National Quality Forum
Renal Measure Evaluation
Web Meeting Fall 2022 Cycle
Friday, February 10, 2023

The Committee met via Video Teleconference, at 10:00 a.m. EST, Lorien Dalrymple and Renee Garrick, Co-Chairs, presiding.

Present:

Lorien Dalrymple, MD, MPH, Co-Chair
Renee Garrick, MD, Co-Chair
Andrew I-Wei Chin, MD, University of California, Davis Medical Center
Annabelle Chua, MD, Duke Department of Pediatrics
Gail Dewald, BS, RN, CNN, Gail Dewald & Associates LLC
Stuart Mark Greenstein, MD, Montefiore Medical Center
Lori Hartwell, Renal Support Network
Frederick Kaskel, MD, PhD, FAAP, FASN, Albert Einstein College of Medicine
Alan Kliger, MD, Yale School of Medicine
Mahesh Krishnan, MD, MPH, MBA, FASN, DaVita Venture Group
Karilynne Lenning, MHA, LBSW, Telligen
Andrew Narva, MD, FASN, National Institutes of Health
Jessie Pavlinac, MS, RDN-AP, CSR, LD, FNKF, FAND, Network 16
Jeffrey Silberzweig, MD, The Rogosin Institute
Michael Somers, MD, Boston Children's Hospital
Cher Thomas, RDH, Renal Support Network
Jennifer Vavrinchik, MSN, RN, CNN, National Dialysis Accreditation Commission
John Wagner, MD, MBA, NYC Health and Hospitals

NQF Staff:

Nicholas Barone, MPH, Analyst
Leah Chambers, MHA, Director
Elizabeth Freedman, MPH, Senior Director
Gabrielle Kyle-Lion, MPH, Manager
Matthew Pickering, PharmD, Managing Director
Isabella Rivero, BS, Associate

Also Present:

Kathy Lester, JD, MPH, Kidney Care Quality Alliance
Lisa McGonigal, MD, MPH, Kidney Care Quality Alliance
Vahakn Shahinian, MD, University of Michigan Kidney Epidemiology and Cost Center

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Proceedings

(10:01 p.m.)

Welcome and Review of Meeting Objectives

Ms. Chambers: Good morning. Welcome to our first Renal Measure Evaluation Web Meeting of 2023. My name is Leah Chambers, and I am the director supporting the Renal project. I'm excited to be here, look forward to the robust discussion we will have today.

Thank you for your time and participation as I understand that this is a significant amount of time and effort to review the measures and prepare for today's discussion. I would also like to thank our measure developers for being on the call today.

We recognize the significant time and effort that goes into the creation, testing and submission of a measure, and we want to highlight those efforts and thank you for this vital work. Lastly, I appreciate your continued patience and understanding as we meet virtually.

We understand the challenges that accompany virtual meetings; however, our team appreciates your understanding and thank you for your continued support and participation.

Next slide, please. At this time, I want to give the co-chairs for the Renal Committee, Dr. Lorien Dalrymple and Renee Garrick, a chance to provide some welcome remarks.

Co-Chair Dalrymple: Thank you, Leah. I'll start, and then Renee will join as well.

I just want to say good morning to everyone. Thank you all for joining today. We're looking forward to a robust discussion of the three measures in front of the Committee, and we really appreciate all of your time and expertise.

CO-CHAIR GARRICK RENEE: Hi, and this is Renee. I hope you can hear me. Okay. Thanks again, just to second what Lorien has already said, and a special thank you to all our patient members who are on the panel with us today. We look forward to a very thorough and robust conversation, so welcome to all.

Ms. Chambers: Thank you both.

I will now pass it over to Dr. Matthew Matt Pickering, who will share some NQF updates before we proceed to the housekeeping reminders and meeting agenda topics.

Matt?

Dr. Pickering: Thanks, Leah.

Good morning, everyone. As Leah mentioned, my name is Matt Pickering. I'm a managing director here within the Measurement Science and Application Department.

It's a pleasure to see everyone on the call today, and I just can't express my gratitude and thanks for this Committee's work leading up to the meeting, but also in the previous years we've worked together, as well as to the developers who will be or are on the call today to answer any questions Committee may have.

Before we proceed, I just have an announcement for everyone today. As you may know, NQF serves as a consensus-based entity that CMS funds and support measure review and endorsement. The CMS contract who serve as the consensus-based entity is set to end on March 26th of this year.

Therefore, CMS just completed a competitive process to award the next phase of work. As many of you may know, CMS announced as of this week that NQF was not awarded that contract, so our work will cease and wrap up on March 26th.

So NQF will be working with CMS and the successor contractor in the weeks ahead to make a smooth

transition, which will include further communication with you and our other committee volunteers.

But this does not change our focus today, and I'm looking forward to your review of the measures in front of us. We will continue to work through the measure evaluations proceedings accordingly as we are set out to do today, and we thank you for that.

