantly looking at it in any systematic process. And so that may be some of the performance gap that exists overall. With two or three nephrologists going to one unit, then each of them having not the number of critical mass at the facility level they need to look at it, not necessarily at the individual level.

CO-CHAIR CROOKS: A hidden performance gap perhaps. Franklin?

DR. MADDUX: So this may come up in a variety of the adequacy discussions over the afternoon and tomorrow, and I think probably less so with this one than the others, but I think on the specifications, clearly with regard to Kt/V

there are a lot of inter-organizational variable ways of doing the actual test. And when that happens, you can get substantial -- not inter-unit variability, but inter-organizational variability. And we've got a -- less so again with PD adequacy, but certainly for some of the others. I think that's one of the things that I would ask measure developers to be very conscious of, is -- the specification is clear enough at the actual level of measurement, because they're not always done the same way and it makes a difference on how the benchmarking goes and what the outcome is.

DR. ANDRESS: Excuse me. So I just pulled up the topped-out criteria just real quick. The first is if the -- depending on directionality of the measure, if the 75th percentile and the 90th percentile of the distribution are statistically indistinguishable. Of course in the alternate directionality it's the 10th percentile and the 25th percentile.

The second criterion is that the

truncated coefficient of variation is less than or equal to 0.1. There's a formula that we provide that we use to calculate that in the rule. And we use that to define whether or not a measure has topped out for the purposes of the QIP.

DR. KLIGER: Yes, so my recommendation would be that those measures, that those calculations be part of what we see when we consider these measures.

CO-CHAIR CROOKS: Those aren't NQF definitions, I don't -- are they?

(No response.)

CO-CHAIR CROOKS: No, they're not. But I guess we could ask NQF to look at that.

DR. KLIGER: That would be right. I request a recommendation.

MS. BAL: We can definitely take that into consideration and moving forward see what we can do to incorporate those, but at this point NQF does not have set boundaries for gap or any of our other criteria.

CO-CHAIR CROOKS: Okay. Michael?

DR. FISCHER: So, the other issue in performance gap that we had talked in our call was if there was a variation performance across race, sex or disparities. And previously that data was somewhat old and/or it focused on receipt of peritoneal dialysis, not adequacy. It seems like Paul had some more recent data. I know, Peter, you and Mahesh were leading this, but I wanted to just see because I think that was another concern we had raised on our working group call. And before we went to voting I just wanted to circle back to it and also to allow the developer to have a time to respond as well if they had more robust or more recent vintage data.

MR. PALEVSKY: As I commented, no, we don't have disparities data.

CO-CHAIR CROOKS: Okay. Thank you for bringing up the disparities potential gap. That's important. Even if a measure was topped out, for instance, there could still be significant disparities. And I know of at least

one in my research point to some disparities in PD use, at least, by ethnicity. I don't know about hitting the target or not, but it is possible that there is some.

DR. KRISHNAN: The data is available. I've just never seen it run.

CO-CHAIR CROOKS: Yes.

DR. KRISHNAN: And I think to Mike's point, the developer submission had to do with access to PD as opposed to differential achievement of a target Kt/V by race or by any other factor could be done.

CO-CHAIR CROOKS: Okay. Other comments before we vote on performance gap?

(No response.)

CO-CHAIR CROOKS: Then we're ready to vote.

MS. SAMPSEL: So I just want to mention real quick this is another area with getting the PQRS data out of PQRS in order to present it to the Committee. And that was something that we were not able to get prior to

the meeting, so this is the data that's available for your consideration. There's definitely cases where other developers have provided this age of data, et cetera, based on what was tested. So it is what it is, but we tried to get the data and we tried to get updated data for RPA.

DR. KRISHNAN: Are you saying, Sarah, that the RPA didn't have access to the data, or CMS didn't have access to the data?

MS. SINGER: Neither. We couldn't get access to the PQRS data from CMS.

MS. SAMPSEL: I think there probably is a mechanism to get the PQRS data that requires a level of analysis and obviously that expertise to do so, and that's something that we can continue to explore. But I know other committees have dealt with this as well, that it's just very limited, what is produced in the public reports that you can just pull of the Web, and it's really only for the top reported measures. And that was back to my comment about how many of the nephrology measures are top reported.

CO-CHAIR CROOKS: Thank you. Okay. Are we ready to vote?

(No response.)

CO-CHAIR CROOKS: Let's do it.

MS. OGUNGBEMI: The Committee is now voting on Measure 321 for performance gap. The options are: one, high; two, moderate; three, low; and four, insufficient. Voting is now open.

(Voting.)

MS. OGUNGBEMI: Results are 4 high, 16 votes moderate, 1 vote low, 1 vote insufficient. The Measure 0321 passes on performance gap.

CO-CHAIR CROOKS: Okay. On to specifications. I had a question about how this is done. From reading through the submission, it seems as if there's a check box the provider checks that says I have measured the residual Kt/V and I've added to the dialysis Kt/V and it's 1.7 or greater. And it's a check box. Is that the way the data is collected? Did I get that right? As opposed to looking at lab data and doing some calculation to --

MR. PALEVSKY: I believe that as this was originally developed, that is correct, that this was an attestation measure. Amy, you correct me if I'm incorrect on that.

MS. BECKRICH: I believe that is correct.

CO-CHAIR CROOKS: So then that gets into the reliability and validity parts. How was that checking done? In other words, was there testing that went back -- okay. You checked this box that they have Kt/V over 1.7. Now, I'm going to the records for that period of time where you checked the box yes and I'm going to see if they really did. Is that the type of checking that was done? It mentions use data element and inter-rater reliability. Now, if it was inter-rater reliability about noticing that a check box was checked or was it actually tested against real values in the chart?

MS. SAMPSEL: Can you please go to page 24 of the evidence? So it would be the evidence form, or the custom form.

Yes. So, I mean I shouldn't be doing this, but I think my interpretation of this was that -- and this measure was tested in conjunction with the AMA-PCPI and RPA as the Lead Clinical Specialty Group when PCPI was developing the PQRI PQRS measures. And so what they did from my recollection was pulled a -- out of a number of practices; and we'd have to go somewhere else to find that, but pulled 30 to 35 charts from each practice.

And then you can see here on page 23 in the testing form what exactly they were looking for documentation of in the medical record. So they were looking for the Kt/V, which I don't know what that is, and I should know from all your work groups so far, but obviously I didn't. So that is what they tested and the information they pulled from each medical record.

CO-CHAIR CROOKS: That does seem to be consistent with what they're saying in this section, that they had reviewers on site; this is in the validity section, that looked for the data

including -- well, that the clinical records were a valid representation of what had transpired. So the wording is a little loose. I would like to be reassured that this isn't just a check-box metric and that it actually reflects reality. And I'm not totally reassured about that. That's my take.

Mahesh?

DR. KRISHNAN: Yes, I was just going to add that I think that that data capture mechanism also -- if we look at what Myra was just saying about the minimum cell size. So there has to be at least 11 patients, which we'll see in some of the other measures. I think that having the actual data may help with that. But I think you need to have a minimum number of patients in order to make it reasonable, because It think if it's less than 11, there's just too much variance, right? One patient here or there can completely screw up the values. So I mean, it goes back to data collection, but it's also in the specifications. I'd like to see a minimum

number. And we'll get to maybe as we harmonize. But that's something I would comment on.

CO-CHAIR CROOKS: Is there a minimum number required for a -- this is a clinician level.

MS. SINGER: Yes, and actually moving forward these are in the electronic health record, so they're being reported through PQRS through the electronic health record.

CO-CHAIR CROOKS: So the minimum facility size wouldn't apply, I don't think, to this --

MS. SINGER: No, they're clinician level.

DR. KRISHNAN: It would be the minimum number of patients that a clinician would see. What Myra just said, right? I think that's what you just said, right, Myra?

DR. KLEINPETER: Yes.

DR. KRISHNAN: You'd want to see 11 patients per physician.

DR. KLEINPETER: And I think that's

what in this -- that's what's required on page -- I think it was on page 5 or 6 where they're doing the validity testing. Page 6 of 34, 321. First statement says -- somewhere it mentions were there 11 patients.

DR. KRISHNAN: Usually the 11 comes from the facility-level measure. I don't know if it was in -- or is it also in the clinician-level measure?

DR. KLEINPETER: I don't think we have it.

DR. KRISHNAN: Yes, I don't think it's in the physician-level measure, but the minimum cell size for the facilities is there. I just wonder whether or not there should be a minimum cell size for clinicians for this to be meaningful as well.

DR. KLEINPETER: Well, the other thing for clinicians, a lot of times we're seeing people at multiple sites. So you may have your 11, but you're going to multiple facilities as opposed to going to one individual provider.

CO-CHAIR CROOKS: I'm still left with questions, and I would put the burden on the developer when creating the submissions to make it -- really draw it out for us. Show us the money. Where is the connection, that the Kt/V was actually looked at? And also that validity fits the metric. Because here is this facility testing. I guess you're comparing facility testing to physician office testing. Was that the validity -- in other words, I'm just not seeing a clear line of how this was done and why we should be convinced from this that it's a reliable and valid measure.

MS. SINGER: Well, when it was originally tested, it was -- the data was pulled from charts. It was the old days before electronic health records. So now they're all e-specified for electronic health records. And we haven't gone back and tested since the original testing was done on the original measure.

Moving forward they're part of our registry, which is a qualified clinical data

registry by CMS. So they'll be in our registry, which will allow us easy access to the measures to know what's happening. But in the past it was done by hand by going in and taking charts and checking.

CO-CHAIR CROOKS: Okay. Other concerns about specifications or reliability?

DR. DALRYMPLE: So, Peter --

CO-CHAIR CROOKS: Lorien?

DR. DALRYMPLE: Can I just ask a point of clarification? Just when we were looking at the reliability testing, the numerator would only be those who achieve a Kt/V above 1.7, not those with less than 1.7 and a plan of care documented, is that correct? Just since that's included in the reliability testing, I just want to make sure I understand the numerator that's the focus of the measure. You have to achieve the Kt/V, is that correct?

CO-CHAIR CROOKS: And I think it would be fair to say it's more a measure that two raters rated it the same.

DR. DALRYMPLE: Oh, I just wanted to specify --

CO-CHAIR CROOKS: Rater A versus Rater B.

DR. DALRYMPLE: -- who gets counted in the numerator, not the inter-rater reliability. In the reliability testing they list people who have a Kt/V less than 1.7 with a plan of care versus without a plan of care. And so, sometimes numerators allow for you not to meet the target as long as you have a plan of care. I just want to make sure I understand this measure. The numerator you have, to achieve the Kt/V, not not achieve it and have a plan of care to get counted.

MR. PALEVSKY: That is correct. This is the numerator of the patients who have a total Kt/V greater than or equal to 1.7.

DR. DALRYMPLE: Okay. Thank you.

MS. SAMPSEL: The other thing I just might want to draw your attention to, one of the documents that the developer did provide that was

in your measurement folder are the actual specifications that walk you through very clearly -- I mean, the testing data is one thing, and that was a good question to clarify that, but then how the measure is currently implemented as an e-measure is, in my opinion, extremely clearly specified in a five-page e-specification document.

DR. KRISHNAN: So, Dale, the current measure will be done to the e-specification as Sarah said, but the validation data we have is only in the chart review from 2007-2008?

MS. SINGER: That is correct.

DR. KRISHNAN: Do you have plans to revalidate it with the e-specifications?

MS. SINGER: Absolutely. On an ongoing basis that we will have access to the data.

DR. KLIGER: I just want to say a word about the cell size that you mentioned before. In peritoneal dialysis, if we are only examining physicians caring for more than 11 patients,

we're talking about a handful of physicians in the United States. So my take is that it's less important to show a statistically significant difference for a cell than it is to have in place an appropriate measure of adequacy. So I think it's appropriate in this physician-level measure not to have a minimum cell size.

CO-CHAIR CROOKS: Okay. Other comments?

DR. DALRYMPLE: Can I just ask one more --

CO-CHAIR CROOKS: Yes, Lorien.

DR. DALRYMPLE: -- clarification question using the e-specification? So I think the numerator, the last four are all total Kt/V. Are there rules on how long you can carry forward the residual clearance of urea? So for example, we can only see these total Kt/V fields, but I presume residual only is allowed to carry forward for three months or four months and then it drops as being included in the total calculation. Is that correct?

MR. PALEVSKY: If a patient has significant urine volume, the residual is supposed to be reassessed when you do the Kt/V calculation.

DR. DALRYMPLE: Right, as specified I just can't quite tell from these EHR what the time limiter is on when you allow to use the past measure. Will it cut out in this new data set at four months so that it drops if it hasn't been repeated? And I'm sorry. Does this make sense or should I ask it another way?

MR. PALEVSKY: It makes sense. I don't have available to me the full e-specifications.

CO-CHAIR CROOKS: I'm a little confused by a comment a while ago about either they have the Kt/V over 1.7 or there's a plan of care. Was that the old measure? Is that still in this measure, too?

MR. PALEVSKY: That is not in this measure.

CO-CHAIR CROOKS: Okay. That was a

prior version, as I recall. Okay. Thank you.

DR. DALRYMPLE: Could we just make that recommendation then that perhaps it would be helpful to have clarity on how long your residual kidney function is allowed to carry forward, that perhaps at four months it drops if it hasn't been repeated for your total Kt/V calculation?

MR. SAMPSEL: I mean, so what we'll do it is, when we're done with this conversation, everybody has their comments out, we'll go ahead and vote. And depending on the vote, whether it's recommended at this point or not, you still have that opportunity to say this is additional information we'd like to see. And it will be brought back to you before public comment.

DR. KRISHNAN: Should we vote?

CO-CHAIR CROOKS: I guess so.

MS. OGUNGBEMI: The Committee is now voting on reliability for Measure 0321. The options are: one, high; two, moderate; three, low; four, insufficient. Voting is open.

(Voting.)

