National Quality Forum
Renal Measure Evaluation Web Meeting Spring 2022 Cycle
Wednesday, June 29, 2022

The Standing Committee met via Video Teleconference, at 9:00 a.m. EDT, Lorien Dalrymple and Renee Garrick, Co-Chairs, presiding.

Present:

Lorien Dalrymple, MD, MPH, Fresenius Medical Care
North America, Chair
Renee Garrick, MD, FACP, Westchester Medical
Center, New York Medical College, Chair
Andrew Chin, MD, University of California, Davis
Medical Center
Annabelle Chua, MD, Duke University
Rajesh Davda, MD, MBA, CPE, Cigna Healthcare
Gail Dewald, BS, RN, CNN, Gail Dewald & Associates, LLC
Stuart Greenstein, MD, Montefiore Medical Center
Mike Guffey, Patient/Caregiver Perspective, UMB Bank
Lori Hartwell, Patient/Caregiver Perspective, 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, Yale New Haven Health System
Mahesh Krishnan, MD, MPH, MBA, FASN, DaVita, Inc.
Karilynne Lenning, MHA, LBSW, Telligen
Precious Mccowan, ESRD Network
Andrew Narva, MD, FASN, University of the District of Columbia
Jessie Pavlinac, MS, RDN-AP, CSR, LD, FAND, Oregon Health & Science University
Jeffrey Silberzweig, MD, The Rogosin Institute (New York Presbyterian)

Michael Somers, MD, American Society of Pediatric
Nephrology, Harvard Medical School, Boston
Children's Hospital
Cher Thomas, Patient Advocate
Jennifer Vavrinchik, MSN, RN, CNN, National Dialysis Accreditation Commission
Bobbi Wager, MSN, RN, Patient/Caregiver Perspective, American Association of Kidney
Patients
John Wagner, MD, MBA, Kings County Hospital
Center
Gail Wick, MHSA, BSN RN, CNNe, Consultant, GWA

NQF Staff:

Peter Amico, PhD, Consultant
Poonam Bal, MHSA, Senior Director
Erica Brown, MHA, PMP, Project Manager
Tricia Elliott, DHA, MBA, CPHQ, FNAHQ, Senior Managing Director
Matilda Epstein, MPH, Associate
Paula Farrell, MSHQS, Director
Oroma Igwe, MPH, Manager
Gabby Kyle-Lion, MPH, Analyst

Also Present:

Claudia Dahlerus, UM-KECC
Joe Messana, UM-KECC
Jon Segal, UM-KECC
Vahakn Shahinian, UM-KECC

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Proceedings

(9:00 a.m.)

Welcome and Review of Meeting Objectives

Ms. Farrell: All right. Hello. Good morning, everyone. And thank you for joining us for our Renal Spring 2022 Measure Evaluation Meeting.

I'm Paula Farrell, the director for the project. And today we have six measures that we're going to be discussing.

We have five measures that are new and one measures that is a maintenance measure that we're going to be reviewing.

So, before I turn the call over to the co-chairs, I would like to welcome our newest co-chair, Dr. Renee Garrick. She is, has been a member of the Renal Standing Committee since 2017. She's also a practicing nephrologist with over 30 years' experience.

And she's going to be serving alongside our current co-chair Lorien Dalrymple. And as we have mentioned in previous communications, Connie Anderson has been transitioning off the project over the past couple of months, but we would like to thank her for her commitment, the expertise that she's given to the committee, and also her years of service that she brought to the Renal Standing Committee.

So, with that, I'll turn it over to our co-chairs to provide their welcoming remarks.

Lorien and Renee.

Chair Dalrymple: Thanks, Paula. I just want to say good morning to everyone. And thank you all for all of the work you do on behalf of this committee. We're looking forward to a robust discussion today. And really want to thank all of our presenters and

contributors and all of the committee for the thoughtful input they will provide today on the measures under review.

Chair Garrick: Hi. It's Renee.

Thank you. And thanks for inviting me to serve along with Lorien and the rest of the committee as a co-chair. I'm looking forward to a very robust meeting today.

In addition to the remarks that Lorien already made, I just wanted to welcome our clinical advisors who are patient advisors, Bobbi Wagner and Precious McCowan, who will be joining us. And we'll be asking them to participant as we move long. And it's great to have them with us.

So, thanks for being here. And thanks for all the hard work you've already put into this proceed.

Ms. Farrell: Great. Thank you.

All right. Next slide, please.

So, I'm going to go through a few housekeeping reminders and then we'll start with introductions and disclosures of interests.

So, as a reminder, we are on a Webex meeting with audio, and it also has video capabilities. So, if you can, we do ask that you please turn on your video.

Please also remember to always put yourself on mute when you're not speaking.

And we also encourage you to use some of the features that are available on Webex. So, we do have a chatbox that's available. And you can either message NQF staff individually, or you can message the entire committee through that chat.

We do ask on the call that you please utilize the raised hand function if you'd like to speak and the co-chairs will call on you in order, instead of just

speaking up, because this allows us to make sure that anyone who would like to speak has an opportunity to do so.

And, finally, if you're experiencing any technical issues, please feel free to contact the NQF project team at renal@qualityforum.org.

Next slide, please.

All right. So, now I'd like to introduce the great team that we have that worked to put this meeting together.

Myself, I'm Paula Farrell.

Our manager is Oroma Igwe.

Our analyst is Gabby Kyle-Lion.

Matilda Epstein is our associate on the project.

And then we have Erica Brown who is our project manager.

Poonam Bal, who is our senior director.

And Peter Amico, who is our consultant for the project.

And just so everyone's aware, Erica, Poonam, and Peter are supporting staff for the project, but we did want to go ahead and introduce them because they may be joining in the discussion as the day goes on.

Next slide, please.

All right. So, for the agenda today we're going to jump into introductions and disclosures of interest. And during that time we'll ensure that we have quorum to hold the call.

We're also going to provide an overview of our evaluation process and the voting process.

And we're going to do a voting test just to make

sure that everyone has access and is able to vote.

So, yesterday the standing committee members should have received an email with a voting link. And you will need that for this meeting today. If you happen to have not received the link or are not able to find it, please let us know in the chat function right now. Or you can send an email to renal@qualityforum.org and we'll make sure that we get that link to you.

And then after our voting test I will provide brief introductions to the measures that are under review.

And then I'll hand it over to our co-chairs to lead the discussion by the standing committee on our first measure.

We have about an hour planned to discuss each measure, with NQF Measure 3659 going first.

We'll then take a 30-minute lunch break at around noon, and we'll reconvene in the afternoon to review the additional measures after lunch.

Also, after we've discussed all the measures we'll review the related and competing measures.

We'll then end the meeting with NQF member and public comments to see if they have any additional input to provide.

And then we'll provide you with some next steps and what to expect going forward.

We are going to try to do our best to get through all of the measures under review today. However, if the standing committee has an in-depth discussion, that is fabulous and we look forward to that.

And we do have tomorrow's schedules. You should have a calendar invite for tomorrow and a calendar, and we ask that you keep that invite for now in case we do require the extra time tomorrow. But we'll

determine that at the end of the day when we see where we are.

All right. Next slide, please.

So, now I'm going to turn the meeting over to our senior managing director Tricia Elliott for committee member introductions and disclosures of interest.

Tricia.

Introduction and Disclosure of Interest

Ms. Elliott: Thank you, Paula.

Good morning. And thank you so much for your time and energy, and commitment to the NQF processes, particularly for this Renal Committee today.

So, today we will be combining introductions with disclosures of interest. You received two disclosure of interest forms from us. One is our annual disclosure of interest, and the other is disclosures specific to the measures we are reviewing in this cycle.

In those forms we ask, ask you a number of questions about your professional activities. Today we will ask you to verbally disclose any information you provided on either of those forms that you believe is relevant to this committee. We are especially interested in grants, research, or consulting related to the committee's work.

Before we begin, a few reminders.

You sit on this group as an individual. You do not represent the interests of your employer or anyone who may have nominated you for this committee. We are interested in your disclosures of both paid and unpaid activities that are relevant to the work in front of you.

Finally, just because you've disclosed does not

mean that you have a conflict of interest. We do verbal disclosures in the spirit of openness and transparency.

We will now go around our virtual table, starting with our committee co-chairs. I'll call your name. Please state your name, what organization you are with, and if you have anything to disclosure.

If you do not have disclosures, you can just state "I have nothing to disclose," to keep us moving along.

If you experience trouble unmuting yourself, please raise your hand so that our staff can assist.

I'll begin.

Lorien Dalrymple.

Chair Dalrymple: Good morning, everyone. My name is Lorien Dalrymple. I am the head of population health and medicine for Fresenius Medical Care in the Global Medical Office. As such, I am employed by and I also have share options in Fresenius Medical Care.

My husband is a physician partner at Kaiser, and has shares in the Permanente Medical Group.

I am a member of the KCQA Steering Committee, and Fresenius is a member of KCP. I have participated in TEPs, and also provided input and guidance for development of quality measures in the last 5 years.

With today's measures under review I am not recused from any of the measures.

Ms. Elliott: Excellent. Thank you so much.

Renee Garrick.

If you're speaking, Renee, you're on mute.

Chair Garrick: Does that work now?

Ms. Elliott: Yes.

Chair Garrick: All right, thanks. Unmuted the wrong mike.

So, my name is Renee Garrick. I'm chief medical officer and vice dean at Westchester Medical Center and New York Medical College in New York. And I'm a practicing nephrologist with 30 years' experience as a medical director, and work at a not-for-profit dialysis facility in New York.

I have participated in TEPS. And in the past, but not within the last 5 years, participated in measure development.

And I have no conflicts and no recusals for today's measures.

Ms. Elliott: Thank you, Renee.

Next, Stuart Mark Greenstein.

(No response.)

Ms. Elliott: We'll circle back.

Frederick Jeffery Kaskel. Dr. Kaskel, are you there? We can't hear you.

Member Kaskel: (No audio.)

Ms. Elliott: We will circle back. If you are speaking, we are not able to hear you.

Myra Kleinpeter.

(No response.)

Ms. Elliott: I don't see Myra yet.

Alan Stewart Kliger.

Member Kliger: Yeah, I'm really here. And I'm hoping you can hear me.

My name is Alan Kliger. I'm a clinical professor of

medicine at Yale. Have been in the quality measurement and quality improvement space for several decades.

Currently, I am the Chair of Excellence in Patient Care for the American Society of Nephrology.

And I have no conflicts of interest to report.

Ms. Elliott: Thank you very much.

Next is Mahesh Krishnan.

Mahesh, I see you on the call. We don't hear you, so you may be double muted.

Member Krishnan: I am double muted.

Ms. Elliott: Okay. There you are.

Member Krishnan: Mahesh Krishnan, one of the chief medical officers for DaVita Group. Vice president for research and development and oversee public policy here in D.C.

I'm employed by DaVita, have stock options by DaVita. I'm a member of Care Partners. I have served on various TEPS. Have no conflicts with any of the measures being described.

Ms. Elliott: Thank you so much.

Karilynne Anne Lenning.

(No response.)

Ms. Elliott: We'll circle back.

Next up, Jessie Pavlinac.

(No response.)

Ms. Elliott: Next we have Jeffrey Silberzweig.

Member Silberzweig: Good morning. My name is Jeff Silberzweig. I am the chief medical officer at the Rogosin Institute in New York City, and an

associate professor of clinical medicine at Weill Cornell Medicine.

I am a member of Kidney Care Partners and a member of the KCQA Steering Committee.

I am also the co-chair of the American Society of Nephrology's COVID-19 response team.

I have no conflicts for today.

Ms. Elliott: Thank you, so much.

Michael Somers.

Member Somers: Hi. I'm Michael Somers. I'm a pediatric nephrologist from Boston Children's Hospital, and I'm on the faculty at Harvard Medical School.

I have served on TEPS but I have no conflicts with today's discussions. Thank you.

Ms. Elliott: Thank you.

Next is Jennifer Vavrinchik.

Member Vavrinchik: Hi. This is Jennifer Vavrinchik. I'm sorry, I'm on day three of COVID, so I'll do the very best I can.

I am chief operating officer and owner of National Dialysis Accreditation Commission. I have been on TEPS previously but not in several years.

And I have nothing to disclose. Thank you.

Ms. Elliott: Thank you. And we hope you're feeling better soon.

Member Vavrinchik: Thank you.

Ms. Elliott: Next -- and thank you for joining today. We really appreciate that.

Next up is John Wagner.

Member Wagner: Good morning. My name's John Wagner. I am associate medical director in New York City Hospital Center, Kings County. I am also the Service Lead for New York Health and Hospitals, ad hoc member of the National Forum of Neurosurgery Networks, and a member of Network Two Medical Review Boards. I've participated in TEPS in the past.

But otherwise I have no conflicts or things to declare.

Ms. Elliott: Thank you very much.

Next on our list is James Michael Guffey.

(No response.)

Ms. Elliott: We'll circle back.

Next up we have Andrew Chin.

Member Chin: Hi. Good morning.

I'm Andrew Chin. I am a practicing nephrologist at the University of California at Davis. I'm also a medical director for a dialysis clinic run by a not-for-profit organization. I still serve on the Health System Accountable Care Governing Body.

I have no conflicts related to these measures.

Ms. Elliott: Thank you very much.

Next, Anabelle Chua.

Member Chua: Yes. Hi.

I'm Anabelle Chua, pediatric nephrologist and associate professor of pediatrics at Duke. And I have no conflicts of interest to disclose related to these measures.

Ms. Elliott: Thank you.

Next is Rajesh Davda.

(No response.)

Ms. Elliott: We'll circle back.

Next is Gail Dewald.

Member Dewald: Hello. I'm Gail Dewald from San Antonio, Texas. And I'm a practicing nephrology nurse. I'm representing American Nephrology Nurses Association.

I have no disclosures or recusals.

Ms. Elliott: Thank you.

Next, Gail Wick.

Member Wick: Good morning. I'm Gail Wick. I'm retired now but I'm still active in AK application groups, and serve on numerous committees.

I'm also a member of KCQA Steering Committee. I have no conflicts with the measures being considered.

Ms. Elliott: Thank you.

Lori Hartwell.

(No response.)

Ms. Elliott: Circle back.

Precious McCowan.

Member McCowan: Good morning, everyone.

I am Precious McCowan. I am a kidney disease patient advocate, educator, and mentor. And I am affiliated with ATW Health Solutions.

And I have no disclosures. Thank you.

Ms. Elliott: Thank you very much.

Cher Thomas.

(No response.)

Ms. Elliott: We'll circle back.

Roberta Louise Wagner -- or Wager. I'm sorry.

(No response.)

Ms. Elliott: We'll circle back.

Andrew Narva.

Member Narva: Hi. I'm Andrew Narva. I am a nephrologist. I've spent most of my career in the Indian Health Service and at the NIH. I retired a couple years ago. And I'm in the doctoral program at the University of the District of Columbia. I see patients as a volunteer at Walter Reed.

And I have Active Appointment unit Uniformed Services University of the Health Sciences.

I have no conflicts.

Ms. Elliott: Thank you so much.

I think a few people have joined since we started roll calling. I'm going to circle back with a few folks.

Dr. Kaskel, are you on the line now?

Member Kaskel: Hi. I'm Frederick Kaskel. I'm a pediatric nephrologist at Montefiore Albert Einstein in the Bronx. I've been involved for a number of cycles with the NQF representing the ASTN in pediatric nephrology.

Thank you.

Ms. Elliott: Thank you. And I believe Rajesh Davda joined.

Member Davda: Excuse me. Hi. Rajesh Davda. I am the medical director for the kidney program for the Cigna Health Care. And I have no conflicts to disclose.

Ms. Elliott: Okay. Thank you very much.

And I believe we have Bobbi Wager on the call. I'm not sure if you're unable to unmute. We weren't able to hear you.

Member Wager: Hi. Can you guys hear me now?

Ms. Elliott: Yes, we can.

Member Wager: Thank you. Hi. I'm Bobbi Wager. I'm a nephrology nurse, former in-center hemo patient, and two time kidney transplant recipient.

And I have no disclosures and conflicts with the measures.

Ms. Elliott: Thank you, Bobbi.

There is an echo when you talk so you might have two instances of the audio in place. So, you may just want to double check.

There's a few more folks I'm just going to double check on.

Did Dr. Greenstein join?

(No response.)

Ms. Elliott: Okay. Dr. Kleinpeter?

(No response.)

Ms. Elliott: Karilynne Lenning?

(No response.)

Ms. Elliott: Okay. Jessie Pavlinac?

(No response.)

Ms. Elliott: James Guffey.

(No response.)

Ms. Elliott: Lori Hartwell?

(No response.)

Ms. Elliott: And I believe Cher Thomas is going to join later.

So, if any of these folks join a little bit later in the meeting, we'll have them share any disclosures.

So, thank you. And I'd like to let you know that if you believe that you have a conflict of interest at any time during the meeting as topics are discussed, please speak up. You may do so in realtime during this web meeting, or you can send a message via chat to your chairs or anyone on the NQF staff.

If you believe that a fellow committee member may have a conflict of interest or is behaving in a biased manner, you may point this out during the meeting, send a message to your chairs or to the NQF staff.

Does anyone have questions or anything you'd like to discuss based upon the disclosures made today?

(No response.)

Ms. Elliott: I'm not seeing any hands raised or any questions in the chat.

And, lastly, as a reminder, NQF is a non-partisan organization. Out of mutual respect for each other we kindly encourage that we make an effort to refrain from making comments, innuendos, or humor relating to, for example, race, gender, politics, or topics that otherwise may be considered inappropriate during the meeting.

While we encourage discussions that are open, constructive and collaborative, let us all be mindful of how our language and opinions may be perceived by others.

With that, I will now turn it back over to the team. Thank you.

Ms. Farrell: Great. Thank you, Tricia.

So, now I'm going to turn it over to our project manager Oroma Igwe, and she's going to provide us with an overview of the evaluation process and the voting process.

Oroma.

Overview of Evaluation Process and Voting Process

Ms. Igwe: Thank you, Paula.

Greetings, everyone. I'm going to take a moment now to transition to a group overview of the evaluation process and the voting process. And, again, my name is Oroma Igwe.

Next slide, please.

If you could go one slide further. Thank you.

So, we're here to remind you that your role as a standing committee member here is to act as a proxy for the NQF multistakeholder membership. As the Renal Committee, you not only oversee the portfolio of renal measures, but you do work collaboratively with NQF staff to provide recommendations for endorsement of the measures based on our CDP evaluation guidance.

It also tasks to respond to comments that are submitting during our public commenting period.

Today you will be asked to evaluate measures against these criteria and, subsequently, make recommendations for NQF membership.

Next slide, please.

We want to remind you that this is a shared space of interdisciplinary multistakeholder committee members. Every voice is, indeed, important. And we want to emphasize that each committee member holds equal value on this call and, of course, in the

broader scope of your work.

As NQF staff, we do do our due diligence to encourage you all to adequately review and prepare for the measure in advance of the meeting. And so, today we invite you to remain actively engaged and cognizant of the varying experiences of those on the call.

Please remember to allow others space to contribute. And aim to keep your comments concise and focused on the criteria.

So, this slide that you see describes the process by which we will conduct today's measure discussion and evaluation.

Each measure discussion will begin with a brief developer introduction. The overall facilitation will be led by the co-chair. And the discussion will be stewarded by our assigned lead discussant, supporting discussant.

So, thank you again, really to everyone on the call, but especially our discussants for your leadership today.

The lead discussant will briefly explain information on the criterion, and besides notable areas of concern, and note the preliminary staff rating if needed.

And the full committee discussion will then commence, followed by the criterion vote. And then this process will be repeated with the subsequent criteria.

Developers, of course, will be available to respond to questions, however, at the order and discretion of the co-chairs and the standing committee.

Next slide, please.

So, here on this slide we've listed the endorsement criteria. Our measures are evaluated for their

suitability based on what you see here is a bit of standardized main and sub criteria in the order depicted on the screen.

So, you have importance to measure and report;

Scientific acceptability of the measure properties;

Feasibility;

Usability and use;

And then related and competing measures.

The assessment of each criterion is a matter of degree. However, it's either a new or a returning measure, otherwise known as a maintenance measure, that's judged as not passing for the first criterion you see there, importance to measure report, also scientific acceptability and measure properties. And use for maintenance measures, it cannot be recommended for endorsement and will not be evaluated against the main criteria.

If the measure meets the above criteria and there are endorsed or new related or competing measures, a discussion will be held that identifies those measures.

Just to remind you all, there will be no best-in-class voting activity today as it relates to competing measures because we don't have any currently identified measures being reviewed at the same time, so.

So, here is a short list, a breakdown of the main endorsement criteria again, and subcriterion as well.

Again, the votes will be taken after the discussion of each criterion. Please make special note of what you see here as the "must pass" nature of several of these criteria.

If the measure progresses to the last criteria, then the overall suitability for endorsement will be the

last vote.

Next slide, please.

So, reiterating some of the points that have been made. NQF staff will provide a brief overview of the related and competing measures, and then we'll invite the committee to weigh in with any further comments if desired. And it's important to reiterate that measures that fail on one of the "must pass" criteria will not proceed to additional discussion or voting on subsequent criterion.

However, if we reach CNR, or consensus not reached, discussion will continue to the next criterion, but a vote on overall suitability will be deferred to the post-comment meeting.

Next slide.

So this is a particularly important slide here.

In order to conduct live voting today, the standing committee must achieve and maintain a quorum. And so, quorum is 66 percent of the active committee roster, which for us is 16 of 24 members. And so, thankfully, today so far we definitely have quorum and will be conducting business as usual on this call.

The chart also displays the margins within which voting outcomes are indicated. A measure that does not meet consensus, as I said earlier, will move forward throughout the process, the draft report commenting period. And then the committee will reconvene in the subsequent months to re-vote on that measure post-comment meeting.

If a measure is not recommended for endorsement, it will also proceed to the draft report commenting period, but the difference here is the committee will not be called to re-vote on the measure unless the committee decides to reconsider their own recommendation based on either comments from

the draft report commenting period or a formal consideration request from the developer.

Next slide, please.

So, as stated prior, 16 active committee participants must be present in order for the committee to vote live during this call. And, of course, we've gone beyond the 60 percent attendance mark, so we certainly know we can continue having the call altogether.

So, attendance is significant. If at any point during the call you step away or you anticipate a change in your attendance status, you're welcome to notify us through the chat. You can chime in on the call via audio as well.

And in the event that the attendance drops below quorum, we will resume the discussion but we'll have to defer the voting activity to an offline written survey.

So, thank you. Many of you all have already let us know about your intermittent absence throughout the call. So, thank you for that.

Next slide.

So, before we proceed to the voting test I'm going to pause here for any questions regarding the evaluation process.

(Pause.)

Ms. Igwe: Okay. I don't see any in the chat. And I don't believe I see any raised hands.

So, thank you very much. I will now turn the presentation over to my colleague Gabby for the voting test.

Voting Test

Ms. Kyle-Lion: Good morning, everyone. You should

have gotten -- this is we'll do a voting test. This will be just for the Renal Standing Committee members. And you should have received an email yesterday with the Poll Everywhere voting link.

If you need us to re-send that to you, just let us know either via chat or you can come off mute.

And I'll go ahead and open up the poll.

So, our question is What is your favorite season? Your options are A for spring; E for summer; C for winter; and D for fall.

And as Oroma said, we need 16 votes to have quorum. But I believe we are looking for 17 votes here.

(Voting.)

Ms. Kyle-Lion: We have 13. Just need a few more.

(Voting.)

Ms. Kyle-Lion: We're still at 13.

If you're having trouble accessing the Poll Everywhere poll, please go ahead and send a chat to either myself, Oroma, or Paula. Or come off mute and let us know.

Member Davda: Hey, this is Raj. I'm having trouble. Can you send the instruction again or?

Member Wick: This is Gail Wick. I'm having trouble.

Ms. Kyle-Lion: Okay, perfect. I'll go ahead and send the email to you both with the link in it.

Chair Garrick: And this is Renee. I have the poll up, but it doesn't seem to submit.

Member Wick: That is my case.

Chair Dalrymple: Same.

Chair Garrick: Me, too.

Ms. Igwe: You need to refresh your screen if you've having, if you're having issues. And if that doesn't correct it, let us know.

Member Somers: Also, just make sure you're not trying to vote on the Webex screen. Because sometimes it's confusing because it has the same choices up.

Ms. Farrell: All right, we have NQF staff that will reach out to those that have notified us that they're having some difficulties with the voting. But we will move on for more voting tests and show the results for our standings, and to see what our favorite season is.

Ms. Kyle-Lion: Sure. Okay. So, we have 4 votes for spring, 2 votes for summer, 0 votes for winter, and 7 votes for fall.

So, I'll go ahead and pass it back to you, Paula.

Ms. Farrell: All right, great. Thank you.

So, now I'm going to -- maybe if we go to the next slide, please.

I'm going to introduce our measures that we're going to be reviewing today.

Go to the next slide.

Measures Under Review

And we have six measures that we're going to be discussing during our meeting. There's one maintenance measure, and then we have five new measures that we're going to be discussing.

Next slide, please.

And as I'm sure you're all aware, we have a Scientific Methods Panel which reviews measures that are deemed to be complex. And that panel

consists of individuals with methodologic experience. And the panel is established to help us ensure a higher evaluation of our scientific acceptability criteria of complex measures.

Next slide, please.

The maintenance measure, NQF No. 2594, was not reviewed by the Scientific Methods Panel because it was deemed to be non-complex.

All of the other measures that the Standing Committee is going to be evaluating today for review by the Scientific Methods Panel because they were deemed to be complex measures.

We did have three additional measures that were submitted for the Renal Spring 2022 cycle. And those were evaluated by the Scientific Methods Panel, but they did not pass the panel's review. So, the Standing Committee will not be evaluating them today.

Next slide, please.

All right. So, before I before I bring in the evaluation, before we begin the evaluation of the first measure I'd like to outline our structure for discussion today.

First, I will turn the call over to our co-chair who's been designated as the lead to facilitate the discussion. And then the co-chair will turn it over to the developer who will provide about a 3- to 5-minute introductory remarks on their measures.

We'll then begin with the Standing Committee's discussion on the first measure evaluation criteria, which is evidence. And the co-chair who is leading the discussion will ask the lead discussant to provide a summary overview of the evidence that was submitted on the measure, the pre-evaluation comments that we received and, also, a summary of the Standing Committee's pre-evaluation survey

results.

The backup discussants will then be asked to provide any additional remarks that they would like to get.

And once the information regarding the evidence has been presented, the Standing Committee will then begin their discussion on that criteria, evidence, which is our first measure evaluation criteria.

And as a reminder, the Standing Committee is asked to review and discuss each measure as it has been submitted.

And during the Standing Committee's discussion any questions that come up that are specific to the developers, we're going to be collecting them. The co-chairs are going to help out by jotting those down. And NQF will be tracking those questions.

And once we have, once the Standing Committee has completed the initial discussion on the criterion that we're reviewing, then we'll give the developers an opportunity to respond to questions that have come up and provide any clarifying information for the Standing Committee.

If a Standing Committee member does have a question for the developer, we do, when we're discussing a certain criterion, we do ask that you please enter those into the chat or, if you're verbalizing your question, please let us know before you verbalize it that it is a specific question for the measure developer so that we can drop back down when we get to the time for them to respond to questions.

All right. Next slide, please.

So, with that, let's get started with our review of our first measure which is NQF No. 3659, Standardized Fistula Rate for Incident Patients.

And I'm going to turn the call over to our co-chair Lorien to facilitate the discussion.

3659 Standardized Fistula Rate for Incident Patients (University of Michigan Kidney and Epidemiology Cost Center/Centers for Medicare & Medicaid Services)

Chair Dalrymple: Thank you, Paula.

So, I will briefly introduce this measure, which is Measure No. 3659, Standardized Fistula Rate for Incident Patients.

Our measure steward developer is CMS/UM-KECC. And this is a new measure under review.

I'll briefly read the description of the measure and then the measure developers will give a more comprehensive overview.

I would like to point out a couple things that are not on this slide that will be important for the committee to note.

The measure type is an intermediate clinical outcome.

The level of analysis is facility.

The setting of care is outpatient services.

And the data source will be registry data or claim -- or claims.

And this measure is meant to look at the adjusted percentage of adult incident hemodialysis patient-months using an autogenous arteriovenous fistula as the sole means of vascular access.

The Standardized Fistula Rate for Incident patients is based on the prior SFR, which was NQF No. 2977, that included both incident and prevalent patients.

This measure was initially endorsed in 2016, but as part of measure maintenance review by our

committee in 2020, concerns were raised about the strength of evidence supporting that prior measure, particularly as it related to updates to the KDOQI guidelines.

Given that, the guidelines do suggest that under favorable circumstances an AV fistula is preferred to AV graft in incident patients due to fewer long-term vascular access events. And given that over 80 percent of incident dialysis patients begin treatment with a tunneled catheter, and that 12 months after dialysis initiation AV fistula rates exceed 60 percent, the incident SFR was developed to focus on the subset of dialysis patients that the evidence suggestions may benefit the most during a time of intense vascular access creation.

Specifically, blood stream infection rates are the lowest in incident patients with AV fistula compared to long-term catheters.

Therefore, the goal of this new measure is to evaluate facility performance in increasing fistula use in the incident population in order to reduce the heightened risks patients face due to bacteremia and infection-related hospitalizations.

So, I will now ask Dr. Segal to provide a overview from the measure developer.

Dr. Segal: Hi. Thanks.

This is Jon Segal from UM-KECC. And I appreciate the opportunity to speak to you all today.

And I think you've kind of outlined at least some of the historical components of this measure. I was actually going to go through that myself. So, you've maybe saved a couple minutes of time, which is great.

And so, in addition to trying to focus this incident measure on a time where we feel like the evidence best supports the potential creation of fistula in

patients who are suitable candidates, there was also some discussion at the 2020 meeting about the prior standardized fistula measure being potentially topped out since fistula rates at the national level had plateaued around 64 percent.

During that meeting there was very little, if any, discussion about the ongoing large performance gap between facilities, as well as the disparities in fistula rates between different patient groups.

So, with this incident patient measure, we find that the performance gap between facilities is even larger than in the prior SFR. And, not surprisingly, there are still significant disparities in fistula rates that continue to be an issue.

I'll add that one of the difficulties with the prior standardized fistula measure was the inability to account for patients that had extensive dialysis exposure and multiple failed vascular accesses such that they were deemed catheter-dependent.

While, while there was widespread agreement that these patients should be excluded from the fistula measure, there's been no way to operationalize that exclusion criteria, and no consensus was reached by our 2015 TEP as to how best to do so.

So, this measure, by focusing on patients in the first 12 months of dialysis tends to avoid the problem of exhausted vascular access since it's typically not encountered in such a relatively short time span.

In addition, there's been issues of patient choice with regards to the type of vascular access. And it's certainly understandable that some patients will decide that they don't want further attempts at a surgical access during their dialysis journey.

Most often this is in patients who have been on dialysis for longer periods of time. And because there's no standard criteria for how to validate a truly informed decision by a patient, the prior SFR

measure, and many quality measures for that measure for that matter, are unable to account for this component in shared decision-making.

So, by focusing just on the first year of dialysis exposure, the incident SFR should largely avoid this issue since the vast majority of patients are initially willing to undergo attempts at a surgical access.

So, in summary, we drafted a fistula measure that's now more narrow in scope to better align with the strengths of the existing evidence. And it's done in a way that's been responsive to feedback we've received from stakeholders, as well as the feedback we've received from this committee in the past.

We find that there's still a significant gap in performance between facilities in fistula creation. And the Scientific Methods Panel that reviewed this measure earlier indicated that there was sufficient reliability and validity.

So, I think really the key comes down to the evidence and the literature, and that in general we find that both fistula and graft are better than long-term catheters in terms of lower risk of infection.

And we find that fistula have some advantages over grafts in terms of the long-term ability to maintain a patient access without the need for declots, and fistulagrams, and other procedures.