I will also just say that many of you may have questions as to what I've just stated. Please kindly ask you refrain from direct Teamsing our NQF staff with any additional questions. We are unable to comment on those at this time.

So please just know that communications will be going out in the weeks ahead to all of our NQF volunteers, including you all, about the transition and any next steps with this process. But again, it doesn't change what we have to do today.

We look forward to reviewing the measures in front of us as we normally have before and using your great insight and expertise in these evaluations.

With that, thank you, and I'll turn it back to Leah to go through housekeeping items and the agenda.

Co-Chair Dalrymple: Thank you, Matt.

Next slide, please. Okay, I want to review a few housekeeping reminders. Most of you know we are using the Zoom platform to host this measure evaluation meeting today. I know there are inherent challenges we face using a virtual platform.

In the spirit of engagement and collaboration, I encourage everyone to turn on your video to see each other's faces and bridge some of those virtual gaps. If you need any technical help, please let us know. Our team is ready to assist you via chat or by emailing us directly at renal@qualityforum.org.

Next slide, please. If you are not actively speaking, we ask that you place yourself on mute to minimize

background noise and interruptions. To mute, click on the microphone at the bottom of your screen. To unmute, click on the mic again. There is also an action to chat with people directly.

We encourage everyone to use the chat box and raised hand features throughout today's meeting. NQF staff and co-chairs will monitor the discussions and highlight chat comments throughout our call. We also encourage using our raised hand feature. A raised hand icon appears in your video and the participants' panel. To raise your hand, please click on the participant list where you find and hover over your name, and the hand icon will appear. Clicking on the raised hand icon again twice will lower your hand.

Next slide, please. The same directions apply for phone users. The placement just may be a little bit different. Shortly, our managing director, again, Dr. Matthew Matt Pickering, will conduct roll calls and review disclosures of interest. It is important that you know that we are a voting body, and therefore need to establish a quorum to vote during our meeting today.

If you need to separate from the call, please notify the NQF team using the chat so that we can remain aware of attendance and quorum members throughout the meeting.

Introductions and Disclosures of Interest

Next slide, please. It is now my pleasure to introduce our project team. Again, my name is Leah Chambers, and I am the director of the project. Our senior director is Elizabeth Liz Freedman. Our manager is Gabrielle Kyle-Lion. Our project manager is Erica Brown. Our analyst is Nicholas Barone. And our associate is Isabella Rivero.

We also have our managing director, Dr. Matthew Matt Pickering, and our project consultants, Dr. Peter Amico and Poonam Bal, that can't make it in

attendance to today's call.

Next slide, please. I will briefly review today's agenda. We will begin by taking attendance and asking Committee members to state any disclosures of interest. After this, Gabrielle will provide overview of the evaluation and voting process. Isabella will then conduct a voting test. Poll Everywhere is the online platform we will use for voting.

You should have received an email from Poll Everywhere link this morning. The link has also been added to the meeting invite. If you cannot find the link in either place, please send us a Teams chat or email us directly.

After the voting test, Matt will briefly introduce our measures under review and then hand the discussion over to our co-chairs to facilitate the consideration of candidate measures. The Standing Committee will discuss each criterion and vote on each. The last vote will be an overall recommendation for endorsement of the measure.

Following discussion of all measures, we review related and competing measures for all measures that are recommended for endorsement today. We will then host an opportunity for NQF members and the public to voice their comments. We will conclude today's meeting and then adjourn.

Next slide, please. I will now hand it over to Dr. Matthew Pickering for introductions and disclosures of interest. Matt?

Dr. Pickering: Great. Thank you so much, Leah.

We can go to the next slide. Thank everyone again for your time today. Today, we'll combine the introductions with disclosures of interest. And so you received two disclosure of interest from us. One is our annual disclosure of interest, and the other is disclosure specific to measures we'll be reviewing this cycle.

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

And just a few reminders, you sit on this group as an individual. You do not represent the interest 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 disclosed does not mean that you have a conflict of interest. We do verbal disclosures in the spirit of openness and transparency. Now, we'll go around our virtual table starting with our committee chairs, and I'll call your name.

So then please state your name, what organization you are with and you have anything to disclose. If you do not have any disclosures, please just state that I have nothing to disclose to keep us moving along. If you experience trouble unmuting yourself, please raise your hand, and our staff can assist you with that.

Lorien, I'll start with you, and we'll proceed from there.

Co-Chair Dalrymple: Thank you, Matt.

Good morning. My name is Lorien Dalrymple. I serve as one of the co-chairs. I'm the head of Population Health and Medicine for Fresenius Medical Care. My disclosures are as follows. I'm employed by and have share options in Fresenius Medical Care.

My husband is a physician partner and has shares in the Permanente Medical Group. I have served on the KCQA Steering Committee, and Fresenius is a

member of KCP.