MS. OGUNGBEMI: Results are 2 votes for high, 16 votes moderate, 4 votes low and 0 votes insufficient. Measure 0321 passes on reliability.

MS. SINGER: So, Lorien, can you go ahead and reiterate the comment of additional data that you'd like to see just so we make sure we have it in our notes?

DR. DALRYMPLE: Oh, sure. The only recommendation I'd make to the stewards for consideration is creating a drop date for the residual kidney function, that it be measured every four months and that if it's not remeasured, it doesn't get to continue to contribute to your total Kt/V, that that way people are encouraged to measure it as appropriate and not get credit for old measures.

CO-CHAIR CROOKS: All right. Moving on to validity. Validity testing was limited to face validity; that is, pulling a TEP panel with some impressive names on it. They voted 4.62 on a scale of 5. Mahesh?

DR. KRISHNAN: Yes, I thought that the data was good in terms of that, so I don't have anything else to add.

CO-CHAIR CROOKS: Other thoughts on their validity testing?

(No response.)

CO-CHAIR CROOKS: Okay. Well, let's vote on validity then.

MS. OGUNGBEMI: The Committee is now voting for Measure 0321 on validity. The options are: one, high; two, moderate; three, low; and four, insufficient. Voting is open.

(Voting.)

MS. OGUNGBEMI: The results are 5 votes high, 16 votes moderate, 1 vote low, and 0 votes insufficient. Measure 0321 passes on validity.

CO-CHAIR CROOKS: Okay. Feasibility. They claim it's all electronic, and I guess we just heard that it's moved to electronic database claims. And they state it's feasible and timely.

Mahesh, anything else?

(No response.)

CO-CHAIR CROOKS: Lorien. Sorry. Yes?

DR. DALRYMPLE: Sorry. Just one question. So the new database, is this something where individual EHRs transfer to it, or do physicians upload their own data?

MS. SINGER: Physicians are responsible for entering their own data, but ideally they integrate with their EHRs. But it's the physician's responsibility.

DR. KRISHNAN: And, Dale, is your sense that -- what will that look like between manual data entry and electronic? Do you have a sense?

MS. SINGER: It will not be feasible manually.

DR. KRISHNAN: It will not be feasible?

MS. SINGER: No.

CO-CHAIR CROOKS: So just to be sure I understand. You're saying that currently it

depends on physicians, but you're trying to get that link out of there?

MS. SINGER: I'm sorry. Say that one more time?

CO-CHAIR CROOKS: So you're saying currently the data entry depends on nephrologists sitting down and putting numbers into the system, but you're trying to move away from that by getting it directly from electronic health records?

MS. SINGER: No, physicians are not entering it manually currently. The registry just launched in March. And so, right now we're uploading data from EHRs.

DR. KLIGER: I mean, the challenge it seems to me with this and many of the other measures is that we're doing feasibility measurements retrospectively and talking about the feasibility moving forward, which is in a different system often using electronic records and electronic databases. So I mean, I think all we can do is judge feasibility as it's presented

to us and discuss the future, but I think we have to on what the feasibility testing looks like.

CO-CHAIR CROOKS: We don't have feasibility testing per se and we only have what they've submitted.

Okay. Other discussion on feasibility before we vote?

DR. KRISHNAN: Dale, your sense when it was being done prior to the registry, were there any issues? I know we talked about the original feasibility efforts, but then there were eight or nine years, or seven or eight years that elapsed.

MS. SINGER: Right. I mean, we do know it was being used in PQRS reporting, so -- well, yes, I mean, most of the PQRS reporting was also being done electronically. I mean, yes.

DR. KRISHNAN: I think, Peter, we just got to go with that as the feasibility, right? So if it worked originally in the chart review and it worked for the last X number of years, we got to work on that. There will be another data

system. It's hard for us to evaluate that. And there's no data.

CO-CHAIR CROOKS: We'll go with that. Okay. Are we ready to vote?

MS. OGUNGBEMI: The Committee is now voting for feasibility on Measure 0321. The options are: one, high; two, moderate; three, low; and four insufficient. Voting is now open.

(Voting.)

MS. OGUNGBEMI: The results are 6 votes high, 15 votes moderate, 1 vote low, and 0 votes insufficient. Measure 0321 passes on feasibility.

CO-CHAIR CROOKS: For usability and use. It is currently in the PQRS system. And also payment. So payment is being adjusted by this metric. And on the RPA Kidney Quality Improvement Registry with the possibility of having it used in the future for professional certification and recognition. So it is in use. It's probably usable.

(Laughter.)

CO-CHAIR CROOKS: Mahesh?

DR. KRISHNAN: I concur. I concur.

CO-CHAIR CROOKS: Others?

(No response.)

CO-CHAIR CROOKS: Okay. Let's vote.

MS. OGUNGBEMI: The Committee is now voting for Measure 0321 on usability and use. The options are: one, high; two, moderate; three, low; and four insufficient. Voting is now open.

(Voting.)

MS. OGUNGBEMI: The results are 15 votes high, 7 votes moderate, 0 low, and 0 insufficient. Measure 0321 passes on usability and use.

CO-CHAIR CROOKS: All right. Before we vote on recommending for endorsement, any other general comments? Speak now or --

DR. KRISHNAN: I think we'll get to this when we do the competing measures reconciliation, but clearly --

CO-CHAIR CROOKS: Yes, we'll talk about competing and related measures in a while.

Hopefully not too long a while.

(Laughter.)

CO-CHAIR CROOKS: Okay. Let's vote then for recommendation for endorsement.

MS. OGUNGBEMI: The Committee is now voting for Measure 0321's overall suitability for endorsement. Options are: one, yes; and two, no. Voting is open.

(Voting.)

MS. OGUNGBEMI: The results are 21 votes yes and 1 vote no. Measure 0321 passes for suitability for endorsement.

CO-CHAIR CROOKS: Okay. Thank you. And now the coat comes off --

(Laughter.)

CO-CHAIR CROOKS: -- as we have 15 minutes until our break or so. And we're going to jump into the next group of three measures. We're only probably two-and-a-quarter measures behind for the time, so that's not too bad.

So I'd like to invite to the stand Joe Messana and, Joel, again, if you'd like to. For

Measure 318. Three-one-eight on your programs, folks. Three-one-eight now starting in center field.

DR. MESSANA: Okay. So I remember this morning where the Committee and the measure developers were charged with trying to keep this group on time, and I'm going to do my very best.

So my opening statement is we're talking about 0318. I think you've all had the opportunity to read it. There were a couple of questions that came up from the work group that I just want to address. I did a little bit of background work with the analysts figuring out -- or making sure that I understood the calculation algorithm because people were asking about that based on the measure that was submitted. And I think the other comment that came up for all of our PD adequacy measures was this upper bound issue.

So let me start with the upper bound bit first. The upper bound is intended to exclude clinically implausible values from the PD

adequacy. A PD Kt/V that's that high is almost impossible -- it is impossible to achieve, in my 30 years of clinical experience, unless you have enormous residual kidney function to the point where you wouldn't need to be on dialysis. However, I don't think it's that big a deal if it's not acceptable to the Committee to leave it on. I think we can discuss it further. But it was just intended to weed out clinically implausible values, data submission errors. Okay?

The issue about how the calculation actually occurs in CROWNWeb is a bit interesting. So what we do to calculate this measure; and this is consistent with the calculations we did for all the validation and reliability that you see, is at the patient level we obtained PD Kt/V values from CROWNWeb at the patient level. And those have a month associated with them. Okay? And we store those. And those Kt/V values include residual kidney function, because that question came up.

But every place we describe the measure, it's dialysis and residual. That's intended to be residual kidney function, but it was shortened or abbreviated just to provide a lack of clarity, because we think that's important. But this is the standard traditional way of calculating PD Kt/V with inclusion of residual kidney function if there's any residual urine. So that patient level value with a month attachment is stored.

And so, when we go to calculate the measure, the denominator exclusions apply for any one month. We look at patient months where they meet all the inclusion criteria in the denominator and then we look back and say, is there a PD Kt/V within the four months of that calculation? And we use the most recent one. So that's how it is calculated.

So you're not penalized if the data are in CROWNWeb if the patient level data about a Kt/V having been done anywhere are on CROWNWEb. You're not penalized on transfer if you haven't

done a Kt/V in the first month or first two months.

DR. LATTS: But you're only looking for one value within the four months and then you use the most recent? It's not that you're looking every single month?

DR. MESSANA: We have all of those. We use the most recent Kt/V if we have multiples. Okay? So that's a clarification. And we can update the calculation logic and measure specification to represent that, but that is what is happening. I've checked, and I've threatened, and I've plied analysts with candy and all sorts of stuff. But that's what's going on.

So I'm going to stop my comments there to save time, and I think that addressed a couple big issues that came out of the work group. Thank you.

DR. LATTS: I am going to take this one.

CO-CHAIR CROOKS: Lisa?

DR. LATTS: We're oh for one so far,

so we'll see how we do here.

(Laughter.)

DR. ZARITSKY: I disagree. Maybe we're one for one.

DR. LATTS: Yes, maybe. Exactly.

(Laughter.)

DR. LATTS: So as we've discussed, this is a similar measure to the previous measure in the sense that we're looking at dialysis at PD adequacy. So Kt/V, looking at a lower bounds of 1.7. And then this one does have an upper bounds of 8.5. As we discussed on the last measure, there is pretty good evidence now for dropping the bounds from the -- this is a re-approval of this measure. This is a previously existing measure. It was two prior. So we are dropping to 1.7 for this measure. Good evidence from that. From my understanding a lot of questions and perhaps less adequate evidence for the upper bounds.

DR. ZARITSKY: (Off microphone)

DR. LATTS: Well, yes, I was being

kind. So it is an intermediate clinical outcome measure and there is reasonable evidence that if we achieve this outcome it will lead to lower mortality. At least a small reduction in mortality and hospitalization was shown based on the data. And I will stop there.

DR. ZARITSKY: I agree with Lisa. I think that the one thing that we've all -- looking at these measures is that the upper bound; and we're going to talk about evidence, we're going to get really stuck. And I understand why it was included, but with that upper bound in place and we have to do an evidence analysis, I don't see how there's any evidence to support an upper bound.

CO-CHAIR CROOKS: It seems going to the specifications that any value over 8.5 is thrown out as being a spurious value and it doesn't need to be --

DR. KLIGER: Yes, but just to clarify, we often have methods of excluding implausible data that are not part of the specifications of

the measure. That's in sort of the Manual of Operations about how we deal with all measures. If you're measuring calcium, if you get a value that's 20.8 rather than 8.8, we don't include that in the specification. We have a way of making sure that we functionally can exclude implausible numbers.

But when it's in the specification, it suggests that the outcomes are worse when it's below the lower limit or above the upper limit. That's really what it implies when you have two limits like that. And I would suggest that there's no evidence that the upper limit for any of the measures we're going to look at that are being proposed for adequacy -- no evidence that we have worse outcomes above the upper limit that's been proposed.

CO-CHAIR CROOKS: Okay. Other thoughts on the evidence?

DR. KRISHNAN: So are we voting on it as is, or are we voting on it with the --

CO-CHAIR CROOKS: No, we have to vote

on it as it is.

MR. SAMPSEL: Yes, you vote as it has been submitted. I mean, so and then just so we can walk through this, in the event that you would vote it down saying there's not enough evidence, we would then -- while it wouldn't go through the full criteria at this in-person meeting, we would then say, okay, help these developers out. What are your recommendations that would make this more plausible for you? And then would have time to revise during the public comment period.

DR. LATTS: And then if they revise it during the public comment period, does it come back to Committee for review in totality from soup to nuts?

MR. SAMPSEL: Well, basically it would come back to the public. Yes, if you stop it here, it stops. We're not going to have any more votes. But we can have the discussion. And then when it comes back, you would do a total review. At the same time you could say that that's lovely

what you did, but to us we don't agree it requires a re-vote. We still don't want to recommend it.

DR. LATTS: And could we just for efficiency's sake, since the developers have already told us they'd be okay tossing out the upper bounds, go through the rest of it for -- not for actual voting, but to give the developer input now on the rest of it, just again to save us time later since it's so much easier to do this in person than in a phone call?

MR. SAMPSEL: Yes, you can do that as well.

CO-CHAIR CROOKS: That was my thoughts, too. Right.

DR. KLIGER: With the understanding that we're saying for today we'd be saying no.

MR. SAMPSEL: Correct.

CO-CHAIR CROOKS: Correct, but with the understanding that we're working with the developer to improve their metric. And they might as well hear whatever other feedback we

have, but we're not going to vote on the rest of the criteria. So it would be less of a formal structure, but they'll get to hear other thoughts from the Committee.

MS. BAL: The only thing additionally I would say is you could also again vote with exception or you can vote it down as well. Or you can continue to vote it as is, and they can still bring that back revised if you recommend or don't recommend it. So either way, if you want them to come back with revisions, they can, and that can be something that we discuss at the post-comment call. So it doesn't necessarily have to be that it's not recommended and then you're given new information. I just wanted to let everyone know that that is -- there's both options. If you recommend it to move forward and then we can discuss it that way. They can bring more information. And if you recommend not to, they can bring more information and then we'd move forward.

DR. KLIGER: Yes, but I mean again, I

presume you're suggesting that our judgment here about evidence has to be based on what we have currently about the evidence, and the evidence is for the measure as presented to us, right?

(No response.)

DR. KLIGER: Okay. Thank you.

DR. SOMERS: But we can vote insufficient evidence and move forward, is what --

(Simultaneous speaking.)

MS. BAL: You can vote insufficient with exception --

DR. SOMERS: Yes.

MS. BAL: -- and move forward, yes.

CO-CHAIR CROOKS: With the exception that they need to fix the upper limit?

MS. BAL: Well, there would be no exception listed, but all you're saying is that you're moving the evidence forward even though you feel that it's weak or low. And you're saying that despite that you feel that you should move forward with the measure. That's what

you're saying. So you can choose that right now what evidence you've been provided you don't feel that it's -- if you vote just insufficient, that means it goes down. If you vote insufficient with exception, you're saying that it's okay to go for now and the developer can bring updated information for you at the post-meeting.