And so, in the end, for many patients, particularly in their first year of dialysis where they start with a tunnel catheter and haven't had attempts at surgical access creation, a fistula for many of these patients is going to be a reasonable choice. And so, we tried to craft the incident fistula measure to reflect that decision making that's often occurring in dialysis facilities.

So, let me stop here. And I look forward to the discussion. And I'll try and answer questions to the best of my ability. Thanks.

Chair Dalrymple: Thank you, Dr. Segal.

So, our lead discussant for today will be Alan Kliger. And Raj will be a supporting discussant.

So, Alan, I'm going to hand it over to you to start the discussion on evidence, please.

Member Kliger: Thanks.

All right, I'm going to follow the script. So, I will be repeating briefly some of the things you've already heard. But let me go through it.

First of all, the description of this method is, really is the percentage of all incident dialysis patients. That means patients in their first year of dialysis, and what percentage of all of those patients are using AV fistulas.

The denominator excludes patients on hospice care, those who've had metastatic cancer, end-stage liver disease, and coma or anoxic brain injury. So, those are the exclusions.

And later in the discussion if we get past evidence, we'll be talking about that.

As Lorien said, the level of analysis is at the facility level. But inclusion or exclusion is at the patient level, which is an appropriate decision.

It's a new measure, but it's based on the 2016 Standardized Fistula Rate Measure that was passed. But as we've heard, in 2020 the measure was eliminated. And it was eliminated largely for two reasons.

One, there was concern about the strength of the evidence which had been downgraded by KDOQI and other reviewers, since virtually all of the evidence is observational retrospective data, and the usual concerns and biases about those types of data.

But probably more importantly was the discussion that it's evolved to be clear that eliminating central catheters is really the most important goal. We used to say "fistula first." But now it's clear we should probably be saying "catheter last." And that we do have now a measure to minimize central venous catheters.

And so that this was a measure that was felt to be the appropriate and adequate one, rather than a measure of fistulas.

This new proposed measure is aimed to better focus a standardized fistula rate by making it incident patients only, so only patients in their first year of dialysis care with a higher opportunity for AV fistula gap. That is, the data showing that early on 80 percent of patients start dialysis with a catheter, and so that there's a large opportunity to get an AV fistula.

So, number one was, to focus it, was to limit it to the incident patient population only. But, secondly, by focusing on the outcome of infection or sepsis, which is clearly more directly related to abscess type.

And the probable reason that "catheter last" is most important, because eliminating catheters eliminates the major source of bloodstream infections in patients on hemodialysis.

The type of measure, the developers call it an intermediate outcome measure. I think it's a process measure. But it doesn't matter, because in the algorithm intermediate outcome and process measures are handled the same way. So, this is either an intermediate outcome or a process measure.

So, let me get to discussing the evidence.

So, first for prevalent patients, that is all patients on dialysis, the evidence was examined in 2020. And

as I mentioned, it was thought to be weak at that time.

But now, with this new focus on incident patients only and the outcome of most interest is infections. I had a chance to just go through all of the references that the developers cited in this. And let me just briefly summarize what those were.

So, there were 14 references that were offered by the developers. There were also a couple of proceedings of other review groups. But of the 14 studies specifically dealing with this, first of all, seven of them did not primarily examine incident patients in their first year of dialysis, but were wider and really were looking at the experience of all dialysis patients.

Of those studies that were studies of incident patients, which is the focus of this measure, three of them examined the effect of pre-dialysis education on vascular access; one examined individual surgeons' effect on access choice; and one examined the relationship of vascular access type to survival and hospitalization rate.

So, leaving really four studies that the developer cited, examining infection, that is bloodstream infection in incident patients, which is the focus of this measure.

So, let's talk about those four studies.

One showed that the AV fistula rate of infections clearly showed a 61 percent lower risk of infections than central venous catheters or AV grafts.

Two of those four studies examined elderly patients in which -- and looked at infections after switching access to AV grafts or AV fistulas. One of them showed that the infection rate was highest in AV grafts compared to AV fistulas. And the second of those two studying the elderly showed that of patients who switched from central venous

catheters to AV fistulas within 6 months, that they had a lower likelihood of death and fewer hospitalizations than those who got AV grafts.

And then one study, and I think this is important, understanding the problem of the observational retrospective studies such as the ones I've just cited, this last study used observational data to emulate a target RCT, a target rate, a randomized controlled study.

Since there are no randomized controlled studies, this one used data to emulate a randomized controlled study. And it was found that the type of AV access created was not associated with the risk of sepsis or motality, or infection-related hospitalization.

In other words, we have to be careful in the retrospective observational studies suggesting that converting to an AV graft causes more infections than converting to an AV fistula. Without randomized controlled trials we can't know that for sure.

And in this one study that emulated a targeted randomized controlled trial there was no difference between the two.

So, to summarize these data, I believe that they do confirm that central venous catheters are at the highest risk of bloodstream infections compared to other vascular types.

The beta supports the existing measure that we have on the books right now that are intended to measure and minimize central venous catheters. But at least in my review, I'm not sure that these are strong evidence that adding a measure for the creation of a fistula adds substantial value to the existing central venous catheter measure.

In the outline we were also asked to give the pre-evaluation comments that all had. And those are

some of the outside sources had.

So, let me quickly do that.

While several of us endorsed the evidence showing better outcomes with AV fistulas than central venous catheters, others concluded that looking at incident patients only was essentially no different than looking at prevalent patients.

The standardized fistula rate measure eliminated two years ago for weak evidence, and that the evidence presented here added marginally to the evidence we'd already seen, but was not substantially different.

It would largely eliminate the problem of exhausted fistula, that is when patients run out of vascular access and have to be catheter-dependent, is almost always in people beyond their first year. So, it surely would eliminate that problem.

But this advantage alone may be outweighed by a focus to increase patient-months with an AV fistula in the first year.

So, the measure here is a measure of how many months of AV fistula use. So that any one patient could contribute multiple times. It's a count of the number of months for each patient that the AV fistula is used.

There may be good reason for some patients to delay AV fistula surgery. This is a measure, you know, each month in that first fistula year patients come on usually with catheters. And there are some who commented that it actually is a robust response that by the end of the 12 months that 60 percent of patients have AV fistulas.

So that, not at all sure that that's a performance gap or an inappropriate movement, and that there may be reasons that patients delay AV fistula construction for several months, or even longer.

Many patients have short-term expectation on hemodialysis, and so don't get a permanent access as soon as they start, for example, those who expect a live donor transplant or short life expectancy other than the exclusions listed, or the need to clinically stabilize after starting hemodialysis before getting a surgical procedure of an access.

Also, then the AV graft may be the best choice for some patients, like those with small blood vessels or other anatomical considerations.

So, for these reasons, a measure to minimize central venous catheters were thought by some of us to be better than a standardized fistula rate.

Two organizations made comments on the evidence. One was the American Society of Nephrology which said that the proposed measure is inherently unchanged from the previous measure and did not support it.

The other is Kidney Care Partners that says they do not support this measure and support long-term catheter rate measure instead.

So, that's the evidence and that's the comments that we and some of the other organizations had about the evidence.

Chair Dalrymple: Thank you, Alan.

Raj, I'd like to give you an opportunity to add anything that you felt perhaps Alan did not cover or if you agree with everything that's been stated. And you're under no obligation to add additional commentary.

And we will then open it up to the full Standing Committee for discussion.

Member Davda: Yeah, thank you.

I think Alan did a great job. I think, you know, my

view is that the evidence adds marginally to the previous evidence. But we can open it up.

Chair Dalrymple: Okay, thank you.

So, we'll ask committee members to raise their hands so that we can call on you. You can also put things in the chat. But, obviously, our preference would be raised hand and open discussion.

So, both Renee, I, and all of the NQF staff will be looking for hands to begin the discussion.

And, Paula, I'm hoping raised hand goes to the top, or do we have to scroll through the entire participant list to see raised hand?

Ms. Farrell: Unfortunately, you have to scroll through.

Chair Dalrymple: Okay. No problem.

Chair Garrick: I see Andrew's hand up. Dr. Narva's hand is up.

Member Narva: Sure. I think one of the problems that exists in kidney care is sort of the way care is siloed into pre-dialysis, dialysis, and transplant. And the difficulty we have in impacting, impacting it I think leads to lack of change.

And I just wonder if this, one of the impacts of this measure would be to effect pre-initiation care in that it would promote the need for education and for better, better attention to preparation of people who are not yet on dialysis.

And I understand Alan's summary. And I think that it's great that the fistula rate has increased to 60. But the expense and difficulty, and what the very high catheter rate initiation represents in terms of patient morbidity I think is significant.

And I just wonder, we have to find some way of leveraging the performance measures that we

create to sort of improve care before people start dialysis, as well as their access to transplants.

Chair Garrick: And Alan?

Member Kliger: Well, if I might, Andy, I agree with you. This discussion is a discussion of the evidence really, not of the potential power to change minds or to change practice but on the evidence.

So, happy to have that discussion later. But I chose here to focus on the evidence itself.

Chair Garrick: And, Alan, if I may, because I don't see hands yet, but I know Renee and Tricia are helping.

When I look at the revised KDOQI guidelines, there is a very specific conditional recommendation that suggests that most incident HD patients starting dialysis with a CVC should convert to either an AV fistula or an AV graft, if possible, to reduce the risk of infection, factoring in infection-related hospitalizations and adverse consequences.

There was a range of that quality of evidence but it ranged from very low to moderate. So, I actually felt like this measure had been revised to align more with evidence and clinical practice sidelines that suggest an incident patients where we clearly -- and I'm going to talk about performance gap -- but clearly have an opportunity to include vascular access type.

So, I probably felt more strongly than you did that there actually was more evidence for this measure than what was reviewed last time by focusing on incident patients and recognizing where we are today in the U.S. with vascular access.

And I see your hand, and I see Jeff's hand. So, Alan, I wonder if you'd like to respond to me and then we'll have Jeff on that.

Member Kliger: No, no, sure.

I mean, I'd just say I went through and then reviewed all of the evidence that the developers cited. If there's other evidence, of course I'd be happy to review that.

But my comments were based on the evidence that the developers presented to us. And, as I said, I found that it was little changed from what we've seen before when you look at incident, those studies that were looking at incident patients and were looking at bloodstream infections or infection rates.

Chair Garrick: Yeah. And, Jeff, I'll just briefly respond.

I am citing a clinical practice guideline that they included in their submission. So, they did provide that in their submission as part of their justification. So, I feel like it's important for us to acknowledge that clinical practice guide's been submitted.

Jeff, you're next.

Member Silberzweig: I just wanted to comment on the idea of communica -- enhancing communication prior to patients starting dialysis. The problem with this is that it's a facility-level measure. So that it is aimed at dialysis facilities who don't have access to patients until they start. So, they're not able to provide the education to patients pre-dialysis. They don't even know who those patients are for the most part.

So, I think that this measure may be aimed at the wrong place. And if it were aimed at nephrologists, then it would have a really good chance at enhancing that communication.

You know, in terms of the evidence, I think, as Alan said and as Lorien suggested, you know, the data is strong that getting catheters out is the best way to go. And a fistula-specific measure may or may not enhance that. And that's my concern with it.

Chair Garrick: Thank you, Jeff.

Andy and then Renee. Andy Chin.

Ms. Farrell: I'm sorry, Lorien, can I just interject with you? We've had someone join the call, Karilynne Lenning.

So, we just need to ask, Karilynne, do you have any disclosures of interest that you'd like to disclose, as you just joined?

Member Lenning: I do not. And apologies for joining late. I was having difficulties getting in.

Ms. Farrell: No worries. Thank you for joining us.

Member Lenning: Thank you.

Ms. Farrell: Back to you, Lorien.

Chair Dalrymple: Thanks, Paula.

And thank you for joining, Karilynne.

Andy Chin and then Renee Garrick. So, Andy, you're next.

Member Chin: Yeah. So, I think this kind of goes along with the previous comments.

You know, I see this push towards fistulas as running potentially counter to this idea of "catheter last." But then we have to remember the primary failure rate for fistulas is still 25 to 30 percent in this country compared with the primary failure rate for AV grafts of about 10, perhaps 15 percent.

In other words, grafts are much better initial accesses, whereas fistulas may take, you know, 3 months or so, and still at that point 25 to 30 percent will not be usable for dialysis. Which runs counter to the idea of "catheter last."

So, I think that we have to be careful what measures and what things we put on dialysis

providers. If they stick with this fistula first process we end up with more catheters for longer periods of time.

Chair Dalrymple: Thank you, Andy.

Renee.

Chair Garrick: So, thanks, Andy.

My comment is fairly similar to that, which is that that's an important unintended consequence. And I think that the most recent KDOQI with regard to the choice of fistula versus graft, and with particular attention to infection, actually said that they couldn't make a definitive recommendation as to whether fistula or graft was superior, especially with regard to infection.

And I think that the point that Andrew just made is really important because that is an unintended consequence of people ending up with long-term catheters while waiting for fistula to mature, rather than getting a graft which, in the most recent KDOQI, is believed to be of equal value.

Chair Dalrymple: Thank you, Renee.

And I am looking for hands. If I do not see your hand, please feel free to speak up.

I would -- we will be moving to vote on evidence soon. If there are any questions specifically for the developers that we need to ask them prior to voting on evidence, this is the opportunity. And so, if more information is needed from the developers before voting on evidence, please let us know now.

I do not see any hands or chats. Can I verify that with you, Paula, and other NQF staff?

Ms. Farrell: Yes. I agree.

Chair Dalrymple: And, Renee, I do not believe we have questions for the developers as it relates to

evidence. Is that correct?

Chair Garrick: No, I didn't find any. I didn't hear any. If there are, please let us know.

Chair Dalrymple: And, Alan, did you have any questions for the developers before we move to vote on evidence?

Member Kliger: No.

Chair Dalrymple: Okay. We will move to vote on evidence.

This is importance to measure report. Our first vote will be on the evidence. And, as noted, this is an intermediate clinical outcome and should be voted on as such.

Ms. Kyle-Lion: Okay. Just give me one second to pull up the poll.

All right. Voting is now open for Measure 3659 on evidence. The options are A for high; B for moderate; C for low; and D for insufficient.

I believe with Karilynne joining we are looking for 18 votes.

I did just send an email out to the Standing Committee with instructions and the Poll Everywhere link. If you're still having trouble, please send me a private message via the Webex platform and I can count your vote that way.

(Voting.)

Member Wick: This is Gail Wick. It says the site cannot be reached in your email.

Ms. Kyle-Lion: Okay, Gail, give me one second.

I'm going to, I'll private message you the link again via the Webex platform.

Or, if you want to just send me your vote privately,

you can, whichever you prefer.

We are at 15 votes. We need one more for quorum.

If you're having trouble accessing the Webex platform, again please feel free to private message me your vote on the Webex platform.

Chair Garrick: If it says "response recorded" does that mean it actually got submitted? Because normally it tells me.

Ms. Kyle-Lion: Yes.

Chair Garrick: Okay. Thank you.

Ms. Kyle-Lion: Whoops. Sorry.

We're still at 15 votes.

Member Wager: Hi. This is Bobbi. Can you hear me?

Ms. Kyle-Lion: Yes, Bobbi, we can hear you.

Member Wager: My vote is not going through.

Ms. Kyle-Lion: Okay. If you want to, can you private message me your chat?

Member Wager: Okay.

Ms. Kyle-Lion: Or can you private message me your vote via the Webex platform?

Member Wager: I will do that. Thank you so much.

Ms. Kyle-Lion: Sure.

Okay, we are at 16 votes now with the private messages that I have received. I will go ahead and close the poll.

There were 0 votes for high; 7 votes for moderate; 9 votes for low; and 0 votes for insufficient. Therefore -- Sorry, give us one second.

Therefore, consensus is not reached on evidence for

this measure.

Okay. I'll pass it back to Paula.

Ms. Farrell: Okay. Thank you, everyone. We will move on to our next discussion which is on performance gap.

And I'll turn it back over to Lorien.

Chair Dalrymple: Okay, thank you. And I will hand it right back to you, Alan.

So, the next area for discussion is on performance gap.

Member Kliger: Thanks.

So, in terms of performance gap I guess opportunity for improvement is the way that I would look at that. The current evidence shows a dramatic increase in AV fistulas in the first year of dialysis, going from 20 percent up to greater than 60 percent.

And the developers cite this as an opportunity for improvement.

A different view is that for patients just starting dialysis this shows a robust change in increasing the use of AV fistulas and reducing catheters.

In the previous rejection the measure was thought to be topped out at 64 percent, which is similar to where we are at the end of the first incident year.

So, the major question there is does improvement mean sooner conversion to AV fistulas? The evidence overall shows more infections and complications with a central venous catheter. In subpopulations of incident patients like those awaiting live donor transplant, or who have life-limiting disease, other than those excluded in the denominator, we don't have any evidence for that.

So, there surely is at the beginning of the year a large opportunity to increase fistula. It's, I guess, to me not clear that that's an appropriate way to look at it since patients coming on dialysis often are not stabilized as yet, and other subpopulations have reasons not to get a permanent access immediately, but rather to allow patients and their families to consider it, think about it, get several months into it, and then make a decision about what to do.

The metric that was used is the number of patient-months that they don't have a fistula. So, the developers, I think, clearly thought about this and shows, therefore, to count the number of patient-months using a fistula rather than whether one had ever been created by the end of the time, by the end of the year.

I just think that one has to consider whether that truly is a performance gap that needs to be shortened, or whether it does leave appropriate time and space for patients and their families to make a decision themselves about the best, the best course.

The second in terms of performance gap is that AV grafts are not considered at all in this metric. So that, of those people who choose to get AV grafts, just looking at fistulas alone ignores them and so doesn't, it doesn't appear in the numerator of the measure at all.

So, performance gap, it depends on how you look at it. Part of the performance gap also was disparities. And, yes, the data that the developers showed does show that there are some differences. The mean standardized fistula rate is higher for males than females, Whites than Blacks. There were, there were other differences. So there were disparities that may be worth looking at.

And then, finally, is there a gap in care that warrants a national performance measure? And, again, I think that's what we need to discuss.

My own take on that is there is a gap for eliminating central venous catheters. And we already have a measure that does that. But I'm not sure that a gap in performing with a fistula within that first year is an important gap for us to consider.

Chair Dalrymple: Thank you, Alan.

Raj, do you have any additional comments before we open to the committee?

Member Davda: Yeah, thank you.

I would agree. I think there are two sort of considerations here is, first, the AV graft was not included, which I think is a big problem here.

And then, and then second is, really, I, you know, a performance measure like this I think will deter from what we're really trying to do which is, which is work on the gap of reducing catheters. That continues to be year over year a continued problem.

We've actually not seen a substantial reduction in that gap and/or improvement in that gap. So, I think our focus there is important.

So, in terms of performance gap, I think there are issues that need discussion within the group.

So, thanks, Alan, for doing that.

Chair Dalrymple: Thank you both.

And, Alan, I may have missed it, but did you review the variation in performance that was submitted as part of this measure, the median and either the lower and upper quartile or some of that distribution between facilities?

Member Kliger: Thanks, Lorien, for reminding me that I didn't.

And, yes, there is evidence that there are facility-to-facility differences, meaningful differences in this

performance.

Chair Dalrymple: Thank you, Alan.

I will now open it up to committee discussion. Please raise your hand. And if for any reason we don't see your hand, please feel free to speak up.

And, John, I see your hand. Please go ahead. Thank you.

Member Wagner: Excellent discussion. I just had a question for the group.

Although one can discern differences between facilities, as expected or worse than expected, the percentage given is rather low, it's less than 5 percent. So, how do we interpret the importance to measure when the number of facilities that are underperforming by the way that it's been defined is so low?

Chair Dalrymple: So, John, I'll respond. And then Paula, of course, will correct me if my guidance is incorrect.

At least when I'm assessing performance gap I look at the information submitted by the developers and focus in particular on what the median SFR was and what the lower and upper quartile were. Because I think many of us on this committee appreciate although when it comes to public reporting there is, as expected, better than expected or worse than expected. In reality, many of these measures also end up in programs like the QIP where it is optional performance.

So, when focusing on variation, I do look at that measure-submitted information to see, well, you know, if all the facilities are at 50 percent, there's not a lot of variation, there's not a lot of difference.

I also heavily look at disparity. Because we are also asked not just is there an overall performance gap, or overall variation, but are there important

disparities that warrant a quality measure, which in and of itself can be important for a quality measurement endorsement.

So, I hope that helps, John. I think others like Alan may add their perspective as well.

And, Paula, obviously if the NQF has any staff guidance on how we think about this. I know this seems to be a stumbling point for the SMP, too, John. So, I don't think you're alone in struggling through this one. You're supposed to look at as expected, because, you know, almost everyone ends up there.

Member Kliger: May I?

Chair Dalrymple: Alan, please go ahead, yes.

Member Kliger: Thanks.

I completely agree, Lorien, with what you're saying.

You know, if you look at the publicly-reported measures that have been reported for nearly two decades now, the as-expected for virtually any of the approved measures are 90 percent or more of the population. It's always a marginal population that's reported as either lower than expected or, you know, better or worse than expected.

So, I find it hard to make that a meaningful criterion for thinking about approving a measure.

I think disparities are important. But looking at the fact that it's a very small number of people who are performing lower than expected is virtually the same as you find in any of the publicly reported measures.

Chair Dalrymple: And, John, I see your hand again. Please go ahead. Thank you.

Member Wagner: So, I agree that disparities are important. But since those aren't the things that get

back to the facility, how do they then use this information?

And I know we're going to be talking, we're going to be talking about usability. But I get it, importance to measure means that what the way that we're thinking about the data that we generate as a result of this measure is supported by the evidence.

And if we're saying that knowing that at the end of all of this all you find out is the facility is worse than expected, does that help driving the improvements and elimination of disparities?

Chair Dalrymple: And, John, at least for me it was a little bit difficult to hear part of your audio. I was able to hear part of it.

But do you have a specific question for the committee where you'd like other's thoughts as it relates to how we consider disparities? Or was it more you just wanted to offer your thoughts on how these were used in practice?

Member Wagner: Yeah, I mean, again, we're going to be talking about usability. But I think that if the way the measure is constructed only tells the facilities that they're worse than expected, then I'm not sure how the disparities are sufficiently addressed by the facilities and their efforts to diminish the gap that we're observing.

I mean, the data that we're seeing as part of the evidence are important, but nonetheless that's not, unfortunately, information that's fed back to the facility. So that they are then stuck with is this importance to measure if it doesn't provide improvement in reduction in disparity?

Chair Dalrymple: Yeah, what I would suggest here, John, is this may be a good question for the developer. What we're trying to do for today's meeting is let everyone discuss on a certain area. So, for now it will be performance gap.

And then if we hear questions that sound like they may best be answered by the developer, we let them respond to those questions before we go to voting.

And, again, I don't want to make presumptions on behalf of the developers. But, for example, I do believe this is the kind of measure that's put in somewhere like the QIP where you would actually see your performance.

But I think it's best that we let the developers respond to the issues you're raising, if you're comfortable with that, after the committee's finished discussion.

Is that okay, John?

Member Wagner: Yeah. That sounds like a plan.

Chair Dalrymple: Okay. Then we will turn to the developer to further help us understand what performance would potentially be viewed by facilities to demonstrate that they would have an ability to act upon those gaps.

Are there other questions from the committee? Or other comments or contributions to the discussion, especially, you know, if anyone feels like there's points we have not discussed but that are important to discuss for importance gap, please raise your hand or comment.

(No response.)

Chair Dalrymple: I do not see any hands. So, if Renee and the NQF staff and others do not see hands, I would suggest we give the developer an opportunity to respond to some of the issues that John raised. And then we would proceed with our vote.

So, Dr. Segal, could I ask you to respond to some of the discussion around as-expected and also John's commentary about ability to see gaps and respond

to those?

Dr. Segal: Sure. Thanks for the opportunity to add some additional information. I'll try and summarize things into three points.

Let me start with the performance gap.

There are, clearly, a couple different ways at looking at performance gap. And what we really focused on was the distribution in performance between facilities. So, even though on average there's great improvement in fistula creation over the course of the first year of dialysis, there is enormous differences in how that plays out at the facility level, which is the unit of measurement here.

So, of the over 7,000 dialysis facilities, we find that a quarter of them are at 30 percent or less at fistula rates. And yet, a quarter of them are 50 percent or higher. So, when we focus on performance gap as developers, we see an enormous distribution in what's achieved amongst the various facilities over the course of the first year.

So, I don't think it's enough to say that on average there's great progress in getting fistula in because, clearly, some facilities are doing significantly different than others.

So, when we focus on performance gap, that's the, that area that we see an enormous gap in performance at the facility level between one versus the other.

The other point I'll make that was brought up about not accounting for grafts, is to please remember that when, when the fistula and catheter measure were initially created, they were designed to be used in conjunction with each other. Since, obviously, there's only essentially three choices for vascular access, if you understand what the fistula rate and you understand what the catheter rate is, we have a pretty good idea of what the graft rate is

for any given facility.

So, we feel that the fistula measure complements the existing catheter measure in terms of understanding the total breakdown of vascular access at the facility level.

And then, lastly, to comment on the issues of performance gap and the comments that were raised about facility performance in terms of as better or worse than expected, remember that we want to be confident when we highlight a facility as an outlier, okay, whether they're better than expected or worse than expected, we don't want to make mistakes and identify facilities as being worse than expected if we think there's a possibility that that's not true.

So, we set the bar at a very high level to be considered an outlier. And we use statistical techniques to do that. And we have some ability to change that bar.

So, if people wanted to be less certain about the outliers but wanted more people to be included, we could do that. We don't think that's the best approach, but technically it's possible.

So, when we highlight relatively small percentages of facilities as better or worse than expected, we do that intentionally because we want to be conservative. And we actually view that as a strength of the measure, not as a weakness because we want to make sure that facilities, if they're doing okay and they're similar to their peer facilities, that they get that message and not being called out.

So, you know, that's different, how we evaluate facilities and their performance is different than the performance gap. You know, that, typically that's part of the discussion that comes up a bit later on. But since it was brought up earlier, I think it's reasonable to address it now.

But that has to do with our flagging techniques and where we set the bar.

Chair Dalrymple: Thank you, Dr. Segal.

Renee, I see your hand.

Chair Garrick: Thanks. Thanks, Dr. Segal for that comment.

I just have a quick question regarding the performance gap. You mentioned that a fair number of units have a low rate of fistulas compared to the better-performing units. And I have two questions.

The first is do those units have grafts or are you looking at truly the catheter rate?

And the second is, have you looked at that grouping in terms of the size of the facility and its geographic location?

Dr. Segal: So, we don't specifically look at grafts. And so, we haven't at a facility level paired them.

So, I think what you're asking is of those facilities that have relatively low performance on fistula, is the difference made up between catheters, which obviously would be bad, or grafts, which may be fine based on the patient population.

Chair Garrick: Right. That's correct.

Dr. Segal: Yeah, so that's a great question. We have not done those analyses at the facility level. So, I don't have a solid answer for that question.

And then in terms of so the second question was about geography and what else?

Chair Garrick: The size of the unit, the size of the facility.

Dr. Segal: The size of the facility.

So, we, we do, we do know that, particularly for

smaller facilities -- well, so the short answer to the question is, no, we don't have that broken out by facility size.

We do know that for, obviously, for smaller facilities, you know, very small changes in numbers can have an impact on their results. And so we're mindful of that.

And so just because the flagging issue has already been brought up, what I will tie back is that for small facilities, they have to have even more extreme results even further out from their peers to be flagged as either better or worse than expected. And that accounts for the, you know, the recognition that there may be some more differences and with small changes in numbers.

So, we do account for small facility size when we, when we go through our flagging part of things. But, but I can't tell you whether that relates to the low fistula rate particularly.

Chair Garrick: Thank you.

Chair Dalrymple: I do want to give the committee an opportunity to add any additional discussion before we vote on performance gap. I am looking for hands and do not see any.

Okay. So, yep, I think I gave it enough time, Renee. And if you also do not see any hands we will --

Chair Garrick: No, I don't see any.

Chair Dalrymple: Perfect. Thank you.

We will move to vote on performance gap.

Ms. Kyle-Lion: Okay. Give me one second to get the screen pulled up.

I did want to correct our last vote on evidence. We did receive another additional vote via chat.

There were 7 votes -- 0 votes for high; 7 votes for moderate; 10 votes for low; and 0 votes for insufficient.

The measure is still consensus not reached on evidence. But I did want to clarify the votes for the record.

And I will go ahead and share my screen and open up the vote for performance gap.

Okay. Voting is now open for Measure 3659 on performance gap. The options are A for high; B for moderate; C for low; or D for insufficient.

And we are looking for 16 votes here. Again, if you are having trouble voting by the Poll Everywhere, please send me a message via chat and/or you can send an email to the inbox and we will include it that way.

(Voting.)

Ms. Kyle-Lion: Just waiting on two more votes.

One more vote.

Okay. If you're having trouble voting, please, like I said, send me a message via Webex or you can email the inbox.

We're still waiting on one more vote.

(Pause.)

Ms. Kyle-Lion: Still need one more vote.

Chair Dalrymple: And, Gabby, at least my poll has closed. I don't know if others have as well.

Ms. Kyle-Lion: Sorry about that. Okay. I think that we now have our 16 votes, so I'll go ahead and close the poll. Okay. Voting is now closed for Measure 3659 on performance gap. There were zero votes for high, six votes for moderate, ten votes for low, and zero votes for insufficient. Therefore, the

measure does not pass on performance gap.

I'll pass it back to you.

Chair Dalrymple: So, Gabby, I just wanted to confirm the measure did not pass on performance gap, so, Paula -- was a consensus not reached or did not pass?

Ms. Farrell: It did not pass.

Ms. Kyle-Lion: Yes, no pass.

Chair Dalrymple: Okay. So, Paula --

Ms. Farrell: We will stop -- correct, yes. We will stop our discussion and voting on this measure, and we will move to the next measure.

Chair Dalrymple: Okay. Thank you, Paula.

3696 Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) (University of Michigan Kidney and Epidemiology Cost Center/Centers for Medicare & Medicaid Services)

Ms. Farrell: So the next measure we're going to be reviewing is Measure #3696, Standardized Modality Switch Ratio for Incident Dialysis, and Lorien, again, is going to be facilitating our Committee discussion on this measure, so I'll turn it back over to you, Lorien.

Chair Dalrymple: And, Paula, I'll just ask a quick clarification. Last time, I kind of gave the brief description of the measure shown on this slide. Would you prefer that we just briefly introduce them and let the developers do all of that introduction? What's the preference here?

Ms. Farrell: Sure. That works so that we can give the developer a little more time to provide some introduction to their measure. That would be great.

Chair Dalrymple: Okay, great. Thank you.

So our next measure is Measure #3696, which is the Standardized Modality Switch Ratio for Incident Dialysis Patients. The measure steward and developer is CMS UMKECC. This is a new measure.

The only comments I will make because they are not on this slide are that the measure type is an outcome. The level of analysis is the facility. The studying of care is outpatient services, and the data sources are claims and registry data.

And with that, I will ask Dr. Dahlerus to present the measure on behalf of the developers.

Ms. Dahlerus: Great. Thank you, thank you, Dr. Dalrymple. And I want to thank the Committee for your review and comments on the standardized modality switch ratio.

I just want to set a little context for the discussion that you're all going to have today for this measure. Home dialysis in the United States is significantly underutilized compared to many industrialized countries in the world. There are many challenges facing the U.S. dialysis community in increasing the use of home dialysis. For example, approximately 90 percent of patients starting dialysis in the U.S. begin on in-center hemodialysis. This suggests a gap in facilitating greater uptake of home dialysis, a modality that can afford patients greater independence in their daily lives. For example, being able to hold a full-time or part-time job.

Well over half of patients that switch to a home modality do so early on by the end of their first year on dialysis, which implies that their initial home dialysis education was ineffective or that their modality decision was not final. There is also a significant facility-level variation across U.S. dialysis facilities in the switch rate to home. It is highly likely that in the incident population a switch is an indicator of effective education and facilitation by the dialysis facility care team.