I have participated in technical expert panels and provided guidance on the development of quality measures. For today, I am recused from Measures 3722 and 3725. Thank you.

Dr. Pickering: Great, thank you. Lorien, and confirming, yes, recused on both 3722 and 3725. Thank you.

Renee Garrick?

CO-CHAIR GARRICK RENEE: I'm Renee Garrick. I'm a nephrologist in New York. I'm the chief medical officer and vice dean at New York Medical College in Westchester Medical Center. In terms of my disclosures, I am a practicing nephrologist and serve as the medical director for DCI dialysis in Hawthorne, New York.

I have served on TEPs for the NQF and have served in process of the Renal Physicians Association in the past for measure development. And in terms of today's measures, I have nothing to disclose.

Dr. Pickering: Thank you, Renee.

Andrew Chin?

Member Chin: Hello, good morning. I'm Andrew Chin. I'm the chief of nephrology at the University of California Davis Medical Center. I am a medical director for a DCI clinic. As it relates to the measures, I have nothing further to disclose.

Dr. Pickering: Thank you, Andrew.

Apologies if I mispronounce your names as I go through this. Please excuse me.

Annabelle, is it Chua?

Member Chua: Yes. I'm Annabelle Chua, one of the pediatric nephrologists at Duke. I'm medical director

of Pediatric Peritoneal Dialysis, our outpatient DaVita unit. But otherwise in regards to these measures, I have nothing else to disclose.

Dr. Pickering: Great, thank you so much.

Is it Rajesh Davda?

Rajesh?

Okay. Gail Dewald?

Member Dewald: Yes, I'm here. I'm Gail Dewald from San Antonio, Texas. I'm an independent nephrology nurse consultant, and I have no disclosures to make.

Dr. Pickering: Great, thank you.

Stuart Greenstein?

Member Greenstein: I'm Dr. Greenstein. I'm a transplant surgeon representing American Society of Transplant Surgeons, and I have no disclosures.

Dr. Pickering: Thank you so much.

James Guffey is inactive, but just checking if he is on the call. James Guffey?

Okay. Lori Hartwell?

Member Hartwell: Good morning, everyone. My name is Lori Hartwell. I'm the president founder of Renal Support Network. I've been a patient for, I can't even believe it, since I was two years old, which over half a decade. Measures are very, very important. I'm very sad to see that NQF was not awarded the contract. I need to say that.

Just to specify, I need to recuse myself from two measures, 3722 and 3725. I'm a member of Kidney Care Partners and participated in KCQAs. For that, I think I have no other disclosures.

Dr. Pickering: Thank you, Lori, and that is correct. Confirming the recusal on 3722 and 3725. Thank you

so much. And thank you so much for your time and participation as a patient representative on our committees.

Frederick Kaskel?

Member Kaskel: I am Rick Kaskel. I'm a pediatric nephrologist at Montefiore Children's Hospital at Albert Einstein, and I've enjoyed working with NQF over the last, probably, eight years or so. I have no conflicts and nothing to disclose. Thank you.

Dr. Pickering: Thank you, so much.

Myra Kleinpeter?

Or Myra, maybe? I apologize.

Okay. Alan Kliger, Kliger? Sorry.

Member Kliger: You got it right the second time, thank you.

Alan Kliger. I'm a nephrologist in New Haven, Connecticut. I'm a clinical professor of medicine at Yale. And regarding the measures we're looking at, I have no conflicts of interest.

Dr. Pickering: That is correct. Thank you so much, Alan.

Mahesh Krishnan?

Member Krishnan: Good morning. Mahesh Krishnan. I'm one of DaVita chief medical officers. Disclosures, chair elect of KCP. KCP was the funding entity for KCQA, although I myself do not participate in KCQA. DaVita's specific disclosures include salary and stock.

Dr. Pickering: Great. Thank you, Mahesh. Just confirming, Mahesh, if you were involved in the development of the measures?

Member Krishnan: No.

Dr. Pickering: Okay, thank you. Thank you so much.

Just in review as well based on our conflict of interest policy recusals, Mahesh would not be recused from 3722 or 3725 due to the lack of direct involvement with the development of the measures in any way. Thank you, Mahesh.

So then I have Karilynne Lenning?

Karilynne Lenning?

Okay. Precious McCowan?

Precious McCowan?

Okay. Andrew Narva?

Member Narva: Good morning. I spent my whole career in the public sector at Indian Health Service and NIH, and I'm currently seeing patients at Walter Reed. I have an adjunct appointment at Uniformed Services University of the Health Sciences, and I have nothing to disclose.

Dr. Pickering: Thank you so much, Andrew.

Jesse Pavlinac?

Member Pavlinac: Very good. Yes, you did fine.