CO-CHAIR CROOKS: So if we did vote to accept it with exception and then later they didn't meet our criteria, would we be able to take it down at that point?

MS. BAL: Yes. So at the post-meeting call if you -- because it would be with any measure, even if it didn't have to do with this one.

MR. SAMPSEL: Can we just go on break for a minute. The steward has some issues. So can we just go ahead and do the break and then come back?

CO-CHAIR CROOKS: It's been suggested that we take a break.

(Laughter.)

CO-CHAIR CROOKS: All in favor?

(Chorus of ayes.)

CO-CHAIR CROOKS: Okay.

(Whereupon, the above-entitled matter went off the record at 3:27 p.m. and resumed at 3:45 p.m.)

CO-CHAIR CROOKS: We're going to have Sarah I think will give us an update on where we're at with this issue on the upper limit.

MS. SAMPSEL: All right. Luckily I've had renal measure training over the past couple of years. So I was ready for you all.

But anyways, I think what we're going to do here and have had discussions with our colleagues here at the University of Michigan and CMS. And we're going to do a couple of things.

First of all, they're going to make some stipulations to the Measure, which I will let them discuss. And then we want to continue to have the discussion for this Measure.

And we'll continue to go through the vote based on the stipulations that they are

making. We fully understand then that means what you will be voting on is not exactly what's in the paperwork that you received.

But we don't think the changes that they are going to stipulate and the clarifications that they're going to make, are big enough to warrant not considering them now versus the future.

So we will go all the way through the discussion. You will vote on the measures. It will be with the stipulations that the Committee is making. Therefore to streamline and have some efficiency in our discussions moving forward.

Because the stipulation frankly impacts all of the adequacy measures that CMS and the University of Michigan will be discussing, we will also then try to group discussion of the measures.

And although we need to vote on the measures separately, just kind of keep in mind that going forward for the rest of today, we want to make sure that we're drawing out anything else

that you think needs to be discussed on these measures. But also recognizing there are a lot of similarities between these measures.

And the University of Michigan is going to do that as well. So I'll ask Joel to make the stipulations on how they want to change the Measure.

DR. ANDRESS: So I, just -- you know, just to make clear. You know, the upper bounds were put in place more as an administrative means of ensuring that the data integrity were maintained.

And they were included in the description of the Measure as a means of being transparent to you and others in the community for understanding how we were calculating the Measure.

You know, I -- we are willing to stipulate at this point that we can remove the upper boundaries as a matter of moving forward with the Measure. I think there's no expectation on our part that we're presenting them as a

meaningful clinical guideline or boundary of performance of dialysis displays.

As I understand it, by doing so, we offer the opportunity to continue discussion on the Measure today. The alternative being that we shut down discussion now and attempt to review all -- I think it's next six or eight, whatever measures in a two-hour time period at some point after public comments.

And I would suggest that this is probably not feasible to accomplish. It doesn't make a whole lot of sense since we're all here anyway.

So we will stipulate that we will remove that boundary. The expectation will be that as has been stated, that the impact on the measures, the analyses that we have provided, will be negligible to trivial.

We will however, provide updated documentation for each of the dialysis adequacy measures. As well as updated analyses prior to the end of the public comment period for you to

review.

I think the goal in doing this is not to substantively change the measures as we presented them. But to provide us a path forward for discussing the measures. We're often clinical in reporting issues as we would wish to do for all of our measures.

And so we lay that before you for your consideration.

DR. DALRYMPLE: There's just one other question I wonder if I can bring up as long as there's going to be stipulations made about all the PD measures?

I noticed in all of them, weekly Kt/V is interchangeably used with single pool Kt/V, including in this one. And I'm wondering if we could actually specify that's what intended in all the PD measures is not a single pool, but weekly Kt/V?

DR. MESSANA: No. Since Microsoft is not represented at the table, we would like to --

(Laughter)

DR. MESSANA: Glean, replace function and Word for that. Someone went through and was a little over zealous in trying to standardize measures. And got into a couple of the PD ones.

Clearly single pool Kt/V is not what we ever intended with this. And part of that stipulation will be to clean that up for all -- for the PD measures.

It comes up mostly on the pediatric one, 2705 I think.

DR. DALRYMPLE: It's in this one for example. And I think it shows up in almost all the PD measures. But I'm just wondering as long as we're stipulating.

DR. MESSANA: Yes. That's --

DR. DALRYMPLE: Clarifications for purposes of us making progress through today, would that be also acceptable to stipulate that that's not?

DR. MESSANA: More than acceptable. It's accurate.

CO-CHAIR CROOKS: Thank you for

clarifying that. And thank you for reading the measures very carefully Lorien.

Okay. Alan?

DR. KLIGER: I just have a procedural question for the NQF staff. I don't remember a precedent for this. That is, changing the specifications of a measure based on a discussion and then moving forward with the discussion.

So, just help me understand whether this is something that you have entertained and do with stewards other then CMS?

MS. SAMPSEL: No. I mean, this is definitely something, it may not have ever happened in renal, but has happened in other measure development activities.

And I think folks who have participated on other committees would recognize that. And it's not just for CMS measures.

DR. KLIGER: So, I'm sorry, but does that mean that as we continue to hear measures through the rest of today and tomorrow, or in the future, that our policy will be that we will

consider revising those measures based on what we say as we move forward?

MS. SAMPSEL: Well, I don't think in this case that -- I mean, I think even as Joel said, that there's kind of an interpretation of how the specification is written. That I don't believe that they are substantially revising this Measure based on your input or on the evidence input.

And that's still not on the table. You still -- you know, it's still not up to the committees to tell measure developers how to revise the measures.

You can make recommendations for their consideration. But, you know, I really think in this case as in the previous cases, that just kind of the -- kind of small magnitude of the change that's being made to this Measure and based on the evidence presented and everything else that's in the submission form it goes in line with that change that they're making.

MS. BAL: And just to --

DR. KLIGER: I think it's a wise choice. I just want to be clear about the precedent that we're setting here. That's all.

MS. SAMPSEL: So, it really is not a precedent. So, go ahead Poonam.

MS. BAL: I just wanted to say, the difference is that the change they can make, they are guaranteeing that they're going to implement it before we get to the pre-meeting comment meeting.

If the developer said that they would look into it and attempt to make that change, then you should not be taking that into consideration. However, they have said that they can make these changes and will have them made by the next meeting.

That's why -- that's the difference of why this is okay and perhaps another one would not be.

DR. LATTS: Well, and I would say the other difference to my mind, is that it does not affect any of the downstream reliability,

validity or clinical utility.

Because it was almost a -- it was a misinterpretation I think of what you were trying to do that this sort of got added into the measure specs. Is my interpretation.

CO-CHAIR CROOKS: Okay. Thank you. The Chair is comfortable with this too. And I'm the senior renal steering -- I think I'm the only original one left from all four.

So, yes. Okay. So, where were we?

(Laughter)

CO-CHAIR CROOKS: We're going to vote on evidence that we have to this point. We talked about the bonds and that's gone. Other comments on the evidence before we vote on this?

DR. LATTS: And again, just to clarify, we're voting on evidence -- are we voting on evidence based on what's here and then moving on? Or are we voting on evidence based on lopping off the top -- lopping off the top?

CO-CHAIR CROOKS: Yes. It's gone. So, we're going to vote on the evidence as it

applies to the metric as now stipulated and specified.

Okay. Any other comments on the evidence?

(No response)

CO-CHAIR CROOKS: I think I'm the -- Okay, let's vote.

MS. BAL: Oh no. You know, evidence is a bad slide. We'll just --

(Laughter)

MS. BAL: Just for the sake of time, let's just go ahead and do a hand count again. We're having some issues with our evidence slide.

So, for -- if you vote high for 0318, evidence, please put your hand up now. Please, very high.

Okay. I have three. All right, moderate?

All right, that's 20. And then I will just go with zero for the other two because no one else can vote at this point.

So then the results for 0318,

evidence, is three high, 20 moderate, zero low, zero insufficient. And we can move forward to gap.

CO-CHAIR CROOKS: Okay, Lisa?

DR. LATTS: Okay. Next up. Opportunity for improvement. So based on 2013 Crown Web data, there was -- and again, looking at the four-month spec, which was not something that I understood, so thank you for explaining that.

So at least once in four months it was 78.6 percent. So just about 79 percent in terms of the PD adequacy across the board. When they looked at subsets of racial and ethnic populations, it was statistic -- again, similar to what we've seen in the previous measures.

Statistically significant but not clinically significant with ranges from 76.9 percent to 79.3 percent between the old, the young, the black, the white, the Hispanic or not, and male or female.

So, I would not take that to be

clinically significant. So, my take away is, I think that there is opportunity for improvement. But there are no significant racial/ethnic differences.

DR. KRISHNAN: And Developers, when you guys looked at the distribution of PD Kt/V, was it in the bell curve? Or was there -- was it asymmetrical?

Because I could just see based on the lack of microspecifications, you know, you're assuming that there's residual renal function in there. I am too.

But did you know, did you look at a histogram and see if there was a bimetal distribution suggesting that there are some people that are thinking with or without?

DR. MESSANA: I don't think I can answer that question right now and right here without making something up. And I'm not willing to do that.

I don't recall exactly. I can find out for you.

DR. KRISHNAN: Yes. And it would be worthwhile if you do. I mean, this is something that we've seen before.

DR. MESSANA: Yes.

DR. KRISHNAN: It's what happened with Kt/V in the claims data before.

DR. MESSANA: Yes. Yes.

CO-CHAIR CROOKS: Okay. Reliability? That was specs any. I have one question.

So the reliability testing in this case -- we're on performance gap. That's well --

(Laughter)

MS. OGUNGBEMI: The Committee is now voting on performance gap for Measure 0318. The options are one high, two moderate, three low, and four insufficient. And voting is now open.

MS. BAL: Or not.

MS. OGUNGBEMI: Oh, my gosh.

MS. BAL: Okay. Old school it is. So for 0318, gap, please put your hand up for high.

Okay. We have one. Okay, so for moderate?

Okay, 21. And then low? And insufficient?

Someone didn't vote. Or I counted wrong. But, so 0318, gap, one high, 21 moderate, zero low, zero insufficient.

And this Measure moves forward to reliability.

DR. LATTS: All right. So reliability, we've talked about the specifications. Basically anybody on PD who -- and looking at Kt/V -- weekly Kt/V, but then looking at the most recent measurement within a four-month period.

One question I had for the Developer is what if they do not have a Kt/V measured within that four-month period? How does the facility get assessed for that?

Because again, we don't want people to be able to get away with not measuring it. So that's one question I had.

Otherwise, when they looked at the IUR, it was the inter -- the within clinic

variation was very high -- or reliability, sorry, was very high at 91 percent.

They did note that it was not a -- sorry that it was not a -- what's the word I'm looking for? A standard distribution. So that needs to be viewed with some -- a normal, thank you. A normal distribution.

So, and the test was designed to be a normal distribution. So there was some, you know, just something to file away. But that it seems to be a fairly reliable measure.

DR. MESSANA: So, the response missing is counted against a facility. I mean, the intent is to -- is to report. And to meet a minimum threshold.

DR. FISCHER: I have one minor book editor comment. When you read your denominator statement on the first page as the Developer. You don't specify that it's people on PD.

And later down on page 15 or wherever, farther in, it's indicated but on the front it's not. It looks like there was a gap. I'm just --

anyway. So that's a minor comment.

More major comment is, if the data has a non-normal distribution and you're trying to apply a statistical test that requires that, did you transform the data and then apply the statistical test?

Or I just am curious for your rationale, just in terms of the robustness of assessing the statistical significance.

DR. MESSANA: So, thank you for the book editor comment. I was going to point out the denominator detail. But for the sake of time we won't -- hopefully won't have to go there.

We did check with our biostatistical colleagues. The ANOVA, one of the assumptions for ANOVA is normal distribution. But it's not very sensitive.

The IUR analysis is apparently not sensitive to that and still provides a pretty robust comparison between facilities and within facilities. So, they are very comfortable using it even though the data are not strictly

speaking, normally distributed or somewhat skewed.

DR. KRISHNAN: So I just, back to what I said before. Joe, it may be worthwhile just looking to see if there are some people that are reporting with residual/without residual, depending on how it's mapped.

That could be the -- I don't know. I'm just saying that could be the other reason why this normal -- not distributed. You can just file that away.

The other question I have is, it may be worthwhile to think about the first value in a month rather than the last value in the month. We've seen facilities that sometimes try to -- will keep the lab until they get something they like.

So we've gone internally to a system where we just take the first value. Because you can't fix that.

DR. MESSANA: So, two comments. The data element and CROWNWeb that we use is a

complete value. Right? It doesn't separate out the residual renal function from the -- it's the 1627.

DR. KRISHNAN: I hear you. Just I know how it works in the background, right. It's like a telephone game. Someone has hooked up a data variable to another data variable.

I'm not saying it's right or wrong. I'm just saying you may just want to look to see if that's what's happening.

I hear you, the specification is like that. I just can't --

DR. MESSANA: Okay. Mahesh, thank you for the comment. I can't -- it's not actionable for us based on the CROWNWeb extracts that we have.

DR. KRISHNAN: You can't do a histogram to see what --

DR. MESSANA: No, no. I can do a histogram. I can't do a residual renal function --

DR. KRISHNAN: Yes.

DR. MESSANA: Versus without residual renal function.

DR. KRISHNAN: Yes.

DR. MESSANA: Because the data element is a combined data element --

DR. KRISHNAN: Yes.

DR. MESSANA: In CROWNWeb. So, thanks.

DR. KRISHNAN: Yes. And then the second one was the issue around the first value of the month rather than the last value of the month.

DR. MESSANA: Yes, we -- so I'd have to go back and look. I don't think there are multiple values or many cases, if there are any with multiple values in a month.