Several studies have also reported that about 30 percent of dialysis patients felt their modality selection was really not their choice, that the doctor made it for them, or that they did not get the information they needed to help them make a decision. What is more striking is that, among in-center hemodialysis patients, this number is much higher.

The research has consistently shown that effective education by providers, including dialysis providers, results in more patients selecting home dialysis. There are even a few studies of nephrologists and nurses that show if they had to go on dialysis, they would overwhelmingly choose a home dialysis modality.

The standardized modality switch ratio is based on this body of evidence, specifically a switch to a home modality is considered to be the result of effective education and facilitation by the dialysis facility care team. Moreover, some of the patient comments from the modality talked about the challenges faced when they were new to dialysis, stating it is difficult for a patient to process everything that is happening as a result of their disease, for example, uremic symptoms, and also the effects of dialysis itself. Several stated that education is not a one-off but rather requires an iterative sustained approach with new patients to give them time to process the information they're taking in and to allow them an opportunity to make an informed choice, particularly for patients that had little or no prior nephrology care or previous RD education.

We fully agree that effective education is iterative and that it allows one to build their knowledge over time and deepen their understanding. Because many patients start on in-center hemodialysis, effective and timely education is also essential to avoid prolonged use of a dialysis catheter or time spent for unnecessary procedures for a permanent

access versus focusing on developing and implementing the right plan at the right time built around a patient's for home dialysis. So this could include planning to get a PD catheter placed and also training for home dialysis.

Disparities in home dialysis uptake are also well documented, such as in the recent study published by Wilk earlier this year showing much lower use of home dialysis among younger black and Hispanic adults. And research published last year by Thorsness, et al. reporting that facilities with higher percentage of patients with social risk factors of race, ethnicity, or Medicaid coverage, were less likely to offer peritoneal dialysis to those patients and have lower rates of initiation of home dialysis. We agree these disparities exist, but there is no clear consensus, as we know, whether they are a result of unmeasured confounding or reduced access to home dialysis modalities.

There are several options, as we know, for addressing disparities. One is to adjust for social risk factors, but that risks increasing or reifying disparities. When we presented the standardized modality switch measure results to the TEP that had adjustments for race, ethnicity, sex, and age, the TEP strongly reacted and they recommended against adjusting for social risk factors because this would further conceal and possibly exacerbate existing disparities in home dialysis uptake.

Another option to handle these difference and to illuminate disparities is to stratify results, and this is an approach NQF has recently highlighted in its own guidance. Stratified reporting can be an alternative to risk adjustment and may illuminate those potential disparities. However, this approach is much less feasible for dialysis facility measures because of the average clinic-patient census at many clinics, which, as we know, is much smaller than hospitals. And then that would present the need to suppress reporting for a potentially large

strata of facilities due to small cell size.

So the option we selected, again, based on TEP input and the issues that we highlighted, was not to adjust for social risk factors, absent definitive evidence demonstrating these disparities are due to unmeasured confounding versus access to home modalities.

Finally, as many of you know, there is increasing emphasis on pre-ESRD education to support greater access to home dialysis before patients have to begin dialysis. One example is the current kidney models being tested by CMMI that place emphasis on increasing access to and rates of home dialysis, and this is in the ETC and KCC models. The standardized modality switch ratio measure is meant to complement what is already being done in those models and is not intended to be a substitute.

And, again, we thank the Committee for their time and look forward to addressing any questions you have during the discussion.

Chair Dalrymple: Thank you, Dr. Dahlerus. So our lead discussant for this measure is Annabelle, and we do have contributing discussants, John and Rick. But, Annabelle, I'd like you to go ahead and start with the review of evidence.

Member Chua: Thank you. And thank you, Dr. Dahlerus. She actually went through a lot of what -- so this may be a little bit repetitive. But in terms of this measure, again, it was looking at the standardized modality switch ratio, and the rationale was that switches to home dialysis in the first year are thought to reflect robust education, effective presentation of modality educational materials, and facilitation of patient discussion by the dialysis unit. And the basic premise is that patients consented to changing their treatment modality to a home modality after initially starting on in-center home dialysis as a result of ongoing education efforts and effective decision support by

the dialysis facility and that these processes can lead to helping patients select a home dialysis modality that may best fit with their personal goals and values and that it improves alignment between the patient goals of cares and values of their dialysis modality, leading to an increase in switches from in-center to home dialysis.

As Dr. Dahlerus mentioned, there was a technical expert panel that was convened in spring of 2021 to obtain feedback on the draft measure of modality switches from in-center to home dialysis. It was co-chaired by a clinical nephrologist and a patient, and it was made up of six ESRD patients that had experience with in-center and/or home dialysis and eight clinicians, nephrologists and nephrology nurses that treat ESRD dialysis patients, and there was a strong consensus that the rates of home dialysis are very low in the U.S. and that there needs to be a greater emphasis on ongoing and effective education by nephrologists and the facility care team to allow patients to make an informed choice for home dialysis. Again, as mentioned, it was recognized that well over a majority of the switches to home dialysis occur within the first year of beginning chronic dialysis.

They determined that physicians play a critical role in providing that dialysis education and that, if physicians are knowledgeable about home dialysis, they're more likely to provide a balanced education to the patients while considering co-morbidities that may impact the modality selection.

Some patient members described bias towards in-center hemodialysis and that education that they experienced where the risks of home dialysis were highlighted and overemphasized, whereas those of in-center dialysis were downplayed. And they comment that modality education and decision-making ideally should occur in the pre-dialysis stages. However, since many patients start abruptly on dialysis, they may have had little or no pre-

dialysis education, and so that process of education really should continue in the dialysis center after initiating chronic dialysis. And the modality education should be an iterative process since patients new to dialysis may not be ready to absorb that information or make a modality decision immediately after starting in-center hemodialysis.

And so, overall, through that TEP panel, there was a broad consensus that home dialysis is underutilized and that a quality measure to monitor facility performance would be useful to patients, providers, and other stakeholders. And so the TEP supported the basic concept of the standardized modality switch ratio measure.

Other evidence that was provided was that home dialysis rates remain low in the United States compared with many other countries, hovering around 12 percent. But there's not really any formal randomized control trials of modality uptake, and so this is really based on observational studies in the U.S., as well as outside of the U.S., such as Canada, several European countries, Australia, and New Zealand.

They evaluated the studies looking at epidemiology and characteristics of home dialysis uptake and found that educational interventions and processes to support shared decision-making and studies comparing or assessing outcomes between a home dialysis modality and in-center modality or the association of home modalities with comorbidities and other health outcomes. They did look at clinic, operational, economic, and patient factors that have been identified to barriers to uptake of home dialysis modalities. There was a study in 2019, and clinical factors include a lack of physician competency in prescribing home dialysis modalities. Operational issues include lack of clinical and staff training. The economic obstacles include lack of sufficient housing or storage space for dialysis supplies. And patient barriers include lack of

adequate education.

Studies also have identified demographic characteristics of black race, male sex, older age, and comorbidities as predictors of low uptake of home dialysis. And while small dialysis facility size and low physician and nurse experience with home dialysis are facility-level barriers.

And there are the studies that Dr. Dahlerus mentioned about looking at the role and impact of education on home modality uptake and shows that about 30 percent of chronic dialysis patients reported that their modality selection was not their choice and did not feel that they made an informed choice and that the percentage is higher among in-center hemodialysis patients. There's also studies that found there's a mismatch between stated preference for dialysis modality being home modality and the actual modality in which the patients start, and the preferred modality was a home therapy but, in many cases, those patients started on in-center hemodialysis. There were three studies that were cited in regards to that.

And so the developers said that these studies suggest that existing educational efforts fall short of supporting decision-making by the patient, and specifically decision-making efficacy and satisfaction of modality selection has been reported as greater among PD versus in-center hemodialysis patients.

So, again, the data is observational. There are a lack of randomized control trials comparing dialysis modalities and outcomes. But, again, they also cite that some studies have shown a survival advantage associated with PD as the initial modality, but evidence is mixed about longer-term outcomes and survival benefit for PD versus in-center hemo. And then the comment that, in one review, some differences were observed in physical and mental quality of life domains between patients on PD versus in-center hemo.

And so the evidence that they present, they state that it indicates that persistently low rates of home dialysis are associated with both patient and facility-level factors. Education and shared decision-making interventions suggests an opportunity to improve the uptake of home dialysis. Moreover, home modalities offer patients potential flexibility and intervention, and so they feel that, collectively, these studies support the construct that the standardized modality switch ratio as an indicator of successful education by the facility to facilitate a decision to switch to a home modality through ongoing educational efforts after a patient starts on in-center hemodialysis.

The pre-committee comments that were made was that it's really not a direct measure of the education that switching could align with patient choice but that they feel that, because most of the data was observational, that we're really using the modality switch as a marker of education and it's not really clear if that truly is substantiated because there's no control trials or measurements. And this measure, while there's a lot of comment about the importance of education, there's not really any guidance or any recommendations on how that education is provided. And, again, it's just used as an indirect marker of that education process.

Chair Dalrymple: Thank you, Annabelle. Was there anything else you wanted to cover on evidence, or should we ask John and Rick if they have additional commentary?

Member Chua: We can go ahead and ask John and Rick.

Chair Dalrymple: Thank you. John and Rick, do you have any additional comments or thoughts as it relates to evidence for this measure?

Member Wagner: Yes, thanks for the nice review. I was struck by the fact that the evidence that is presented dates back multiple years in the large

extent, and we've obviously gone through an evolution or a thinking about how we promote home therapies and there has now been new programs that incentivize movement towards of expanding home therapies.

So I just wonder whether using data that is five years old tells us what the current situation is today. We know that the networks are working on trying to improve home therapies. ETC model, KCC, all of these are trying to get to enhancing the adoption of home therapies, and yet the data that we presented have to do with things from several years ago.

I think also, in thinking about the use of education and how that might influence the choice of modality, education can result in several things. It can result in a patient deciding not to choose home therapy; and it also could result in a patient choosing the home therapy but, because of our current staffing issues and resource issues, it may be very difficult for patients to access a program and to expand to the extent that this measure seems to anticipate the use of home therapies, given what our current infrastructure for that is.

So I'm concerned that this idea that the switch represents a quality of care measure supported by evidence that is multiple years old is not as compelling as one would like.

Chair Dalrymple: And, Rick, I'm not sure if you're on the call currently. Paula or others, are you able to comment on whether Rick is currently on the line with us?

Ms. Farrell: It looks like he is on the line. I don't know if he -- Rick, are you having trouble unmuting yourself? Yes, if you are able, if you want to put, he can put a comment in the chat. If he has anything additional to add, he can do that.

Chair Dalrymple: Okay, thank you. Rick, please feel

free to put something in the chat, and we can share that with the Committee if you have any additional comments to what Annabelle and John shared.

With that, I will go ahead and open it to the Committee for discussion. I see Mahesh's hand is raised. Mahesh, please go ahead.

Chair Garrick: Mahesh, I think you're muted.

Member Krishnan: It's the double mute thing. I've got to work on that.

I totally agree that we need to get more patients on home modalities. But if I look at it from the level of evidence, I think the point that was made prior on the observational data may serve the data is true. There are many, many, many, many, many programs that are currently underway to try to educate patients. And as John mentioned, there are many, many incentives to try to get patients onto home modalities.

You know, Hippocrates said an outcome is one of three things, right? For patient, for provider, and the disease. Unless all three are perfectly aligned, the outcome is not guaranteed. I think the assumption here from the data is that it's the provider, but, obviously, there are issues at the patient level. And we have up to 50 percent of attrition for home modalities, right? So it's really hard to grow a modality when you have up to 50 percent attrition.

Whereas I'm a huge proponent of home and trying to figure out how we do that, even have, like, reality programs and all sorts of things, from a data perspective, I do think that the confounding nature of the data, especially the older data, is a big issue in terms of the evidence.

Chair Dalrymple: And, Bobbi, I see your hand is raised.

Member Wager: Yes. Can you hear me?

Chair Dalrymple: Yes, we can. Thank you.

Member Wager: I guess I'm just taken back. I love what Dr. Narva said to the first measure, and I'm going to hit this one, that, you know, you all talk about education, but why are we waiting and why is this a facility-level measure when all of this education should have started before the patient gets on dialysis? And you all know, you take care of us patients, that when we start dialysis we're, like, in the six-month fog. You all are telling us all this stuff. I don't hear a darn thing you're saying. This education should be beforehand, and I do not think this should be at facility-level. It should be a clinician.

I know that Dr. Chua mentioned that maybe the physicians are not familiar with PD. Well, I totally disagree with that. I think the nephrologists, if you're going to offer us care, you should be aware of all the options of what's out there.

I know, as a practicing nurse, that the reason why our doctors, and, please, no disrespect, this is me talking from a patient point of view, that some of the doctors didn't want to send the patients for PD because they did not see patients in PD, plus they would lose their patients. Just a fact. But I can't emphasize enough with Dr. Narvo saying I don't understand why this is a facility level. It should be a clinician, so we can find out individually, not just at facility, what's going on. My thoughts.

Chair Dalrymple: And the next hands I see raised are Alan's, followed by Renee. So, Alan, you're next.

Member Kliger: Well, first, Bobbi, I love you for your passion and focus. So thanks for that comment.

I want to go back to the evidence just quickly. The evidence, the measure is for switches. The evidence largely have to do with use of home dialysis

programs. Although it was noted, of course, that many patients during the course of that first year have an opportunity to go to home, and that's what a switch is.

But I'm not sure that the evidence helps with the definition of this measure. As an example, in New Haven, we've had a very robust home peritoneal dialysis program for many years, and our switch rate is extremely low. The reason I think our switch rate is low is because PD candidates go on PD before they're ever on hemodialysis.

So I'm not at all sure what a switch measure is measuring. I think the measure really should be use of home dialysis, whether that be hemo or PD, rather than switch.

Chair Dalrymple: And I am -- Renee, before you go, Annabelle, because you're a lead discussant, I'm actually going to ask you to go next because you may be trying to respond to some of the comments. And then, Renee, we'll come back to you.

So, Annabelle, please. You may have taken your hand down, Annabelle. Did you have any --

Member Chua: Yes, sorry, sorry. I took it down thinking I unmuted, too. I just wanted to say I agree with Bobbi's comment that a lot of the education should be occurring before they get to the facility. I think the comment of the developers was that sometimes that education may not happen if things start abruptly. But I wholeheartedly agree that education should be happening at the beginning before you even get to needing dialysis.

The other thing is, in terms of, I forgot to mention and I thought it was nice to follow this up with Dr. Kliger because of his comment about, you know, some centers already have a high home dialysis modality rate, the ASN actually did make a comment that they felt that this measure was not patient-centered and that it actually incentivizes

initiation with hemodialysis prior to a modality change and that it may actually lead for people to encourage the hemo and then, that way, they can achieve this modality switch ratio.

The Kidney Care Partners also did not support it because they really felt like that modality switch, again, alluding to what Dr. Kliger was saying in terms of what is this really measuring, they said, you know, again, there was so much focus on this education piece and they were saying the modality switch is not a valid proxy for education.

So I just wanted to throw that out there because I did forget to mention those two public comments. It also aligned with what we were talking about.

Chair Dalrymple: Thank you, Annabelle. Renee, you're next.

Chair Garrick: Thanks. Bobbi, I loved your comments, too, like Alan did, and I think you're absolutely right. I think Alan's point about units that have a high rate of home before patients ever come into an inpatient center could be inadvertently struggling with this measure. And I think the evidence for this measure is difficult on that issue, but I also have a lot of trouble finding the evidence for this measure as to how it will work because I don't understand how we're using undocumented evidence of education as the proxy for someone who switches from in-center to a home modality because there's nothing in the measure that actually measures ongoing educational activities or what those activities might be.

So I'm having trouble with the construct of the evidence around this measure that it's a measure for education prompting a switch to a home modality from in-center, and I didn't hear that actually from the developer during their comments.

Chair Dalrymple: So, Renee, I would suggest we do give the developers an opportunity to respond to

your question once that committee has finished discussion, so we will flag that for Dr. Dahlerus and her colleagues to come back about the construct of evidence and how it relates to this.

Chair Garrick: Okay. Thank you.

Chair Dalrymple: Are there other Committee members that have comments? John, I see your hand.

Member Wagner: Yes. Correct me if I'm wrong, but I think where this measure is going is the outcome is really not that a patient goes on home therapy. Rather, it's patient centeredness is the outcome. I think the purpose of this measure was to make sure that patients get the education that they need so that they can make an informed choice about the therapy that they want, and so that's why there's the focus on education. And the fact that a patient is on a particular modality is not necessarily telling us one way or another whether they're on the therapy that they want, although, presumably, because you have to invest more into home therapy, that that would be evidence that you actually got some education. But you might have equally gotten education and decided not to choose home therapy.

So I think that's why it's very confusing, and I agree it's not really directly measuring the education that's offered to patients, even though we understand that it may be problematic in some areas. And if the idea is to make sure that someone chooses the therapy that they want, the specifications for the measure, for example, you need to be on the therapy for 30 days, why 30 days as opposed to 35 days or 28 days? If you've chosen a home therapy because of your education, you've obviously then been educated. If that's what we're trying to support, mainly a patient centeredness and choice, then we've done it.

So, again, I agree with the comments about this is

not really speaking to that part of the process.

Chair Dalrymple: So I think I will add a comment as co-chair. This is an outcome measure. It has been designated as such, and we will review it as such. And for Annabelle and John who are the leading contributing discussants, that means that we will follow the evidence algorithm that relates to outcomes. And the question, once you answer that, yes, something is an outcome, it is does the steering committee agree that the relationship between the measured health outcome and at least one healthcare action, structure, process, intervention, or service is demonstrated by empirical data.

So, Annabelle and John, maybe we can ask you to specifically address that aspect of evidence review as it relates to the algorithm.

Member Chua: I, personally, based on what you just said, don't think that the evidence supports what the outcome is because it really, again, it was looking, it wasn't a direct, I guess, or it's not a direct measure of what we're trying to achieve.

I don't know if John wants to -- I'm not being very eloquent about it. Maybe John can add in.

Member Wagner: Yes. I mean, I think the data about 30 percent or more of patients have said that they didn't feel that they had the confidence and the modality chosen or enough knowledge about it. I think that's the one study. I think those are data from surveys done in 2015. And, you know, I think there is ongoing research into structure and education and how that impacts modality that might be more specifically answering the question of what's the relationship between education and modality choice.

So, yes, I think it's a very, it's very difficult to understand is a modality switch the outcome that is supported by the evidence or not.

Chair Dalrymple: And I see Andy Chin's hand. Andy.

Member Chin: Yes, thank you. I also want to point out that approximately 30 or 35 percent of incident patients on dialysis have not had pre-dialysis nephrology care, so, clearly, no modalities have been discussed with them prior to starting dialysis. So I think that's important as we look at these surveys of patients that say did they receive any education. Now, clearly, by a year into it, hopefully they've received additional education on modality.

And then the question of healthcare outcomes is, I think, has to go back to is our outcome basically patient-centered care? Because we know that there's no outcome or no clear outcome superiority of the home dialysis modality versus in-center hemodialysis, so I think that kind of puts in the question of what is the outcome we're trying to get. Is it just patients making the right choice for themselves? If that is the case, you know, then education certainly is an important part of it. But simply driving more patients towards home may not be the correct outcome.

Chair Dalrymple: And, Andy Narva, I see your hand.

Member Narva: Sure. You know, there's lots of evidence that education impacts patient satisfaction, quality of life, ability to self manage. As far as I know, virtually all based on data from patients where the education occurred before dialysis was initiated. I'm not really clear that there's much evidence about after people start dialysis, and I am concerned that there would be a permissive effect of this performance measure or this quality measure in that it would give people, providers permission almost not to do what is clearly the best intervention, which is to have an effective education program prior to initiation of dialysis.

And even patients that see nephrologists, as Alan's colleagues at Yale showed, a significant proportion of people who are seen by nephrologists start

dialysis without adequate understanding of their treatment modalities. So, you know, I think it's great to get more people on home dialysis, but this is kind of instructing people that the horse will run out of the barn after the door has already been opened. It seems an odd kind of measure and may direct energy in a way that may not be productive.

Chair Dalrymple: And Michael.

Member Somers: Thanks. I have a question, Lorien and Renee and maybe NQF staff. It has to do with the actual algorithm. You know, the longer I stare at the algorithm, sometimes the more confused I get.

So where it's supposed to look at the relationship between a measured health outcome, which this measure, I guess, would be the switch from in-center hemo to home dialysis, and we're supposed to say whether at least one healthcare action may influence that. So does that mean, you know, we've been discussing education influences that choice. Is it as simple as that that we have to draw the connection there? Because it just says empiric data.

Chair Dalrymple: I think it's a great question, Michael. And we did have a little bit of free discussion with the NQF staff, so I do want to make it clear to the Committee today we are not deciding whether modality switch is a health outcome. It has been submitted as such and agreed to as such by NQF staff, so we have to evaluate it as an outcome.

So to your point, when you look at the clinical evidence, and we rarely go down this path, right, Michael? We almost always end up in intermediate clinical outcome and process that we're all obsessed with boxes, like eight through ten, and where are we. This is not that. We almost never go down this route, and it is a fairly straightforward question in my mind. And that's why I, you know, was just kind of trying to highlight that because it's really asking is there something, if this is how I interpret it, you know, Paula and Poonam may still be on the line,

others will correct us if I'm wrong, it's are there things that we do that affect the likelihood that someone switches modality? Are there care processes and structures, and I personally think the answer is yes. It would be hard for me to answer no to that question, to say that we, as care providers, don't influence whether someone does or does not switch modality.

But, you know, the reason we have committee discussion is these aren't always as straightforward as they say, so if there are people who feel like there are not structures, processes, interventions, or services that affect someone changing their modality, then this would be a good opportunity to share that perspective.

And, John, I'm going to let you go first consensus you're a contributing discussant and we always yield to our lead and contributing discussants, and then that will be followed by Renee.

Member Wagner: Yes, thank you. So, I mean, yes, in a sense, it's a very simple question. If you switch modalities, does education affect that? Sure. But I think the developer is also saying that the reason that's important is not because we have shown that one modality is necessarily better than another. They argue that it shows that is there a collection that a patient has made an informed choice, and that is a patient-centered action that we have facilitated.

So should we ignore that, that underpinning logic, or is that part of this? Otherwise, why are we discussing whether it's important to go home?

Chair Dalrymple: And, John, I think you're adding more commentary than direct question to the Committee, but do you want Committee members to weigh in on what you just posed?

Member Wagner: Yes. I think, again, if it's as simple does education influence choice of modality, then

that's one way of thinking about it. If it has to do with what the developers stated is the reason why this measure has been proposed, then it's a little bit more complicated.

Chair Dalrymple: And so I think, John, Paula, I think I will ask the NQF staff to help respond to that specific question.

Ms. Bal: This is Poonam from NQF. Sorry for being off video. My internet is not being so friendly. But in terms of John's question, I think, Lorien, you did a great job of explaining, you know, what we're looking at for evidence for the outcome. The concerns that you're having, we can bring up as we look at specifications, is this measure specified in a way that you can understand it and it can be moved forward, and so on.

So while for evidence we're really just focusing on for this outcome is there at least one process or structure that we can put in place to get the outcome that we're looking for, I mean, and then we'll get to gab about is there actually a need for this. We can still have some of these discussions, it just would be somewhat different. For this purpose, we would base it off the algorithm and just that there is something that can be done to achieve this outcome and basing it off of what the developer has provided as empirical data. There actually has been a connection seen by an action that can be done to achieve this outcome.

Chair Dalrymple: Thank you, Poonam. Renee, Annabelle has her hand up now, as well. So if it's okay with you, I'd like to yield to Annabelle as our lead discussant, and then we will definitely go to Renee.

Annabelle.

Member Chua: Yes. I guess I'm just really, I guess it's just very confusing and I'm appreciative of all this additional discussion and the question that

Michael brought up. But I guess my fundamental issue is, yes, I agree that education can affect outcome of the modality switch, but it's not really measuring -- again, it's a proxy for education in the sense that you may educate and they may decide to stay on hemodialysis, right, and not do peritoneal dialysis, and so how is that captured in that sense just based on a modality switch from in-center to home?

And so that's where I struggle with how does this really truly relate to that outcome of switching in-center to home just based on that education. So, yes, absolutely we can influence what the patient chooses, but how is it that that modality switch is the outcome from that when it could be that they choose to say in-center?

Chair Dalrymple: And so, Annabelle, I'll attempt to answer that. And since Renee goes next, I will also ask her to attempt to answer that.

The way I think through this really is as simple as I answered Michael, which is what we're asked to evaluate is modality switch. And then to answer the question do we think there are care processes, structures, or interventions that change the likelihood someone may go on peritoneal dialysis if they're currently on in-center dialysis. And that's really the only question I ask myself: do I think there are care processes, interventions that influence that outcome?

And I don't know if that helps because I know we can all quickly go down different rabbit holes and me included, but that is simply the question I ask myself. And I think, for me personally, we have a broad committee because we all have different perspectives, but sometimes we, as co-chairs or Committee members, we'll share our personal views just to give a lens to our thought process and to have others challenge it so we can be really thoughtful about this. But when I ask myself that

simple question, my thought is, yes, there are things we do that change the likelihood of someone being on a different modality, specifically switching from in-center to home.

But, you know, again, I think it's always really helpful to me if other Committee members are like, Lorien, no way. Like, that's why we have committee discussions, so please feel free to disagree, all of you. I'm going to let Renee go next because she may have a very different perspective than I have.

Chair Garrick: Thanks. So I think we're all struggling with the same thing. The measure itself is asking a specific question: does education prompt someone to go home? Does it prompt someone to switch from their current choice of in-center to a home modality? And the answer, and the reason why I'm struggling with the evidence, is not necessarily. It may be that we educate enormously, we do all kinds of iterative training, and the patient chooses to stay on an in-center modality. And that educational activity will be penalized, you won't get credit, and they'll say that facility failed, even though what that facility really did was have enormously positive patient-centered activity and shared decision-making said I'm staying on in-center dialysis, it's right for me, it's right for my family.

So my problem with the evidence is there's only an upside. For this measure to work, it has to be that we educated and the patient went home. It could equally be we educated and the patient decided, you know what, not for me, I'm really better on an in-center modality, for whatever reason. That's why I have trouble with the evidence around this. And I view, with what someone said earlier, by having an outcome measure, we're putting ourselves in this little box, and I think, Lorien, you said it really well: we're trying to put a lense on to ask a very simple question, but the answer could go in either direction but the measure doesn't. The measure says the

only way this measure works is I educated and I switched modalities, but it could be I educated and I stayed in-center. That's why I don't think that this is, I don't think the evidence supports this unilateral outcome.

Chair Dalrymple: Well, let me ask if the following construct helps, Renee. Imagine two facilities -- and I do see other hands and, as soon as I respond to Renee, it will be Gail Wick, followed by Precious.

Imagine you have two facilities, one provides education, one provides no education. Do you think there would be differential performance on this measure in that setting, meaning the goal is not to get 100 percent but do you think there is an intervention we deliver that will cause differential performance between facilities?

Chair Garrick: So that's the question I kept trying to ask myself, and here's where I went down the rabbit hole. I can't tell from this measure because I could have provided no education and, basically, pardon the expression, kind of coerced the patient to go home. I could have said you're going home and then no education. So how can tell from the way this measure is organized whether I educated or not?

So my concern has been, on your two-facility model, it might be that one facility sent a whole bunch of people home without the right support, without good education, because there's nothing in the measure that shows what I did to get them home.

Chair Dalrymple: Thanks, Renee. And Gail, then Precious, and then Alan. So please go ahead, Gail Wick.

Member Wick: I agree with Renee. I don't see the evidence there. And I also see ways of getting to the outcome that doesn't necessarily benefit patients. Instead of preemptively putting them on

home dialysis, you put them in-center and then you put them on home dialysis. But I just don't see the evidence there that one thing leads to the other.

Chair Dalrymple: And, Precious, you're next.

Member McCowan: Yes, thank you. I have to agree solely with Renee. And just to share a little bit of my experience, I did in-center hemodialysis for eight years before I received my second kidney transplant, and I was highly educated about the different modalities. I was a perfect candidate for home dialysis. My nephrologist talked to me about it. I was educated. I received all the resources. However, I still decided to stay in-center because it was best for me.

You also have to consider, like, social determinants as to why a patient may or may not choose home dialysis. And me just being a layperson, I didn't see the evidence. I really didn't understand how patients would benefit from this measure.

Chair Dalrymple: Thank you, Precious. Alan, you're next.

Member Kliger: Lorien, I just want to address your limited question about the algorithm itself. If, for argument's sake, we feel that the question we're asked, this is an outcome, is there something that we can do to affect that outcome, and if the answer is yes but the price of doing that is to subvert patient choice or to encourage people not to put anyone on home dialysis initially, put everybody in-center so that switch rate goes up, if there are multiple unintended consequences that make this measure unacceptable, yet in the limited question of the evidence that it goes, you know, there is something you can do to increase switch rate, at what point does that overwhelming, is an opinion that there's overwhelming unintended consequence come in to our discussion?

Chair Dalrymple: Yes. This is always a challenge, at

least for me personally, Alan, because unintended consequence, as you know, doesn't come up until we get to usability, which is not, to my recollection, a must-pass criteria.

So what often, I think, happens, from my observations and our Committee over the many, many years we've all served together, is that often some of those topics start to come up in validity depending on the measure specification. But I think, you know, we want to have a robust discussion of evidence. I find it challenging to consider modality switch an outcome, but we are trying to follow the construct we have been given by the NQF because that is our responsibility and, as such, we work very hard to stick with NQF guidance to make sure that we are consistent with what the NQF is trying to do versus us as individuals.

But unintended consequences is something this committee debates vigorously, I would say, and frequently, which is part of our job. But it is often later in the discussion. But I think it is fair game for you to raise that issue. And as I mentioned, Alan, I can't remember the last time we ended up in this part of the algorithm, if ever, quite honestly.

Member Kliger: Right. And I guess part of the reason I'm asking it that way is that my take is that it has to be considered earlier because a measure like this, in a very limited way, may look like there's evidence connecting A to B, but that that's not relevant to the acceptability of the measure overall.

Chair Dalrymple: If I can, Alan, can I have Poonam or Paula respond to your question? Because this is where we do often defer to NQF staff because, much like you, you know, we are not the NQF experts. So, Poonam or Paula, I would appreciate you responding directly to Alan's concern about unintended consequences as we consider evidence.

Ms. Bal: Of course. So as Lorien stated, unintended consequences is under usability. However, when

you're weighting evidence, you can think about is the evidence showing that -- you know, everything comes with pros and cons, right? There's always some benefits with risks that you're doing something. So while you don't want to be focusing heavily on unintended consequences, you do want to make sure that the action that can be taken is going to have the result you're looking for and that it would be benefitting the patient.

So while, yes, the action of evidence can occur, if the evidence is showing that education does not have a major influence or does not have the influence that you would expect it to have, that is a discussion that you could have in this area and then talk through, you know, could education not produce the result you're looking for or could there be a lot of risk associated with that.

So while we don't want to focus heavily on unintended consequences, there can be some discussions about that the risks are outweighing those benefits.

Does that help?

Member Kliger: Yes, thank you. It tells me that, yes, it's relevant to have this discussion now in terms of the evidence of this particular measure.

Chair Dalrymple: And so I'm going to look to see if there's any additional hands or comments because we then are going to give the developer an opportunity to respond some of the questions that have been raised throughout this discussion prior to proceeding for a vote on evidence.

So I do not see any other hands at this time. Renee, can you confirm that? Do you agree?

Chair Garrick: Yes, I don't see any other hands. Thanks.

Chair Dalrymple: Okay, great. So, Dr. Dahlerus, I'm

going to ask you to respond to some of the questions that have been raised around the construct and the evidence.

Ms. Dahlerus: Okay, yes. Thank you. And thank you for all the questions. So I'm going to try to respond to all of the issues that came up. A lot of them did center on education. So I just want to remind everyone that the intent of the measure is to increase the uptake of home dialysis. This is, for example, based on the executive order of 2019 and all the subsequent activity in this healthcare space, including the current and recently rolled-out ETC and KCC models.