Jesse Pavlinac. I'm a renal dietician. Retired, so I'm not seeing patients. I'm a member of the Network 16 Medical Review Board and board of directors, and I did serve on TEP for quality measures for assessing delay of progression of dialysis. I have nothing to disclose that directly affects these measures.

Dr. Pickering: Thank you so much, Jesse.

Jeffrey, I apologize about this, but Jeffrey Silberzweig?

Member Silberzweig: Silberzweig. Nice to be here today. I, too, wanted express my disappointment that NQF will not continue to have the contract for reviewing measures going forward. I think they've done a terrific job over the years.

I'm a nephrologist in New York City. I'm the chief medical officer at the Rogosin Institute where I'm employed. My wife works for Anthem Blue Cross Blue Shield. I have been a member of the Kidney Care Quality Alliance steering committee, so we'll recuse from Measures 3722 and 3725 today.

Dr. Pickering: Thank you so much, Jeffrey.

Michael Somers or Somers, excuse me.

Member Somers: Yes. Hi, I'm Michael Somers. I'm a pediatric nephrologist at Boston Children's Hospital. I've served on TEPs related to the role of quality measures, and I was a member of the KCQA steering committee as part of my role as president of the American Society of Pediatric Nephrology and my involvement with KCP. I am also recused from 3722 and 3725.

Dr. Pickering: Thank you so much. Just confirming that as well, as well as Jeffrey, I didn't confirm that. But, yes, Jeffrey and Michael also being recused from those two measures, 3722 and 3725. Thank you.

And Cher Thomas?

Member Thomas: Good morning. I'm Cher Thomas. I'm a patient advocate with Renal Support Network. I've been a patient living with kidney disease for 25 years now. I have nothing to disclose this morning, and I also happen to be a registered dental hygienist.

Dr. Pickering: Thank you, Cher. Had you been involved in the steering committee with KCQA at all in the development of Measures 3722 and 3725?

Member Thomas: No.

Dr. Pickering: No, okay. We'll just confirm with the team. That may be a --

Member Thomas: Absolutely. I know I had to recuse myself in the last go around, but I don't believe those were the measures.

Dr. Pickering: Okay. We'll circle back on that, too, Cher, but thank you very much.

Member Thomas: Okay.

Dr. Pickering: And then we have Jennifer Vavrinchik. Sorry, Jennifer, if you're on.

Member Vavrinchik: Jennifer Vavrinchik. Good morning, everyone. Retired nurse practitioner, currently owner and chief operating officer of National Dialysis Accreditation Commission, and I have nothing to disclose for these specific measures.

Dr. Pickering: Thank you so much, Jennifer.

I also have Roberta Wager?

Roberta?

Okay. And lastly, John Wagner.

Member Wagner: Good morning, everyone. I'm John Wagner. I'm a nephrologist in Brooklyn, New York. I have a position as the service line lead for New York City Health and Hospitals as well as a substitute medical officer at Kings County.

My academic (audio interference) I am an ad hoc member of the National Forum of ESRD Networks and medical review board member of ESRD Network 2. About ten years ago, I participated in a TEP that was look at metrics for the end stage seamless care organizations.

And my national forum had been a participant in a KCQA years ago. I was not part of that process, so I have no conflicts to announce for today's measures.

Dr. Pickering: Great. Thank you, John.

Again, thanks everyone as well.

Cher, the team is looking back into that, and we'll follow up before we get into the voting on measures to confirm any potential recusal, but thanks, Cher,

for your patience.

I will just state that it brings us to 21, so we needed to have -- at least for voting on the first measure without any of the recusals, that was the 3179 measure, we needed to have 15 members present, which we do, so we do have quorum.

To vote on the other two measures in which there were recusals, we needed to have at least 16 members, excluding those individuals that were recused, which we do have that for quorum for as well, so we will be able to proceed with voting.

However, if you need to step away at any point in time during today's meeting, please direct message one of the team members or drop it into the chat just so we can monitor attendance. Because, again, we have these recusals on these measures, which we're really being attentive to quorum so we can continue and close out voting today without doing offline voting. Please let us know if you need to step away at any time.

We do have breaks built our agenda today. We have three measures to review. So if we end early, we will do so accordingly. But if we need to use the full time, we do have breaks built in. But again, just please let us know if you're going to step away at any time.

But I at least want to say thank you and like to let to let you know if you do believe that you might have a conflict of interest at any time during the meeting as topics are discussed, please speak up. You may do so in real time during the meeting.

You may send a message via chat to our chairs or to anyone on the NQF staff. If you believe that a fellow community 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 the chairs or to NQF staff.

So before we proceed, does anyone have any

questions or anything they'd like to discuss based on what was disclosed today?

Lorien, you have your hand raised.

Co-Chair Dalrymple: Yes. Matt, it's actually a slightly different question. I was hoping we could review count of members present because at least there were several members who weren't here, so I wasn't sure how we got to 21. I think I had 17 for members. Could we just review the counts real quickly?