We're talking about multiple values over four months. Remember, the reporting period is four months. So, I can check and see if there are any patients that have more than one PD Kt/V value within a month.

As someone who's provided home

dialysis and particularly PD for a long period of time, I would think that there would be negative marketing implications of asking people to present multiple 24 hour collections in a month.

But, it's possible. We can look at that certainly. So, thanks for the recommendation.

DR. KRISHNAN: Yes. It's just we've done that consistently now with all of our internal metrics to preventing gaming of the system.

CO-CHAIR CROOKS: I have a comment that is more of a comment than a question. But, it appears to me that this is -- still would fall in the category of a checkbox measurement.

You take the -- you have to take them at their word that the criteria was met for and then check that box. Interunit reliability is not going to verify that they checked the box right or not.

The fact in the validity testing you did test it against mortality and hospital days,

does show that there's some validity to it. But there was really nothing in there to really verify that the patients actually, you know, that when they checked the box the patients actually had that value.

And because this is a pay for performance measure, it just worries me that that's not really checked or acted, unless I'm missing something.

DR. MESSANA: It's not a checkbox. The value is reported. But it is -- the value is reported combined dialytic and residual renal function Kt/V.

So the number that shows up in that data field is a 1.8 or a 1.9 or a 2. And to Mahesh's question about residual renal function, there is no more granular data about what was the contribution of residual renal function.

CO-CHAIR CROOKS: Right.

DR. MESSANA: So, it's -- we are dependent upon providers reporting accurate data for all measures. And I -- we don't have any

evidence that that's not the case here.

But it's not a checkbox. It's the actual data volume.

CO-CHAIR CROOKS: Yes. I appreciate the difference. They're reporting a value, but you're -- you have to accept it.

And there's no place in the reliability/validity testing to actually go in and see that they're, you know, just on a spot, random sample, that they're actually putting in the right values.

That would strengthen it, but, okay. Other -- right.

DR. MADDUX: Joe and Claudia, I'm wondering if there was any consideration made for patients new to the modality and the timing?

You have in the denominator the SRD greater than 90 days in adults. And being in the facility for an entire month.

But that period following training with a PD patient is a period that takes some time to modify. And I just was wondering if

there had been any analysis done on the reliability results of those new to the modality?

DR. MESSANA: I don't believe so.

CO-CHAIR CROOKS: Lori?

MS. HARTWELL: I just have a quick question following up to Mahesh about the time of the month. As a former PD patient, I'm not always available at the first of the month to do the test.

So, it really is based on my availability to accomplish. So it's really not in the control of the person doing the test. It's in control of the patient in this one.

DR. KRISHNAN: I was thinking measures in general, right. If you put up a lab measure, people may keep retesting until they get what they want. The way to stop -- the results of the Measure.

The way to stop that is you just take the first value and not allow them to do that value in the future.

MS. HARTWELL: Yes, what you're

saying, I was just -- I didn't want to put it at a time of the month. Maybe they can just do one test. I don't know.

DR. KRISHNAN: Right.

MS. HARTWELL: As opposed to having the patient have to come in the first of the month. And then the patient is seen as a failure because they're not meeting that goal due to other obligations.

DR. KRISHNAN: Yes. It makes sense.

CO-CHAIR CROOKS: But this is -- the Measure is that it has been done once in the last four months, right. So, less important then what day I suppose in this metric.

Okay. Other thoughts on reliability and specifications before we vote?

(No response)

CO-CHAIR CROOKS: All right. Let's vote. Maybe?

MS. OGUNGBEMI: Well try.

CO-CHAIR CROOKS: Okay.

MS. OGUNGBEMI: The Committee is now

voting for Measure 0318 on reliability. The options are one high, two moderate, three low, four insufficient. Voting is open.

The results are three votes for high. 17 votes moderate. One vote low and zero insufficient. Measure 0318 passes on reliability.

CO-CHAIR CROOKS: Thank you. Validity.

DR. LATTS: All right. Validity. So, there was validity testing and I'm a little out of my depth here. Using the Spearman correlation between this Measure and the 2013 SMR and SHR, the numbers were high or low and statistically significant. So it was good.

It was also face validity using TEPs and 2006, 2010 and 2013, which were all in agreement that this Measure did have face validity.

I'll stop there. It was, you know, it looked pretty solid to me in terms of the validity testing and the face validity.

CO-CHAIR CROOKS: Other comments? Lorien?

DR. DALRYMPLE: So, my interpretation of the validity is there was no statistical association with the SMR and the SHR association was quite weak at .139. Which I think the Developers acknowledged.

So, weak correlation with SHR and SMR. So I think the validity is based on TEP. If we agree there's face validity to it.

But I don't think it would meet it on association with outcomes based on these correlations.

CO-CHAIR CROOKS: The results were in the right direction though. As opposed to other metrics where we just --

(Laughter)

CO-CHAIR CROOKS: Okay. Any other comments on the validity testing?

(No response)

CO-CHAIR CROOKS: Okay. Thrust of validity. Anything else? Okay, let's vote.

MS. OGUNGBEMI: The Committee is now voting on validity for Measure 0318. Options are one high, two moderate, three low and four insufficient. Voting is open.

Results are one vote high, 17 votes moderate, three votes low and zero votes insufficient. Measure 0318 passes on validity.

CO-CHAIR CROOKS: Feasibility?

DR. LATTS: From a feasibility perspective, this is being done today, you know, both feasibility and usability, it's feasible. It's done out of CROWNWeb.

It's doable. I don't know what else to say.

CO-CHAIR CROOKS: You're all over it. Okay. Other comments on feasibility before we vote?

(No response)

CO-CHAIR CROOKS: Okay. Let's vote.

MS. OGUNGBEMI: The Committee is now voting on feasibility for Measure 0318. Options are one high, two moderate, three low and four

insufficient. Voting is open.

Results are 14 votes for high, eight votes moderate, zero votes low and zero votes insufficient. Measure 0318 passes on feasibility.

CO-CHAIR CROOKS: Okay. And usability and use.

DR. LATTS: Nothing else to add.

CO-CHAIR CROOKS: No, it's in use.

DR. LATTS: It's being used.

CO-CHAIR CROOKS: There has been a slight improvement in 2013 demonstrated. Any other comments in usability and use?

(No response)

CO-CHAIR CROOKS: Okay. Let's vote.

MS. OGUNGBEMI: The Committee is now voting on usability and use for Measure 0318. The options are one high, two moderate, three low and four insufficient. Voting is open.

The results are 16 votes high, six votes moderate, zero votes low and zero votes for insufficient information. Measure 0318 passes on

usability and use.

CO-CHAIR CROOKS: Before we vote on recommendation for endorsement, any other general comments?

(No response)

CO-CHAIR CROOKS: Is the voting machine working? Okay, let's vote.

MS. OGUNGBEMI: The Committee is now voting on overall suitability for endorsement for Measure 0318. Options, one yes, two no. Voting is open.

The results are unanimous. 22 votes yes and zero votes no. The Measure passes for meeting NQF criteria for endorsement.

CO-CHAIR CROOKS: Okay. We're going to move on -- right onto 2704. Another CMS metric. Same tag team.

DR. ZARITSKY: Yes. So for the sake of time, I think I'll defer any comments. What I said about 0318, I think is the same is true for this Measure.

This includes children in the Measure

along with adults.

CO-CHAIR CROOKS: Okay. Who's on first?

CO-CHAIR ANDERSON: I think it's going to be me.

CO-CHAIR CROOKS: Constance?

CO-CHAIR ANDERSON: Yes.

CO-CHAIR CROOKS: Okay.

CO-CHAIR ANDERSON: Okay. This is an intermediate outcome where the process of care can influence the outcome of patients. This is a combined for adult PD patients and for pediatric PD adequacy targets.

The -- it is a -- in terms of the evidence, the measure focus is supported by KDOQI guidelines. There were two randomized control trials.

There was a correlation demonstrated between morbidity and mortality. Kt/V less than recommended, of two, has been changed and dropped and lowered to 1.7.

And the body of evidence shows a

strong correlation between total solute clearance and morbidity and mortality as I said. So, there is a high degree of association with the efforts.

CO-CHAIR CROOKS: Okay. Elizabeth? Do you have anything to add?

(No response)

CO-CHAIR CROOKS: Okay. So this is open for discussion. The one thing that is different is that for the pediatric patient, the minimum is 1.8 instead of 1.7.

I believe the submission parallels the last in almost every other aspect. Is that -- am I reading that right? Are there important differences that we should know about?

DR. MESSANA: No, just the pediatric criteria are consistent with the clinical performance recommendations and prior TEP recommendations for a 1.8 value. And I think every six months for the interval.

So, the numerator includes the number of adults who achieved the 1.7 threshold within four months. And the number of kids who achieved

the 1.8 threshold in six months.

CO-CHAIR CROOKS: Right.

DR. MESSANA: The denominator is the combined set of two.

CO-CHAIR CROOKS: Alan?

DR. KLIGER: So for the kids, as I understand it, the evidence is basically face, you know, face validity evidence that clearance ought to be at least as good as it is in adults. And maybe a little bit better given, you know, the body surface area relationship.

Is that true? Or is there any additional data or evidence to support this?

DR. SOMERS: There's a little bit of data from very small numbers of patients about increased solute clearance increase growth. And some data from adolescents.

I think they come from the UK, showing kind of better outcomes, fewer hospitalizations. Mortality sort of data.

But, very much it's more expert opinion face validity sorts of issues.

DR. ZARITSKY: I'll just add that, you know, for pediatrics especially with growth, the importance of a single Kt/V value in the face of other several other parameters, it's sort of weighted.

And I think that adding the .1, you know, if there's an extra .1 when you look at surface area, the surface area is tracked pretty well with, you know, peritoneal surface areas.

So, there's not necessarily that just a, you got to be better for some reason.

DR. KLIGER: So, if I could just follow on. Is there any data to have this particular -- I mean, more sounds like it's better.

Is 1.8 -- any evidence for 1.8 versus 2 or 1.9, or any of that?

DR. KASKEL: We don't have that. We don't have a study to look at that increase.

One of the other unknowns is the effect on, besides growth and development, is neurocognition. We have very little information

as to how this clearance may affect neurocognition at critical periods of time.

So we opt for a higher number without studies.

DR. KLIGER: And can I just ask one more question? The Developer, it was confusing to me about why the Developer has submitted several clearly overlapping measures.

What do you have in your minds in terms of making so many -- such similar measures?

CO-CHAIR CROOKS: Yes, I think it would be a good time to ask kind of why the suite of measures?

DR. ANDRESS: Well, I'm a masochist.

(Laughter)

DR. ANDRESS: So, that was part of it. No, so, this is actually in part a policy issue.

We have minimum reporting requirements for most of our programs that includes dialysis facility, compares public reporting. But it also includes the QIP.

Wherein, we don't report on facilities

that -- or on where -- we don't report measures on facilities with fewer than 11 patients who fill the denominator.

The original formulation for these measures essentially created a situation where you had originally three. And you know, with pediatric PD adequacy as a new measure we're presenting here today, potentially four segments that a facility's populations can be broken into.

And in order for a facility to have a rating for each individual measure, it must have a total of 44 patients within it. The problem that we were finding is that many facilities would have a handful of PD patients, a handful of pediatric patients.

And these patients were systematically excluded from assessment on these measures because of the reporting requirements. The reporting requirements are there for a couple of reasons.

The 11 case minimum. One is the reliability of the assessment. The other is the

risk of revealing patient identities when you start getting to really small numbers in the facilities.

So, there were a couple of reasons why we couldn't do away with that. And but I think we had a very vested interest in ensuring that we were assessing dialysis adequacy for as much of the population as possible.

Particularly for peritoneal dialysis patients where, you know, there's a lot of interest in pushing the use of PD as an alternate therapy to -- instead of hemodialysis.

But I think, you know, most especially for pediatric patients. Where the conclusion I think we reach is that pediatric only measures have some difficulty getting any traction because you only get an assessment of I think 13 facilities, something like that.

And the QIP is a good -- 30? Okay, 30. So 30 facilities. Very -- it's very low impact.

So in terms of how to address this, we

hit upon the potential solution of essentially creating combined measures. Where we -- and where we combined the denominator.

And the question is less, are you hitting this particular target, and it's more an issue of, are you hitting the -- an adequate level of dialysis dependent upon your modality and your age in the case of peritoneal dialysis.

And so we constructed those measures after determining that we felt that they were a reasonable approach. And we presented them here for consideration by the Committee.

I think the reason we still have the other four individualized measures is that those measures are, you know, NQF endorsed. They are implemented in the QIP.

And it makes sense for us to maintain their endorsement until such time as it's determined whether or not implementation of the other measures is appropriate.

Our intention I think is that if that does come to pass, that we would seek to retire

the four original measures that divide by -- that divide the population by age and modality.

And that we would go forward with the whole peritoneal dialysis measure and the whole hemodialysis measure and the combined measure between the two. And then the purpose of having those three measures together is that you can maximize coverage in a population for assessment with the combined measure.

Or you can get some more granularity in terms of how peritoneal dialysis versus hemodialysis are handled within -- or at the facility level as distinct modalities. And that gives us some flexibility in terms of how it can be reported in different programs.

So that was the rationale. We didn't want to lose the measures that we had for obvious reasons I think.

But we wanted to have the opportunity to present the other measures. And then the anticipation is that we will not maintain all of them forever. But we will eventually start

walking back -- or retiring rather, the measures that we deem to be less useful at a later date.

CO-CHAIR CROOKS: So, to maybe reinterpret, to make sure I understand. Are you saying that in theory, but not with a guarantee that you might be moving towards Measure 2705 as your Grand Poobah.

And that would be the only measure you need in the long run?

DR. ANDRESS: I think it would be more accurate to say that we are moving toward getting -- including more patients within our quality assessments. But the degree of granularity that's required for any one program leads us to want to consider both the combined measure, which is itself actually just a -- is a composite of the two -- of the hemodialysis and the peritoneal dialysis measures.