A switch to home dialysis is based on not only education but facilitation of a dialysis facility care team to enable the patient to get training and do dialysis at home. It's not likely that a patient will choose home without going home. Also, not measuring education, the measure, again, is not measuring education or the quality of education. That would be an entirely different measure. It would be a patient-reported outcome measure that would have to go through additional psychometric testing.

The incentive, there was some concern mentioned about the incentive to put everyone on in-center dialysis. Well, given the current state of things, 90 percent of patients already begin on in-center hemodialysis, and so we're already at a very high threshold of patients who begin and many of them stay on in-center hemodialysis. And we're not saying that's not due to their choice, but, again, it points to the performance gap.

We want to also emphasize that this is an outcome. Dialysis modality is a health status, as it impacts other clinical outcomes: for example, anemia, cardiovascular-related outcomes, and infection. And it also impacts patient-reported outcomes through their experience of care.

A switch of modality from in-center hemodialysis to PD or home hemodialysis is a change in health states, from health state 1 in this in-center hemodialysis, to health state PD, which would require placement of a PD catheter or home hemodialysis. And this is akin to being in the hospital, which is a different health state than being at home.

Switches to home dialysis in the first year, again, reflect facility processes of the delivery of robust education and effective presentation of modality educational material and dialysis facility care team facilitation of the shared decision-making process on modality selection. Facilities are also responsible for these processes, and education and facilitation of modality choice are a part of the CMS conditions for coverage where facilities are evaluated on whether they're providing modality education.

So the measure is not intended to and it was not designed to achieve 100 percent of home dialysis. As everyone said, that would not be patient centered. It really is to address a current gap in uptake of home dialysis, again, as demonstrated by other initiatives that are ongoing.

There was some concern about the data being old, and I just want to remind everyone, and this will come later, but the data that we used for testing goes through 2019. And several of the studies that we highlight are also more recent studies.

There was a question about why not just report a rate of home dialysis uptake. Well, doing that would exclude about 40 percent of dialysis facilities because they do not even offer home dialysis, and that would result in less useful or informative information to patients that are deciding which facility they want to go, particularly if they're interested in home dialysis. It would also not meet the needs of other consumers who use dialysis facility Care Compare.

In terms of pre-ESRD care and education, we do agree that there is also an apparent gap in pre-ESRD education, but that's not the scope of this measure. This is a dialysis facility measure. And as stated a few seconds ago, the dialysis facility care team does have a responsibility, a regulatory responsibility, to provide education and facilitate modality decisions and uptake.

There was also, I think there were a few comments about unintended consequences and potential coercion. Well, informed consent is required for treatment, especially in base of procedures. So informed consent indicates acceptance of a switch to a home modality. Now, we do recognize there is a risk of unintended consequences of coercion for any quality metric because those measures have incentives to achieve a certain outcome. But based on the ethical principles underlying informed consent, we do hope that coercion is rare. We do hope that providers are not forcing their patients or strongly nudging their patients to go on a modality that they may not want to go on, be that in-center or home dialysis. Any actual coercion we assume would be the exception. But, overall, we think this is a pretty small risk.

In contrast, not focusing efforts on incident patients that are just starting their dialysis journey is a much larger risk of failing to allow them to develop a longer-term plan of care that is commiserate with their life goals and does not put them at risk for extended chronic catheter use and infection risk or having unnecessary procedures for a permanent access.

I also want to just recall some of the discussions at a different TEP a few years back on patient-reported outcomes that recommended a measure of life goals. Many of the same arguments were made at that TEP that there aren't actual effective decisions in education being done to allow patients to select a modality that is commiserate with their life goals,

and it allows them, for example, to hold a part-time or a full-time job or to travel more, to do hobbies, or whatever their goals are. And modality choice came up repeatedly throughout that discussion that many patients who are on the TEP, or certainly several of them, felt that they didn't get the education they needed to make a decision about their modality that would allow them to do the things in their non-dialysis life that are important to them. One member, in fact, said that they had been on in-center hemodialysis, they had never really gotten information on home dialysis, even after starting dialysis, and they literally had to struggle to get their facility to put them on PD, but that was as a result of their own intentions.

So we think that, you know, there is a connection between providing effective education and letting the patient digest that information and figure out what is best for them. Again, the goal is not to achieve 100 percent of home dialysis uptake, but it's definitely to move the needle from the current 90 percent of patients that start in in-center and the still pretty large percentage of patients that remain on in-center hemodialysis throughout their time.

And I will stop there.

Chair Dalrymple: Thank you, Dr. Dahlerus. Before we move to vote, I believe Stuart Greenstein has joined us; is that correct, Stu? Are you on the line? Paula, is --

Ms. Farrell: We saw that, Stuart, we saw that you just joined. We just need to verify and ask about any disclosures of interest that you may have since you just joined the call. You may be on mute.

(No audible response.)

Ms. Farrell: Okay. We can follow up with him on the chat to find out about disclosures of interests.

Chair Dalrymple: Okay. Thank you, Paula. Renee, I

see your hand is up.

Chair Garrick: Thanks. So I wanted to thank the developer for your comments. I think we all appreciated them.

I think the issue on the evidence is not that we don't think that education is critical. Education is vital, and it's one of the foundational bedrocks. I think the concern about the evidence is that the measure doesn't contain any ability for me to really show that a patient received the right or any or effective education, and many facilities can, as I said a second ago, can educate and educate and a patient can make a very good, very wise decision to not go on a home modality. And the way the measure is constructed doesn't allow me to judge did a facility do that and do good education, or did a facility not do good education but encourage the patient to go home without all the right facility support and without all the right things at home. And that's why I have trouble with the concept that the evidence around what we're looking at is an outcome measure can be utilized this way because I can't determine did the facility do the right thing at a patient-centered level or not.

So that's why I'm struggling with the evidence around this as an outcome measure.

Chair Dalrymple: Renee, it does at least sound to me that some of the concerns you're raising relate more to validity. Is part of this a validity versus an evidence discussion? I just want to make sure we align the Committee appropriately on validity versus evidence.

Chair Garrick: So, thanks, Lorien. I think that's been my problem with this as an outcome measure because it's a yes/no question, and so the way you phrase it is, I think, helpful from the standpoint of saying does education affect an outcome, and the answer is yes, but it could affect the outcome in either direction. That's why I think that, at the very

outcome level, I have a problem with the evidence around this measure.

Chair Dalrymple: And I see a number of hands have gone up, including one from the developer. What I would like to suggest is we continue with the committee discussions, and we will give one more opportunity to go back to the developer before we vote on evidence.

So Jeff and then Annabelle, please.

Member Silberzweig: I think my question may also come back to validity in that, you know, it feels like this measure is aimed to measure education, but it's not actually doing that. As Renee pointed out, patients may be very well educated and may choose to stay in-center, so that modality switch doesn't measure education necessarily and it may simply be, again, that that's because this is an intermediate outcome measure and not truly measuring the outcome, which may relate more to validity.

Chair Dalrymple: I don't know if this helps, Jeff, but I think I would say this is not intended to be a measure of education. So I think we really do have to evaluate it as an outcome measure of modality switch. And I clearly appreciate that many of us are struggling with the different constructs, but I think it's important to be clear. If NQF staff disagree with me, I'd like them to say so, but we are not assessing this as a measure of education. It is a measure of modality switch and whether there is evidence to support that that was presented by the developers.

So, Annabelle, you're next.

Member Chua: I just wanted to bring back up again all the evidence that was presented was observational data. There was no randomized control trials. Again, it's all observational. And so just, you know, I know that we know anecdotally

and through our own practice that education makes a difference, but when we're looking at the evidence, again, it's observational data. I just wanted to throw that back out there.

Chair Dalrymple: And I'm just looking for any other hands from Committee members before I give an opportunity for the developer to respond one last time because we will then move to a vote for evidence unless there's other critical discussion points just because I do want to be mindful of time for this measure review.

So let me just offer the Committee members one more opportunity for discussion. I do not see additional hands. I'm just going to scroll in case it's taking people a minute to raise their hands.

Okay. I do not see additional hands, so, Joe, did you have additional comments?

Ms. Farrell: Lorien, I'm sorry, if I could just interject real quick. We saw that Cher Thomas just joined the call. Cher, so if we could ask if you have any disclosures of interest to advise the Committee of.

Member Thomas: Hi, thank you. No, I do not. I have nothing to disclose, and I apologize for being late this morning.

Ms. Farrell: No worries. Thank you for joining us. And then I just wanted to check again, Stuart Greenstein, we saw that you joined the call, so we just need to check to see if you have any disclosures of interest to advise the Committee of, if you could please come off mute and let us know.

(No audible response.)

Ms. Farrell: Okay. We can move on. Thank you.

Chair Dalrymple: Okay, thank you. Dr. Messana.

Mr. Messana: So just a couple of comments, and I think some of these were covered in Dr. Dahlerus's

responses, but I noticed Dr. Kliger's face scrunched up with one of them, and I wanted to provide a clarification.

So the alternative or the options here I think one has to consider, we did, when we tried to initially look at a rate-based measure for the percentage of patients who are on home dialysis in the facility, and it turns out that was a nonstarter for us. There's another measure that has floated around considering that. That was a nonstarter for us because we were instructed to develop a quality measure at the dialysis facility level. And when we looked at the data, the current state, the most recent data that was available to us, 2019, 40 percent of U.S. dialysis facilities are in-center only, and that's when Alan's face scrunched up because the implication is, if you just look at that number on the surface, that those facilities are not educating their patients and are not offering home dialysis modalities to their patients. And I know from personal clinical experience and we know from looking at the facility-level data that most of those facilities are, in fact, fulfilling their responsibilities under the regulations, but they're in a cooperative business arrangement or they have a referral relationship with a home-based program or a program that does have home-based services so that those patients who want to switch are typically allowed to switch by transferring to a program under a pre-arranged situation to allow them to be trained and to go home.

So we thought, we believed strongly then and we believe strongly now that a facility-level metric, an outcome that evaluates the fraction of your patients who are on health state home dialysis is a nonstarter if you're talking about a transparent dialysis facility metric. And so we chose to look at the initial switch rate, and the only comment I'll make is, because I'm droning on here, is that the context here is very important. Claudia mentioned this, and I want to reiterate it. Almost all incident

patients are starting on in-center hemodialysis. That may be a good thing, may be a bad thing, it may be a neutral thing, there may be equipoise about that. There are a lot of reasons for it. But what it does is it places the dialysis provider, both facility and physician, in the driver's seat in offering home modalities to most of those patients, even those who were first approached about it in the pre-ESRD arena. Maybe they were uremic, maybe they were confused. They apparently weren't ready enough to make a decision to pull the trigger. They ended up on in-center hemodialysis. That fact, that context, puts the dialysis facility in the driver's seat in offering education under the regulations and in facilitating the patient choice.

We assumed in development of this measure that most dialysis providers, both facilities and nephrologists, are ethical and are trying to fulfill the patient's wishes. If that is not the case, then there's an unintended, there's an unintended consequence of any measure like this. We hope to God that's not the case. We believe that this is a valid assessment of the choice that a patient makes because they have to sign an informed consent to have a PD catheter placed, to have to voluntarily come for training, right? You can't send a patient home unless they show up for training. All of these things suggest that the decision to go home, the modality switch, is motivated by the patient. If we're wrong about that, then the whole NQF can disband and all quality measure development is nil if all of this is just being driven by coercion.

I'll stop there. Thank you.

Chair Dalrymple: Thank you, Dr. Messana. I am looking to see if there are any other Committee members raising their hands. I do want to make one point of clarification just because it was raised. Observational studies are accepted forms of evidence. And so it's important to me that we make that clear prior to proceeding to voting since that

issue was raised.

Renee, I see your hand.

Chair Garrick: So thanks, Joe, for the comment. I wanted to try to clarify something. I don't think anyone on the Committee is saying it's coercion. And I agree with you, no one gets up, no one has done this for 40 years as a dedicated physician or serves on these committees to do anything except try to have really great patient-centered care. So I agree with you. Nobody in this room certainly or no one I've ever worked with.

I think what we're struggling with is the concept of the effectiveness of the education, and I understand that, as an outcome measure, I think Lorien did a nice job framing that up. But as an outcome measure, what we're saying is that education is being used as a proxy saying if I change my modality it's because the driver for that was good education. And I think that's what we're all struggling with. I think all of us want patients to go home if it's the right thing for them and we want to have great support around it and great, good education. I think what we're struggling with is that concept that patient went home because I gave them good education.

So I just wanted to clarify that because I don't want someone to ever think that anyone I work with would coerce a patient in any way, shape, or form because I strongly disagree with that.

Mr. Messana: Lorien, may I provide a quick response to that comment?

Chair Dalrymple: Yes, Dr. Messana, go ahead and provide a response, but I think after that we will need to move to voting.

Mr. Messana: Okay. So thank you, Renee. I think we both agree about the motives of most in the healthcare community. You're absolutely correct

education -- by the way, the focus on education here is because that was what a lot of the literature showed. We believe that facilitation by the dialysis facility is just as important, although most of the comments from the Committee have been about education. However, there is coercion by omission of information.

And the point that Lorien made earlier I think is central. It's very unlikely and very rare that someone ends up going home if they're not aware of the modality and not aware of the issues surrounding it. It's much more likely that they will go home if they are aware of the options, and we believe that's the central issue here in the context where almost everybody is starting on in-center hemodialysis. So the risk of mis-specifying the switch to home modality as being credited to the facility is very low, and the likelihood that that modality switch is the result of actions taken by the facility is very high.

Thank you.

Chair Dalrymple: And we will proceed to the vote now.

Ms. Kyle-Lion: Okay. Just give me one second to pull up my screen.

Okay. Voting is now open for Measure #3696 on evidence. The options are A for pass or B for do not pass. There are 18 Committee members on the call, but we need 16 votes to reach quorum. And, again, if you're having any trouble with the Poll Everywhere platform, you can send a message to me privately via the Webex platform.

We are at 16 votes, but I'm going to just give it a couple of seconds just in case any additional votes come in.

Ms. Farrell: I just wanted to jump in one more time and ask if Stuart Greenfield, or Greenstein, I'm

sorry, he recently joined, if he could please come off mute and let us know if he has any disclosures of interest before he votes.

Ms. Kyle-Lion: Okay. I'm seeing 17 votes. I'm going to go ahead and just close the poll. Voting is now closed for Measure #3696 on evidence. Just give us one moment to calculate the results.

Okay. Apologies for that delay. There were seven votes for pass and ten votes for do not pass. Therefore, the measure is consensus not reached on evidence.

I'll pass it back to you, Paula and Lorien.

Chair Dalrymple: Okay. Giving consensus was not reached on evidence, we will move to performance gap. So, Annabelle, can you please start the discussion on performance gap?

Member Chua: Yes. Give me one second. I got to find my right page.

Ms. Farrell: I did want to jump in real quick, Lorien, and ask we do have a lunch break scheduled for noon, if we wanted to go ahead and break at this point and then come back at 12:30 Eastern Time.

Chair Dalrymple: Yes, I am happy to do whatever works best for the Committee. In my ideal world, we would get through performance gap quickly, but that may not be feasible, Paula. And I imagine many of you have scheduled your day around these pre-scheduled breaks to take short meetings and other things, so can I just get a quick sense from the Committee, would you all like to break here and you can just kind of shout out, or would you like to work through performance gap before we break? Anyone with strong preferences, speak now. And you can just come off mute.

Member Krishnan: I would vote to break.

Participant: I would vote to work through.

Chair Dalrymple: We're going to need a tiebreaker now.

Chair Garrick: Work through lunch.

Chair Dalrymple: I couldn't hear that last one.

Chair Garrick: Work through it. Vote on the performance gap.

Chair Dalrymple: Okay. So far I think we do have a number of voices voting for work through on performance gap, and it would give us a nice break to get to scientific acceptability, if it were to pass performance gap. So if the Committee is generally agreeable, I would ask Annabelle that we go ahead and try and vote on performance gap before breaking so we can get through this section of importance to measure.

Member Chua: Okay. So in regards to the performance gap, the developers' comment again that the home dialysis rates remain low in the United States compared to many other countries. As of 2019, it was 10.8 percent PD and 1.8 percent home hemo, and the measure allows one to compare the effectiveness of facility modality education and/or effective utilization of home dialysis modalities and allows for a facility outcome metric for comparison across the U.S., including longitudinal monitoring, patient-centered in that it's intended to facilitate ongoing education. That may result in patients choosing a home modality, particularly if no pre-dialysis modality education was provided. Quality of care will be improved by better alignment between patients' goals and values and their dialysis modality and then focus on incident patient since most modality changes occur during the first year.

And then they presented performance scores. They said after applying all exclusion criteria, they evaluated all Medicare-certified dialysis facilities with a number of 6,039; treating incident patients,

316,382, that had at least one expected patient modality switch in the reporting years; and the distribution was that there was a mean value of 1.07 and the standard deviation was 1. And remember the switch ratio of one is what's expected, greater than one is better than expected, and less than one was worse than expected.

In terms of disparities data, they comment that race and ethnicity have been shown to be predictors of switches to home modality. And using data from 2016 to 2019, black, Native American, and Asian Pacific Islander patients had a lower hazard of modality switch, which was 0.59 for black, 0.67 for Native American, 0.86 for Asian Pacific Islanders, compared to white patients. Hispanic patients had lower hazard of modality switch of 0.67 compared to non-Hispanic patients, and the hazards of modality switches were not statistically significant between male and female patients.

There was also a finding that patients employed six months prior to onset of ESRD had a higher hazard of modality switch of two than patients that were unemployed. And then Medicare dual-eligible patients had a lower hazard of modality switch of 0.57 than other patients.

I don't know if John or Rick have anything to add.

Member Wagner: No, I think that covers it. Thank you.

Member Kaskel: I agree, as well. Sorry.

Chair Dalrymple: Okay. Thank you to Annabelle, John, and Rick; so I will now open it to committee discussion. And, Alan, I see your hand.

Member Kliger: It's just a question. In looking at the data we just were quoted, were the subjects people who switched or people who were on each of the kinds of modality? The measure is switching, switching from hemodialysis to a home therapy. As

I quickly looked at those data, it was the gaps, the disparity in treatment type, not in switch, and this is the measure of switch. Could I just ask for that clarification?

Chair Dalrymple: So I think, Alan, what we're trying to do based on NQF guidance is have Committee members respond to, as they are able. If we're not able to get a satisfactory answer, then we will go the developers before we vote.

Annabelle, I took the data you presented to represent the O over E, so the observed switches compared to the expected switches based on characteristics.

Member Chua: And that's how I interpreted it, as well. Hazard of modality switch.

Chair Dalrymple: Alan, does the observed over expected help address the question, and we're talking about, for example, I believe, Annabelle, you'll correct me if I'm wrong, Q-1 was 0.37 and Q-3 was 1.52. So, again, looking at variation and observed difference in the ratios; is that correct?

Member Kliger: I'm just looking for clarification that that's dealing not with modality type but switching from in-center hemo to a home therapy.

Member Chua: Again, that was my understand, again, with less than one being worse than expected, greater than one being better expected.

Member Wagner: The data are hazard of a modality switch.

Member Kliger: Thank you.

Chair Dalrymple: And, Alan, just to ensure our interpretation is correct, at the end I'll give the developers an opportunity to respond so you can ask additional questions of them, as well, on this point and to make sure we're interpreting it correctly.

Do any other Committee members have comment or discussion before we move to the developers to clarify the variation data presented? I do not see any other hands, so, with that, Dr. Dahlerus, could you help address the question and our interpretation of the variation in the standardized modality switch ratio.

Ms. Dahlerus: Yes, yes. So, Dr. Kliger, so this refers to switching to a home modality. It's not a distribution of modality type. And the different deciles reflect a ratio value, so higher ratios mean that those are facilities that are performing that have switches at a much higher rate than the national rate, the national rate being around one. So it's not just a straight percentage distribution of modality type. It's actual switches that result in a durable switch to PD or home hemodialysis.

Member Kliger: Thanks.

Chair Dalrymple: I do not see any other hands. Oh, Renee, I see yours. My apology. Renee.

Chair Garrick: Thanks. So in my role as co-chair, I was asked to bring up any questions that someone might have raised to the developer, and so there was one question that came up in the conversation that I don't think has necessarily been directly addressed. I was just going to read it to you. It says gaps in both -- I'm sorry. Gaps in both provider performance and between racial and ethnic groups is presented. However, it's unclear how expected, in quotes, modality switches were determined. Request clarification from the developer.

So I thought I would raise that for completeness.

Ms. Dahlerus: I can address that. I just want a caveat that the model, the risk-adjusted model used that calculates the observed-expected is in the testing section under threats to validity.

But just very generally, the expected value is based

on the national rate of switches across facilities, adjusting for given the patient case mix at the facility.

Chair Garrick: Thank you.

Chair Dalrymple: Okay. Seeing no other hands, we will move to vote on performance gap.

Ms. Kyle-Lion: Okay. Give me one moment to start sharing my screen. Okay. Voting is now open for Measure #3696 on performance gap. Your options are A for high, B for moderate, C for low, or D for insufficient. And I believe we're looking for 17 votes here.

We're at 16. I'll just give it a couple more seconds in case we get that last vote. Okay. We are at 17 votes, so I will go ahead and close the poll. And give me one second to pull up the results.

Okay. Voting is now closed on Measure #3696 on performance gap. There was one vote for high, fourteen votes for moderate, two votes for low, and zero votes for insufficient. Therefore, the measure passes on performance gap.

I'll pass it back to you, Lorien and Paula.

Chair Dalrymple: Thank you, Gabby. So, Paula, I presume we'll take a 30-minute lunch break, is that correct, that we'll come back at 12:40 Eastern Time; or would you like us to shorten that lunch break?

Ms. Farrell: If we could come back at 12:30, that would be great so that we can stay on top of our agenda. That would be appreciated.

Chair Dalrymple: Okay. I tried. Everyone heard. But you're right, Paula, we must stay on task, so 20 minutes it is for lunch.

So we will reconvene at 12:30 Eastern Time where we will resume the discussion of scientific

acceptability. We will see you all in 20 minutes. Thank you so much.

(Whereupon, the above-entitled matter went off the record at 12:11 p.m. and then went back on the record at 12:30 p.m.)

Ms. Farrell: All right, it looks like we are at 12:30, so we will jump back into reviewing Measure 3696, and we will start with the reliability discussion, and I'll turn it back over to our co-chair Lorien.

Chair Dalrymple: Thanks Paula, and right now 3689 is up, I don't know if we should go ahead, and change that to 3696 just for clarity. So, next we'll move onto scientific acceptability. We will start with reliability, this measure was reviewed by the SMP. So, first I will hand it over to Annabelle to start the discussion of reliability.

Member Chua: Okay, it looks like in terms of specifications, there was a lot of information about the expected to observe, I didn't know -- it doesn't sound like we need to go to that, right, just talking about the reliability specifically? Is that correct?

Chair Dalrymple: I think we can start on the data specifications, it's a good place to start on the reliability, and then the reliability testing.

Member Chua: Okay, I just wanted to make sure I wasn't being too in depth. Okay, perfect. So, again for the specifications, basically again, this is number of observed modality switches centered to home dialysis, and home dialysis being either peritoneal, or home hemodialysis that occurs for adult incident ESRD dialysis patients treated at a particular facility.

To the number of modality switches that would be expected given the characteristics of that dialysis facility's patient, and the national norm for dialysis facilities. And this measure includes only the first durable switch that is defined as lasting 30

continuous days or longer.

And again, the standardized modality switch rate estimates the relative switch rate from in center to home dialysis for a facility as compared to the national switch rate, qualitatively the degree to which the facility's standardized modality switch rate varies from one is the degree to which it exceeds greater than one, or is below less than one, the national modality switch rate for patients with the same characteristics as those in the facility.

So, as we mentioned before, ratios greater than one indicate better than expected performance, and ratios less than one indicate worse than expected performance. And so when used for public reporting, the measure calculation will be restricted to facilities with at least one expected modality switch in the reporting year, and this restriction is required to ensure that patients cannot be identified due to the small size.

And so this affects patients with end stage kidney disease, the specific measure domain areas that apply to the measure are access to care, and person, and family centered care, and the populations that are targeted are adults age greater than 18, and the elderly population, age greater than, or equal to 65. And it is a facility level of analysis, and again, care settings are outpatient services.

And then again, the numerator is the observed number of switches from in center hemo to home dialysis modality among eligible patients at the facility during the time period. And they're getting that information on modality type, and modality switches from several sources including CROWNWeb, Medicare dialysis claims, and medical evidence form.

And again, the numerator includes only the first durable switch to a home dialysis modality lasting greater than, or equal to 30 continuous days. And

an eligible modality switch is considered as an in center hemodialysis patient that switches to home dialysis within 365 days of ESRD onset, and the home modality is maintained for greater than, or equal to 30 days.

Only the first durable modality switch is included if patients have multiple switches, and modality switches during the first 30 days of dialysis at a facility are not counted for that facility. And the denominator is the expected number of switches from in center hemodialysis to a home dialysis modality among eligible patients at the facility during the time period given the national average of modality switches, and patient case mix at the facility.

So, as far as the denominator, so it says as patients can receive dialysis treatment at more than one facility in a given year, we assign each patient stay to a facility, or no facility in some cases based on a set of conventions below, and they've tried to go through, and explain that.

So, general inclusion criteria for chronic dialysis patients where all eligible incident ESRD patients, dialysis patients not restricted to Medicare beneficiaries. To be included in the denominator, the patient must be ESRD as defined by a submitted CMS 2728 form. And then patients must be at least 18 years old as of the first day of ESRD.

And in order to exclude patients who only receive temporary dialysis therapy, we assign patients to a facility only after they have been on dialysis there for the past 30 days. And for patients, they identify the dialysis provider using a combination of CROWNWeb, Medicare paid dialysis claims, and the CMS2728 form. These sources are used to identify patients that are on chronic in center, or home dialysis for the entire reporting period.

Starting with the first day of the ESRD, patients are attributed to facilities according to the following

rules. If the initial modality is home dialysis, we exclude the home modality period from the denominator, and consider the first day following in center dialysis as the first day at risk.

A patient is attributed to a facility once the patient has been treated there for the past 30 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 30 days, and then is attributed to the destination facility from day 31. In particular a patient is attributed to their current facility on 31st day of ESRD if that facility has treated him, or her for the past 30 days.

And it just gives some examples. So, if a patient who is on in center hemo changes from facility A to B, and then switches to home dialysis within 30 days of arriving at facility B, facility A would get the credit for the switch. In this scenario, given the short time frame between changing facilities, and switching modalities, it is likely that facility A is responsible for the modality education.

After 30 days, the switch would be attributed to the receiving facility, facility B. And when a patient is not treated in a single facility, or a span of 30 days, so if there were two facility transfers within 30 days, we do not attribute that patient to any facility. We use the number of days at risk in each of these patient records to calculate the expected number of modality switches for that patient record.

And some, the total number of expected modality switches during all patient records at the facility as the expected number of modality switches for that facility. The exclusion criteria for the denominators are patient's time at risk under hospice care. Patient's time at risk when in a nursing home, and on home hemodialysis. Pediatric patients less than 18 years of age.

And patients with no CMS2728 form due to patients maybe having AKI. Patients who are attributed to

clinics with fewer than one expected modality switch are not excluded from the measure. All patients who meet the denominator inclusion criteria are included, and used to model a given facility expected switch rate to home dialysis. If the facility -- if the switch rate is less than one, then the facility is excluded from reporting outcomes.

They just talk about the -- I just lost my place, sorry guys. So, and then they go through the details needed to calculate the denominator exclusions, and again, the missing CMS2728, nursing home status information, for those who are in a nursing home on home hemodialysis is excluded. And then age, so less than 18 years as the first day of reporting month are exclude.

And then hospice status determined from a separate CMS file that contains final action claims submitted by hospice.

Chair Dalrymple: Thank you Annabelle, and I may have missed this, but did you mention the IUR for the reliability?

Member Chua: That's coming next, so yeah. So, that was conducted at the accountable entity level. Testing was conducted using an inter unit reliability with a bootstrap approach. This approach utilizes a resampling procedure to estimate the within facility variation that cannot be directly estimated by Inova. The developer calculated a profile inter unit reliability, and that approach assesses the measure's ability to consistently flag extreme providers.

The developer calculated an IUR value of 0.605, which indicates that over 60 percent of the variation in the measure can be attributed to the between facility differences, and less than 40 percent to within facility variation. And then the profile inter unit reliability was 0.606. And the developer notes that this IUR value is moderate.

Indicates that the measure can reliably detect differences in performance scores across facilities, and the PIUR demonstrates a similar ability to flag outliers. And so I know that there were -- the scientific method panel, it passed their preliminary review, and said it wasn't discussed. They didn't have any significant concerns regarding reliability.

And then there was the question to the committee about do you have any concerns that the measure cannot be consistently implemented? And so, in terms of the comments from the committee, most people had no concerns. I think there was clarification of the requirement for the 30 continuous days of home dialysis included training days, or if that was after training.

There was a question again about expected modality switches, but I think that was answered previously, and there was just somebody had commented I'm curious why the switch has to be durable if the point is that the patient received education, and agreed to the switch. Units that have less than 90 days to educate a patient might be at a disadvantage.

And I don't think there were any concerns about the reliability.

Chair Dalrymple: Great, thank you Annabelle. John, and Rick, do you have anything further to add to the reliability overview? John, you're muted, but I believe you're trying to --

Member Wagner: Yeah, double muted, the old double mute. Yes, so I had -- I think that covers the specifications, and the reliability, but I did have questions about the specifications.

Chair Dalrymple: And John, are those questions for the specifications, should we cover those now in reliability, if there were questions about the specifications, do you want to share those questions now?

Member Wagner: Yeah, if the developer can answer.

Chair Dalrymple: Okay. So, we have developer questions. Rick, did you have anything you wanted to add? Okay, and Rick may not be on now. Because this was voted on by the SMP, we do have the option to accept their rating without further discussion, but if the committee chooses that. But Paula, I feel like if there's questions for the developer, before we ask that question of the committee, we actually should go to the developer.

Because I know John has a specification question, I also have a specification question, so if you all agree that's a reasonable route to proceed with, we'll go to the developer for questions, but for discussing whether the committee would, or would not like to accept the SMP decision.

Ms. Farrell: Sure, yeah, that's great.

Chair Dalrymple: Okay. So, John, do you want to start with your specification questions for the developer?

Member Wagner: Sure, thank you. I was unclear as to the attribution, if the patient is in a dialysis facility, but receives only one treatment during the month because they become sick, and are hospitalized, or they receive transient dialysis elsewhere, is that patient still attributed to that facility for the purpose of deciding the 30 days before which they get attributed to that facility for which measure?

And the second question would be the question that was posed by a commenter about how home training is included. And I guess the third question would be if you start the therapy, and it extends beyond the 30 days, if you start training, and by the time you actually start home, it's beyond the 30 days, who gets the credit for the switch?

Ms. Dahlerus: Okay, it's Claudia again from the

University of Michigan. So, in terms of the patient being in the facilities, as in your example, for one day, they have to be at the facility for 30 full days. So, they would not be attributed to that facility yet, and so therefore that facility would not be accountable for whether, or not they switched. Was that the specific question you were asking?

Member Wagner: I mean if a person is still registered with the facility, even if they are hospitalized, as long as they are claimed by that facility for that month, they may miss most of their treatments because of a hospitalization for example. And some of the measures we've talked about have to do with how many treatments are actually rendered during the course of the month.

But this one doesn't seem to look at that, so again, if they're on this unit census, would that then, even if they're not physically present for most of the month, would that still result in them being attributed to that facility?

Ms. Dahlerus: If they're still admitted to the facility, if they're assigned to that facility, yes. If they're discharged from the facility because of an extended hospitalization, or some other reason, they would not be attributed to that facility. But we do base it on the admit discharge information that we have.

Member Wagner: Okay. And with respect to the beginning of training, versus the starting at home, how does that figure into that?