Dr. Pickering: No, you're correct. I'm sorry. I miscounted. It's 17. I apologize. It is 17. My fault. Too many tick marks on my end. I apologize. So it is 17. I'll go back to that. So we needed 15 to vote on the first measure, 3719. We do have that. And then with the recusals, we needed 16 members eligible to vote with the recusals, so we still are in good shape.

Any other -- oh, Alan, yes.

Member Kliger: I just wonder given how close we are to a voting quorum for the two measures where there are recusals if you might considering altering the order and doing those first?

Dr. Pickering: Great question, Alan. We do work with our developers to ensure that they are available for these discussions. Also, the members of the public are also paying attention and probably joining when certain measures are slated to be discussed.

So we probably don't want to make too many big changes with agendas at this point, but are there any concerns with folks possibly leaving towards the afternoon when we are going through those remaining two measures?

Okay. Well, thank you, Alan. If need be, we'll continue to monitor and see where we can ensure quorum is maintained. But for now, we'll proceed with the agenda as is. Again, just knowing that the developers are trying to attend during those times as

well as members of the public as well. But if need be, to try to monitor, or we can make some adjustments. Okay, any other questions or comments?

Okay, so as a reminder, NQF is a nonpartisan 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's all be mindful of how our language and opinions may be perceived by others.

So with that, I'll turn it back the team, and we'll go through the overview of the proceedings today.

Overview of Evaluation Process and Voting Process

Ms. Kyle-Lion: Thanks, Matt. We'll now transition to a brief overview of the evaluation analysis.

Your role as the Standing Committee is to act as a proxy for the NQF multistakeholder membership. As the Renal Standing Committee, you not only oversee the portfolio of renal measures, but you work collaboratively with NQF staff to provide recommendations for endorsement of measures based on our evaluation guidance.

You're also tasked to respond to comments that are submitted during our public commenting period. Today, you'll be asked to evaluate measures against each criterion and subsequently make recommendations according to your evaluation.

Next slide, please. We want to remind you that this is a shared space of interdisciplinary multistakeholder Standing Committee members. Every voice is important, and we want to emphasize that each Standing Committee member holds equal value on

this call and in the broader scope of the work.

As NQF staff, we do our due diligence to encourage Standing Committee members to adequately review the measure information prior to the evaluation meeting. 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 keep your comments concise and focused on the criteria at hand.

Next slide, please. This slide describes the process by which we will conduct today's measure discussion and evaluation. Each measure discussion will begin with a brief three to five-minute developer introduction.

Facilitation will then be led by the co-chair, and discussion will be stewarded by our assigned lead discussant and supporting discussants. Thank you again, discussants, for your leadership today.

The lead discussant will briefly explain information on the criterion, provide a brief summary of the measure evaluation comments, emphasize notable areas of concern and note the preliminary staff rating if needed.

Full Standing Committee discussion will then commence, followed by the criterion vote. The process will be repeated for the subsequent criteria. Developers will be available to respond to questions at the discretion of the Standing Committee.

Next slide, please. Measures are evaluated for their suitability based on standardized main and subcriteria in the order depicted on the screen. Importance to measure and report, which assess the extent to which measures are evidence-based and whether a variation exists where there is overall less than optimal performance.

Scientific acceptability of measure properties, which assesses a measure's reliability and validity.

Feasibility, which assesses the extent to which the specifications require data that are readily available or could be captured and implemented without undue burden.

Usability and use, which assesses the extent to which the measure is being used for both accountability and performance improvement to achieve the goal of high quality.

For the comparison of related and competing measures, only a measure that meets the above criteria and are compared to address harmonization for related measures and/or selection of the best measure for competing measures.

Of note, a competing measure's discussion will occur when measures are evaluated under the same cycle. If either a new or returning measure is judged as not passing for importance to measure and report, scientific acceptability of measure properties and use or maintenance measures, it cannot be recommended for endorsement and will not be evaluated against the remaining criteria. The reason is that these criteria are must pass.

Next slide, please. The breakdown of main endorsement criteria and subcriteria is listed here. Votes will be taken after the discussion of each criterion. Please make special note of the must pass nature of several of these criteria. If the measure progresses to the last criteria, the overall suitability of endorsement will be the last vote.

Next slide, please. NQF staff will provide a brief overview of the related and competing measures and will invite the stand committee to weigh in any further commentary. For the measures being reviewed this cycle, no best in class voting activity will during the related and competing section as none of the currently identified measures are competing.

It is important to reiterate that measures that fail on one of the must pass criteria will not proceed to additional discussion or voting on subsequent criteria. However, if consensus is not reached, discussion will continue to the next criterion, but a vote on overall suitability will be deferred.

Next slide, please. In order to conduct live voting today, the Standing Committee must achieve and maintain quorum, which is 66 percent attendance of the active foster of participants. With 22 active Standing Committee members, that equates to 15. The chart that you see on the screen displays the margins within which voting outcomes are indicated.