Or have the capacity to look at the two modalities separately. And that's really what we're wanting to move toward eventually.

CO-CHAIR CROOKS: Right. Yes, with

2705 you can always break out your other metrics because they're all within there. And you could break it out and look at it --

DR. ANDRESS: Yes.

CO-CHAIR CROOKS: As if the other metric still existed. So, okay. Alan, did that answer your question? Okay. Franklin?

DR. MADDUX: Just for my pediatric colleagues here, is there any rationale other than logistics why six months instead of four months on the pediatric patient would be chosen as the interval of measurement?

DR. SOMERS: No. And I think most of us check it much more frequently than that.

DR. MADDUX: Okay. Okay. We're still discussing evidence.

DR. KRISHNAN: Is the question, should we formalize those frames? Should they both be in the same time frame?

DR. MADDUX: Well, I just think, you know, complexities of measures are one of the issues practically that gets into the usability

side of things. And so when you're using 1.7 to 1.8 when it's all made up on the 1.8 side as to whether it's really right or not. And then you're using four month interval versus six month interval, it just increases the complexity of interpretation for those you're trying to standardize in the measure.

CO-CHAIR CROOKS: Yes, it seems counterintuitive that the growing child should be measured less often than the non-growing adult.

Okay, evidence?

DR. MESSANA: Well, I just wanted to follow up with a comment. If an organization or facility chose to measure every four months, they would exceed the minimum.

And so, there's a work around for the complexity issue. And the only justification for including six months was because the clinical performance recommendation, not guideline, stated it that way.

So, it's not evidence based.

CO-CHAIR CROOKS: Okay. Any other

cards up in the air? Well, Lorien, of course.

DR. DALRYMPLE: Can I just ask a point of clarification? Because I'm struggling, before we vote on the evidence.

The clarification was very helpful. But it actually brought up several concerns for me when we start adding pediatric to adults. Because I'm actually worried we then lose the children.

And now how do you intervene on quality when you don't know who's actually getting the low Kt/Vs? Especially if you have 150 adults and ten kids in your program.

The program might look good, although eight out of ten of our children may have low Kt/Vs. And so you won't actually know, because my understanding of this measure is we're not age stratifying it by pediatrics or adults.

So, as we go to vote on the evidence, yes, evidence for peds stand alone. Evidence for adults stands alone.

But for the concept of a quality

metric that throws those two groups together, do we consider this during our evidence voting? Or later in our specification voting?

In case other Committee members reconcile that.

CO-CHAIR CROOKS: I think it's appropriate for you to bring it up here. That, you know, where's the evidence that doing a measure like this will work for the group uniformly and not just --

DR. DALRYMPLE: I understand the rationale of wanting to report on more units.

CO-CHAIR CROOKS: Right.

DR. DALRYMPLE: But what I worry is we actually lose useful measures of quality. Especially for the pediatric population.

CO-CHAIR CROOKS: Yes. And it's better than not measuring those kids at all because they don't have 11 kids in the unit.

DR. ANDRESS: So, that's what I was referring to on that. So, you have the minimum case requirements are for two reasons.

On the one hand, you know, there's a concern -- there's a -- it's a policy concern at CMS about the reliability of the assessment.

On the second hand, there's the issue of -- there's the issue of patient identification. If you get to a point where you have too few patients, it's potentially possible that a patient could be identified based off of the performance. Or something about the patient could be identified.

And so this is a policy that's in place at CMS in general. And I think you would be hard pressed to find any quality measures that we report where a denominator is under 11.

I wanted to hit on your point a little bit about the -- you know, the risk of, you know, pediatric patients being subsumed in the whole and lost.

I think, you know, there is certainly some reasonable concern with regard to that. Certainly the vast majority of patients in the combined measure for instance are in center adult

hemodialysis patients. And they drive much of the performance.

The alternative is not that we have a measure or an assessment of the pediatric patients separately. The alternative is that we have no assessment whatsoever because they don't have enough numbers within the facility.

And the number of facilities again, in total, that get assessed by the QIP is something like 30. Certainly there are many more facilities with pediatric patients. But they are not currently assessed at all for the quality -- for the adequacy of dialysis that their pediatric patients receive.

CO-CHAIR CROOKS: Okay. Thanks. I think we understand the logic there.

So, before we vote on evidence, any other comments or questions? Oh, Lori's first. I'm sorry.

MS. HARTWELL: I just have a quick question, just being new to this process. Because we're missing so many pediatric patients,

is there a way to measure like regional? Or citywide?

Or something to basically capture the patients that aren't being measured? The pediatric patients? It's just a question.

DR. ANDRESS: You could. You would not be able to attribute responsibility to a particular dialysis facility.

So, for reporting programs or payment programs that are dependent upon attribution to the facility level, you would not be able specifically to say that that facility was responsible. And then say adjust their payment as a consequence of it.

Something where you have a situation like what -- the demonstration that's coming out of the Innovation Center right now with the ESCO project might be a circumstance in which you could have something like that more broadly applicable to the population as a whole.

But that's not something that we currently have those as an option.

CO-CHAIR CROOKS: Okay. Michael?

DR. FISCHER: So just to fall back to Lorien's point. So to me it's less about evidence, more about validity.

Because, is the measure going to really be a valid or true measure of quality, of adequacy, of dialysis care? For adults, yes. For kids, maybe not as it's currently written.

And that means that it may not be a valid measure when, you know, pediatrics are included in this as it's currently written.

And then I guess my question back to the Developer is then about stratification. I mean, to me it seems like the way to resolve some of that is required of the measure.

And just in an aggregate report, help stratify reporting by adults and pediatric patients.

CO-CHAIR CROOKS: So, what you're asking the Developer if it would be -- even if there are less than 11 patients could stratify it in their reports to the --

DR. FISCHER: Precisely. I mean, if that's a concern, that's one potential option.

CO-CHAIR CROOKS: Is that a possibility? Is that in the plan?

DR. MESSANA: So if you stratify it for adults and children, if you have less than 11 children in that facility, you run into the same problem with potentially identifiable information.

CO-CHAIR CROOKS: Well, if you're not adjusting payment, but you're just giving them the data so they can -- to let them know if you're not --

DR. MESSANA: If I know the geographic location of a facility and there are five kids in that facility, that's the potentially identifiable information issue. That's why we always suppress.

In the DFRs, we suppress for small cells for that very reason. So it's a fairly widespread practice.

And I think with the -- the

stratification would fulfil the concern about losing some of the pediatric information. But it doesn't address the concern about potentially identifiable information for very small cells.

CO-CHAIR CROOKS: Okay. That's the answer. Mahesh is next I think.

DR. KRISHNAN: Just I'm thinking more about this. So you're saying if there's a facility that has 100 adult patients and three pediatric patients, I'm just wondering how you can -- what the clinic would do?

Why the clinic would -- the performance in the adult patients would overwhelm any under-performance by the pediatric patients. It just seems to me like I -- I get -- it almost feels like, well Peter, this is a check the box.

We want to have something to cover pediatrics. We have this 11 cell problem. But from a practical reality standpoint, I don't know how to deal with that.

CO-CHAIR CROOKS: Don't ask the Developers. Let's ask the Committee. I think

what the -- yes, what we're hearing is that it's better than not measuring them at all.

And I accept that. I see it's not perfect. I'm not going to let the perfect be the enemy of the good in this case, in my vote.

I think it's good that the kids are going to be included in the measure. Hopefully each unit has their own quality improvement program. And we'll want everybody to hit the target.

DR. KRISHNAN: But do we think it will actually improve care for pediatric patients?

CO-CHAIR CROOKS: I hope so. I can only hope. I can't make -- the granularity isn't there. Until we have larger PD units for kids, I guess.

Go ahead.

DR. ZARITSKY: Just a technical question. It might also get to reliability. But so, if you have a unit that has 50 adult patients and five pediatric patients, those five patients are still reported in this kind of algorithm,

right.

So in some senses, by adding them you are encouraging the dialysis unit to at least make those measurements. Because if they don't, that's going to show up on their bottom line.

So, I mean, there is a little bit -- you are getting that data out. Whereas if you said there is a -- I mean that goes more to your -- I don't know if that goes to reliability or the evidence. But I do see that advantage of those limited circumstances.

CO-CHAIR CROOKS: Okay. Rick, one more comment.

DR. KASKEL: Even though the numbers are low, each unit, and I think we can fairly say that in the States anyway, we'll look at this data very closely on the monthly basis. And they will change therapy, the dialysis prescription accordingly if they're not making the measure.

There's no question that the team will look at that value and determine why they're not making it.

CO-CHAIR CROOKS: Okay. Are we ready to vote on the evidence?

(No response)

CO-CHAIR CROOKS: All right. Let's do it.

MS. OGUNGBEMI: The Committee is voting on evidence. This is an intermediate outcome measure. So the options are one high, two moderate, three low and four insufficient. This is for Measure 2704. And voting is open.

Results are one vote for high, 18 votes moderate, one vote low, and three votes for insufficient. Measure 2704 passes on evidence.

CO-CHAIR CROOKS: Okay. Is there a gap?

CO-CHAIR ANDERSON: In the analysis of the CROWNWeb and Medicare claims data, 78.1 percent had met the adequacy target in the four-month period for adults and the six-month period for pediatrics.

Approximately 18 percent of the patients do not reach the target Kt/V. So it

looks like moderate performance gap. And the percent of patient PD adequacy numbers falls way below where the hemodialysis adequacy numbers are.

There was no disparities in care noted. And I guess that's it. Do you have anything Beth?

MS. EVANS: No. The only thing I had thought was really you explained. I had concern over that clinic size less than 11. And were we missing a lot? And actually you answered that. So that took care of a lot of my concerns.

CO-CHAIR CROOKS: So there appears to be a performance gap that could be improved on this Measure. Are there other comments about performance gap? Alan?

DR. KLIGER: Just a question. When it says -- when you record 18 percent of patients fell below compared to hemo, do you mean failed the test? Is that what you mean by that?

CO-CHAIR ANDERSON: Approximately 18 percent don't reach that 1.7 as adult.

DR. KLIGER: Okay.

CO-CHAIR CROOKS: Okay. All right, let's vote.

MS. OGUNGBEMI: The Committee is now voting for Measure 2704 on performance gap. The options are one high, two moderate, three low and four insufficient. Voting is open.

The results are for performance gap, five votes high, 18 votes moderate, zero low and zero insufficient. Measure 2704 passes on performance gap.

CO-CHAIR CROOKS: Okay. Specifications and reliability. Connie?

CO-CHAIR ANDERSON: Okay. The data elements are clearly defined. Again, clinics with less than 11 PD patients are excluded. And if the Kt/V is not measured, it's still included in the denominator.

The logic and the algorithm is clear. And again, I think you've answered the question about if it's not collected every four months, is it going to start skewing the results.

So, I would say that this has a moderate reliability.

CO-CHAIR CROOKS: Okay. Other comments? Specifications, reliability, testing?

CO-CHAIR ANDERSON: Oh, the other comment I might use is out of 46,307 PD patients in 1,557 units, the inter unit reliability was at 91 percent.

CO-CHAIR CROOKS: Okay. Other comments?

(No response)

CO-CHAIR CROOKS: Okay. Let's vote on specifications and reliability.

MS. OGUNGBEMI: I need to reset the slide. One moment.

The Committee is now voting on reliability. The options are one high, two moderate, three low, and four insufficient. This is for Measure 2704. Voting is now open.

MS. BAL: All right. We're hand voting. Okay. So, we're going to have to go old school because now there are more people than

voting is possible.

So, for reliability for 2704, put your hands up really high for high. If you're voting high on reliability. Please high. So I have five.

Okay. So for moderate? Okay, I have 18.

Okay. And then low? Yes. No need to actually count for the other ones.

Okay. So the results are five high, 18 moderate, zero low, zero insufficient for reliability for 2704. And we can move forward to validity.

CO-CHAIR ANDERSON: All right. In terms of validity. There were no exclusions and there's no need for risk adjustment because there was no disparities.

Noted, the measure specs are consistent with the evidence provided. For pediatrics the validity was established on face value validity.

This measure is included in the 2015

QIP which is a pay for performance. It's also reported in the Dialysis Facility Compare. On the peds it will be reported in QIP in 2018 as a measure.

The magnitude in correlation between SHR and SMR is low. In terms of meaningful difference, 82.5 percent achieves the expected Kt/V. 17.4 percent were worse than expected.

CO-CHAIR CROOKS: I think you jumped ahead of us on that.

CO-CHAIR ANDERSON: Oh, did I jump ahead? Sorry.

CO-CHAIR CROOKS: But the validity testing, I see that they had -- they did Spearman --

CO-CHAIR ANDERSON: Correlation.

CO-CHAIR CROOKS: Or they did the TEP too, yes.

CO-CHAIR ANDERSON: Yes.

CO-CHAIR CROOKS: So they correlated with hospital ratios and mortality.

CO-CHAIR ANDERSON: Right.

CO-CHAIR CROOKS: It's a low correlation with the TEP. Okay. So let's vote on validity.

CO-CHAIR ANDERSON: We need to have a discussion first.

CO-CHAIR CROOKS: I'm sorry. I forgot to open the discussion.

CO-CHAIR ANDERSON: Beth? Do you have anything more?

CO-CHAIR CROOKS: Jump in.

DR. DALRYMPLE: I don't want to belabor this point. But I think this is actually the right place to talk about combining a pediatric and adult measure.

And so I think it's worth the Committee maybe just rehashing this one last time. Because I am trying to think, if I'm a parent, and I want to know about performance for my child at a dialysis unit, would I rather see something that says we don't have enough information to tell you anything useful?

Or do I want to see something that

looks really good, and oh, by the way, this is all being driven by the adults. And do you understand that as a consumer of healthcare?