Ms. Dahlerus: So, training days are included in that 30 days.

Member Wagner: And with respect to the durability, if one starts within 30 days, but because you're towards the end of that 30 days period where you were attributed to one unit, but now you've been sent to another unit for home training, and the actual going home occurs after the 30 days, is that also attributed to the initial unit that had the

patient, or did they lose that patient?

Ms. Dahlerus: So, if the switch, if they go to facility B, which is their new unit, if that switch occurs before the 30 days from starting, which would include the training, that would be attributed to facility A, the sending facility. But if the switch happens after that 30 day period at the new facility, then it's attributed to the new facility.

Member Wagner: Okay. And can you speak to the durabilities issue? Why do we need 30 days if this is a reflection of patient education, choice, et cetera.

Ms. Dahlerus: So, this was a very lively debate actually at the TEP. We had presented several options in our analyses, 60 days is what we showed the TEP, and an assumption was made that you want to allow enough time for the patient to be clinically stable. So, if a switch was made, and lasted less than two weeks, that would not be considered a durable switch, just as an example.

However, many of the patients on the TEP disagreed with that, because they felt any -- and this is to quote someone at the TEP, any days at home is better than no days at home. On the opposite end of the spectrum, many of the nephrologists felt that the time period should be longer to be able to say this is a durable switch, and the patient is clinically stable.

And they favor something towards 60, or 90 days. And so there was no clear consensus about either end of the spectrum, so we discussed 30 days, and thought that that was a sufficient period of time for the patient to be clinically stable, and it's still -- it allows the patient to be considered a durable switch, and is considered a more patient centered outcome, but it also gives the facility the benefit of the doubt, that they're able to make that a lasting, or durable switch within the 30 day period.

Mr. Messana: Claudia, this is Joe. If I might add,

one of the concerns about not defining a durable switch was potential unintended consequences. And switching a patient modality for a day, or for a short period of time, which would then put a patient through a variety of one, or more procedures, and spend time training.

And there is a certain responsibility for identifying patients who would not be a good candidate. Someone who, a variety of reasons that I'm sure you're aware of, I don't need to educate you about those. And so the idea of having some period of time so that the facility was not rewarded for careless, or inappropriate facilitation of a modality choice.

It's interesting that the providers on our TEP were much more concerned about that, and wanted a longer period of time to define a safe switch, or a good switch, and many of the patients wanted shorter. So, it's a conundrum that we have, as Claudia pointed out.

Member Wagner: It's interesting, because some of what we've said already suggests that we rely on the professionalism of the providers to do the right thing. And yet then we have this kind of a conversation. So, I get it. And when patients are in nursing homes, if they're on dialysis, home hemodialysis in a nursing home, that is excluded. But if they're in the nursing home, and getting in center dialysis they're not included?

Ms. Dahlerus: you mean from the denominator?

Member Wagner: Correct.

Ms. Dahlerus: Correct, they would still be included in the denominator, it's around in center. There's a period of time --

Member Wagner: So, what is it, they're candidates for switching if they're in a nursing facility, but not on home hemodialysis specifically, or (Audio

interference.)

Ms. Dahlerus: After being discharged from the facility if they switch to home at any point during their nursing facility stay, that period would not be counted. But if they switched after discharge from the nursing facility, then that would be counted, assuming it meets all the other criteria. So, nursing home patients are not excluded outright, just any period of time on home hemo.

Chair Dalrymple: And I do think John, we may need to come back to that at validity, so if we can, I'll ask for -- unless there is lack of clarity around how an exclusion is defined, or specified, but otherwise I'll ask that we discuss exclusions, and risk adjustment in validity.

Member Wagner: That's good for me.

Chair Dalrymple: So, I don't see any hands yet, and we actually have an informal step now. So, my understanding, and again, Paula will keep me honest, is we're not going to take a formal vote. But before we brought in the discussion on reliability, we have the option to choose to accept the SMP's reliability rating.

Paula, my understanding is if the committee informally says yes, we're comfortable with where the SMP landed, we would stop here on reliability, vote to accept it, and then move onto validity. The alternative is if committee members want to discuss reliability, this is the time to make that point. And we don't -- Paula, to my knowledge, require majority, or anything else.

It's simply are there committee members who would like to have a full discussion of reliability?

Ms. Bal: Lorien, just a clarification. For SMP, we do do a formal vote, there's a slide we have for it. What we were saying was informal, as if it's a maintenance measure. That's when it's an informal

vote.

(Simultaneous speaking.)

Chair Dalrymple: Yes, and Poonam, I apologize, I probably wasn't very clear. My understanding is this part is informal, where we say would you all like to discuss it further? We're not going to -- or are we just going to go ahead, and put up the voting slide? And I'm trying to follow some of the guidance that I was sent.

So, Poonam, would you like us to formally vote to accept, or do you want us first to clarify if more discussion is needed?

Ms. Bal: Sorry Lorien, I got confused. Yes, the informal vote is if there's more discussion needed, but the accepting is a formal vote.

Chair Dalrymple: Yes, thank you Poonam. And I know we always struggle with this as a committee, so, everybody is very familiar with this. But this is the part where I ask you all would you like to discuss reliability? This is our opportunity to do so before any voting of any kind begins. So, it would just be helpful for me to know if the committee would like to have more discussion around reliability.

And Annabelle, John, and Rick if he's been able to join, I even might ask you all as lead, and supporting discussants, based on everything you've reviewed, do you think it would be helpful for the committee to have a discussion of reliability, and have a conversation about what was submitted?

Member Chua: Based on what the pre-committee evaluation comments were, I think it was in line with what the SMP had recommended, and so I don't think there needs to be discussion. But of course if anybody disagrees, please speak up.

Chair Dalrymple: Thank you Annabelle. Would

anyone like to discuss reliability? John, I almost thought you were going to say something, so I was waiting to make sure.

Member Wagner: We've done this many times now, the IUR, and the PIUR, we've had these discussions before. We've landed on moderate, and that's where we're looking stable.

Chair Dalrymple: Okay. I am not hearing that any committee members would like to have a full discussion of reliability. Therefore we are going to move to vote. Our first vote will ask us whether we are willing to accept the SMP reliability vote I believe, or the rating of the SMP. So, we will move to that vote.

Ms. Kyle-Lion: Okay, before we move to that vote, I do think that Dr. Greenstein is on now. So, Dr. Greenstein could you come off of mute, and just state your disclosures please?

Member Greenstein: I have no disclosures, I'm kosher.

Ms. Kyle-Lion: Okay, thank you so much.

Member Greenstein: No problem, thank you.

Member Greenstein: Sorry, okay, I'll go ahead, and share my screen, and open up the poll. Okay, voting is now open for Measure 3696 on if you accept the SMP's rating for reliability, and I believe that we are expecting 19 votes for this. So, if you're having any trouble voting, please feel free to message me privately via the Webex platform. We're at 17 votes now.

I'll just give it a couple more minutes -- sorry, a couple more seconds to see if anybody else submits a vote. Okay, we are still at 17, but we have quorum, so I'll go ahead, and close the poll. Just give me one moment to pull up the results. Okay, there were 17 votes for yes, and zero votes for no,

therefore the committee accepts the scientific method panel's rating for reliability. I'll pass it back to Paula, and Lorien.

Chair Dalrymple: Thank you Gabby. So, we will now move onto our discussion of validity, and we will ask Annabelle to start the discussion on validity.

Member Chua: Okay, so for validity, this was assessed using several different statistical tests to examine the relationship with other facility level quality measures. They looked at standardized mortality ratio first year, standardized mortality ratio, standardized hospitalization ratio, standardized weight list ratio.

Ratio incident dialysis patients, and then the ICH CAHPS providing information to patients, and the percentage of home dialysis patients at the facility. The different statistical tests that were used were Spearman's row correlations with quality outcome performance measures. Gamma tests for concordance analysis with performance classification.

Association with patient reported outcomes, providing information to patients, association between the percentage of home dialysis patients, and performance on the standardized modality switch ratio. And then there was a two part semi continuous model. And then the statistical results from that testing, and their interpretation, I don't know if you guys wanted to pull up the different tables.

But they basically said that the -- the first table reports the results of the Spearman correlations testing between standardized modality switch rate, and standardized modality rate the first year. Standardized, I guess post transplant -- sorry, I can't remember all the different acronyms. FYSMR, the SHR, and the SWR, and they basically said that it was associated with a standardized wait list ratio, and expected direction.

This suggests that facilities that do well facilitating education on transplant that results in patient wait listing within the first year are also performing well providing effective education on home dialysis that results from in switches from in center to home dialysis within the first year.

As expected, all other associations were very weak based on Spearman correlation coefficients. This lack of association is supported by peer reviewed literature that has failed to demonstrate a clear relationship between dialysis modality, and hospitalization, or mortality. And due to the positive correlation between the standardized modality switch rate, and the wait list rate the positive -- sorry.

We expect moderate agreement in facility classification of performance between the two. The positive gamma coefficient, .29, was statistically significant, indicating that facilities that perform significantly better helping patients switch to home dialysis also do significantly better in helping patients in their referral, and wait listing process.

And so they just said that facilities that have processes in place to support effective modality education are also likely to have higher waits of transplant wait listing, as well as higher switch. So, that was the big takeaway from that. That it really correlated well with wait list rate. And so in terms of the comments for validity, a lot of people said no concern, but they said it's acceptable at low, moderate level.

There was no assessment of capacity for home training at a time when staffing is a major issue. There was one comment that they weren't sure that all data was provided, and it just said that there was another comment that said the validity test was performed by comparing this measure to other measures with which the developer expected to find no correlation other than pre-existing home dialysis

patients already at the facility, the standard transplant wait list ratio was the only significantly positive correlated measure.

And then it said there's no evidence presented to support this statement as a test of measure validity. And then there was some that said uncertain validity that were low to moderate, but a lot said no concerns. So, John, or Rick, do you have anything to add? Am I supposed to talk about threats already, or is that after this?

Chair Dalrymple: Annabelle, I would talk to any threats at this point, and risk adjustment as well.

Member Chua: Okay, so threats to develop validity. As Dr. Dahlerus mentioned before there had been race, and Hispanic ethnicity, I think other socioeconomic factors were not included in the risk adjustment. And so, I think there was some concern, again, that those issues should be included. And there was a request that there should be some more discussions about exclusions in risk adjustment.

And they also asked about those patients who are living solo, or without support at home, that these individuals may be unsafe for home modalities, but they don't seem to be excluded from the denominator. And then I think that might be -- again, there are other -- I think even the SMP noted some concerns about the risk adjustment model leaving out the social demographic factors that might improve the model's fit.

And lots of comments about that issue, how that should be included. And then I think there was a concern again, are patients who choose not to use home therapies excluded? If not, this provides a substantial risk of harm of coercion. I think that those were the biggest ones. And I guess there was one thing about honoring patient choices interpreted as a quality outcome.

Patient centered care, access to care, but not choosing home therapy may reflect patient choice. So, this is really a measure about adequacy of education, and the Spearman correlation to the standardized wait list ratio of .12 in concordance data offered as evidence. Units with more PD switches, patients had more switches.

And then they were just talking about the exclusion of hospice in the nursing facility home hemo depend on Medicare as payment source, but these have minimal impact. And then one comment, it's not clear that 30 days of switch is adequate to derive the benefits, if patient switches back to in center on day 31, it may do more harm than good. John, or Rick, do you have anything to add?

Member Wagner: Yes, thank you for that overview. I guess even though we talked now extensively about the idea that this is a measure that relies on education, and the correlation to the wait list, which is significant, but not any monumentous correlation is also a function of education that goes along with, I guess the role of education, and the method by which we implement the in home care.

I was curious about the risk adjustment for comorbidity. Dialysis is necessary to treat the disease, end stage renal disease, I'm not sure that all the comorbidities necessarily influences the choice of a modality. So, I was aware of socioeconomic factors, and demographic factors where that may not apply. So, I was wondering why we chose to use all of those risk adjustments that were used.

Some of which don't really speak to why we would choose one modality over another, and not use socioeconomic factors, particularly if it requires a greater educational effort to overcome some of them. I think that is an issue for the (Audio interference.) amount.

Chair Dalrymple: And Rick? I'm sorry John, my

apologies.

Member Wagner: Just for the additional testing of the missing data, and what would happen if we don't have the exclusions, and in doing that, none of that seems to make much of a difference, although I do note that the dialysis assist residency, and the hospice status is a -- I guess dependent on Medicare as the payer, as opposed to the numerator patients, being all patients, not just those who are on Medicare.

But again, if the exclusion of those data (Audio interference.) and the exclusion of those with missing (Audio interference.)

Chair Dalrymple: And Andy, I see your hand, I just want to give Rick an opportunity to provide input if he is on the call, and maybe Paula, or someone could let me know if you see Rick, if not, we will go to Andy. Andy, why don't you go ahead, and we'll come back?

Member Chin: Yeah, just so I understand it correctly, it looks like the correlation of switch rates is basically correlating with transplant wait listing, but not necessarily any other hard end points like standardized hospitalization, or mortality rates. And I just want to bring up that wait listing is not really a function of what the dialysis provider is in charge of.

This is a function of a whole bunch of other things outside of the dialysis provider's purview. Obviously a referral has to be made, but beyond that it depends on the transplant center, it depends on the proximity to a transplant center. So, things like rural areas versus urban areas may differ in transplant wait lists.

So, I think this correlation of switch rates to wait lists bewilders me a little bit, what that really means. I just wanted to -- it's more of a comment than anything else.

Chair Dalrymple: And Renee, I see your hand, I almost wonder, I feel like we are starting our discussion of validity, so, can I just get an informal concurrence from the committee that they do wish to discuss validity, as opposed to going straight to a vote on the SMP? It would just be helpful for me to get that confirmation versus assume it. Would the committee like to discuss validity?

I see heads nodding, I will take that as concurrence, the committee will start the discussion of validity, and Renee, you are next.

Chair Garrick: Thank you, so I probably commented at the wrong time during the conversation about validity, in terms of the issue of whether, or not the switching is really a good proxy for education, so I won't repeat that. But I have two other related questions, and the first goes back to the prior comment.

So, when we think about teaching people, we think about all the things we do to educate patients to take better care of themselves, weight control, phosphate control, blood pressure medications, et cetera. I think in our prior conversations, when we all work through the hospitalization ratio, which is an outcome measure that we all know about, it struck me as unusual that there was a very weak correlation between the risk of hospitalization, and education.

So, in this measure we're saying if I educate patients really well, they'll switch modalities, but they'll still be hospitalized. And I guess it's really a question for the developer, but I was confused by that. And I also want to be a little thoughtful about this issue of whether, or not patients who live alone really should be in the denominator.

Because many of those individuals don't feel safe going home alone. And in the more elderly population, which are included in this measure, I think that's something that we all want patients to

feel comfortable with. So, I was wondering if we were comfortable that that's a part of the mathematics of the measure.

Chair Dalrymple: So, I probably have a similar line of questions for committee members, so I'll just add this to what Renee has said. One area that I thought did warrant discussion by our committee in clarity, is both the exclusions selected risk adjustment with the specific question of were they sufficient from the committee's perspective?

Obviously the SMP are methodologists, but we are content experts, and are required to comment on whether, based on our content expertise, and we thought that at least from my perspective, I think we should comment on whether the exclusions were sufficient. I feel like John already alluded to one aspect, which is what if you live in a nursing home.

Are you really able to be on home dialysis given current access to home dialysis within nursing homes in the country today? And then as Renee has pointed out, are there other exclusions that should have been considered, and what would that potential impact be? I see Alan's hand, so I'll stop there, but I would also like the committee's perspective on whether the risk adjustment that essentially creates what I'll call the O to E is sufficient. And Alan, please go ahead.

Member Kliger: All right. Speaking as someone who has helped run a robust home dialysis program for several decades, there are many factors we use to help patients figure out whether they're appropriate to be going home. The socioeconomic factors, which are clearly important ones, living situation, support from family.

There are a whole bunch of variables that go into our assisting patients in deciding whether to go home. Now, in our case of course they go home before they ever switch, we have almost no switches. But for argument's sake, if we were

putting all of our patients into hemodialysis, and then talking to them about who is appropriate to go home, there are many factors that will weigh on that that are not considered here at all.

And I'm concerned that these specifications are a bludgeon, that don't really adequately help examine which are the appropriate patients to be switched, versus all patients should be switched, which I think is a mistake.

Chair Dalrymple: And Alan, I believe your hand is still up. Thank you, I just wanted to confirm that you didn't have something else to see. Cher, I see your hand.

Member Thomas: Yes, thank you. I just wanted to chime in from the patient perspective in that I did peritoneal dialysis in 1998, and it was my only mode of treatment for dialysis. And luckily my nephrologist identified me as being a good candidate, and that discussion was with her, and she -- that many years ago it was more unusual to have somebody who would direct you towards that immediately.

But I just want to say that in addition to selecting all of the right candidates to do home dialysis, is that with that, whenever we're making that decision, and who we're deciding, and one thing that has been left out is the amount of time that goes into doing home dialysis. It is literally a part time job.

And it's worth it, but you also have to have a patient that also has the time available to commit to that part time job, that they're dependable to do it every time, and that they understand that it's an investment that in the end will be worth it. That's my only comment. They need to know about how much time, and we need to acknowledge that it is a timely process to do it at home.

And with the renal support network we do have a

Zoom support group that we provide for patients, and I'm thinking specifically about a patient who started in center, she transitioned to PD, she had an unusual circumstance, a complication happened with PD, and she didn't want to go back to in center. She actually liked doing at home.

And she's trying to do home hemo, and she has a wonderful care partner to help her, and they're really struggling. They're struggling because the home hemodialysis is taking them twice as long as what PD did. That's -- I've said my piece.

Chair Dalrymple: Thank you Cher. And Precious, I see your hand up.

Member McCowan: Yes, thank you, and please pardon my ignorance, but is there any consideration, or any type of measurement, or evaluation of a patient who qualifies to do home dialysis, and are a perfect candidate, but just chooses not to. Are they included, are they excluded, or included in this measure?

Chair Dalrymple: So, Precious, today that individual would not be excluded in the measure as specified, so there isn't a data element that captures what you've described. And I think it is part of our broader discussion, is do we think the exclusions are sufficient? Because that is part of our validity evaluation. But there is not an exclusion for what you have described.

Member McCowan: Okay, thank you.

Chair Dalrymple: And then I see John's hand.

Member Wagner: Yeah, I agree that the exclusions, and the risk adjustments are problematic. Also that these are incident risk adjustments that are based on 27, 28, and in particular as patients evolve over the course of the first year of their dialysis experience when they are still considered incident patients, a patient's medical conditions can

profoundly change, frailty can become more of an issue.

And so, I think without adjusting for that, where patients are clearly not going to be candidates for home therapy because of the evaluation of medical conditions, and not being able to invest to those is another problem. I was also wondering if we could hear a little comment from the developer about the adjustment that they did statistically for the units that don't have a home program.

And in particular, some of the external commenters were concerned that holding units accountable at the facility level was potentially not as valid an approach as using a parent corporation level, ownership level, where there were multiple facilities, only some of which have a home program, as a way of assessing the modality switch.

So, I'm concerned that the units that don't offer home training somehow will not be perceived typically in the same way as the units that do with respect to the number of expected to occur. I was wondering if it would be appropriate to ask the developer to comment on that.

Chair Dalrymple: John, I think that's a great question, and we will give the developers an opportunity before we move to any formal voting, because I think there are a couple questions specifically for them. But can I see if I understand your question correctly, in the event that there's committee members who would like to respond to it?

Is one of the questions about case mix adjustment related to we know there is many facilities that are only in center facilities, and there are some facilities that offer both home, and in center, and show up under the same Medicare ID. Is your concern that the case mix between those two facilities would be different, resulting in a different E so to speak for your O to E?

I just want to make sure I understand, and maybe the developers will probe a little bit more. I think it's a great question, because I think we want to make sure we understand that in those facilities that offer both home, and in center, which patients contribute to the expected? I think I had presumed in my mind it was only the patients receiving in center dialysis within those facilities.

But is case mix part of your question, or not at all? Just, because when we get to the developers, I do want to make sure we're clear, and again, other committee members may have thoughts about this before we get to the developers.

Member Wagner: Yeah, it was mostly a concern about attribution.

Chair Dalrymple: Attribution, and case -- okay, or mostly attribution, and then mine will be about case mix. So, we'll ask the developers to note those questions, they will have an opportunity to respond to them. And Renee, I see your hand.

Chair Garrick: It wasn't a question, it was just John, we have a couple of messages in the chat. Some people are having a very hard time hearing you, maybe there is a problem with your mic, or maybe it's partially covered, or something, so thanks.

Member Wagner: Okay, sorry about that, I'm using my speaker phone, and I'm probably not close enough to it. Could you hear me better there?

Chair Dalrymple: Yes John, that was better, so maybe just proximity to the microphone.

Chair Garrick: Sorry, thanks, I couldn't get to my mute button.

Chair Dalrymple: Do any other committee members have thoughts, or comments before we give the developers an opportunity to respond to the questions raised during the validity review? I don't

see any other hands at this time, but there will be an opportunity after the developers answer the questions raised so far. So, Dr. Dahlerus, would you like to respond to those questions around exclusions, attribution, and case mix adjustment?

Ms. Dahlerus: Yes. And I -- because there were a series of questions, so I may ask the respective committee members, or you Dr. Dalrymple, to repeat the question. But I will start with patient case mix, because there were a few related questions, several having to do with not adjusting for social risk factors. And I think we addressed that in our opening comments, and also in our submission.

And considered where CMS policy currently stands on adjustment for social risk factors. As you all are aware, there is a movement towards implementing screening for social determinants of health, so that is a potential way that that could help, at least begin help to address those patients that may be seen as not as likely to be suitable for certain treatments, whether it's home dialysis, or other therapies.

But I don't want to get bogged down in a repeat of sort of why we chose not to address for social risk factors. With respect to incident comorbidities, again, the population here are incident dialysis patients. And we want to be careful that we are adjusting for comorbidities that are not a result of facility care. So, that's one reason why we use those incident comorbidities.

As opposed to including more current prevalent comorbidities. If the other reason has to do with that this is an all patient measure. So, those who may develop comorbidities throughout the year, we are not documenting any potential prevalent comorbidities in the risk adjustment approach. Let's see.

I think there was a question about exclusions, and I

believe -- can you repeat the specific question? Because there were a couple of topics that came up related to nursing home exclusion, and how we handled exclusions generally.

Chair Dalrymple: Yeah, and I can at least raise mine, and then if others have theirs to clarify. The way I understood the measure is if you are a resident in a nursing home, you are not excluded, and you are included in the denominator. And I think my question was is that appropriate, given that most nursing homes do not offer home dialysis.

Meaning are you really a candidate for home dialysis if there is no possible way for you to get that therapy in a nursing home? At least that's my understanding of the U.S. today. I know it varies greatly regionally, but if in essence, nursing home residents don't have access to the therapy because they're residing in a nursing home, shouldn't they be excluded from the measure? Especially if there is variability in nursing home populations across facilities?

Ms. Dahlerus: So, just to be clear, nursing home patients that are on home hemodialysis, they are excluded from the measure, and we do that because again, we don't see that decision to be on home hemodialysis as a result of education, and facilitation by the dialysis facility. It is potentially a temporary modality that the patient is on, more at the convenience of the nursing home in providing care.

Nursing home patients that are on in center hemodialysis continue to be attributed to that dialysis facility. We assume they are not forever in the nursing home, so that we -- there is an opportunity for them to have the ability to switch. And again, we are talking about incident patients, so we're not looking at as large a percentage of nursing home patients within the incident population.

But no, they are not excluded from the measure, only time at risk on home hemo among nursing home patients.

Chair Dalrymple: And I just want to clarify that my assumption is correct, that we do look at other measures where months in nursing homes are excluded, so that would have bene an option, to say that this patient is in a nursing home this month, and therefore we feel like it's highly improbable they have an opportunity to go in home. So, that could have been accounted for if that was desired, is that correct?

Ms. Dahlerus: So, we adjust for short, and long nursing home stays in several of our other measures. In terms of whether we exclude them across all measures, that is not my understanding. Across all the measures, I would have to look at them. But I know that in many of them, we do make adjustments for nursing home stays that are less than 90 days, and those that are longer, but those patients are not excluded.

Chair Dalrymple: Okay, and Claudia, we may be discussing measures later today where at least the impression was certain months, but I may be incorrect on that. But I'm just trying to understand what is feasible. So, sometimes decisions are made because it can't be done, versus it's chosen not to be done. And it sounds like in this case it was chosen not to exclude months where individuals were in nursing homes.

Do you have a rough percentage of that in incident? Because you mentioned you think it's lower, I know the number in my head for prevalent patients, I guess I don't know what proportion of the population if you've restricted to the first 12 months may be residing in a nursing home.

Ms. Dahlerus: I don't know off the top of my head, I may defer to Dr. Messana, because I think he may have a better sense of that. The other thing that I

also wanted to emphasize is that the switch ratio is based on what's expected based on the national average, and patient case mix. So, in that way it does take into account sort of the average population at all facilities.

So, even though those patients are excluded, or we don't include a risk adjustment for nursing home patients, this is based on sort of what is the switch rate nationally, and then makes accounts for certain patient factors at the facility level. Again, the measure is not aiming towards 100 percent achievement of switching from in center to home. So, it's just based on performance relative to pairs.

Chair Dalrymple: And then did anyone have questions for the developer that they feel were not answered? And Renee --

Member Wagner: A comment about the use of the additional statistical manipulation to account for the zero home patient units, and how that might affect attribution.

Ms. Dahlerus: So, those facilities are -- excuse me, facilities that only offer in center, they are included, they are evaluated, and again, they can be given credit for a switch if the patient they refer to a sister facility that offers home modality, if they refer that patient, and the patient switches within 30 days. So, it does allow them to be evaluated.

Member Wagner: But based on your empirical testing, how does that pan out for those facilities? Does it look like those facilities are characterized differently than facilities that do offer home?

Ms. Dahlerus: So, facilities that offer in center, and home tend to do better in their switches than those that only offer in center. And this -- we don't have specific reasons why that may be the case, other than it could be related to if they're only offering in center, there's less familiarity with home modalities.

And so there may be less of a push to be able to provide referrals, or education on home modalities, and then refer those patients to a facility that does offer home.

Mr. Messana: Claudia, I'd just like to interject one thing to make sure we're not heading down one of these rabbit holes that the committee has found many of today. So, Dr. Wagner, if your question is how is the expected being calculated for in center only facilities, versus in center, and home facilities, the only patient experience that is included in the model, which determines the expected are incident in center hemo patients in both types of facilities.

So, we're not taking a facility level snapshot of all the patients, and using that population to define the risk adjustment. We're only looking at incident in center patients in the in center only facilities, and we're only looking at incident in center patients in the -- I'll call them full service for lack of a better explanation.

So, we're looking at only a common population of incident in center hemodialysis patients, hope that helps.

Member Wagner: Right. So, the statistical assessment of those facilities that only do home to derive an expected number is the same whether the program offers in center only, or in center with home, is that correct?

Mr. Messana: It's using -- can you ask that a different way? I'm not sure I exactly understand what you just said.

Member Wagner: Well, I think in the description of statistics, there was a model that talked about an adjustment for the -- a logic model that talks about an adjustment that talks about the fact that some units did not offer home therapies. So, I just want to be clear that when you're calculating an expected number for any facility, are you using the same

statistical model regardless of whether they offer home therapies, or not?

Mr. Messana: Yeah, we use the same model. I think there was one statistical analysis we did under the validity section, a zero inflated model that basically separately accounted for some of the asymmetric information, it was a sensitivity analysis that our statistician included.

The fundamental issue is when we're developing the expected model for the measure, we're only looking at the incident in center population in both types of facilities, so it's an even playing field.

Member Wagner: But if there are differences in the switch rate in those facilities that have full service, versus that are in center only, the reason might be because of the practices of the facility, or the reason might also be because of the availability of home training, and other programs adjacent to that facility that offers only in center treatments.

Mr. Messana: I guess that statement is true, we're agnostic to that, because we make the observation that full service facilities have a higher switch rate than in center only facilities. As Claudia pointed out, we're trying really not to draw conclusions about that observation, because we can't inform that discussion further. It could be case mix, but that we're adjusting for case mix.

It could be staff familiarity, and the opportunities, or the comfort level, it could be any number of characteristics, we're adjusting for the patient case mix so that hopefully, at least statistically to the extent that our case mix is adequate should be dealt with statistically.

Chair Dalrymple: Thank you Dr. Messana. And Renee, I see your hand, but I think we need to move to vote, unless you feel like -- okay. And Dr. Dahlerus, I see your hand, but we really need to move to vote, so if you could make this very brief,

we will be moving to vote.

Ms. Dahlerus: It is, it's a quick clarification. Our analytic lead got in contact with me, and we do exclude nursing home patients from the denominator, and numerator, so they are excluded in center, and home patients. So, I apologize that was not clearer in the description.

Mr. Messana: I believe Claudia, that probably means their time at risk while they're in a nursing home.

Ms. Dahlerus: Yeah.

Mr. Messana: Because some of those patients will be out of the model once they're out of the nursing home, or before they're in a nursing home.

Chair Dalrymple: Okay, well I do appreciate the clarification before we move to vote. So, as you all recall, and I believe Poonam, and Paula, this is correct, we'll first be asked to vote on whether we accept the SMP rating, if we vote no on that, then we vote on validity according to high, moderate, low, insufficient. So, this will be a two step voting process if you answer no to the first one.

If majority answers yes, then I believe we stop there, is that correct Paula? And once we bring up the question, I think it will hopefully be a little clearer.

Ms. Kyle-Lion: Voting is now open for Measure 3696 on whether the committee accepts the Scientific Methods Panel rating for validity. I believe we are looking for 19 votes here. We're currently at 16 votes. We're at 17 votes, I'll just give it a couple more seconds in case a couple people -- okay, we're at 19, so I'll go ahead, and close the poll.

Give me one moment to pull up the results. Okay, voting is now closed on Measure 3696 on whether the committee accepts the Scientific Methods

Panel's ratings, and there were nine votes for yes, and ten votes for no. Therefore we'll go to the full vote on validity. And just give me one second to pull that up as well, sorry.

Okay, voting is now open on Measure 3696 on validity, the options are A for high, B for moderate, C for low, or D for insufficient. And again, I believe we are looking for 19 votes here. Okay, we're at 19 votes, just give me one moment to pull up the results. Okay, voting is now closed on Measure 3696 for validity. There were zero votes for high, seven votes for moderate, 12 votes for low, and zero votes for insufficient.

Therefore the measure does not pass on validity. I will pass it back to you Lorien, and Paula.

Chair Dalrymple: Thank you Gabby. So, Paula, the measure did not pass on scientific acceptability, which is a must pass, and therefore discussion will stop at this point, and we will move to our next measure, which Renee will be leading the discussion of, 3681.

3689 First Year Standardized Waitlist Ratio (FYSWR) (University of Michigan Kidney and Epidemiology Cost Center/Centers for Medicare & Medicaid Services)

Chair Garrick: Yes, that's correct. And give us just a moment just to pull back up the PowerPoint slides. Okay, thanks. So, in the interest of time, I'll be very brief. This is Measure Number 3689. It's first year standardized wait list ratio measure, the developer CMSUMKECC, it's a new measure, and they briefly -- I'll describe, it's an outcome measure.

The goal of the measure is to track the number of incident patients in a particular unit inclusive of all members of the practice group, meaning physicians, and advanced practitioners for patients who are under the age of 75 who are listed on kidney, or kidney pancreas transplant wait list, or have

received a living donor in the first year.

I think I'll stop there, and turn it over to the developer who is with us today to cover more information, rather than taking more time, the developer who is with us today is Dr. Shahinian, if you'd like to take over, and walk us through the measure.

Dr. Shahinian: Yes, thank you very much. So, this is Vahakn Shahinian from University of Michigan KECC, and I'd like to start by thanking the NQF staff, and the standing committee members for consideration of the three kidney transplant wait listing measures being evaluated today. For this opening statement, I'm going to start by -- since we've got three, discussion issues that are relevant, and applicable to all three.