A measure that does not reach consensus will move forward to the draft draft report commenting period, and the Standing Committee will reconvene in the subsequent months to revote on that measure.

If a measure is not recommended for endorsement, it too will proceed to the draft reporting commenting period, but the difference here is the Standing Committee will not be called to revote on the measure unless the Standing Committee decides to reconsider their recommendation based on either a comment or comments from the draft report commenting period or a formal reconsideration request from the developer.

Next slide, please. As stated on the previous slide, 15 active Standing Committee participants must be present in order for the committee to vote during the call. We will also add that a baseline of 50 percent of active committee membership must be present in order for the call to be held.

This is where attendance plays a significant role. If at any point during the call you need to step away or you anticipate a change in your attendance status, please notify NQF staff verbally on the call or through the chat feature.

In the event that the attendance drops below voting

quorum, we will resume discussion respective to the measure at hand, but we will defer voting activity to an offline voting survey that will be sent to the Standing Committee after the call.

Next slide, please. Before we proceed to the voting test, I will pause here for questions on the evaluation process.

Voting Test

Okay, hearing none and seeing no hands on the call, I'll actually be doing our voting test, and I'll go ahead and get that pulled up for everyone.

If you want to just go to the next slide real quick, please. This is what voting via desktop or a laptop computer with your Poll Everywhere. If you click on the voting link that was emailed to you, you will see a wait message until voting begins.

When voting opens, you will see the screen below. Enter your first and last name, then click continue to access voting from the options that will appear on the screen. Please alert an NQF staff member if you are having difficulty with our electronic voting system.

I'll go ahead and pull up the test vote here.

Okay. We sent the voting link via email. If you do not have access to that link, please let us know and we will resend that link to you. As a reminder, this test vote is only for Standing Committee members. The question is would you rather receive 100 roses or 100 pieces of chocolate?

The options are A for 100 roses, and B for 100 pieces of chocolate. And as a reminder, for voting quorum we need 15 members to vote on this poll. We're at 11 right now. If anybody's having any issues, please go ahead and speak up or share your vote via chat if necessary, and we can try to figure out the technical stuff later.

Member Greenstein: Yes, I have the link open. I don't

know where it went, so I'm trying to find it.

Ms. Kyle-Lion: Okay, no problem, Stuart. Just take your time with that.

If you want to, you can also --

Member Hartwell: Who do I go to again? Can you just -- I'm trying to get the chat.

Ms. Kyle-Lion: You can send your vote to me, Lori, Gabby.

Dr. Greenstein, if you also want to send your vote to me via chat, we can do it that way for now as well, if needed.

We are 15. We are expecting 17 because there are some people on the call, so we'll just keep it open. Okay, we're at 16 with the direct -- I got a direct message, so we have 16 votes.

Okay, we're holding at 16, which is okay, that's above quorum. I'll go ahead and close the poll. But if you are having any issues voting, please feel free to reach out via chat, hand or via email, and we can try to get the voting done.

Okay, and I actually did out 17th vote via chat as well. Voting is now closed on our test vote of would you rather receive 100 roses or 100 pieces of chocolate, and with our chat votes, we had six votes for roses and 11 votes for chocolate. It seems like chocolate is the preferred treat for Valentine's Day in this group.

I will go ahead and pass it back to Matt now to proceed forward.

Measures Under Review

Dr. Pickering: Thank you.

For Stuart and Lori, we are going to follow up with emailing you the link again. Just make sure that you'll

have it at the top of your inbox so that we can get probably get you voting for the measures coming up.

We'll go to the next slide, please, talk about the measures under review today. We have three new measures for the standing committee's review today. NQF 3719, which is the prevalent standardized waitlist ratio measure. This is the CMS-stewarded measure, and the developer is University of Michigan-Kidney Epidemiology and Cost Center.

3722 and 3725, these are both developed -- the developer is KCQA or Kidney Care Quality Alliance. 3722 is the home dialysis rate measure, and 3725 is the home dialysis retention measure.

Next slide, please. As many of you are aware, NQF also had the Scientific Methods Panel, or SMP, which evaluates complex measures based on their reliability and validity testing. They also advise the Standing Committee on evaluating those components of complex measures, which the Standing Committee can take into consideration for their votes today of the measure that were viewed by the Scientific Methods Panel.

The SMP also advises NQF on potential updates to our criteria as well, and we take those into consideration. And for the purposes of today, if we go to the next slide, please. We had two measures that went to the SMP for review, 3722 and 3725. The measures passed SMP's review on reliability and validity.

So for those measures, you will be asked if you want to uphold the SMP's rating on those criteria. But again, if you do have major concerns or if you view that differently, you're able to disagree or not uphold the SMP vote and assign the -- the Committee can assign its own rating if there is any disagreement for those two measures.