So, I know perfect is the enemy of good. But at the end of the day, if this is going to be publically reported, as a parent, I'm not sure which of those two I would rather have available to me to understand.

CO-CHAIR CROOKS: Okay. So, I don't think we're -- and we've kind of gone over that. And I don't think we have a perfect solution for it.

DR. KLIGER: I mean, a solution as Andy says, is that we have both. So you'll be able to tell your parents that when you look at a whole unit, including adults and children, the numbers look really good. We can't separate out the kids.

But when we look at the kids specifically with the kids measure, we really don't have sufficient numbers to make a meaningful comment. So you'll have both.

CO-CHAIR CROOKS: You have a -- and on one you can say, and your child is reaching 1.8 or higher. Or we're working on getting them there.

DR. DALRYMPLE: And maybe the Developers can weigh in. Because perhaps I misunderstood. I thought that there was a possibility this measure was going to overtake the individual measures we've had in the past of a pediatric one and an adult one.

So that would be more reassuring if all three are being kept.

DR. ANDRESS: So Joe is here throwing me under the bus. Thanks Joe.

So, that is the initial intent. That is not to say of course that it has to be the course of the measures.

I think we have that intent in mind with the thought that we didn't want to have, you know, 10 million dialysis adequacy measures that we're, you know, maintaining for no purpose whatsoever.

I think it probably makes more sense in this case to have something like the more, you know, composited measure. And that you can report on.

And then, you know, investigate ways that we can report more granularly on the detailed data within that measure. Then to have multiple measures.

Because I think the comment earlier was right. You can take the peritoneal dialysis measure and then break down reporting by adults and children where that seems like it's feasible and then simply not report anything on the children where it is.

That's not something that we've done in the past. So I don't want to pretend like, you know, we've figured this all out.

But, I mean, it's certainly something that we can consider doing. I guess the -- you know, we're okay doing it either way. I mean, you know, we're going to be here no matter what.

But I think it's -- we'd certainly

appreciate your input in what the best way is to manage the measures in terms of how we're, you know, moving forward with this.

You know, and at the end the day I think we'll have the information we need. But if we don't have the broader -- the like larger measure constructs, then we have limitations in terms of the extent to which we can report on the composited data.

It's easier I think to break those down and provide reporting on them at a lower level. If that's something that we should, you know, choose to do.

DR. MESSANA: With the caveat about the small cell size. So, but you would have data at the facility level. And for a subset of facilities you would have data stratified.

CO-CHAIR CROOKS: Okay. We're bumping up against our mandatory public input time. Should we try to vote through this measure? Or should we stop here?

MS. BAL: Well, we try to keep the

public commenting on time. So I would say vote on this and then let's go to public comment and then continue.

CO-CHAIR CROOKS: Okay. Are they on the phone or are they behind me?

MS. BAL: Oh, vote on validity first.

CO-CHAIR CROOKS: Oh, we're going to vote first. I heard you guys -- I heard you say exactly the opposite.

(Laughter)

CO-CHAIR CROOKS: Okay. Let's vote on the evidence then. I mean, not the evidence, we're going to vote on validity. Validity at this point.

MS. OGUNGBEMI: The Committee is now voting on validity for Measure 2704. The options are one high, two moderate, three low and four insufficient. Voting is open.

The results are zero votes for high, 18 votes moderate, four votes low and one vote insufficient. Measure 2704 passes on validity.

CO-CHAIR CROOKS: Okay. Poonam and I

have put our heads decided and we've decided to pause for public comment.

We're going to -- I know we really want to try to stop at 5:00. We need to stop at 5:00. And I know at least one member has to leave at 5:00.

But, we're going to have to go ahead a little.

MS. BAL: Yes. So, unfortunately we have gone way past where we should be. We should have done with these at 3:30. And it's almost 5:00 now.

So, due to that, we will have to stay a little later. We're trying not to go too much further. But there are a couple of measures that we do need to get done today before we can leave.

So if we can quickly get through public and member commenting, quickly go through the rest of the measures. Hopefully we can get that done and get you guys out of here quickly.

CO-CHAIR CROOKS: Okay. The phones are open.

OPERATOR: Okay. At this time if you would like to make a comment, please press star then the number one.

There are no public comments at this time.

MS. BAL: Are there any comments in the room?

CO-CHAIR CROOKS: On site?

MS. BAL: Okay. We're good. Let's continue.

CO-CHAIR CROOKS: We're good. Okay. Thank you.

So that gets up to feasibility I believe.

CO-CHAIR ANDERSON: Feasibility is based on CROWNWeb data and claims data. And appears high.

CO-CHAIR CROOKS: Other opinions, thoughts, comments? On feasibility?

Okay. Let's vote on feasibility.

MS. OGUNGBEMI: The Committee is now voting for feasibility on Measure 2704. Options

are one high, two moderate, three low and four insufficient. Voting is open.

Results are 15 votes high, eight votes moderate, zero votes low and zero votes insufficient. Measure 2704 passes on feasibility.

CO-CHAIR CROOKS: Okay. Usability and use.

CO-CHAIR ANDERSON: Okay. For usability and use, this is a new measure. It's not currently in use. Although if you look at the existing NQF endorsed adult PD Kt/V measure, 0318, it's currently publicly reported.

And the pediatric PD Kt/V measure is under NQF review. And has been finalized actually for payment year 2018 for the ESRD QIP.

CO-CHAIR CROOKS: Dr. Kliger looks about --

DR. KLIGER: Just a question for the pediatricians. Do you have any concerns about usability of this?

DR. KASKEL: I don't. Because most of

the families that we would take care of, would ask us and talk to us.

So public information, to answer your question, it doesn't matter what their social or economic background is. Our experience has been they are a parent. They will talk to us.

And they will look at data. We can explain data. And it's a one on one or a team approach. That's the best we can do with these numbers.

CO-CHAIR CROOKS: Okay. Other comments on usability and use?

Okay. Let's vote then.

MS. OGUNGBEMI: The Committee is now voting on usability and use for Measure 2704. Options are one high, two moderate, three low, four insufficient information. Voting is open.

Results are eight votes high, 12 votes moderate, one vote low and one insufficient information. Measure 2704 passes on usability and use.

CO-CHAIR CROOKS: Okay. And now

before voting on recommending endorsement, are there any other comments before we vote? General comments?

Let me know when we're ready.

MS. OGUNGBEMI: The Committee is now voting on overall suitability for endorsement of Measure 2704. Options are one yes, two no. Voting is open.

The results are 21 votes yes and one vote no. The Measure passes. That's 2704 on the overall suitability for endorsement.

CO-CHAIR CROOKS: Okay. Thank you. Now, what we'd like to do is guarantee you a 5:30 exit and get through measure 2706, which may not take so long because it's got a lot of the same--

(Off microphone comment)

Yes, good idea. So, 2706. Take it away.

DR. MESSANA: Really quick. Same typographical errors in this submission. And one thing that is -- needs to be brought up.

In the workgroup discussion there was

a question raised about residual renal function being measured using combined creatinine clearance and urea clearance. And I wasn't the measure developer or I wasn't the clinician involved in this measure development.

So I had to do a little digging. It turns out that the TEP report from the pediatric TEP held in 2013 included a statement that said, we recommend use of combined creatinine and urea clearance to measure residual kidney function because that comports with, and I'm paraphrasing it, because that is consistent with how it's done in adults, which is not the case.

So, my interpretation of that was that they intended the residual renal function assessment to comport with the adult approach, which is measuring your urea clearance.

And that would be consistent with the clinical performance recommendations for pediatric measures. I throw it up to you. That's what I know.

CO-CHAIR CROOKS: Okay. Andrew?

Thanks for staying around.

DR. NARVA: My pleasure. So this measure bears a haunting resemblance to the previous one except it pertains only to the pediatric population.

The evidence is largely based on the inference from adults that adequate -- measurement of adequate peritoneal dialysis results in better outcomes.

Along with the consensus that when no pediatric specific data exists, performance measures for adults should serve as the minimum of standard.

The one thing that's not in here, it doesn't really specify how often adequacy is supposed to be measured, or I couldn't find it.

DR. MESSANA: For consistency's sake, you know, again, I didn't write it. But it should be consistent with the pediatric portion of the last measure. So, within six months to be consistent with the KDOQI CPRs.

CO-CHAIR CROOKS: Okay. Karilynne?

MS. LENNING: No further comment.

CO-CHAIR CROOKS: Any other comments? Okay. Any other discussion about the review of the evidence? Alan?

DR. KLIGER: So, I just want to be clear. Are we again making a change to the document?

When we calculate the combined Kt/V for either kids or adults, we're using urea. We're not using any other solutes.

So I just want to be clear about what we're doing here?

DR. MESSANA: Well, we have three pediatric members of the group. We would be interesting in making sure that they're in agreement with that.

But I think that would be a stipulation that we would be very comfortable making. Assuming we didn't get any push back from the pediatricians.

That the -- I believe that the intent of the technical expert panel was to be

consistent with the adult measure. And that the information they had at the TEP may not have been accurate.

That's my interpretation.

DR. KLIGER: I mean, even more to the point thought, I don't know how you'd use a clearance. Since we're talking about a combined urea measure, Kt/V.

DR. ZARITSKY: It's kind of nonsensical because the Kt/V is your urea kinetics. So you're, you know, and so you're in steady state. You have to use the urea for the residual Kt/V.

So I don't even know how you would factor in creatinine. I don't know what calculated it.

DR. KASKEL: If you're saying that the TEP modeled this to be comparable, at least partly with the adult analyses, and the adults are not doing that combined. Then we have a problem to go back to them next time.

It's too late to change now. But

that's what you're indicating. That you think there was a misunderstanding at that level?

DR. MESSANA: The information that I just shared with you was in one sentence essentially, it said we recommend using combined creatinine in the urea clearance because that's consistent or that's to be consistent with how it's done in adults.

So, my interpretation is they were intending to comport with the adult approach. And that they were misinformed.

That's my best interpretation.

DR. KLIGER: Just again so I understand. So you're suggesting that you make a clarification and change the document now. Right?

DR. MESSANA: Correct. We would recommend urea clearance to measure residual kidney function be consistent with 2704 and 0318, the adult measure.

CO-CHAIR CROOKS: So we'll consider it a typo, but you'll get back to us if it's not?

DR. MESSANA: Yes.

CO-CHAIR CROOKS: Okay. Other --

DR. ZARITSKY: I think we're all in agreement that you have to do this. It doesn't make any sense. It's a urea clearance, so, but you can't throw it out.

CO-CHAIR CROOKS: Okay. Other comments on evidence?

Okay. I think we're ready to vote.

MS. OGUNGBEMI: The Committee is now voting on evidence. It will come up on the screen soon. There we go.

This is for Measure 2706. The options are one high, two moderate, three low and four insufficient. Voting is open.

The results are zero votes for high, 18 votes for moderate, two votes for low and one vote insufficient. The Measure 2704 passes on evidence.

CO-CHAIR CROOKS: Gap, Andrew?

DR. NARVA: Okay. Again, there's less data. They site CROWNWeb data from 2013 showing

that only about 50 percent of pediatric patients had a measure of PD adequacy during the six months which was looked at.

Data on disparities, there's not enough data to identify disparities.

CO-CHAIR CROOKS: Okay. Other considerations in the performance gap? They're hitting about 50 percent, so it sounds like there's a ways to go. Alan?

DR. KLIGER: It was 50 percent that had no measure. Not that had an inadequate measure.

CO-CHAIR CROOKS: I wrote down the mean of hitting the measure was 49 percent.

DR. KLIGER: Forty-nine percent had a measure.

CO-CHAIR CROOKS: Oh. Well, --

DR. NARVA: Percentage of pediatric patients with PD adequacy measurements that achieved the target at least once in six months.

CO-CHAIR CROOKS: Okay. On gap, other comments, thoughts?

All right. Let's get ready to vote.

MS. OGUNGBEMI: The Committee is voting on performance gap for Measure 2706. Options are one high, two moderate, three low and four insufficient. Voting is open.

Results are 14 votes high, eight votes moderate, one vote low and zero votes insufficient. Measure 2706 passes on performance gap.

CO-CHAIR CROOKS: Thank you. Specifications and reliability. Andrew?

DR. NARVA: This is well specified. Except for this particular version of it doesn't specify the interval. But presumably it's the same. And it's well defined for CROWNWeb purposes.

CO-CHAIR CROOKS: Okay. Any other concerns about the specifications or the reliability? Lorien?

DR. DALRYMPLE: Just a very small comment. Occasionally in this document, I think 1.7 shows up when the numerator and other things

are specified.

So if just for consistency, it can be changed to 1.8 throughout.

DR. NARVA: Thank you.

CO-CHAIR CROOKS: Frederick -- Franklin?

DR. MADDUX: Was their intent to have a time frame on this that it would be tested?

DR. MESSANA: Yes. I think Dr. Narva brought that up. Within six months to be consistent with the prior measure. Yes, we are.

Again, this was left over from a prior year and the clinician who was involved is not available. So we will clean that stuff up.

CO-CHAIR CROOKS: Okay. Other comments?

We're clear on the specifications and the reliability. Let's go.

MS. OGUNGBEMI: The Committee is now voting on reliability for Measure 2706. The options are one high, two moderate, three low and four insufficient. Voting is open.

Results are three votes high, 19 votes moderate, zero low and zero insufficient. Measure 2706 passes on reliability.

CO-CHAIR CROOKS: Validity Andrew?

DR. NARVA: This is put forward on the basis of face validity.

CO-CHAIR CROOKS: Nice and succinct. Other thoughts on the validity testing or lack thereof?

(No response)

CO-CHAIR CROOKS: Okay. Well, let's vote. Are we going to accept the TEP's validity?

MS. OGUNGBEMI: The Committee is now voting on validity for Measure 2706. The options are one high, two moderate, three low and four insufficient. The voting is open.

MS. BAL: Okay. Hand vote it is. So, for validity, please put your hand up very high for high. I see no hands.