And then I'll move on to provide additional detail on this one, the first year standardized wait list ratio, and in the subsequent discussion, I'll provide a very brief opening statement for those. So, I'll provide kind of a broader context for this one. So, I'll start by saying it is well established that kidney transplantation provides best health, and quality of life results for most patients with end stage kidney disease.

And the opportunity to receive a transplant is dependent on the outcome of wait lists, which itself represents a beneficial health status, as it results from optimization of health, and psycho social issues that are required for transplant candidacy. Never the less, wait listing rates among the end stage kidney disease population on dialysis have been essentially stagnant for the last two decades.

Only a little more than a third of the very best candidates for transplantation based on the top 20 percent of estimated post transplant survival scores are wait listed by three years following initiating of dialysis. Importantly, there are persistent socio economic disparities in who has access to the wait

list. Additionally, data provided as part of our NQF submissions demonstrate wide variations in wait listing across dialysis practitioner groups.

In most cases it's almost an order of magnitude difference between the lowest decile, and the highest decile. In recognition of this urgent need for improvement, increasing access to kidney transplantation has become a national health priority reflected in the Advancing American Kidney Health Initiative, and subsequent models of care.

Including the ESRD treatment choices, and kidney care choices marked. Our proposed quality measures directed at dialysis practitioners will provide additional support, and incentives to move the needle on improving wait listing rates, and helping to ensure equitable access to the opportunity for transplantation.

We wanted to also briefly address a couple concerns raised in committee member comment. Chief among these is the argument that because transplant centers are the ones ultimately wait listing patients, that dialysis practitioners should not be held accountable for wait listing. We believe the following analogy can help clarify our reasoning for directing these quality measures towards dialysis practitioner groups.

Consider a competitive sport that involves judging such as diving, or figure skating. In such cases, the judges assign the scores which ultimately determine the athlete's ranking. But if you were to assign accountability, and credit for the athlete's performance beyond the athlete themselves, you would place it on the coach, not the judges.

The judges simply evaluate the performance. In the context of transplant wait listing, the patient is the athlete, the transplant centers are the judges, and the dialysis practitioners are the coaches. Like the judges, transplant centers evaluate the patients that present to them.

Whereas it is the dialysis practitioners that help prepare patients for the evaluation, educating them, providing medical, and psycho social support to optimize their chances of being deemed candidates for wait listing. All of these are responsibilities of the multi disciplinary team codified in the CMS conditions for coverage.

This is relevant both for the initial evaluation that can lead to wait listing, but also for maintenance of patients on the wait list. As many of the issues that can lead to placement of the patients in inactive status by transplant centers can be addressed by the dialysis practitioner, such as managing acute deteriorations in health.

Further, recognizing that as with judges, transplant centers can vary in their assessments to some extent, we do additionally include adjustment for transplant center effects in the models for these methods. Ultimately placing the accountability on dialysis practitioners ensures credit is given to the tremendous work already being done by them in supporting of getting their patients wait listed.

One other issue to note is that our measures, much like the other ones discussed today are structured to assess performance of dialysis practitioner groups relative to a national average, rather than setting an absolute standard. There is no expectation built into the measures that all patients in a practice should be wait listed, which should allay concerns that not all conceivable reasons for patients to be turned down for wait listing are included in the list of exclusions.

Again, as for the other measures that we've presented today, we take a conservative approach with the goal of the measure to identify clear outliers in performance after robust adjustment for a variety of factors potentially affecting candidacy for wait listing. Turning to the measure under current consideration, the first year standardized

wait list ratio.

This assesses new wait listing, or living donor transplant events within the first year of dialysis initiation for the vast majority of patients who get to start dialysis without being preemptively wait listed. It uses the time to event framework, therefore incentivizing rapid attention to wait listing of patients. This is crucial, as patient's health may deteriorate leading to missed opportunities for wait list candidacy.

And longer time on dialysis is associated with worse survival, and poor outcomes following the decision for those that do eventually receive it. I will stop there, and thank you all for your consideration.

Chair Garrick: Thanks very much for your comments, and I think our lead discussant is Michael, and the supporting discussant will be Karilynne, so I'll turn it over to them to begin our conversation on evidence.

Member Somers: We're at the next measure I believe Renee.

Chair Garrick: Yeah, I believe, yeah.

Member Dewald: I think that it's me.

Chair Dalrymple: I think it's Gail.

Chair Garrick: Is it? You know what, I'm so excited by my measures, I'm one page ahead of myself, I do apologize. Thanks Gail, so Gail is the lead discussant, and Mahesh is the supporting discussant, thanks guys.

Member Dewald: Yes, and my friend Cher is also a discussant. So, this is my first time doing this, so I hope I do a decent job. So, the importance of the measure boils down to the nine bodies of evidence, and the references that were given by the developer. The quality of life is significantly, and subsequently better among transplant recipients.

So, despite the increases of age, and comorbidity of contemporary transplant recipients, the relative benefits of transplants seem to be increasing over time. So, we've gotten better with our skills at transplantation, and with our pharmaceutical available drugs. Our second reference states that higher wait listing rates tended to have lower transplantation rates in geographical variability.

And that states with lower wait listing rates had higher transplant rates. Six states demonstrated both high wait listing, and decreased donor transplant rates with six others, plus the District of Columbia, and Puerto Rico. They were below the national average for both parameters. Transplantation rates in our third reference varied widely, from very low in Japan, this is a DOP study, so very low in Japan to 25 fold higher in the United States, and 75 fold higher in Spain.

Factors associated with higher rates of transplantation included younger age, non-black race, less comorbidity, fewer years on dialysis, higher income, and higher education levels. The likelihood of being wait listed showed wide variation internationally, and by the United States region, but not by for profit dialysis unit status in the U.S.

So, DOP wanted to confirm large variations in kidney transplantation rates by country even after adjusting for differences in case mix. Facility size, and in the United States, profit status were not associated with varying transplant rates. International results consistently showed higher transplantation rates for younger, healthier, better educated, and higher patients.

Another reference concludes that factors significantly associated with lower transplant rates that actually were statistically significant included for profit status, facilities with higher percentage of black patients, patients with no health insurance, and patients with diabetes.

A greater number of facilities staff, more transplant centers per 10000 ESRD patients, and a higher percentage of patients who were employed, or utilized peritoneal dialysis were associated with higher transplant rates. The effect is dominant enough that a cadaveric renal transplant recipient with an ESRD time less than six months has the equivalent graph survival of living donor transplant recipients who wait for dialysis for more than two years.

So, the urgency to transplant equals a better outcome. Longer waiting times on dialysis negatively impact on post transplant graft, and patient survival. The data strongly supports the hypothesis that patients who reach end stage renal disease should receive a renal transplant as early as possible in order to enhance their chances of long term survival.

Many patients with end stage kidney disease qualifying for the top 20 percent of estimated post transplant survival scores are not placed on the transplant waiting list in a timely manner. So, this is a significant variation on the basis of demographic, and social factors. Patients are preemptively listed more likely to receive benefits of top 20 percent EPTS status.

Efforts to expedite care for qualifying candidates are needed, and automated transplant referral for patients with the best prognosis should be considered. And lastly, the older patients, age 65 had longer life expectancy when they accepted an EC, expanded criteria donation, or ECD kidney within two years of ESRD onset compared with waiting for a standard kidney, or a living donor after four years of dialysis.

So, older, and frailer transplant candidates benefit from accepting lower quality organs early in end stage renal disease. Whereas younger, and healthier patients benefit from receiving higher

quality organs even with longer dialysis exposure. So, when we look at the numerator statement, it's the number of patients in the practitioner group listed on the kidney, or kidney, and pancreas transplant wait list.

Or who received a living donor transplant within the first year following initiation of dialysis. The denominator statement would be for the FYSWR, is the expected number of wait list, or living donor transplant events in the practitioner group according to each patient's transplant treatment history for patients within the first year following the initiation of dialysis.

Adjusted for age, incident comorbidities, dual Medicare, Medicaid eligibility, area depravation index, which is via their zip code, and of transplant center characteristics among patients under 75 years of age who were not already wait listed, and do not have kidney transplantation prior to the initiation of ESRD dialysis.

So, the exclusions include patients who are under 75 years of age on their initiation of dialysis gauge, they are excluded. Patients who are admitted to skilled nursing homes, or hospice during the month of evaluation were excluded. These exclusions represent conditions through which transplant wait list candidate is highly unlikely, and which can be identified readily with available data.

Patients were also excluded if wait listed, or transplanted prior to initiation of first dialysis. Patients who were attributed to dialysis practitioner groups with fewer than 11 patients, or two expected events are not excluded from the measure. All patients who meet the denominator inclusion criteria are included, and used to model a given dialysis practitioner group's expected wait list rate.

If a dialysis practitioner group has fewer than 11 patients, or two expected events, then the dialysis practitioner group is excluded from reporting

outcomes. So, this is a health outcome measure, and it's based on the clinical group practice. So, to summarize, the developer noted that according to two technical expert panels that were convened to discuss measures that improve access to kidney transplantation, there is broad support for the importance of wait listing.

And further, that a vote demonstrated that a majority of the technical expert panel members were in favor of developmental measures that targeted wait listing. The TEP was comprised of transplant nephrologists, transplant surgeons, social workers, researchers, and patient representatives with a history of end stage renal disease.

In addition, the developers also noted empirical support for the value of wait listing to patients, which came from a study published in the American Journal of Transplantation. The participants of the study were primarily patients with advanced chronic kidney disease prior to transplant, and those who had transplants. They were asked about their priorities, and choice of transplant center.

They stated that they were most likely to rank wait listing characteristics as the most important feature of course. Further, the developer cited several studies that provide strong support for the association between processes under dialysis practitioner control, and wait listing.

In the first study at a dialysis center in Georgia, the authors conducted a correlation analysis between ranking of referral ratios, and wait list rates, and found that the correlation was statistically significant. The second study, which used national registry data to investigation the association between whether patients were informed about kidney transplantation, and access to transplantation found that about 30 percent of patients were uninformed about kidney transplantation.

Which was associated with the rate of access to transplantation. A similar study noted that patients who reported receiving transplantation information were associated with a three fold increase in likelihood of wait listing. The last study that developers looked at examined transplant education practices. The study found that facilities that used greater than three education practices had 36 percent higher wait list rates than facilities that used less education practices.

So, would you like to hear the comments from the committee on evidence?

Chair Garrick: Well, maybe first we could ask Mahesh, or Cher if they have anything they'd like to first add before we do the comments, would that be okay?

Member Krishnan: Cher, would you like to go first? I think you might be on mute Cher.

Member Thomas: Sorry about that, I should know better. If you would like to go first, I can follow, it's your preference.

Chair Garrick: Go ahead.

Member Thomas: Okay. So, thank you very much, as Gail mentioned that she, and I are friends, I know that I am relatively new to the group, just for you to know that I am not only a patient, I am a dental hygienist, and so I did have to take statistics as part of my degree plan. I probably just know enough about reading the statistical data in this to be dangerous.

In other words I've never worked a day in nephrology, unless you want to count my part time job of giving myself PD. And I was really a, as far as this measure goes, I should be the poster child. I did PD for ten months, and received a living donor, and I've had my kidney now for 23 years. So, I agree with the theory of everything that this

measure is trying to accomplish.

However I do want to temper some of the responses, or the conversations that might come up today because what I have noticed over the last 23 years is a lot of fear in patients about transplantation for different reasons. Sometimes they're afraid to ask a living donor, or they're afraid of the disappointment of going on the wait list.

Because they've heard they've had to wait five, to seven years to get one. Travel, if their dialysis center is only ten minutes away, versus the transplant center is going to be a two hour transit each way, they're not crazy about seeing a new doctor. They're afraid because they've heard all about the side effects of medications, they're afraid of the money, the financial aspect of it.

The surgery, and transplants just -- it would be great if they worked for everybody, but I've seen a handful of cases where it just wasn't the best choice. And lastly, I do have to say that I'd like to know -- this is probably something completely different. It would go on a different measure, but this measure, I'm assuming is for anybody in a dialysis center to propose a transplant to somebody.

And really it is the nephrologist who can answer the questions accurately. I know that that would be more of a provider measure, and I'm sure that they wouldn't want to pile one more thing on top of the responsibilities that they already have. But I think that it can be frustrating for a patient to maybe finally engage with it.

And they're told well, you have to get in touch with your nephrologist to discuss it further. It would be great if the nephrologist could speak with them about it originally. Because really, they're the only one who is going to be qualified to answer the questions.

Chair Garrick: Cher, thanks very much. I think your

points about this being a very patient centered activity drive home a very important point, so thank you. Mahesh, do you have other comments that you'd like to make before we go to the committee?

Member Krishnan: Sure, and I'll be brief, I think you covered it well. So, I think that the evidence that was presented on the correlation between transplant, and outcomes is pretty straight forward, right? We all think that's the right thing to do. And clearly the correlation between getting transplant, and being on the wait list is one to one, can't do one without the other.

I think where the evidence is not 100 percent clear is the correlation of whether the nephrologist can actually influence the wait listing itself, right? Because I think as the developer mentioned, I guess he modified hypocrisy, any outcome in transplant is apparently due not to patient, provider, disease, but apparently is due to athlete, coach, and judge.

And at this point the judge is really important, right? And so what I didn't see a lot of evidence was can the nephrologist, even if they were to refer 100 percent of the patients, or educate everyone, can they really make a difference because of the heterogeneity of what happens in the transplant center? The individual transplant centers have a lot of variations.

There is 253 transplant centers in the U.S., there's probably 500 different ways of how they do things, and that's going to be complicated, and I don't think you can statistically adjust for that. And then there's a lot of subjectivity within the evaluation of an individual patient at the transplant center, right?

The committees have variability, just like ours do. So, for me that was the biggest issue in terms of the strength of the data. And then secondly, similar to the conversation we had around peritoneal dialysis, or home dialysis, I do think there's got to

be some mechanism to understand how to modify the numerator for patient preference.

If there is a patient who decided that they were educated, and didn't want a transplant for whatever reason, we don't really have a mechanism to adjust for that, we don't collect the data from that, I get that, but I've heard from multiple patient groups that that's really important, to understand that the patient actually has a choice.

Just because what seems logical, and rational to use on the outside might not be relevant to the patient. And so, I don't know how that factors in, but I think that's the other concern that I have. Is that always affecting how many transplant patients if you're an in area where the patient doesn't want that, it counts against you, but we should allow the patient to have a choice, so those are my two comments.

Chair Garrick: Thanks. Before we open it to the committee's comments, Gail did you have other things you wanted to say regarding people's overall comments?

Member Dewald: One of the other commentators, I wanted to talk about one of the other commentators was a KCP member, and I did not receive any information on their thoughts at KCP, or any of the other groups. I'm wondering if someone else had read off what KCP thought of the measure on one of the other measures we did. But I don't see it in my packet here, so, other than that I'm ready to take comments, or discussion.

Chair Garrick: Thanks. So, I can look for those, and in the meantime, I think Anna, you have a comment?

Member Chua: Yeah, I actually, I just had Gail, I scrolled down, I didn't find it last night, but this morning I found additional -- it's all the way down on page 24, the comments from the community. So, there was a comment from Kidney Care Partners if

you want to take a look there.

Member Dewald: Thank you. So, where does it say Kidney Care Partners? I see these comments, but --

Member Chua: On page 24, it has comment one by Lisa McGonigal, Kidney Care Partners. And then her comment.

Member Dewald: I don't see her name here, but I'll be glad to read these if that's what the committee wants.

Chair Garrick: I think that it's probably okay to let the group look at them, but I think that it would be good now to see what other committee members would like to say, and other comments if anyone would like to add something to what we've already heard, if anyone has their hand up. Alan?

Member Kliger: Let me just say a quick word, number one, Mahesh said it very well. There's no question that the evidence shows that wait listing is directly correlated to successful transplant, and that transplants are the preferable form of treatment in general for patients who have kidney failure. Wait lists are determined by the transplant centers.

The developers argument that coaches are really responsible for performance, and that the judges just judge what the performance comes out to be to me is like saying that if your measure is looking how many people get into medical school, that the people that should be accountable are the faculty that make referrals to the medical schools, that write letters of reference.

It's not the people writing letters of reference that determine who gets into medical school, it's the medical school that makes that decision. In this case it's the transplant centers that make that decision. If you really want to hold accountability for referring doctors, then the unit of measure shouldn't be the waiting list, it should be the referral list, who

is referring, and who is not.

I'm just really disturbed by the specious argument that the waiting list has in any major way accountability by the referring doctors. Of course there's a connection, but the vast majority of the connection, just as in medical school acceptance, is the proximal decider, who in this case is the transplant center.

Chair Garrick: And also Stuart's hand is up.

Member Greenstein: Yes. So, as a transplant surgeon, I think Mahesh said it well about the heterogeneity. But I have to tell you that I think one of the things that this measure pushes is the fact that the patients need to be referred by the nephrologist, or the patient can suffer further, and true, our transplant program has the final say, but if we don't get the patient to us to make our decision, they can't get on the waiting list.

So, the first step is the referral, and I mean --

Member Kliger: So, we can use referral as a measure.

Chair Garrick: And I think there is a referral measure, isn't there Alan, is there a referral measure? Not now, okay, thanks.

Member Greenstein: The active waiting list, I mean the waiting list itself, you're right, you can be on the waiting list, and not be active. I think one of the things that this thing tries to overcome is that the transplant program will see patients first referred after being on dialysis for seven years.

Granted that the wait time now starts from when they start dialysis, so those seven years, they don't lose in terms of getting points on the wait list. But they do lose from the point of view that they could have been transplanted much sooner than seven years when they first got referred, and they could

have gotten possibly matches. So, it's not --

Chair Garrick: I apologize for interrupting, you're fading in, and out, if you could get closer to your mic, thanks.

Member Greenstein: Sorry about that. So, my point was that you have patients who first get -- I mean I've seen patients who got referred after being on dialysis for 20 years. And actually after 20 years they probably have lost all their potential access for us to do a transplant, and that's a big problem. So, what you want to do is get them referred early on.

And yes, the list is very long, they may not get transplanted here in New York, it could be seven years before an O kidney is transplanted to somebody on the recipient side depending upon age, and all these other factors. But the bottom line is unless they're referred, unless they get on the list, there's no way they can get transplanted.

And you want to overcome the problem of being referred after being on dialysis for seven years.

Chair Garrick: Thank you. We have a lot of hands up, so I'm going to go next to Andrew.

Member Chin: Yeah, hi. I think this is a provider level measure, and one of the suppositions is that nephrologists, or nephrology providers can do more for those individuals that they think are potentially eligible for wait list, versus a patient who they may not see as eligible for transplant, or wait listing, and I think that's just not true.

Kind of taking the earlier analogy, as a clinician, I think I coach my patients as hard whether they're a transplant potential, or not. And then to put this measure on providers thinking that we have more to give for those who are not potentially wait listable is, I just don't think that's true. It kind of gets to our earlier discussion where we kind of concluded that most clinicians are doing good, not

evil.

And so, I think that this is attributing the outcome to a group that's already trying their best.

Chair Garrick: Jeff? Thanks Andrew. Jeff?

Member Silberzweig: Thanks, and I would just take the analogy to dive in one step further, which is that the transplant center is the judge, and if the judge doesn't give you a good score for whatever reason, then you don't blame the coach if the guy was perfect. In this case, the referral may be made by the dialysis center.

But if the transplant center decides that that individual isn't the candidate, it doesn't make sense to hold the dialysis center responsible for that.

Chair Garrick: Thank you. I'm going to ask Bobbi to go next as one of our patient advisors. Bobbi?

Member Wager: The only question I have is where in the heck did the under 75 years old come out? I mean didn't you -- aren't these transplant patients kind of like hey, I'm on the list there if I need one. If anyone can explain that to me.

Chair Garrick: Yeah, so we can bring that up with the developer. It's part of the measure, and I think it goes back to the other question. We're really focusing, this is a wait list measure, not a referral measure, so this is about wait listing of patients, that's what we're focusing on in the measure before us. So, Gail's hand is up, Gail?

Member Dewald: Well, to me the issue is not the merits of wait listing, which are well established, and all. But actually who controls who gets on the wait list? And to me, that's outside the practitioner's control for this, and a number of other measures. So, I agree with what a lot of the people have already said.

Chair Garrick: Thank you Gail. And Andrew has his

hand up. Andrew Narva?

Member Narva: Well, as usual I'll be the outlier. I accept the developer's thesis that getting people actually from referral to listing, and getting them to complete the work up is an opportunity to really improve care that dialysis providers, and nephrologists can really impact. I also question the plea of powerlessness that dialysis units, and providers claim.

Because I think most, at least form my perspective, transplant centers are interested in market share. And if they are not responsive to providers, or to referring neprhologists, referral patterns can shift. That may not be the experience in the private sector. But certainly for the native population, which has thousands of patients on dialysis, referral patterns were definitely -- we could adjust referral patterns in response to the responsiveness of the transplant centers.

How well they followed up, whether they excluded people based on BMI, and so on.

Chair Garrick: Thanks, that again would be a transplant center decision, but I think the other hand that's up is Mahesh.

Member Krishnan: Just to add some data, I know one data point that was said it was a single center study, or small center study in general, we've actually kind of an abstract in review now based on referral data, and what we find is there's a lot of referrals. We actually looked at this from a health equity perspective, but where the drop off occurs isn't at the referral side.

The referrals are pretty much equal by race, and other factors, but it's the entire continuum, right? Whether there are social determinants of health, or just the complexity of following through, and actually getting listed, that's where the variability is. So, I guess in an evidence perspective, I guess I

would say that we have data that suggests that even at high referral volumes, the actual wait listing has a lot of variability across the country.

So, it goes back to whether, or not this is actually a measure that the practitioner, whether it's the physician I think in this case, the measure specified, can actually impact, or not. We have data that suggests that high referral volumes still result in a lot of heterogeneity of wait listing.

Chair Garrick: Thanks Mahesh, Gail?

Member Dewald: I will be the devil's advocate in some ways. I probably met over 500 medical directors across the country as a nurse surveyor. And I always looked at transplant rates, and find out if patients know about transplant, and things like that. So, I've been to one clinic, and I think it was in Iowa, where the doctor did more pre-emptive transplants than I have ever seen in my life.

And he was very proud of that, he put that even in his QA for the facility. So, that's like a cream of the crop physician who coached his patients when they were in stage four to get on the list, get a donor, whatever. So, you've got that, and then you've got all the way down to a clinic I went to that was a home therapy clinic with 35 patients, or so, and I asked when I was surveying them how many patients are on the wait list?

Because that's one of the survey criteria, and the doctor told me I have one on the wait list. When you actually looked at that patient's record, it was one referral, not wait list. And I talked to the doctor about that, and I said you can't count them until they're actually on the transplant wait list. So, I think some education for our providers might be needed at least for some of them, so that's my comment.

Chair Garrick: Thanks. Are there other questions, or

are there questions that people would like to take back to our developer? The one question I would have if we want to have the developer -- if we're ready for developer questions, I do have one question for the developer.

Member Krishnan: I have one also Renee, for the developer, if that's okay. The question just is --

Chair Garrick: Can you wait one second? I think we have to bring the developer back up to have them available for questions.

Member Davda: This is Raj, can I make a comment here before we go to developer?

Chair Garrick: Absolutely.

Member Davda: As a payer, I will agree with Andrew, and Gail that we are holding the nephrologists responsible for the center of the EKD dialysis patient. I think we're all moving towards that, and to not have a measure that makes the responsible party the nephrologist, and the dialysis facilities who are getting the patients, and reducing al the fragmentation that goes to getting the patient wait listed, or working with the transplant centers really would be a miss here.

I know the measure is not perfect, and it has problems, but there is no other motion to do this, to hold somebody responsible in accounting for helping get transplantation done. So, I would kind of say I agree, the measure has some issues, but I would strongly be in support of having something that makes the nephrologist do more education.

And be more involved in reducing the fragmentation, and variability that occurs from referral to wait list. Thanks.

Chair Garrick: If there aren't other comments for us, could we go to the developer, if we have a couple of comments? I think Mahesh you have a

question for the developer, and so do I.

Member Krishnan: My question was given the large amount of heterogeneity of criteria that transplant centers use, I believe it was mentioned that there's an actual -- that you guys did a statistical adjustment for that. I'm curious as to how that was done, how did you compensate for the variability both at the transplant facility level, and the surgeon level.

For the wait listing criteria, how did you come up with a way to adjust for that?

Dr. Shahinian: Hi, this is Vahakn Shahinian, so I can respond to that. And if I could, I'd like the opportunity as well to respond to perhaps some of the other discussion points that have taken place. But let me kind of address the question that Dr. Krishnan asked directly.

For this particular measure under consideration, the standardized wait list ratio, we include two transplant center characteristics that are essentially one of them looks at the transplant rates at the transplant center, which gets at issues around organ availability, and decisions that transplant centers might make related to that.

The other thing that it does is that it adjusts for transplant wait list mortality, which is a proxy -- like center wait list mortality, which is a proxy for illness of the population that they take onto, or accept onto their wait list, which therefore is a proxy for the kinds of patients that they're willing to accept. The following measures that you'll be subsequently discussing additionally include random effects for the transplant centers.

Which essentially broadly adjust for things that are unique to each transplant center in their effects on patient wait listing.

Member Krishnan: I think I follow that. Ideally you'd

want to do some ratio of referral to actually acceptance, right? Because that's where the variability is, and adjust for that, but since you couldn't do that, you adjusted for some of the characteristics, mortality, and other aspects at the transplant center level, not necessarily at the intake process for the patients, is that fair?

Dr. Shahinian: That's fair. I mean it's based on the assignment from patients to the transplant centers for this adjustment, is based on historical patterns of where these patients, based on their zip code of residence end up being listed. So, it does to some extent capture those kind of, the flow of patients.

Member Krishnan: But the optimal adjustment would have been something around the variance in referral, to acceptance I guess.

Dr. Shahinian: Right, referral, as you know, is not a data point that we have.

Member Krishnan: Right, exactly.

Chair Garrick: I'm going to hop in, because I think we're getting, as we often do, a little ahead of ourselves, because we're on the evidence conversation of the outcome measure, and I think we popped out to validity a little bit, and to adjustment, and maybe to attribution. So, I'm going to try to refocus a bit. So, the measure before us is the outcome measure.

And so the algorithm would say it's a pass fail measure asking us whether, or not there's something that the nephrologist can do that will change an outcome with that outcome being wait listing by the transplant center. So, I think we have one more hand up.

Dr. Shahinian: This is the developer, it's mine --

Chair Garrick: I couldn't see, I just saw a hand waiting, so I --

Dr. Shahinian: Sorry, if I could just make one more comment, if you're getting ready to proceed to the vote. But we've heard points on both sides on this, but we just want to reiterate that I think there is good empirical evidence that the nephrologist can make a difference in terms of wait listing. One of the papers that we included in the evidence package includes Amy Waterman's work on educational practices that are delivered to the facilities, and the staff at the facilities.

And that increases wait listing rates. If those decisions were completely, and arbitrary, out of their hands, you wouldn't see that connection, you wouldn't be able to see that relationship. And the examples we've heard by various members here that nephrologists can make a huge difference in terms of whether a patient gets wait listed, or not. Thanks.

Chair Garrick: Thanks. I think if there aren't additional comments, I think the vote for evidence, and this is an outcome measure, would be is there compelling evidence that the nephrologist can -- that the actions of the nephrologist can influence the ultimate wait listing of a patient in a transplant facility? So, I think that's a pass fail measure, and I think we could probably have a vote on that, because there are a lot of other conversations about evidence, et cetera that would come.

But I think, as earlier today, this is pass fail on the question before us about this particular measure, which is, is the nephrologist activity impacting an outcome with that outcome being wait listing by the transplant center? So, if there aren't other comments, I think we could call for a vote on that.

Ms. Farrell: Are we ready to vote then, for Gabby to bring up the voting slides?

Chair Dalrymple: Andy does have his hand up, Renee.

Chair Garrick: Sorry. I didn't see that. Thanks very much. Andy? Sorry.

Member Narva: Well, you know, I think we really do need to resolve this because this affects the other two listing measures as well. And if we decide that listing is beyond the control of the nephrologist or the nephrology group, then the discussion of the other two measures becomes somewhat moot.

Chair Garrick: So, thanks, Andy. So I think our first order of business would still be to have this first vote, which is a pass/fail vote on this measure. So, Poonam, is that -- and Paula?

Ms. Farrell: Yes, we could --

Chair Garrick: Barring any other comments, I think we could look at this. And the way the developer has put it forward, the outcome is the nephrologist activity affecting the outcome of the transplant group waitlisting a patient.

Ms. Farrell: Perfect. Yes, so, Gabby could you bring up the voting slides, please?

Ms. Kyle-Lion: Yup. Give me one moment to pull up my screen.

Ms. Bal: Sorry, Gabby. Just before we open that vote. I just want to make sure that -- I know, Renee, you just said it, but I just want to make sure that, we are -- again, there can be at least one healthcare process or structure put into place to get the outcome that we're looking for.

So I want to make sure that's clear that that's what we're voting on. Is there evidence that at least something can be done to improve the chances of someone getting on the waitlist?

Ms. Kyle-Lion: Okay.

Chair Garrick: But this isn't the -- right, this isn't a referral measure. This is the nephrologist doing

something that would affect the outcome of waitlisting by the transplant center. Am I saying that correctly?

Ms. Bal: It's if something can be done by a nephrologist or whoever is helping prepare a patient in order for them to have a better chance of getting on the waitlist. It's not that they would guarantee that that individual would be put onto the waitlist but that essentially doing that would improve their chances of getting on the waitlist.

Ms. Kyle-Lion: Okay. I'll go ahead and --

Chair Garrick: If there are other questions, I can't see hands so please ask them. Otherwise, I think we could vote.

Ms. Kyle-Lion: Okay. I'll go ahead and activate the poll. I believe we are looking for 19 votes here. We're 18 votes. I'll just give it one more second to see if we get that last one. Okay. We're still at 18 votes but that's okay. That is quorum. So just give me one second to pull up the votes.

Okay. Pulling up the votes now. There are 10 votes for pass and 8 votes for do not pass. Therefore, the measure's consensus is not reached on evidence. I'll pass it back to Renee and Paula.

Ms. Farrell: Thanks, Gabby. We can move on to the next criteria, which is performance gap.

Ms. Garrick: Thanks. So we're back to Gail and Mahesh and Cher. So, Gail, if you want to kick us off.

Member Dewald: All right. So performance gap is the requirement includes demonstrating quality problems and opportunity for improvement. The developer presented an analysis of descriptive statistics for the first year of standardized waitlist ratio.

There were 281,479 patients and 2,168 practitioner

groups that had at least 11 patients and at least two expected events included in the analysis.

The analysis demonstrated that the mean value of the first year standardized waitlist ratio was 1.01 and the interquartile range was 0.77.

They further stated that the bottom quartile of practitioner groups had 46 percent lower waitlisting or living donor transplant rates among new dialysis patients during their first year of dialysis than the national average.

Their developer also stated that the top quartile of practitioner groups had 33 percent higher waitlisting, or living donor transplant rates, among new dialysis patients during their first year of treatment than the national average. This data suggests a performance gap exists.

And disparities, the developer presented the first year standardized waitlist ratio by race, ethnicity and sex for the sample used for performance gap.

The mean FYSWR was highest for the categories of other, which was 2.88 and Asian Pacific Islander as 2.04 and the lowest for Black, 1.05.

Black at 1.05 compared to white at 1.13 had similar FYSWRs compared to the mean across the entire sample, 1.01. Non-Hispanics, 1.09, had lower FYSWR than Hispanics, 1.48. Males had a higher FYSWR than females, 1.12 versus 0.87.

The developer stated that the data demonstrated Y variation and performance gaps between different race, ethnicity and sex categories. And they rated it as moderate for performance gap and disparity.

Chair Garrick: Thank you. Cher and Mahesh, do you have other comments you would like to make regarding gap analysis?

Member Thomas: I do not.