Next slide, please. Okay, so before we proceed with our first measure, I just wanted to circle back with Cher as well. Cher, I think we confirmed or we got

some things sorted with recusals.

Member Thomas: Right.

Dr. Pickering: Just for the record, could we go back -- would you mind stating your name and affiliation and if you have anything to disclose?

Member Thomas: Of course.

Cher Thomas, Renal Support Network. I'm a patient advocate for the Renal Support Network, and I would like to recuse myself from 3722 and 3725.

Dr. Pickering: Great. Was that because you were involved with the steering committee or technical --

Member Thomas: Yes.

Dr. Pickering: Yes, great. Okay. Thank you so much, Cher, in confirming that's correct.

That still means we still do maintain quorum for voting on those two measures with those recusals in addition with Cher, so thank you as well as Cher for confirming that --

(Simultaneous speaking.)

Member Thomas: Sure.

Dr. Pickering: Before we proceed, are there any other Standing Committee members that may have joined late that were not recognized during the attendance roll call and disclosures of interest?

Member Hartwell: I would just like to specify Cher was not on the steering committee. It's really confusing. She was on one of the participant calls. I was on the steering committee, so it is a little confusing. It takes you a couple years to figure it out. So just wanted to specify that. I could look more into it if you want me to.

Dr. Pickering: Thank you, Lori. Hold up our recusal form.

Yes, Cher, you had mentioned that you're a member of the Validity Technical Expert Panel for these measures, so I believe as Lori as mentioned, that would be different than the steering committee, is that correct?

Member Thomas: That is true, yes.

Dr. Pickering: Great, thank you.

Member Thomas: Thank you, Lori.

Dr. Pickering: Thank you, Lori, and thank you, Cher.

That still means that you would be recused from that.

Member Thomas: Okay.

Dr. Pickering: Thank you, Cher, and thank you, Lori.

Member Thomas: Okay, thank you.

Thanks, Lori.

Consideration of Candidate Measures

Dr. Pickering: Okay, so let's proceed to our first candidate measure that we have in front of us today, which is 3719. This is the prevalent standardized waitlist ratio. This is a new measure. I just want to check in to see if a representative from UM-KECC is on the call?

Dr. Shahinian: Yes, this is Vahakn Shahinian. I'll be representing.

3719 Prevalent Standardized Waitlist Ratio (PSWR)

Dr. Pickering: Excellent. Thank you so much.

So this measure, or the PSWR, which is the Prevalent Standardized Waitlist Ratio measure, does track the number of prevalent dialysis patients in a practitioner group who are under the age of 75 and were listed on kidney or kidney-pancreas transplant waitlist or received a living donor transplant.

You can see the rest of the description there, which we'll be definitely going through. It is an outcome measure. It's a level of analysis at the clinician group practice level. The setting of care for this is the outpatient services, and it uses claims and registry data as well.

So how this will proceed, as you all know, we have the co-chair who will provide the developer three to five-minute opening remarks, and we kindly ask developers to keep it that time so that we can keep to our agenda.

And then our co-chairs will then give it to our lead discussant who will discuss the preliminary analysis, any issues from the pre-evaluation comments or any pre-evaluation survey from Standing Committee members as well as any questions that they have for the developer.

Then, we'll go to the discussants who will then provide any additional comments or questions or concerns, and then opening up to the rest of the Standing Committee.

The developers will only be recognized if the Standing Committee does have questions, but that will only happen after the Committee has discussed and laid out all of their concerns through that process.

Our co-chairs will capture those questions and then triage accordingly to the developer or to NQF with process questions that come from the discussion.

There may be some back and forth dialogue, but then ultimately we will move to vote on the criterion at hand.

With that, Lorien, I will turn it over to you to kick us off.

Co-Chair Dalrymple: Great. Thank you, Matt.

I think Matt's already given an excellent overview of the measure we're about to discuss, which is the

PSWR, so now I will hand it over to developers and provide an opportunity to give an overview of the measure. I will also invite Dr. Shahinian to consider speaking to the importance of the standardized waitlist ratio given other recent measures the Committee has evaluated as I think that could be important for context. Thank you.

Dr. Shahinian: Okay, thank you.

Thank you, everyone, good morning. This is Vahakn Shahinian from the University of Michigan Kidney Epidemiology Cost Center. I'm a professor of medicine at the University of Michigan, a transplant nephrologist, former medical director at the University of Michigan Kidney Transplant Program and health services researcher.

We'd like to thank the NQF staff and Rental Standing Committee members for consideration of the kidney transplant waitlisting measure being evaluated today. I'll start by discussing our overall rationale for the topic of the measure, provide a basic overview of the measure under consideration today, which is the prevalent standardized waitlist ratio and conclude by addressing some concerns raised in pre-meeting comments by Committee members.