Okay. For moderate. I don't even need to count because that's everybody. Okay. So 23 it is. Thank you.

So we have zero high, 23 moderate, zero low, zero insufficient for validity for 2706. And we can move forward to feasibility.

CO-CHAIR CROOKS: Andrew?

DR. NARVA: This is meant to be implemented through CROWNWeb. And appears well adapted for that.

CO-CHAIR CROOKS: Okay. Any other comments on feasibility?

Will we be hand voting or machine voting?

Okay. Let's vote on feasibility.

MS. OGUNGBEMI: The Committee is now voting on feasibility of Measure 2706. The options are one high, two moderate, three low and four insufficient. Voting is open.

Results are 16 votes high, six votes moderate, zero votes low and zero votes insufficient. Measure 2706 passes on feasibility.

CO-CHAIR CROOKS: Thank you. So Andrew, is it in use or usable?

DR. NARVA: It's definitely usable. My only -- and it's meant to -- it's planned to be reported in the ESRD QIP for 2018.

My only concern would be what is it -- what percentage of dialysis units have too few patients to report what's in the cell? I mean less than 11 patients. Is that half of the dialysis units?

It would just make it less usable for the, you know, the public understanding of quality of dialysis. But do any of the pediatricians have an idea of ---

DR. ZARITSKY: That's the nature of the beast, right?

DR. NARVA: Yes. I'm just curious, you know. If, you know, the way is, is that most dialysis -- most units serving dialysis -- pediatric dialysis patients have less than 11 then it is what it is, but it's not going to be as usable as if most pediatric patients are seen in units that have more than 11.

CO-CHAIR CROOKS: Okay. That is a

limitation. But we've talked about that. Would you like to --

DR. MESSANA: So, Dr. Narva, 27 facilities met the criteria for minimum of 11 patients. So, we lose the majority of the kids from the measure because of the combination of small size and maybe half or so of the kids are distributed through adult facilities.

So, it's a significant step down in terms of the number of kids that are actually reported with a pediatric-only measure.

CO-CHAIR CROOKS: But don't we know from the last measure that some of those kids will get caught in the -- picked up in the other broader measure?

DR. SOMERS: Now with CROWNWeb you actually capture more potential children within the measure then previously.

DR. MESSANA: I think that analysis of 27 facilities is using CROWNWeb data. So it's -- yes, it's better than ten facilities, yes.

CO-CHAIR CROOKS: Okay. So we vote on

usability and use?

MS. OGUNGBEMI: The Committee is now voting on usability and use for Measure 2706. Options are one high, two moderate, three low and four insufficient. Voting is open.

Results are six for high, 15 votes moderate, one low and one insufficient. Measure 2706 passes on usability and use.

CO-CHAIR CROOKS: Okay. And so before we vote on endorsing this or recommending it for endorsement, I just want to warn you that we have one more measure we have to do because the Developers are here in person for this day.

So, we will hang on. Don't just get up and walk away after this last vote. Any other comments before we vote?

Okay.

MS. OGUNGBEMI: The Committee is now voting on overall suitability for endorsement for Measure 2706. Options are one yes, two no. Voting is open.

Results are unanimous. 23 votes yes

and zero no. The Measure passes. That's 2706, meeting NQF criteria for endorsement.

CO-CHAIR CROOKS: Okay.

DR. MESSANA: Can I -- thank you all very much. And I'd like to thank the NQF staff and the Committee for fighting through the brief period of anarchy created by upper bound-gate.

CO-CHAIR CROOKS: Okay. The measure that we're going to finish the day with is Measure 0323 sponsored by RPA. It's a maintenance on the measure of Adult Kidney Disease, Hemodialysis Adequacy: Solute.

MS. SINGER: Thank you all for hanging with us. And actually you will see Amy and I tomorrow. But more critical, Paul Palevsky is on the line and we won't have him tomorrow. So, we're going to let Paul introduce this.

DR. PALEVSKY: Hi. And I am probably fortunate I missed some of the discussion between the RPD measure and now.

But, this is the physician level hemodialysis adequacy solute measure. Which is

the percentage of calendar months within a 12-month period, during which patients age 12 years and older with a diagnosis of end stage renal disease receiving hemodialysis three times a week for greater than or equal to 90 days, have a single pool Kt/V greater than or equal to 1.2.

The rationale adequate dialysis dose is strongly associated with better outcomes, including decreased mortality, fewer hospitalizations, decreased length of hospitalizations, decreased hospital costs.

This is an intermediate outcome measure. We are presenting this as a physician-level measure as contrasted with the CMS facility-level measure.

The measure is currently in use in PQRS. And included in the RPA kidney quality improvement registry.

The issue of performance gap, the measure, this is an area where the performance has steadily improved. And from the USRDS data, we're now at 97 percent of patients obtaining a

single pool Kt/V of greater than or equal to 1.2. So, the performance gap is very small.

Although I would point out that meeting an adequacy measure is still required per the conditions for coverage. And I'm sure you've discussed this in the discussions of the other adequacy measures. And as with the PD, we were unable to retrieve specific disparities data.

And in the interest of your time, I will turn things back over to you.

CO-CHAIR CROOKS: Thank you very much. Mahesh is one of the primary reviewers. And Michael, are you going to do it? Okay.

DR. FISCHER: So, Paul gave a nice summary. I'm not going to repeat the basic definitions of the measure. So I'll just go -- no, it's greater than or equal to 18. This is adults. So it's greater or equal to 18.

And the only other -- originally this in everyone's packet, it was an outcome measure. But in the revised document that was sent separately, it's an intermediate outcome measure

that as Paul indicated, the analysis level is clinician.

The only thing else that I would add is that is was endorsed originally in 2007 and reendorsed in 2012.

So getting the evidence, our conclusion, I'm summarizing not only just my reflections, but those of the working group call we had. Mahesh can chime in to add what I have to say.

But, I think we all thought that it was moderate to high. KDOQI gives it an A rating, albeit that's from 2006. And the application details data that was reviewed by KDOQI from 1999 to 2005.

They acknowledge the data is old. They also spent a lot of time discussing the results of the hemo trial and some of the relevant issues, particularly around V in smaller patients and women. I thought they did a very nice job.

But they also said that, you know,

despite some limitations, they didn't think they were compelling enough to change the specifications of the measure. And the evidence-based remains as is.

And there's a related measure, just to conclude the conversation about evidence 249, that goes into greater detail about the observational trials and randomized control studies.

So with that, I'll conclude the comments about evidence. As I said, I think our feeling was it was moderate to high. And I'll stop there.

CO-CHAIR CROOKS: All right. So open to the Committee. Discussions, comments, thoughts about the evidence?

Alan? I thought you just keep it in the upright position all the time. That's right.

Okay. So I think we -- it seems like we found the evidence compelling. Shall we vote on the evidence?

MS. OGUNGBEMI: The Committee is now

voting on evidence for Measure 0323. The options are one high, two moderate, three low and four insufficient. Voting is open.

Results are nine votes high, 12 votes moderate, zero votes low and zero votes insufficient. Measure 0323 passes on evidence.

CO-CHAIR CROOKS: Okay. Gap?

DR. FISCHER: So the performance gap, so Paul presented more recent data then I believe was in the application. So just to reiterate, he said that 97 percent of the patients were meeting the measure. They don't have disparity data.

In the application there was data from USRDS and PQRI from 2008 where they mentioned that the performance and they had looked prior to 2008 where 99 percent of the patients were meeting the measure.

More relevant I think, is that they did comment a little bit about disparities. They did not notice any gender or sex-based disparities, although they then went on to say that the male and female gap had closed to less

than ten percent by 2000.

They also commented that the performance difference between whites and African-Americans was about three percent. The last comment I'll mention that this data, once again, was largely focused around patients and this is a clinician or physician level measure.

So this is obviously indirect evidence supporting the performance gap just based on the level -- the target level that the evidence was presented in. It's a bit old, although Paul gave much more recent data.

I think our conclusion was that we thought that there was a moderate performance gap. I think that was the consensus of the working group.

DR. KRISHNAN: I think if you were to use the CMS technician it would be even smaller.

CO-CHAIR CROOKS: Well, 97 percent is right up there. It's close to the top and then you have to -- and the disparities gaps are all closed.

There were some disparities gaps with all, at least the ones that were presented in the closing.

DR. FISCHER: I think some of the sentiment was that given the critical nature about the clinical importance of adequacy of dialytic clearance that even this kind of -- Michael kind of touched upon this, that given the clinical relevance of it, that provided it's three or four percent, but of not meeting that, the consequences could be quite negative for patient care.

DR. BHAN: I guess the question is, is there really room for improvement? You know for a 97 percent now, regardless of putting a measure in place, are we really ever going to get -- we're never going to get to 100 percent.

There's always circumstances which are beyond our control. You know, putting an emphasis on this, where we're already doing nearly perfect. That's my thought.

CO-CHAIR CROOKS: Josh?

DR. ZARITSKY: Another technical thing. For the analysis here --

CO-CHAIR CROOKS: Can you get closer to your mic please?

DR. ZARITSKY: Yes. The analysis here, what does this gap in here -- what is this 41 percent of patients reported, did not receive the optimal care.

What is that? Is that just a typo there?

DR. KRISHNAN: I interpreted that to be based on 2008 data that the percentage of patients who did not meet the Kt/V target was 41.36 percent. It seemed high to me, but that's what I interpreted it to be.

CO-CHAIR CROOKS: Okay other --

DR. KRISHNAN: Although as was pointed out now, that's tiny.

CO-CHAIR CROOKS: Frank?

DR. MADDUX: So, in my view, as I think about the portfolio of how we look at doses of dialysis and the granularity of some of the

other measures that are being proposed to look at related to this, this looks to me more like a candidate for reserve measure because of the fact that I think the gap's pretty small at this point.

And just to answer his point, the ability to improve doesn't mean that we don't need to create a high threshold that people need to achieve. But I think it's going to be very hard to make the gains between 2008 and now that are being gained in the future with this.

CO-CHAIR CROOKS: I am in agreement with you Frank. But I think, in my opinion, there's been maybe overemphasis on Kt/V over the years. And now, we're going to start turning more attention to ultra-filtration and maybe other components of what makes dialysis good.

So, I would support seeing this is a reserve measure. I wouldn't support not having it.

Okay. So are we ready to vote on gap?

MS. OGUNGBEMI: The Committee is now

voting on performance gap for Measure 0323. Options are one high, two moderate, three low and four insufficient. Voting is open.

Results are zero votes high, four votes moderate, 14 votes low and three votes insufficient. Measure 0323 does not pass on performance gap.

CO-CHAIR CROOKS: Okay. So in this case we continue our evaluation of the other criteria. And then we'll see at the end whether it meets criteria for being a reserve measure. Okay?

MS. SAMPSEL: Actually, hold on a minute. We actually need the Committee, you know, I know Committee Member indicated it looks like a great candidate for reserve status. We should do a hand vote on that, because technically if it doesn't pass performance gap, the vote should stop in a normal review.

CO-CHAIR CROOKS: So, to move on we need to have a hand vote about this being a potentially reserve measure. If we do not get a

majority of, what 16's a majority? Then the measure will end right here. And it won't be endorsed.

So, I put the question. So, if you're in favor of considering this for reserve status, raise your hand high.

Okay. I think it's unanimous within zero or one. Okay. Thank you.

All right. So let's go on and look at specifications and reliability.

DR. FISCHER: So I thought we -- I thought the specifications were pretty well defined and consistent with the evidence.

Just to be clear, there are no exclusions, no risk adjustment or stratification. However, they do kind of encourage reporting to be stratified by race, sex and primary language is in the application, which seemed not unreasonable.

One concern with there was no mention made of minimum number of measurements per clinician to be meaningful. That was something

one of the people on the working group had raised.

And I think that was kind of our summary. And I'll just stop and we'll talk about reliability testing but just continues its specifications. And we just stopped there.

I don't know if Mahesh, if you have anything to add?

CO-CHAIR CROOKS: Just for the record, there's no -- or correction if I'm wrong. There's no taking into account residual renal function on this measure. Correct?

DR. FISCHER: That's correct.

DR. PALEVSKY: That is correct.

CO-CHAIR CROOKS: And the guideline that it's based on does talk about residual kidney function as being a part of the calculus I believe, no? Am I wrong?

DR. KLIGER: It actually doesn't although I was going to raise that later. Because in all of the hemodialysis measures, currently we do not take residual kidney function

into account.

But in the year 2015, many of us believe we should be. And so I think it's important question to raise.

CO-CHAIR CROOKS: Lorien?

DR. DALRYMPLE: I actually do have a question on that. Because my interpretation of the E specifications was that residual kidney function was a denominator exception.

At least based on the last page with the E's where there were medical exceptions. And then two residual kidney function conditions showing. So I actually interpreted the specification did have denominator exceptions. But is that incorrect?

CO-CHAIR CROOKS: Let's ask the developer. So, to restate her question, I think is, if a patient has significant residual function, then they're not eligible to be in the measure? Is that what you're asking?

DR. DALRYMPLE: I'm looking at the first page of the PCPIE specification, AKD 10.

And for denominator exceptions it states documentation of medical reasons for not having a single pool Kt/V greater than/or equal to one, such as residual kidney functions and other medical reasons.

And then on the very last page where we have the column of IPP and, in E, residual kidney function shows up in there.

MS. SINGER: Paul, I'm going to defer to you.

DR. PALEVSKY: I could not hear. You broke up completely. I gathered you were asking whether the measure includes an exception for residual -- again, I'm trying to get the --

CO-CHAIR CROOKS: That was the gist of it. Yes.

DR. PALEVSKY: Okay. I'm trying a little --

DR. DALRYMPLE: Yes. And I'm sorry. I can speak up. I know it's hard on the phone.

But on our E specifications, there are denominator exceptions that appear to include

residual kidney function and medical reasons for not achieving a single pool Kt/V of 1.2.