Chair Garrick: Mahesh? I think you're muted.

Member Krishnan: I caught the disease. I'll keep it. There can be no doubt that there is going to be massive variance in transplant waitlisting, right? If it's true at the transplant center, so all the people referring it's also going to be true. No problem there.

And it is clearly known that one of the massive health inequities in renal disease is number one transplant and number two home. So I have nothing else to add.

Chair Garrick: Right. Thanks. So I might need a little guidance here from our group. We have to vote on -- we can't accept the Scientific Method Panel's recommendation on gap, right? We vote on gap.

Chair Dalrymple: The SMP does not vote on gap, Renee.

Chair Garrick: That's what we do.

Chair Dalrymple: That is the NQF staff preliminary reading. Yup, so our committee must address and vote.

Chair Garrick: I just wanted to make sure I wasn't going down a rabbit hole. Thank you.

So I think if there aren't other questions or comments or questions for the developer that we probably could move ahead and vote on gap if everyone is comfortable with that. If there aren't other thoughts that people would like to add, I think we could have the vote on gap. So, Gabby?

Ms. Kyle-Lion: Yup. All right. I'll go ahead and pull up my screen. Okay. Voting is now open for Measure 3689 on performance gap. The options are A for high, B for moderate, C for low or D for insufficient.

And we are again looking for 19 votes here. We're at 16 votes, 17. I'll just give it a couple more seconds in case we get that last vote. We're at 18. Okay. It looks like we're voting at 18. So I'll go ahead and close the poll. So voting is now closed for Measure 3689 on performance gap. Just give me one second to pull up the performance results.

There were 4 votes for high, 14 votes for moderate, 1 vote for low and 0 votes for insufficient. Therefore, the measure passes on performance gap. I will pass it back to you, Renee and Paula.

Chair Garrick: Thanks. So I think that will take us to our next section, which is scientific acceptability. The first measure of that is the reliability portion of acceptability.

And we could vote as we did last time to accept the SMP's reliability rating of moderate or we could have a discussion regarding any aspect of the reliability measure depending on the choice of the committee.

So would anyone like to discuss any element of the IUR or any element of reliability? Would our commentators like to walk us through any background from Gail or Mahesh or Cher about reliability?

Chair Dalrymple: Yeah, Renee, just to intervene for a minute. We do need our discussants to introduce reliability and then we can ask the committee if they would like to formally discuss it. But we do need the lead discussant to present the information.

Chair Garrick: Thanks. I did it in the wrong order so thank you. Yeah, discussant, thank you. Thanks.

Member Dewald: So that's my cue, right?

Chair Garrick: Yes.

Member Dewald: Reliability testing conducted by the accountable entity level. The testing was

conducted using the interunit reliability, or IUR, with the bootstrap approach. This approach utilizes a resampling procedure to estimate the within facility variation that cannot be directly estimated by A-N-O-V-A, ANOVA.

The developer calculated the IUR rate value of 0.64 for the measure, which indicates that 64 percent of the variation in the measure can be attributed to the between facility differences and 36 percent to the within facility variation. The developer notes that the IUR suggests a moderate degree of reliability.

Dialysis practitioner groups with less than 11 eligible patients and less than two expected events were excluded from this calculation.

Do you want the SMP summary?

Chair Garrick: I think that we've heard that they found it has a moderate level of reliability based on the IUR of .64.

Member Dewald: That's correct.

Chair Garrick: So thank you. So, Cher and Mahesh, do you have anything to add before we talk about accepting or not accepting the vote of the SMP?

Member Thomas: Thanks, Renee. I do not have anything to add.

Member Krishnan: I'm good.

Chair Garrick: Mahesh?

Member Krishnan: Nope. I'm good.

Chair Garrick: You're good. Okay. So if I have this in the right order now, I think that if this committee is comfortable accepting the reliability portion of the scientific acceptability of the SMP, we would be able to move ahead and have a vote on the reliability. And they, if you recall, accepted it at a moderate

level.

Ms. Farrell: First, we'll do a vote on if the committee accepts this scientific acceptability rating.

Chair Garrick: Right. So if they -- do we need --

Ms. Farrell: So, Gabby, if you could go ahead and put up those slides.

Ms. Kyle-Lion: Give me one moment. Okay. Voting is now open on Measure 3689 on whether you as the committee accept the Scientific Method Panel's rating for reliability. The options are yes or no. And we are looking for 19 votes, and we're currently at 18. Now we're at 19. So I'll go ahead and close the poll.

Voting is now closed for Measure 3689 on whether you as the committee accept the Scientific Method Panel's rating for reliability. And then just give me one moment to pull up the results.

Okay. There were 18 votes for yes and 1 vote for no. Therefore, you, as the committee, accept the Scientific Method Panel's rating on reliability. I will pass it back to you, Renee and Paula.

Chair Garrick: Great. Thank you. So that brings us to the next portion of the scientific acceptability, which is the validity measure, which I think we started to talk about a little bit before so we can open this conversation now to the committee about comments on the validity of the measure.

And this measure was accepted by the scientific -- the SMP, sorry, at a moderate level. So are there comments regarding the validity -- I know we started having that before if people would like to conclude that wrap-up.

Chair Dalrymple: Renee, could we allow Gail, Mahesh and Cher to first provide commentary about specific aspects of validity, such as exclusions and risk adjustment, to give their overview of that

section?

Chair Garrick: Yes. As we usually do. So, Gail, if you would like to go first as our lead discussant?

Member Dewald: Would you like me to read the testing conducted, the ability to do testing in there for the group. I think that makes sense.

Chair Garrick: Well, if you have comments about the validity for the risk or risk adjustment or exclusion criteria, that would be helpful.

Member Dewald: They did use three tertile levels, and the differences were not significant, statistically significant. So I think that tells a lot.

Chair Garrick: So in terms of the exclusion criteria, so this is for, I believe, everyone under the age of 75 except for some exclusions for individuals who have certain pre-existing problems, live in a nursing home, have neurologic deficits that include dementia, have a malignancy or are in hospice. I think otherwise everyone would be included in this measure.

Member Dewald: Yes.

Chair Garrick: So those are the only exclusion that I saw. And the issue, again, in terms of the validity of the measure is this concept that on the logical schema of the waitlist ratio, the transplant team is not part of that evaluation. It only includes the work of the nephrology group. So on the schematic of the standardize waitlist ratio, the transplant -- the work of the transplant team is not included.

So, Mahesh, or Cher, do you have anything you would like to add about validity?

Member Thomas: Well, I would just like to ask a question about the exclusions, and forgive me if it's inappropriate here. But I didn't see, for instance, people who have excessive mental health issues or people who have lack of support.

Chair Garrick: I think that's correct.

Member Krishnan: I think I would just add on to that. Renee, I think your point on the transplant team and the schematic is the big one we were discussing earlier. So that one has come up for me.

And then secondly when the developer comes online for the exclusion criteria those I believe seem to be based on a logical construct. Like, we think that makes sense because we thought about it. I wonder whether or not -- how much the variance that actually explains because to the previous point, Cher's point, that could be on measure confounders.

It could be familial situations, support, economics. There's a bunch more questions in there. I don't know if you can adjust those or not. It would be interesting to understand what degree of the variance these factors actually describe versus don't describe.

Chair Garrick: Right. Alan, you have your hand up? I'm sorry. Alan, you're muted.

Member Kliger: Thank you. While transplant may be in general the best choice or outcomes, this is one choice in particular that has such profound effect on patient's lifestyle and patient's preferences that I once again wonder why we're robbing the patient of the right to make her own decision here. Why are we not excluding patients who, after informed consent, decide that they are not candidates, that they do not want to be on the waiting list.

Now I know that that's technically difficult. And I've heard that discussion before. But to me by not excluding patients who after appropriate education make a decision not to be included, introducing the large possibility of incenting transplant centers, who I think are the ones responsible, I mean, not clinicians, but whoever is involved in making this decision, we're putting a huge incentive at putting patients through all sorts of paces that they should

not be put through just so that we have higher scores.

So to me it's a no brainer that exclusions of this need to be a patient's decision not to get a kidney transplant.

Chair Garrick: Cher? Your hand is up.

Member Thomas: Yes. Alan brings up a good point because I have spoken to many, many patients who were 60, 65 who didn't feel like it was worth the hassle to get on a list for five years, and they wouldn't qualify because of their age. And like Bobbi brought up earlier, you know, on the other end, right, why are you capping it at people at 75? Because I've known many people at 75 who were healthier than 30-year-olds that I've known.

And I think that Alan hit the nail on the head is giving a patient a choice. And there is no option in this for that. I knew a patient on a PD who was, whenever I was on PD, who was in her 60s. And she was traveling throughout Europe. And, you know, she had no desire whatsoever to get a transplant. And so a patient's choice should be considered.

Chair Garrick: Thank you. Gail, I guess, actually, is our discussant, and then Lorien.

Member Dewald: We do have one of the reviewers that said that you must exclude cancer patients, scleroderma patients, within the first two years of diagnosis. So I just wanted to give that assessment there.

Chair Garrick: So that was a reviewer of who believed that that should be part of the exclusion criteria?

Member Dewald: Yes.

Chair Garrick: Thank you. Yes. So, right, this is again, that will probably be the decision of the transplant team. But, Lorien, your hand is up.

Chair Dalrymple: Yes. I thought there were potentially two aspects that it would be helpful for me to hear the committee's thoughts on.

One is attribution. My understanding is this measure does differ from the PPW and the APPW that the MCP is not used to attribute, but instead, the nephrologist who signs the 2728. So I'd be interested in the committee's thoughts about whether that is appropriate attribution given it is a one year measure.

The second is that my understanding of exclusions, and again, if I have any of this wrong, the developers will have an opportunity to respond, is that patients who are waitlisted prior to dialysis initiation are excluded.

And I have a difficult time reconciling that for a practitioner measure because I would nephrologists who are very good at preemptive waitlisting, we would want to perform well on a waitlisting measure.

It goes back to, well, if you're good at doing things when you're caring for people with CKD, shouldn't you, as a practitioner, get credit for that? I'm not sure why those individuals are excluded since we could in theory attribute them again using the 2728.

So I think those are two areas as it relates to validity that it would be helpful for either the lead discussants or other committee members to weigh in on, both attribution and exclusion of preemptive waitlisting.

Chair Garrick: Thanks, Lorien. And I think those are questions that would go back to the developer. Likely, I think we would need their input on that.

Chair Dalrymple: First, I'd like the committee's view, Renee, as to whether those are threats to validity. So if we have a misunderstanding then the developers can correct us. But if other committee

members agree that is how this measure if specified, then I would like to understand the committee's perspective on whether these are threats to validity before we vote.

Chair Garrick: So I could comment on the 2728 just because I tried to actually find out the data about how many patients have a change.

So the way it works for those of you who don't know is that before you can go into a dialysis facility, you enroll patients the doctor fills out a 2728. The physician who fills out that 2728 may not be the physician who cares for the patient in the dialysis facility. In fact about roughly, the guesstimate is that 30 or 40 percent of the patients that are then in a dialysis facility have a different doctor than the doctor who cared for them.

So I think Lorien's point is very important. If others have more data on that, that would be a good time to discuss it.

And the other concern is also correct, which is giving credit for preemptive transplants and credit for work before the patient ever reaches dialysis because many don't. And that's also not part of this measure. That's separate from this.

And so if you did a good job and patients had preemptive transplants, the practice group does not get credit for that is how I understood the measure. Is that the same as you, Lorien?

Chair Dalrymple: Yes. I would just make one subtle difference. I do understand why preemptive transplant is not shown in the measure because those individuals will not come to the dialysis facility. So that will be best outcome.

But why exclude preemptive waitlisting if someone is admitted to a dialysis facility? For example, if a nephrology group has 20 percent of their patients preemptively waitlisted and are clearly working on

the process prior to admission at the dialysis facility, why is that not credited towards that nephrology practice?

I'm perplexed by the decision to leave off preemptive waitlisting and make that an exclusion. Again we will give the developer an opportunity if we've misunderstood this. But that is my read of this measure. And that is a concern to me as is the attribution.

Chair Garrick: So I think that -- if I could get a little help from the committee on this before we go back to the developer. I think the developer feels that this is a measure that can be attributed to the nephrologist. That waitlisting is attributable to the nephrologist and their analogy of the coach.

I think we've already heard comments from others on the call and the committee raising other opinions about that. I don't think we've heard any other comments about the validity that need to go to the developer unless the committee has other comments.

I see, Mahesh, you have your hand up? Still muted.

Member Krishnan: I agree with Lorien's point. We never use the 2728 attributed physician. We always use the MCP attributed physician or someone who is actually taking care of the patient proximally because there is a lot of variance. And sometimes people even move, right?

So theoretically I might have a patient that I started in Virginia, and he's up in New Haven, and Alan is taking care of him. But Alan is off the hook, but I'm still on the hook. So that's a problem.

Chair Garrick: Right.

Member Krishnan: So that's a big issue. I think Lorien's point is the right one.

And I do think since this is a nephrologist measure,

And we assume that the nephrologist spans the transition of care from pre-dialysis to transition into dialysis, then giving the person credit for being able to get that patient on the waitlist seems to be rational.

That might be different than if this was a facility measure for a dialysis facility that per our comments doesn't have a lot of connectivity prior to that patient starting. But I agree with Lorien's two points. And, Alan, I'll still send you patients.

Chair Garrick: Right. More now than ever. Are there other questions or comments? If not, I think we could ask the developer these questions. And Lorien, I would ask you to pose the two questions you've just asked that we agree on to our developer.

Chair Dalrymple: Okay. Thanks, Renee. I'll repose those questions we have for the developer.

The first is why was the 2728 selected as the mechanism of the nephrologist whose care and performances attributed to -- I'll just say my presumption is this was to keep all patients, regardless of payer, in the measure. But obviously there was a big decision on tradeoff made there by deciding not to use the MCP, which would have restricted it, but risk misclassification of who is caring for that individual.

The second question relates really to why exclude preemptive waitlisting in those individuals who do go on to start dialysis when this is a clinician or group practice level measure?

Dr. Shahinian: Hi, there. This is Vahakn. And so I'll address those questions. And if I may, I may go back to a couple of other questions that seem to have been raised along the way, including the issues of patient preference and other exclusions.

So I'll tackle, just because it's fresh in everybody's

mind, the questions raised by Dr. Dalrymple about our choices.

So you're right that for this particular measure, for the SWR, we chose to go with the 2728 so that we could do an all patient measure.

And we certainly appreciate the concerns you are raising. What we did was we did do some work looking for the subset that have Medicare looking at, you know, what does it look like in terms of MCP claims versus the 2728?

And one thing to bear in mind here is that it is correct that frequently it may be a different physician that signs the form, but what we're doing here is looking at the group practice. We do that through their tax identification number.

And when you do that, actually, they're often part, you know, of the same practice. And within the first few months of dialysis, it's well over 90 percent are within the same practice as the physician originally assigned as part of the 2728. So that's one aspect we wanted to point out.

The other thing is, it's correct. We're doing the attribution based on that initial period and things could have changed later. But, again, the idea with is to really push and incentivize rapid attention to waitlisting, which means we want people who are immediately receiving these patients on dialysis to start taking action that will hopefully pay off down the road.

So a lot of waitlistings that are going to happen later in the year are in fact the stages set by actions taken early on. So we think that that attribution still makes sense.

Member Krishnan: Before you go too far on that one, how much does that drift then? So if you start off with 10 percent misattribution, how much of that changes over time?

Dr. Shahinian: I mean, by the, you know, if you look, by, I think, month 9 through 12, you're still at around 70 to 80 percent are the same. So that's kind of what we're looking at.

The issue around preemptive, you know, our answer to that is twofold. One is that, you know, the majority of patients, you know, arrive to dialysis without being waitlisted. And this measure is addressing that large and predominant group of patients.

There are, you know, other measures. The prevalent measures would essentially carry forward waitlisting that occurred prior to dialysis.

So there are other measures that we have that do capture that. This one is specifically focused to say if for whatever reason, you know, a patient arrives to dialysis without having been waitlisted, we want to push them to get waitlisted. That was the reasoning with that.

Going back to some of the other comments, you know, I think, especially with respect to the exclusion, whether it's, you know, particular comorbid conditions that you may be concerned about and whether it has to do with the patient platform, we want to reiterate that, you know, the measure is not structured to have an expectation that all patients of a practice should be waitlisted. We accept that not all will be candidates.

The idea here is to compare practitioner groups to their peers and try to identify those who are outlying in their performance. If you have, you know, a practice that has a tenth of the rate of waitlisting of another, it's extremely unlikely that they just happen to have bad luck and be containing all of the patients, all of their patients who don't want a transplant or all who have a particular comorbidity.

So we're looking at relative performance. We're

already adjusting robustly for a number of factors, including the presence of malignancy. And so for that reason, you know, we're not necessarily -- I don't think that, you know, missing a particular condition for exclusion, you know, undermines the measure.

The other thing specifically about patient preference, I think we would flip that around and say that, you know, one of the issues

is that how patients feel about transplant or their comfort with the transplant option is highly dependent on how it is presented, the education they receive.

So building in a patient preference measure could potentially -- that could disenfranchise patients. That's our concern because it's easier for that to be a check box that providers say, well, the patient didn't want it. But we know that how it's presented can make a difference.

We know, again, harkening back to the study, you know, as we pointed out, education practices directed at facilities can alter waitlisting rates. That essentially reflects that some -- that patients in those facilities that get more education are more likely to agree to waitlisting. We think that's something that influenceable.

Chair Garrick: Are there other hands or comments? My only other question for the developer would again be this issue that the transplant team doesn't appear on a waitlist measure. And I just have problems with that validity construct because it seems that is a pivotal issue because it is the transplant team that decides about waitlisting, and they don't appear -- on the logic of the first graph the transplant team is absent.

And I don't quite understand that as part of the validity construct because it's the transplant team that decides will the patient be waitlisted? The

nephrologist refers, I 100 percent agree with that. That's really important. But the transplant team is missing on the waitlist measure. Gail, you have your hand up?

Member Dewald: Yes. I'd like to ask the developer why they didn't make this a facility measure instead of a provider measure. I see the facility as the team working together to educate the patient in all aspects, including transplant.

Dr. Shahinian: Well, I mean, we do think that the nephrologist plays a significant role. We don't necessarily disagree that the facility also has important roles. And we proposed measures before, and there are quality measures currently in public reporting programs, that are facility measures.

But we also believe that dialysis practitioners have an important responsibility and, you know, importantly contribute to waitlisting. So that's why, you know, we have these measures.

Chair Garrick: You know, I know the hour is getting late, but I just wanted to follow-up on that comment because I certainly do understand that the nephrologist have an enormous responsibility in terms of the referral.

But I still don't quite get the jump between the waitlisting because the nephrologists don't make any of the decisions. Those decisions aren't public. The criteria around waitlisting are dependent upon each individual transplant center. And they are not uniform in those decision-makings.

So that jump from the nephrologist to waitlist from a validity standpoint and attribution standpoint is one I still struggle with.

Dr. Shahinian: So what I would say to that, and I should say I'm a transplant nephrologist and a former medical director of the University of Michigan kidney transplant program. And, you know, what I

would say is there variability in transplant center criteria? Yes.

But, you know, the way this discussion is going it's implying that transplant center's decisions are almost entirely arbitrary. That it's impossible to predict why or why are they making these decision. And that's far, far from the truth.

There is a fundamental set of principles that all transplant centers follow. There are some variations in that. But fundamentally it has to do with aspects of the patient's psychosocial health, their medical health.

These are things that dialysis practitioners are mandated to be doing as part of the conditions for recovery. Regulatorily, they are required to be doing those things. And the output and result of those activities are exactly what transplant centers are using to evaluate.

We don't disagree that there is some variability. But it's not like a complete free for all arbitrary decision. And I think that, you know, dialysis practitioners absolutely, you know, can do things that are going to set up their patients for success. And many of them do that.

Chair Garrick: Andrew has his hand up.

Ms. Bal: So this is Poonam. Before we go forward, I do want to just remind the committee that we do have to vote on the measure as is.

Chair Garrick: Right.

Ms. Bal: -- as a waitlist measure at the clinician level even, you know, though it may be better suited somewhere else.

And when we are looking at validity, we are looking at have they shown testing that they can accurately poll the measure and demonstrate differences in that performance? So I just wanted to make sure

those criteria are clear to the standing committee.

Member Kliger: Also though it's the specs, including inclusion and exclusion criteria.

Ms. Bal: Specifications are reliability, which we've already voted on. But, yes, exclusions are part of this area.

Chair Garrick: So, Andrew has his hand up. So I think we could have one last comments, and we would then next vote on accepting the -- if we choose or not to choose to accept the SMP's rating or vote ourselves. I think we've had a pretty robust conversation. But Andrew has his hand up. So I'll have one last comment.

Member Chin: Great. Thank you. Maybe a question for the developers. But is there any evidence that the provider, the nephrologist, has an influence on the modifiable factors that will allow dialysis patients who are not eligible for transplant to become eligible for transplant? Is there any date on that?

Dr. Shahinian: I mean, so what I could say is that I'm trying to think if there's anything that kind of very directly addresses that question.

But I think, you know, the bottom line is that we look at -- I mean, this is something we see every day, from the transplant center side, is we go back to the referring the dialysis practitioner to have them manage issues that are currently not well controlled, whether that's better volume control, whether that's better diabetes control, there are a whole range of factors that the dialysis practitioners do.

We have to recall that, you know, the transplant centers don't provide direct healthcare to the patients. It is the dialysis practitioners that do. We depend on them to correct issues that are potential barriers to their candidacy for transplant.

And the empirical evidence I would say is that when you look at -- you know, the data we submitted, there is tremendous variation at the dialysis practitioner level and waitlisting rates even after adjustment for a host of medical factors as well as transplant factors.

Chair Garrick: Thanks. Thank you. I appreciate your comments. I think we could have a vote on validity at this point if people are ready for that.

So the first part of the vote would be whether we are accepting the SMP's validity rating of moderate. So we need to say yes or no to that, which we can vote on. And then that will lead us to the next choice of having our own vote on validity.

So I think that the next item would be to actually have a vote on accepting the SMP's position on validity. And that's a yes/no and then we can move ahead depending on the outcome of that vote. Is that, Paula --

Ms. Farrell: That's correct, yes. So if you could bring up that slide, please?

Ms. Kyle-Lion: Yes. I'll go ahead and start sharing my screen. Give me one second to activate the poll. Voting is now open for Measure 3689 on whether you accept the Scientific Method Panel's rating for validity. As a reminder, the SMP's rating was moderate. I believe we are still looking for 19 votes here.

Chair Garrick: And in case I wasn't clear, depending on this vote, if we vote no, then we would have our own vote on validity. If we vote yes, then we move on. I just want to clarify that.

Ms. Farrell: Yes, that's correct.

Ms. Kyle-Lion: We are 18 votes. I'll just give it another second see if we get that last one. Okay. I'll go ahead and close the poll. Voting is now closed for

Measure 3689 on whether you, as the standing committee ,accept the Scientific Method Panel's rating for validity. Just give me one second to pull up the results.

Okay. There were 7 votes for yes and 11 votes for no. So we will go ahead and move to the standing committee doing their own vote on validity. So just give me one moment to pull that up.

Okay. Voting is now open for Measure 3689 on validity. The options are A for high, B for moderate, C for low or D for insufficient. And we are looking for 19 votes. We're at 18. I'll just give it another second. Okay. We're still at 18. I'll go ahead and close the poll because that is still quorum.

Voting is now closed for Measure 3689 on validity. Just give me one second to pull up the votes. Okay. So there were 0 votes for high, 6 votes for moderate, 10 votes for low and 2 votes for insufficient. Therefore, the measure does not pass on validity. I will pass it back to Renee.

Chair Garrick: Thank you. So, Paula, my understanding is that's a must pass vote?

Ms. Farrell: That's correct. Since that measure did not pass, we will move on to our next measure, which is NQF Number 3694, the Percentage of Prevalent Patients Waitlisted in Active Status. And Renee, you are the coacher that is going to facilitate that discussion. So we can start with the discussion on that measure.

Chair Garrick: Great. So --

Chair Dalrymple: Paula, if I can interrupt, and Renee, we are way past when we were scheduled to take a break. I do feel like we should offer the committee an opportunity to take whatever the NQF staff would like to provide before we proceed with measure review.

Chair Garrick: Thank you, Lorien.

Ms. Farrell: Sure. Yeah. I think we had on the agenda a 15 minute break so we can take a 15 minute break if everyone would be back at, let's see, 3:35. Then we will convene at that time.

Chair Garrick: Thanks, everyone.

(Whereupon, the above-entitled matter went off the record at 3:21 p.m. and resumed at 3:35 p.m.)

3694 Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) (University of Michigan Kidney and Epidemiology Cost Center/Centers for Medicare & Medicaid Services)

Ms. Farrell: All right. Thank you, everyone, for coming back to the call. It is now 3:35 p.m. Eastern Time. And we are going to move on our discussion on our next measure, which is NQF Number 3694, Percentage of Prevalent Patients Waitlisted in Active Status. And our co-chair Renee will also be facilitating the standing committee's discussion on this measure. So I will turn it over to Renee.

Chair Garrick: Thanks, Paula. So I will be quite brief in introducing the measure. This is the Percentage of Prevalent Patients Waitlisted in an Active Status, the aPPPW. The measure is by CMS/UM-KECC. It's an outcome measure. It is a clinician group practice measure. The salient care is outpatient services, and the data source will be claims and registry data.

And having said that, I think we'll turn it over to our developer for some introductory comments. Dr. Shahinian, if you'd like to proceed.

Dr. Shahinian: Great. Thank you very much, and I'll keep this very brief.

So the percentage of prevalent patients waitlisted in an active status assesses waitlisting in active status for patients on dialysis on a monthly basis. Active status means they are able to accept organ offers if

they become available.

Given, it is a prevalent measure in distinction to the prior first year standardized waitlist ratio, it is a function of both new placements on the waitlist in active status at any point after the initiation but not restricted to just the first year or even beyond the first year. But it also assesses maintenance of patients on the waitlist in active status and also carries over any active waitlisting that potentially happened, you know, predating the initiating of dialysis.

Ensuring maintenance of active status as much as possible on the waitlist is crucial to provide the best opportunity to receive a transplant.

The other point I'd like to make just to kind of reiterate something that came up in the prior measure discussion, but, you know, from an evidence perspective we again believe that waitlisting as an outcome measure, you know, there are demonstrable activities by a dialysis practitioner groups such as referral that can absolutely influence waitlisting. In fact, waitlisting is in many cases dependent on those actions.

So I'll stop there. Thank you.

Chair Garrick: Okay. Thanks very much. So our lead discussants, correctly this time, are Michael, Karilynne and Jennifer. So I think we'll begin with Michael.

Member Somers: Thanks, Renee. A lot of what we're going to talk about are items that we've already talked about with the last measure. So I'm going to try to summarize things to keep us pretty efficient as we move along.

So, again, this is outcome measure at the group practice level. Some of you will have seen that there are comments about people preferring that it be a process measure, but it's now an outcome measure.

And the developer states how because this measure represents achievement and maintenance of health status, that's their argument for why it should be outcome.

The rationale behind the measure are the same arguments that we heard summarized so nicely by Gail with the last measure. So dialysis providers optimize patient health stay. That can prepare them for the suitability for waitlisting. Waitlisting is necessary to get a deceased donor to kidney transplant. Dialysis providers can exert control over the process of waitlisting in terms of education, referral, assisting with completion of the transplant evaluation process.

Since there is a wide regional and facility variation in waitlisting, there is substantial room for improvement.

And new for this measure in terms of rationale, since most patients wait a significant time prior to transplant on the waitlist, the longitudinal aspect of this measure, the fact that it is looking at the maintenance of their active listing is key.

So in terms of the evidence that's provided to support this measure, again, it's very similar. A lot of it is the exactly same evidence that Gail summarized.

So going towards the rationale, systemic review about the benefits of transplantation, data showing geographic variability to transplantation, variations in waitlisting. And a little bit new to this measure is some data about dialysis facility and network factors associated with low transplant rates as well as the fact that over the last several years there has been an increase in the number of patients on the waiting list who are on the list but inactive versus seen active.

In terms of evidence more specific to this measure, again the measure stewards provide us with the

study that was already quoted to us from the Georgia dialysis facility that looked at referral rates versus waitlist weights and found there is a statistically significant correlation between higher rates of referral and higher rates of waitlisting and also information provided from studies showing information -- association between information about kidney transplant being provided and transplant access.

So 30 percent of patients are uninformed about kidney transplant. Uninformed status is associated with lower rates of access to transplant.

Receiving transplant information increases your likelihood of waitlisting by three times. Getting three different types of educational approaches to transplant leads to a little bit more than a third higher waitlist rate. So, again, a lot of that information is familiar to the committee from our prior conversation.

So finally in terms of member comments that came in after the committee reviewed this, there was a concern that the measure was predicated on the presumption that care was provided -- that the care provided by the practice group is really the driver of being on the waitlist. So, again, it's the attribution argument and point that was brought up in our discussion of the last measure.

And the other key factor that was brought up in member comments that I wanted to mention was, again, the idea that this measure is measuring something tangential to the actual outcome because the group being measured, that is the dialysis group, doesn't have control have the waitlist. It's again a comment that we've heard before.

So that's my summary in terms of the evidence. Karilynne and Jennifer, I don't know if you have anything you would like to add.

Member Lenning: Mike, I think you did a good job

recapping all the information. I think the only thing I might add, and I hope that it's appropriate at this point is, I recognize, you know, a lot of discussion is around the nephrologist not being the driver or those responsible for the outcome and for the transplantation that resides with the transplant facility.

But, you know, in our current environment, you know, collaboration and communication amongst responsible providers and the transplant facility, I think, you know, there is an expectation that there is more collaboration rather than work in siloes. And I know that you're not working in siloes. But some of the conversation kind of leads us down that path.

So I do like this measure in that it does weave in the maintenance piece and that does lend to the nephrologist and responsibility there. So I just wanted to add that along.

Member Vavrinchik: The only other thing I would add -- this is Jennifer -- is that it is at the practitioner level, but these are prevalent patients. And I think many times with these patients we all are educating and doing these referrals and really primarily it is the social worker. The referral work is falling on our social workers in these instances.

So I know it was mentioned earlier, but I think especially for prevalent patients it's at a facility and not necessarily at the group or practitioner level. Thanks.

Chair Garrick: Okay. Thank you. I think we could open it for comments or questions from committee members. If there are any, please raise your hand. Alan?

Member Kliger: Michael, that was a really lovely summary. I wonder in your judgment after careful review, were there any things particular to this measure that would help those of us who had a problem with the evidence based and referring

nephrologists rather than the transplant center having locus of control.

Member Somers: I would like to be able to allay your concerns, but I can't remember seeing anything provided along those lines, Alan.

Chair Garrick: Okay. With that in mind, I'm looking to see if there are other hands up. Paula or Lorien, I might be missing some. If there are other comments you would like to make -- again, this is an outcome measure. So our first vote will be a yes or no vote, a pass/no pass vote as an outcome with the question being that there is a relationship between the measure health outcome and a particular action on the part of the nephrologist to maintain somebody -- remember this is a prevalent patient measure to maintain someone in an active status on a waitlist. Yes, Andrew.

Member Chin: Sure. This is nearly identical except for the active status to the next measure. And I was just wondering if the developer -- this may not be the time, but I guess since it affects all aspects of the review it might be, if the developer could just comment on why they developed these two measures and, you know, whether they think they are both essential or do they just want to provide a maximum number of pools or what they really hope to get at.

Chair Garrick: We can go back to the developer with that. I guess my question is that an evidence question, a validity question? I might need a little guidance from our NQF colleagues to know if it's the right time to ask that of the developer. I'm comfortable doing it if this is the right time.

Member Chin: I mostly asked it because in the context of being respectful of everyone's time, it might help us facilitate this discussion along with the next one.

Chair Dalrymple: And, Andy, I can share with you

how this question was answered at least when Renee and I raised it on the co-chair prep call, appreciating this challenge.