DR. PALEVSKY: I have to admit that I do not have that. I'm trying to pull up all of the pages. And unfortunately that was not -- I don't see that forwarded to me from --

DR. DALRYMPLE: I think there is inconsistency between the E specifications and the measure information form so. I mean, I think we just need some clarification.

Do you mean for those exceptions to be there? Or not mean for, you know, just for consistency where CMS in the last version said, you know, we had some issues with how we -- with edits, et cetera in their form.

You know, is that a similar situation or do you really need to check on it? If you really need to check on it, then, you know, I might suggest we not vote. Or we vote and you come back with public comment.

MS. SAMPSEL: I think we can just double check the consistency.

DR. PALEVSKY: I need to double check it. I --

CO-CHAIR CROOKS: Thank you. Yes, Item S-10, denominator exclusions. There are no denominator exceptions. If there's another section saying what it does?

MS. SINGER: At the E specifications.

CO-CHAIR CROOKS: At the E specification. Okay.

MS. SINGER: We need to go back and correct.

DR. PALEVSKY: I don't have the E -- a copy of the E specifications. I only have the other specs where there are no denominator exclusions.

MS. SINGER: I'm comfortable with the E specifications. We just need to go back and make everything consistent in the documents.

CO-CHAIR CROOKS: Let's put the question to the Committee. What's your comfort level with not having any accounting for residual kidney function on this measure? Somebody must

have some thoughts on this?

DR. PALEVSKY: I believe that the discussion in past NQF reviews on this measure was that since this is patient after three months on dialysis, that the vast majority of patients do not have residual kidney function.

And that's why it was not apt.

CO-CHAIR CROOKS: I think that's old data. I don't know that that's actually true. Franklin?

DR. MADDUX: Yes, I think the only other thing that sort of gets into this is the basic definitions for how we calculate this are not perfectly concordant if you're using your kinetic model and you're using a prepost and pre-BUN, you're getting interdialytic, urea generation included. In the Daugirdas II standard there is two standards, pre and post. You're not including that.

So, it's one of those areas where I spoke previously to where we're not granular enough about the detailed specification to

account for inter-organizational variability that might occur if one organization chooses an equilibrated Kt/V and they take the single pooled component of that.

Or a -- just a standard pre and post single pooled Kt/V calculated off of a pre- and post-BUN.

CO-CHAIR CROOKS: But at the same time, everybody's hitting it. So, maybe that's less important now that the gap is so small.

DR. MADDUX: It may be irrelevant to some degree, but it just gets to the point that I think for some of these measures, we've got to be a little bit careful about source data that might not actually be the same.

DR. KRISHNAN: Yes, microspecifications.

DR. MADDUX: Yes.

CO-CHAIR CROOKS: To the issue of not including residual kidney function, is the Committee okay with that? Or do we --

DR. KRISHNAN: I read this as not

including residual renal function. Because I just went with what was in the measure specification.

I guess the question is, what is the measure? Is the measure as stated in the form? Or is the measure as stated in the E specification? Because if it's different, I don't know how to vote other then what's in the form.

CO-CHAIR CROOKS: Yes, it may be more important that there's an inconsistency perhaps in the two places where it gives specifications and the measure is the measure.

DR. KRISHNAN: The endorsed measure -- the endorsed measure doesn't have residual renal function. Is that correct? The prior endorsed version? Correct?

DR. PALEVSKY? Correct.

CO-CHAIR CROOKS: That's my understanding.

DR. KRISHNAN: So then technically the E specification is inconsistent if we're renewing

this measure.

CO-CHAIR CROOKS: Yes.

DR. KRISHNAN: So, that's the way I think about it.

CO-CHAIR CROOKS: Lori?

MS. HARTWELL: I just have a question for the Committee. Would this disincentivize to try to keep the renal function? Because there's technologies, I believe, out there that can help keep the patients' renal function on hemodialysis.

So, given the fact, I just wanted to ask the experts on the Committee if that would deincentivize -- I can't even talk anymore. If that was not included?

DR. KRISHNAN: I don't think it makes a difference one way or another. It's just the way it's supported.

Right, so today, as he's pointed out, Kt/V as on the claims form is reported without because there's no renal function. That's -- we went to this -- that was the data error --- the

data issue without -- despite the specification we had in 2010.

So it's just the way it is right now. I don't think it makes a difference one way or another.

CO-CHAIR CROOKS: Alan?

DR. KLIGER: Right. I agree. It is not a disincentive. But I do want to raise the question, I mean the majority of hemodialysis patients don't have sufficient urine for it to make any difference.

But, in the incident population where there are many who do, and because we know that residual kidney function is one of the biggest predictors of health and survival in dialysis patients, I wonder if the time has come for us to do with hemodialysis what we've done with peritoneal dialysis, and urge developers to include endogenous kidney function when there is some.

Now it doesn't -- you know, what I mean. You can specify it in a way that's not too

burdensome for facilities. Because it would be very burdensome if we asked them to be collecting urine on everybody.

But I do think that there is a small subpopulation of patients that does have substantial residual kidney function that would be useful to include in these measures as we do with peritoneal dialysis.

DR. KRISHNAN: For this measure, right, because as submitted, it just doesn't have it.

DR. KLIGER: Well, this doesn't have it. Nor do any of the others we're going to consider later. So I'm just raising that question for the Committee.

DR. KRISHNAN: Yes. It's an awesome suggestion, Peter. Could we vote?

DR. PALEVSKY: As the Developer, can I speak up to Alan's comment?

CO-CHAIR CROOKS: In this one instance, you may make a brief comment.

DR. PALEVSKY: So, the one thought

that I would offer, Alan, is that in PD it is often difficult to get over the 1.7 threshold in the absence of residual function. And it becomes a far greater factor in establishing adequacy.

Where that is much less of a case in hemodialysis where it is much easier to achieve the 1.2 threshold even in the absence of residual function.

CO-CHAIR CROOKS: Okay. Alan?

DR. KLIGER: I guess just briefly. In the interest of having patient focused care, we would indeed be doing less hemodialysis on patients that have substantial residual kidney function.

And I think tailoring the therapy appropriately when we can count endogenous kidney function is a patient oriented and patient specific opportunity.

CO-CHAIR CROOKS: Okay. So we need to -- I'm hearing extraneous noise over the phone. Kind of -- Paul? Can you mute your phone when you're not speaking please? Thank you.

DR. PALEVSKY: That's not me. My phone is muted.

(Laughter)

CO-CHAIR CROOKS: Okay, thank you. Whoever it be. All right. I think we're ready to vote on the evidence.

DR. FISCHER: We're on reliability.

CO-CHAIR CROOKS: You're right.

DR. FISCHER: And I should just say one thing about reliability testing for due diligence, all right?

CO-CHAIR CROOKS: Yes, please.

DR. FISCHER: I'll make it brief. I know it's getting late.

So the sources of the data are claims electronic records. They -- in 2008 they did reliability testing by examining four different nephrology practices participating in the PQRI program with hemodialysis/peritoneal dialysis patients.

This included multiple visits at multiple sites across the country. It was

several hundred patient records that were examined.

And the calculated the kappa for inter-rater reliability. And the kappa values were exceptionally high, one or nearing one.

So based on that, and we think we agreed in our working group discussion, the reliability testing seemed to be sound. And demonstrated very high reliability.

CO-CHAIR CROOKS: Okay. If there's no objections, let's vote.

MS. OGUNGBEMI: The Committee is now voting on reliability for Measure 0323. The options are one high, two moderate, three low and four insufficient. Voting is open.

Results are three high, 17 moderate, two low and zero insufficient. Measure 0323 passes on reliability.

CO-CHAIR CROOKS: All right. Next up, validity.

DR. FISCHER: So face validity as some of the other measures we've examined, they had a

21 member TEP.

And on this Likert scale from zero to five with agreeing with the strength of the evidence of this measure in terms of reflecting dialytic adequacy was a mean of 4.63. Which, I think as we've seen elsewhere, suggests high face validity as determined by this expert panel.

They then, once again, looking at practices somewhere to the reliability testing that were in the PQRI program in 2008, they looked at physician level performance to see if you could detect significant differences in physician level performance.

So they provided some inter-quartile -- they provided some percentile range of range of performance. Inter-quartile range is around 49 percent, suggesting that there's a reasonable spread in physician performance around this measure.

Again, this is back in 2008. Things have changed. But that's what was in the submission packet.

So that suggested that there was an important validity from both the face and then also from detect -- being able to detect meaningful performance differences at the physician level.

A couple of things, there wasn't really a comment on missing data. So presumably, you're, you know, if there's missing data, that means you're in the denominator and not in the numerator as there are for some measures, but that wasn't really explicitly stated other then they don't make any exceptions for it. And I think I'll end my comments there. I don't know if Mahesh has anything to add.

DR. KRISHNAN: No. I think again, they did that based on the manual system according to that electronic. And we don't know how close to the gap -- how much the gap has closed, but we just have to vote on what we have.

CO-CHAIR CROOKS: All right. Can we vote on validity?

MS. OGUNGBEMI: The Committee is now

ready to vote on validity for Measure 0323. Options are one high, two moderate, three low and four insufficient. Voting is open.

Results are zero votes high, 19 votes moderate, zero votes low and two insufficient. Measure 0323 passes on validity.

CO-CHAIR CROOKS: So TEP panels don't tend to get high validity votes. But they're moderate.

Okay. Finally we're into feasibility -- almost finally.

DR. FISCHER: It's feasible.

(Laughter)

DR. FISCHER: I mean, it's being -- well, no, I mean it's -- I mean, it's late. This is already being used in CROWNWeb.

CO-CHAIR CROOKS: If CROWNWeb is feasible, then it's as feasible as CROWNWeb.

DR. FISCHER: This was PQRS --

MS. SINGER: It's being used in PQRS actually.

CO-CHAIR CROOKS: Okay.

DR. FISCHER: Right.

CO-CHAIR CROOKS: Okay. Any other comments on feasibility before we vote?

Let's vote.

MS. OGUNGBEMI: The Committee is now voting on feasibility for Measure 0323. Options are one high, two moderate, three low and four insufficient. Voting is open.

Results are 11 votes high, 11 votes moderate, zero votes low and zero votes insufficient. Measure 0323 passes on feasibility.

CO-CHAIR CROOKS: Okay. Use and usability. Michael?

DR. FISCHER: We thought it was high. I mean, it's already currently in use in the PQRS program. We didn't believe there were any unintended consequences.

And kind of circling back to our other comments about the closure of the performance gap further corroborates that it's been useful, used in improving performance. Which in some ways I

guess has been the demise of this measure now perhaps going to reserve status, but, yes, very usable.

CO-CHAIR CROOKS: Okay. Other thoughts to share? Comments?

Okay. Let's vote.

MS. OGUNGBEMI: The Committee is now voting on usability and use for Measure 0323. Options are one high, two moderate, three low and four insufficient. Voting is open.

Results are 15 votes high, five votes moderate, two votes low and zero votes insufficient. Measure 0323 passes on usability and use.

CO-CHAIR CROOKS: Okay. Thank you. So before vote on suitability for endorsement or recommendation for endorsement, any other general comments? Michael?

DR. FISCHER: So just one. So we'll probably talk about this then tomorrow, the harmonization aspect. Just so I'm clear. Is that correct?

CO-CHAIR CROOKS: Right.

DR. FISCHER: Okay.

CO-CHAIR CROOKS: That will have to be tomorrow.

MS. SAMPSEL: Actually we're -- and remember, we're voting on reserve status.

CO-CHAIR CROOKS: We're voting on reserve status. Okay. So we've done all the preliminary work?

MS. SAMPSEL: Yes.

CO-CHAIR CROOKS: Right. Yes, that's -- because that's the way it is. Okay.

So, --

MS. SAMPSEL: No, that was to consider it.

CO-CHAIR CROOKS: That was to consider it for a -- and to look at the rest of the evidence, which we've done. The rest of the criteria.

So now having looked at all the criteria, we're going to vote. And if we vote yes, we're voting for reserve status. A vote no

means that you don't want it endorsed at all.

MS. BAL: And just a reminder, reserve status means that you feel that if the measure does not -- if we don't continue to have the measure, it will have a negative effect on performance. And that you also think that reliability and validity are strong enough to maintain this measure.

So those are the stipulations I want to remind everyone of.

MS. OGUNGBEMI: The Committee is now voting on Measure 0323's endorsement, maintenance potential for reserve status. You heard Poonam's wonderful explanation of it. So, please vote. The options are one yes, two no.

Results are 21 votes yes and zero votes no. The Measure 0323 is -- has a potential for reserve status. Yes.

CO-CHAIR CROOKS: Okay. Thank you all. We're --

MS. BAL: We're going to start at like behind.

CO-CHAIR CROOKS: Yes. We're three measures behind our target. And believe it or not, we're going to make it up by starting a half hour early tomorrow.

So instead of opening at 9:00, we'll start at 8:30 as we did today. And we have to end at 3:00.

MS. BAL: I think it's 8:00

CO-CHAIR CROOKS: Oh, well continental breakfast at 8:00 and gavel at 8:30.

DR. KLIGER: So can I suggest --

CO-CHAIR CROOKS: I'll gavel earlier. I'm --

DR. KLIGER: Let's suggest 8:00? Can we suggest starting it --

CO-CHAIR CROOKS: It's easy for you east coast people to say but -- yes. I'm going to bed.

DR. LATTS: It's up to the Committee to upset the day. It always works out.

CO-CHAIR CROOKS: Let's start at 8:00. I'd like to start at 8:00. I think that would

give us a little more time to consider things.

Okay. Can we have the food here before 8:00? Or --

MS. BAL: Yes. We can have it at 7:30. We just need to know now.

CO-CHAIR CROOKS: Okay. Doors open 7:30.

MS. BAL: Yes.

CO-CHAIR CROOKS: Gavel at 8:00. Okay.

(Whereupon, the above-entitled matter went off the record at 5:43 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Renal Standing Committee

Before: NQF

Date: 05-06-15

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R Gross

Court Reporter