And the instructions we were given is because these aren't competing measures yet and one is not endorsed, we've been asked to simply evaluate each measure independent of the other. But I can fully appreciate the desire to have some clarity about one measure that's active only and then one that evidently, you know, must include active and inactive.

But because these are coming to use for the first time, I think we will go through each of them as if the other does not exist.

Ms. Farrell: Yes, that's correct.

Chair Dalrymple: That being said, Paula, would we like to give the developers an opportunity just to share their thoughts with us in the event that helps us as we go through our decision-making or would you prefer we not pursue that line of questioning?

Ms. Farrell: I think if that's a question that the standing committee wants to ask the developers, you know, we can have that discussion.

Chair Dalrymple: And, Renee, would you favor we just do that now before we get started? Or is there a different interval that would seem better to you?

Chair Garrick: I think we could do -- I think if we asked the developer that question now it might lend some clarity. But since we really have both measures before us it might be cleaner to just go through the two measures, see where they land and then come back if required. Because we really have two separate measures. They do have some overlap. But maybe we should just work through them and see what we feel about them both.

I'm open to comment from others about it. But I'm

comfortable just trying to go through the measures unless the committee would like to hear from the developer now as to the harmonization of the measures and some clarification around them both.

Member Lenning: Renee, this is Karilynne. I'm the supporting discussant, so Michael you can shush me if I shouldn't be saying any of this.

But on the measure worksheet, the first page, there is a section that the developers did indicate to us a little bit of the reasoning between the two different measures, where they are stating it's an important area to which dialysis practitioners can contribute through ensuring patients remain healthy and complete and ongoing testing activities are required to remain active on the waitlist in contrast to this measure.

The first year standardized waitlist ratio focuses solely on new waitlisting and living donor kidney transplants to incentivize early action. So it's more early action on the other and maintenance on this one if that's helpful. And maybe you want more.

Chair Garrick: So, again, not getting -- probably not for this portion of the conversation, but I think probably practitioners strive to keep everyone healthy and not just patients who are waitlisted, but I certainly understand their point. Patients can't get a transplant unless the transplant team has them in an active status on the waitlist. You still keep getting time, but you can't accept the organ if you're not on an active status.

And there are lots of reasons why people might become inactive. But I think that's not for this part of this conversation. I think that's later to talk about more of the validity of the construct rather than the evidence around it, I think, since this is an outcome measure.

Would others like to hear from the developer now or are we comfortable moving ahead with the measure

as two separate measures? If there aren't any comments, I'm going to take that meaning we can move ahead.

So are there things you would like to ask the developer regarding this as a measure, as an outcome measure? The measure, again, is the active waitlist measure for prevalent patients. It's a practitioner level measure.

If not, maybe we could actually move for a vote on the pass/no pass for this active waitlist measure, active status waitlist measure, if people are comfortable with that.

Ms. Farrell: Gabby, can you bring up the slides for the voting on evidence?

Ms. Kyle-Lion: I'll open for Measure 3694 on evidence. The options are A for pass or B for do not pass. And, again, I do believe we are looking for 19 votes here. We're at 17 votes. I'll just give it another second to see if we get any -- we're still holding at 17 so I'm going to go ahead and close the poll.

Voting is now closed for Measure 3694 on evidence. Just give me one moment to pull up the results. There were 9 votes for pass and 8 votes for do not pass, therefore the measure is consensus not reached on evidence. I'll pass it back to you, Renee.

Chair Garrick: Okay. Thanks. So that brings us to the next section, which is again a required vote on performance gap. And I'll turn it back to our lead discussant, Michael.

Member Somers: So the measure developers applied the measure to data from 2019 and dialysis groups with at least 11 patients. The measure results range from 0 to 70.4 percent with a mean of 12.3 percent and the lowest quartile being less than 7.3 percent of patients waitlisted and the highest quartile, more than 15.6 percent of prevalent

patients waitlisted.

In terms of disparities, the developer presented the waitlisting status looking at race, ethnicity and sex with similar results to the prior measure. So waitlisting performance was highest for Asian Pacific Islanders, lowest for Native Americans. Hispanics had a higher waitlisting percentage than non-Hispanics, and men had a higher waitlisting percentage than women.

Chair Garrick: In an active status, right?

Member Somers: That is correct, being waitlisted in an active status.

Chair Garrick: Thanks. Anything else, Michael, you wanted to add to that? If not, do our other discussants have things they would like to add, either Karilynne or Jennifer?

Member Lenning: I have nothing to add. Thank you.

Member Vavrinchik: I've got nothing to add. Thank you.

Chair Garrick: Nothing to add. Okay. Are there comments from the committee members regarding the performance gap as presented? I don't see any hands. Lorien or Paula, anyone see any hands up for questions or comments?

Ms. Farrell: I do not at this time.

Chair Garrick: And I'm assuming no questions there for our developer? So if that's accurate, I think we could move ahead with the vote on performance gap.

Ms. Kyle-Lion: One moment to pull up the poll. Okay. Voting is now open for Measure 3694 on performance gap. The options are A for high, B for moderate, C for low or D for insufficient. And we are looking for 19 votes here. And we're at 18. I'll just give it one more second. Okay. We're at 19. I'm

going to go ahead and close the poll.

Voting is now closed for Measure 3694 on performance gap. Just give me one second to get the results pulled up. Okay. There were 2 votes for high, 17 votes for moderate, 0 votes for low and 0 votes for insufficient. Therefore, the measure passes on performance gap. Back to you, Renee.

Chair Garrick: Thank you. So moving right along, that brings us to the scientific acceptability and the first portion of scientific acceptability, of course, is voting on reliability and before turning to the question of the Scientific Measures Panel, let's have our team with Michael and Karilynne and Jennifer lead us through the background. And then we can decide if we want to accept their position or have our own vote on reliability.

Member Somers: So in terms of reliability in first measure specifications, the exclusion criteria is for patients who were 75 years of age or older, patients who are in a skilled nursing facility, patients in hospice and patients with dementia. Again, as we mentioned earlier, if you're a practice with fewer than 11 patients, you're also excluded from public reporting.

These exclusions would lead to about 29 percent of prevalent patients being excluded from being considered in the measure. That, the measure developers tell us, increases the waitlist proportion from 9 percent to 12.3 percent so that they do think that it has a moderate effect on that. However they looked at the performance rankings of groups with the exclusion. And they felt that it minimally affected how a group would end up ranking and so these exclusions were not problematic.

In terms of reliability testing, they performed an IUR. It was quite high at 0.93, so 93 percent of the variability was accounted for by facility differences.

Based on this, the SMP voted to say that they met

criteria for reliability with five high votes, three moderate votes and there were two indeterminate votes.

Chair Garrick: Thank you. Are there comments from our other discussants, from Jennifer or Karilynne?

Member Lenning: Nothing to add here either.

Member Vavrinchik: Same.

Chair Garrick: Jennifer, anything to add?

Member Vavrinchik: No, I've got nothing to add. Thank you.

Chair Garrick: Great. Okay. Thank you very much. So with that in mind, we have an opportunity to decide if we'd like to accept the reliability vote of the SMP, which was at a moderate level or we can have our own. So I think our vote would be to either accept or not accept if I'm right about that. So we have to have a vote on that and then a decision can be predicated on our vote.

Ms. Farrell: Correct. Yeah.

Chair Garrick: Gabby, if we could have a vote.

Ms. Kyle-Lion: All right. Give me one second to get that pulled up. Okay. voting is now open for Measure 3694 on whether you all as a standing committee accept the Scientific Method Panel's rating for reliability. As a reminder the rating was high. And we are looking for 19 votes here.

We are at 18 so I'll just give it one more second to see if we get that last one. Okay. We're holding at 18, which is okay. That's over quorum. I'm going to go ahead and close the poll.

Voting is now closed for Measure 3694 on whether you all as a committee accept the SMP's rating for reliability. Just give me one moment to get those results pulled up for you. Okay. There were 18

votes for yes and 0 votes for no. Therefore, you, as a committee, accept the Scientific Method Panel's rating for reliability. Back to you, Renee.

Chair Garrick: Thanks. That brings us to the next section, which is the second part of the evaluation of scientific acceptability. And that's to explore the validity of the measure. And for that we'll go back to our lead discussant, Michael, and our supporting discussants, Karilynne and Jennifer.

Member Somers: In terms of validity, the measure developers looked at this measure and compared it to measures of transplants rates and mortality and showed that high measure performance correlated with higher transplant rates and lower mortality rates. They have risk adjusted their model taking into account certain social risks, functional risks, medical and clinical risks.

Members of the Scientific Committee, some members of the committee seem to have concerns about the risk adjustment and how the model was created. I have to say I can't share in specifics what those details were because I couldn't really understand from reading the comments what their concerns about the model was. But that led to some members of the Scientific Committee voting for this to have low validity.

In terms of meaningful differences, again pointing towards validity, when the measure developers looked at how groups would perform based on expected with the model, they found 92.4 percent of groups performed as expected, 2.6 performed better and 5 percent performed worse.

Chair Garrick: So overall what percentage performed at either high or as expected or above expected?

Member Somers: That would be 95 percent would have performed as expected or better and only 5 percent performed worse.

At the end of the day, the SMP could not reach a conclusion about validity with six members voted moderate, four members voted low. So they didn't meet the threshold for the proportion of members for them to have given their stamp of approval in terms of validity.

Chair Garrick: Michael, do you recall how many practices that translated into since this is a practice level measure? How many practices were performing below expected?

Member Somers: I'm sorry. I don't recall that.

Chair Garrick: I think it was -- just for completion, I think it was something close to 112 practices. Since this is a practitioner level measure, I just wanted to have that for completeness, but I can double-check that myself.

Any other comments, Michael, about -- that you would like to add about validity? If not, would either of you would like to say anything before we open it up to the committee.

Member Lenning: I think the only thing I would add, which is very vague, but that the concerns that the SMP had, it did appear in the notes and the measure worksheet that the developer did have some response back to what the concerns were. But beyond that I'm not really sure of a lot detail or understanding. Sorry.

Chair Garrick: Jennifer, anything to add?

Member Vavrinchik: No, thank you.

Chair Garrick: How about members of the committee? Alan, you have your hand up?

Member Kliger: Yeah. I just wonder if any of the staff members could help us understand what the SMP's concerns were about this.

Chair Dalrymple: Alan, I'll go ahead and start with

mine that at least that I thought was substantively raised by the SMP and probably warrants discussion by our committee. And I can't recall if the SMP even said we should discuss this, which is this measure includes the adjustment for social risk, which is highly unusual, but I think based on the input of the TEPs thought it was needed.

So I do think it's within scope for validity discussing and important for other measure development for us to have a discussion as a committee about whether social risk should be included when looking at waitlisting as an outcome.

And, Michael, I'll have you double-check me on this as lead discussant, but I think ADI and dual eligibility were included in the model.

Member Somers: That's what I have written down, too.

Chair Garrick: Yeah. So do I. I believe that's right.

Chair Dalrymple: Does anyone have any other additional social risk factors we should discuss? Because I think there was unfairly strong wording, Alan, from the SMP and clearly divergent opinions on whether social risk should be included.

My recollection of the discussion in the Measures Commission is the TEP's office thought this was necessary presumably because they feel practice groups may differ in patients they care for, and there may be differential social risk that leads to look like an apparent difference in quality that may not be related to the skills of that nephrologist nor their abilities.

But I think, at least to my recollection, and Alan, you can correct me and Michael and others, social risk rarely appears in our models. So I can see why the SMP flagged this for committee discussion.

Member Somers: Yeah, of course, Lorien, you're

right. Rarely have we considered that in previous metrics. But, you know, the world moves on.

I can tell you that in many of the organizations like what ASN is doing now has far more consideration for the socio and economic differences and how that impacts outcomes and therefore what we do, then we did, you know, just

five years.

So you're right. We've not done that before. And the world around us asks us whether it's appropriate to do so.

Chair Garrick: And I think in the submission and the conversation that was, as you said, Lorien, because there may be concerns that various groups may not be evenly distributed across facilities and, therefore, as an outcome measure, could look at one particular group is doing poorly when they're not really doing poorly as a nephrology practice group, but it's because of distribution factors related to people at risk.

And this is complicated because it's an active waitlist measure. So my other question related to the validity issue is that I found several articles demonstrating that the transplant teams are being encouraged to review their lists quite actively and have found on their own sometimes up to 18 or 20 percent of patients that they can change the list status on to active from inactive. And that would reflect very badly on the nephrologist. But it would be something going in a different part of the care continuum than theirs.

And the other concern regarding validity is that there is another initiative going on that's by UNOS. It's called the COIIN initiative that is actually asking transplant groups to very actively manage their lists.

And in that study they've been showing that

sometimes moving people from an active list to an inactive list on the waiting list actually improves the numbers of transplants performed because it makes the list move faster. So when the organ is available, having a list that is a little more robust is a positive thing.

So, again, in terms of the validity, changes to the transplant list can go either way and actually moving some group to the inactive might actually improve the number of final transplants performed.

So I had several questions about how as an outcome measure those factors might inadvertently have unintended consequences reflecting inappropriately on the work of the nephrologist. I'd be interested in hearing what the developer might say as we get to that.

Chair Dalrymple: Cher has her hand up, Renee.

Chair Garrick: Yeah, thank you, Cher. Thanks.

Member Thomas: Yes. I could see how social risk could play a part in that if a patient is underinsured, let's say they can't get the next test to stay on the waitlist or, of course, COVID is an extreme, extreme example. But, you know, loss of income because not being able to adjust to that. I could -- or not even being able to get out because they were afraid of infection. So I could see how social could have an impact on it.

Chair Garrick: Thanks. Are there other comments for the committee before we move back to the developer? Oh, sorry, Alan. I think you have your hand up?

Member Kliger: Yeah. And just quickly, as with the last measure, I have a concern about exclusions. We're excluding people with medical reasons not to get transplanted like hospice or other illness.

We're not excluding people who have made the

informed decision that they are not interested in being actively listed. And to me that's the main determinant of the active waitlist. And by not excluding patients, not allowing them to make that decision, but bunching them together, I believe there is a real problem here.

Chair Dalrymple: So, Alan, just to potentially provide a different view, although I feel like the developer has already spoken to this. But we have discussed this in past committee meetings as this comes up across a number of measures, and I think it's important to discuss again.

I think the concern about allowing for an exclusion based on patient preferences many feel that would be too easy of a check box. That perhaps people could just say, nope, not interested, not interested, not interested. My performance is wonderful because one out of one interested patient is waitlisted in my practice.

And so then I think it becomes a question, and this when I don't know that we have any data on, do you think there is variation between practice groups on the proportion of patients who were truly not interested that is completely unrelated to care, education and other things?

And I think this is something we've really struggled with because if we could reliably and objectively assess that someone truly was given good education, understood all the risk benefits and made a decision and opted out, that would be wonderful. But we don't have such a tool today. So then the question is if you create that measure, does it become an easy opt out, and you are no longer measuring what you need to measure?

So I think we have had the discussion often about patient choice, and we all recognize that its critical role. But for population quality measurement, this is a very real dilemma.

Member Somers: So if I could just respond to that quickly, Lorien. I completely agree with you. Because it's an easy opt out and therefore might be hard to administer as simply a check box, I don't think that that's a sufficient reason to allow it to go by and to ignore patient choice.

You know, with the burgeoning number of metrics we now have, and they are ever increasing, I think our responsibility is to make sure that the metrics we approve really have the rigor to have those few that are really worthy of all the work it takes to measure and then act on those metrics. So I agree with you. It's a hard one. But to me simply having a difficult time identifying patient choice doesn't mean that's not the critical difference.

And in terms of how it's distributed across practices, we just don't know that. There is no data on that.

Chair Garrick: Yeah. So I think this is such a valuable conversation because we're trying to look into a gray box in many ways and figure out what goes on inside there. And we all want to be sure that we're referring every patient that we possibly can and doing all the right education and supporting good decision-making. And we don't know how patients are distributed.

And one of the concerns that people have expressed is there are facilities -- like one of my facilities is the only facility that takes bedbound patients. It's the only facility that actually has many patients who are here without documentation. It's the only facility that takes hepatitis positive patients.

You know, I want to continue to do that. And I want to continue to be that facility. But it is of interest to me that so many other facilities have chosen to not do that. So I always do worry about the possibility of disparities and, as you're saying, of not being able to really understand all the factors that go into some of these decisions.

So we don't want it to be a check box. That's for sure. But we have to find some way of having patients have autonomy and being able to make good choices. And it's a worthy conversation that maybe we could think of measures that would help with that.

Are there other questions or comments? If not, I think we could ask the developer a few questions.

I would ask the developer, my one question is this issue that there's data that suggests moving to an active status or an inactive status, which is done by the transplant group, can be a very large number of patients. And, again it's something that I think might impact this measure in a way that we would have a difficulty tracking back to a particular dialysis facility into the work of those nephrologists if the transplant team, as we found in the literature, can have up to 18 or 20 percent of the patients that we can move up one status to another when they do a waitlist evaluation and how would that impact this measure in terms of the evaluation of the nephrologists?

And the related question was the work of the COIIN study that has been demonstrating that actually sometimes it's good to move people from an active to an inactive status because it actually, although the list is shorter, it's more robust and actually more patients end up getting transplanted, again reflecting on the fact that this is an active waitlist measure, measuring the quality of care provided by the nephrologist in the facility.

Dr. Shahinian: This is developer Vahakn. I can respond to that question. So, you know, you recall this from the transplant center perspective, I mean, it's waitlist management, where you are optimizing who is ready to be transplanted in the list of patients that you have on the waitlist.

So certainly there are processes by which we can undergo, you know, a review of patients to see what

can be done.

But I think what's important to recognize is that, you know, those reviews often identify issues that we need the dialysis practitioners to help us with to be able to correct, address and help the patients kind of get to the point where they can be listed.

This is not something that is unilaterally done by the transplant centers. It is a process that is highly dependent on actions of the dialysis practitioners. So that would be my response. And it's again speaking as a transplant nephrologist and former medical director.

Chair Garrick: And I would say some but not all, because there are many things that go on as was brought up by others, insurance issues, psychosocial issues, acute illnesses, et cetera, that the nephrologist can't really impact. That this measure would make it look like the nephrologist isn't necessarily providing good care when in fact the moving of the transplant list status from active to inactive and back doesn't really reflect the care provided by the nephrologist.

Dr. Shahinian: And, again, you know, the measure is structured to examine relative performance and to identify extreme outliers in performance. So we recognize that there are going to be exceptions. It's a matter of identifying, you know, groups that are outside the usual range of performance.

Chair Garrick: Thanks. And just to clarify before I went back to look at that number, the practice number was not 112. It was 113 practices were identified in the submission as worse than expected and out of 276 practices overall.

Chair Dalrymple: And, Renee, I had several questions for the developer as well if that's okay.

Chair Garrick: Absolutely.

Chair Dalrymple: The one thing I wanted to confirm because I know each of these measures has slightly different populations of focus is this measure restricted to Medicare beneficiaries?

Dr. Shahinian: Yes.

Chair Dalrymple: I believe that it is.

Dr. Shahinian: Yes. You're correct.

Chair Dalrymple: Okay. So I do think that's important to note compared to other measures. This is a measure that is restricted to Medicare beneficiaries and adjusts for dual eligibility in the statistical model.

And are we correct that the social risk factors included were ADI and dual eligibility and that was largely informed by your TEP's input or would you like to just briefly provide rational for including those as social factors and let us know if we have missed any others?

Dr. Shahinian: No. You are absolutely right. And you're right that this was largely informed by the TEP discussion.

You're also right, as you mentioned, that this was a point of contention with the Scientific Methods Panel on, you know, obviously, there were some strong feelings on there. And, you know, they were very interested in hearing the import of the renal standing committee on this issue.

Our TEP felt that -- I mean, obviously it's a tricky issue in the sense that when adjusting for social risk there is always the danger of potentially reinforcing or sustaining disparities. That is particularly or pointedly why we are not adjusting for race.

But the overall thought was because of the known kind of association or assessments that are made with respect to candidacy about issues around economic support and things like that that we

needed to adjust for some measures of that.

And so we include a patient, you know, level adjustment in terms of dual eligibility and then a regional adjustment in the form of the area depredation index.

Chair Dalrymple: And I think it's worthwhile if you don't mind briefly reminding the committee what is inside the ADI. And is this at the ZIP Code level or a different geographic region?

Dr. Shahinian: I want to say the ZIP Code level. You know, I don't know if I can immediately give the details on that. I mean, it's something that was developed by the Agency for Healthcare Research and Quality, and it has been used in various contexts for adjustment in looking at essentially neighborhood kind of factors that relate to particularly financial measures of vulnerability.

Member Narva: I think it uses nine digit ZIP Codes so it gets into neighborhoods.

Chair Dalrymple: And I think, you know, we have a couple more points to discuss. But if on the side, the measure developers, I think it is worth reviewing with the committee, since we're going to specifically discuss inclusion of social risk factors, the components that go into the ADI.

Obviously, there's the ADI, the SDI, the SVI. And I think we want to be clear that we're all having a discussion of the measure and the components of it. So if someone on the measure development group could quickly pull that list that goes into the ADI, I think that would be helpful for us having a robust discussion around social risk adjustment.

And while that's happening, I'll ask my last question, which is I do think adjustment for transplant center characteristics is new, at least I can't recall that in previous measures we've developed. And I think the rationale was explained

in the measure.

What would be helpful for me to understand, and it's possible you have not done analyses around this, is do those adjustments, are they intended to perhaps address some of our concern around transplant center behavior?

In other words, by you including transplant center characteristics, and I think you said there's also a random, in fact, for the transplant center in this model, is that an attempt to account for the variability between transplant centers and their waitlisting behavior or do you view it differently?

Dr. Shahinian: Yes. I mean, that is correct. And, yes, for this measure there is both a couple of essentially fixed effects, you know, one being the transplant waitlist mortality and the other being the transplant rates. So, you know, the transplant rate is getting at potential issues around organ availability that can affect transplant behavior at the transplant centers and then the transplant waitlist mortality reflecting kind of the nature of the population that is accepted onto the waitlist and then finally a random, transplant center random effects that are intended to kind of essentially capture that variability of individual transplant centers.

Chair Dalrymple: Okay. Thank you. And I wonder, Renee, should we just let the developer raise their hand when they have the --

Chair Garrick: Right.

Chair Dalrymple: -- components of ADI to present? Does that make sense so that we can continue our discussion as we wait for that?

Chair Garrick: I think that's fine. Are there other comments that the group would like to make while we're waiting for that? Are there other points?

Member Lenning: I did type into the chat some information on ADI if that's helpful for the group.

Chair Dalrymple: Do you mind just reading it aloud so it's on the record?

Chair Dalrymple: Do we know if this the listing that they used for their adjustment?

Member Lenning: I'd like them to confirm that typically ADI from the measures that I have been exposed to in the value-based payment models look at the ZIP Code and sometimes in an aggregate ZIP Code level. And it breaks down the census data into looking at education, income, employment, housing and then household characteristics. And I would like the measure developers to confirm that that indeed is what they were looking at. But that is typically what the categories are when you're looking at ADI.

Dr. Shahinian: Yes. That is correct.

Chair Dalrymple: And I do want to confirm something. The ADI does not include neighborhood characteristics as it relates to race or ethnicity, is that correct?

Dr. Shahinian: That is our understanding, yes.

Chair Dalrymple: Okay. And I think that is important. And Karilynne, is that your understanding as well as it sounds like you have some experience with ADI just because the point made earlier that we have to be really careful about what we adjust for so that we do not adjust away disparities is critical.

And so I think thinking about indexes that do not include race or ethnicity is important because I don't think any of us feel that race or ethnicity should be adjusted for in these models. Whether we feel other social risk factors can be considered I think does warrant discussion.

Chair Garrick: Could I just ask the developers for

some clarification here? So the factors that are listed, education, income, employment, the ZIP Code analysis, could you help me better understand how those are used in the adjustment for this measure?

Dr. Shahinian: All right. I'm looking for the unmute button. I mean, it's essentially a composite score that includes a range of factors that function -- that relate to those various categories. So there is a number of variables that go into each of the education, income, employment, housing and household characteristic domains.

You know, for example, under education to represent population age 25 years or older with less than 9 years of education or income employment, median family income in U.S. dollars. Under housing, it includes median home value in U.S. dollars, household characteristics include percent of households without a motor vehicle.

Chair Garrick: Thank you. And then how are those used in terms of adjusting the active transplant waitlist measure? How do they (simultaneous speaking).

Dr. Shahinian: Essentially, there's a percentile value that gets entered into the model based on the patient's residence.

Chair Garrick: I guess, I apologize, I don't want to take the committee's time. I guess I'm just confused by it. So --

Dr. Shahinian: So it's essentially a regional level variable that is essentially attached to patients based on where they reside. So it's the ADI percentile where the patient resides.

Chair Garrick: I guess what I'm confused by -- so are we -- as Lorien said before, we don't want to accidentally be overlooking a disparity that we need to be correcting or that we need to be helping. So I

guess what I'm not quite understanding is like how is it -- so we use this in the measure to say, okay, we understand that individuals with certain education, income, employment, housing, et cetera, that impacts their active waitlist status? That's a question on my part.

Dr. Shahinian: Yes. I mean, the idea -- and, again, these are regional level variables so it's not an individual patient basically based on the particular area they live. So it has that limitation.

But the idea is that patients that live in certain neighborhoods that, you know, have factors that would suggest there were higher indexes of deprivation, of financial deprivation, may face greater challenges at being able to remain active on the waitlist.

Member Chin: And, sorry, I mean, I raised my hand. I don't know if I can share my screen. We've used the ADI in a recent study. And if I can share my screen, at least I can show everybody the 17 factors that are in the ADI.

The ADI is just a score. But it's based on these 17 factors. So I'm going to try to -- can everybody see this?

Chair Dalrymple: Now we can see it. Thank you, Andy. And I think that is a really helpful table. Are you able to zoom in on your end by any chance just so people can read? So for example, household characteristics does include percent of households without a motor vehicle.

Member Chin: Yeah. This is from the CDC site. You know, this makes up the ADI score and so we've used it in a recent study. But, you know, I always forget what factors are in it. But these are the factors.

And, you know, kind of to answer the question, you know, race ethnicity is not part of it. But these are

the factors. These are kind of four main domains with a total of 17 factors that make up these domains.

Chair Garrick: Thanks, Andy.

Member Chin: Yeah. Okay. I'm going to try to unshare.

Chair Garrick: Lorien, did you have other questions for the developer that we haven't touched on?

Chair Dalrymple: I did not. And I think my only question for you, Renee, given that SMP commentary to our committee, is do you feel like we've sufficiently discussed what the committee's views are including social risk factors in some of these measures? The ADI and dual eligibility being the ones we've been asked to consider, do you feel like any further discussion on that topic is needed?

Chair Garrick: I guess I feel like we've reached the same lack of clear consensus as the TEP and the SMP did.

Chair Dalrymple: Maybe I could ask it differently. And I apologize for the noise in the background. Are any committee members uncomfortable with ADI or dual eligibility? I have not heard discomfort expressed.

Member Narva: Discomfort with using it or discomfort with the concept?

Chair Dalrymple: Discomfort with using it as an adjustment in this measure.

Member Narva: Yeah, I am. You know, I am --

Chair Dalrymple: Sorry?

Member Narva: I am very worried about, you know, adjusting away the causes for decreased access to care. And there seems to be a tension between making providers or dialysis facilities look bad

versus actually trying to address the root cause. And I don't think we can solve it this afternoon. But, you know, there's a tension there. And, you know, it would be intellectually honest to acknowledge it, I think.

Chair Garrick: I agree with you. And I think that is what we're all struggling with is we definitely don't want to do something to mask disparities. At the same time, I think the tension is because of our thought process around the fact that in the end what we're talking about today is an outcome measure on the work of nephrologists. But I absolutely agree with your comments that both you and Lorien and Alan and Andrew have said.

So to your question, Lorien, are we comfortable? I think we're understanding it. I don't think that we've reached a level of comfort. I think we've reached a level that we're all open in our conversation.

Member Kliger: Just briefly if I may, this is Alan. I think what we can say is that we share -- we understand -- again, Andy said that really well about the tension between adjusting for things that really do make an outcome difference versus not adjusting for things that we can do something about.

And I think what we can say is that we remain uncomfortable with the tension. I'm not sure where to land given the reality of that tension.

Chair Garrick: And thanks. And that's well said. And trying to stay on the topic, but the question ahead of us is voting on the validity of a measure before us.

And the SMP reached -- I think they were unable to reach consensus on validity. So I think our task ahead of us now is for us to either, if I'm getting this right, accept the SMP's consensus or agreeing to not -- is that right and then vote ourselves?

Chair Dalrymple: We will have to vote Renee.

Chair Garrick: Oh, we have to. Yeah, right, yes. They did reach a consensus.

Chair Dalrymple: (Simultaneous speaking.)

Chair Garrick: Yeah, thanks. I knew that, right? I got that wrong, yeah. So we have to reach our own consensus. Thank you. We have to have our own vote.

So if people are ready I guess we could have the vote if there aren't more comments or questions for the developer. And thanks, Lorien, I appreciate the guidance.

So, Gabby, I guess we could have the vote, the vote on reliability -- I'm sorry, on the validity of the active waitlist measure that is before us. And I greatly appreciate everyone's comments or input.

Ms. Farrell: Gabby, I think you're on mute.

Ms. Kyle-Lion: Can you guys hear me?

Chair Dalrymple: Now you're clear, Gabby.

Ms. Kyle-Lion: Okay. Sorry. I'll go ahead and open the poll. Okay? Voting is now open for Measure 3694 on validity. The options are A for high, B for moderate, C for low or D for insufficient. And I believe we're looking for 18 votes here.

We're currently at 15 votes. Okay. I think we're at 18 votes. So I'll go ahead and close the poll. Voting is now closed on Measure 3694 on validity. Just give me one second to pull up the results.

Okay. There were 0 votes for high, 7 votes for moderate, 9 votes for low and 2 votes for insufficient. Therefore, the measure fails on validity. I'll pass it back to you, Renee.

Chair Garrick: Thank you, everyone, for your input.

My understanding is that that's a must pass measure? So I think that would take us -- would end this discussion on this measure and move us to the next measure?

Ms. Farrell: Correct, yes. That is a must pass criteria. And since we are currently at 4:45 p.m. Eastern Time, we are going to adjourn the call for today, and we will keep our scheduled time for tomorrow.

You should have a calendar invite for tomorrow from 2:00 to 5:00 p.m. Eastern Time. And we will reconvene at that point to discuss the two additional measures that we didn't get to today.

So I would like to thank our standing committee, the measure developers and the project team for their work on the call today. And we look forward to discussing the next two measures with you tomorrow.

Ms. Bal: Paula, we still need to do public comment before we adjourn today.

Chair Garrick: Yes. Paula, do you want to open it for public comment?

Ms. Farrell: I think we're just pulling up the slides.

Chair Garrick: Okay. Thank you.

Ms. Farrell: Just give us one -- thank you, Renee.

Member Narva: Will today's meeting invite link work for tomorrow or?

Ms. Kyle-Lion: There is a different link for tomorrow, Andrew. If you need me to resend that to you, just let me know. I can send it to you directly.

Member Kliger: Can I ask that you resend it to everybody, please?

Ms. Kyle-Lion: Sure. Yup. I'll send an email with the

voting link and the link to log on tomorrow.

NQF Member and Public Comment

Ms. Farrell: Yeah. We can just give it a couple moments if anyone that is an NQF member or a member of the public, if they would like to have an opportunity to comment on today's discussion. They can do that. So we'll just take a moment for anyone who would like to put a comment into the chat or would like to raise their hand, and we can call on them.

Okay. And I do not see any hand raises or anything in the chat so we will go ahead and adjourn for today. And we will meet again tomorrow at 2:00 p.m. Eastern. Thank you, everyone.

Chair Dalrymple: Thank you, everyone.

Chair Garrick: Thank you, everyone.

Adjourn

(Whereupon, the above-entitled matter went off the record at 4:46 p.m.)