So it's well-established that kidney transplantation provides the 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 waitlist, which itself represents a beneficial health status as it results from optimization of health and psychosocial issues required for transplant candidacy.

Nevertheless, waitlisting rates among the end stage kidney disease population on dialysis have been essentially stagnant for 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 waitlisted by three years following initiation of

dialysis.

Importantly, there are persistent socioeconomic disparities in who has access to the waitlist. Additionally, data provided as part of our NQF submission demonstrate wide variations in waitlisting across dialysis practitioner groups.

In recognition of an 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 the Kidney Care Choices Models.

Our proposed quality measure directed at dialysis practitioners will provide additional support and incentives to move the needle on improving waitlisting rates and helping to ensure equitable access to the opportunity for transplantation.

So turning to the measure under current consideration, the prevalent standardized waitlist ratio, or PSWR, access new waitlisting or living donor transplant events following dialysis initiation for the vast majority of patients who do not get pre-emptively waitlisted. And it's inclusive of the first year after dialysis initiation and beyond.

It uses a very similar evidence-based and conceptual framework as the percent of prevalent patients waitlisted, or PPPW, a measure previously recommended for endorsement by this committee.

In contrast to the PPPW, which focused predominantly on maintenance the waitlist, the PSWR focuses on timely attention to waitlisting of patients not already listed. This is crucial as patients' health may deteriorate, leading to missed opportunities for waitlist candidacy, and longer time on dialysis is associated with worse survival and poor outcomes following transplantation for those that do eventually receive a transplant.

We also wanted to briefly address a couple concerns raised in committee member pre-comments. One issue to note is that the measure is structured to assess performance of dialysis practitioner groups relative to the national average, rather than setting an absolute standard.

There's no expectation built into a measure that all patients in a practice should be waitlisted, which should allay concerns that not all conceivable reasons for patients to be turned down for waitlisting are included in the lists of exclusions or adjustments.

We took 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 waitlisting.

At higher levels of aggregation, such as the dialysis practitioner group, which include sizeable numbers of patients, the presence of large imbalances and waitlist disqualifying characteristics is very unlikely.

Finally, another concern expressed was that because transplant centers are the ones ultimately waitlisting patients the dialysis practitioner should not be held accountable for waitlisting. For our presentation of the PPPW, we previously articulated an analogy that helps 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 their coach, not the judges. The judges simply evaluate the performance.

In the context of transplant waitlisting, the patient is the athlete, the transplant centers are the judges, and the dialysis practitioners are the coaches. Transplant centers evaluate the patients that present

to them. And although there is some variation in criteria, all use the same fundamental judgment about patient candidacy.

Is the patient healthy enough and well-prepared to benefit from transplantation? And those are aspects that are predominantly under the control of dialysis practitioners, to help prepare patients for the evaluation, educating them, and providing medical and psychosocial support to optimize their chances of being deemed candidates for waitlisting. All of these are responsibilities of the multidisciplinary team codified in the CMS Conditions for Coverage.

Further recognizing that transplant centers can vary somewhat in their assessments, we do include adjustment for transplant center effects in the models for the measure. Ultimately, placing the accountability on dialysis practitioners ensures that credit is given to the tremendous work already being done by them towards optimizing the health of their patients and helping them get waitlisted.

I'll stop there. Thanks very much for considering our measure today.

Co-Chair Dalrymple: Thank you for that introduction and overview.

I think our lead discussant for today's measure is Andy. Would you like to start, Andy?

Member Narva: Sure. Can you hear me okay?

Co-Chair Dalrymple: Yes, perfect, thank you.

Member Narva: I'm going to try to avoid repetition. As we'd just explained, this is the prevalent standardized waitlist ratio, or PSWR, looks at the number of patients in a practitioner group who are under 75 and listed for kidney or kidney pancreas transplant or have received a living donor transplant.

It compares the observed events to expected numbers adjusted for age, comorbidities, previous

transplant, dual eligibility, ADI and transplant center variables. It's a new measure. It's an outcome measure. It's based on claims data and registry data. The level analysis is the dialysis practitioner group practice.

The rationale, as Dr. Shahinian mentioned, is that preparation for listing optimizes patient care, patient status, rather, a transplant is beneficial. And listing is affected by practitioner practice, including education, referral and assistance with completion.

The evidence and discussion is quite similar to that was presented for 3694 and 3695.

You want me to go into the evidence at this point?

Co-Chair Dalrymple: Andy, yes, I think we can move to the evidence discussion. And I agree given the Committee's familiarity with the literature, I would feel comfortable with a succinct overview, and then if Committee members want to discuss specific parts of the evidence, we certainly can. But I agree, we have discussed this evidence pretty significantly.

Member Narva: Yes, thank you for that concurrence.

So previously for the previous measures, there were two technical expert panels that were in favor of the development of measures that targeted waitlisting. There's a logic model that outlines the steps in transplant evaluation process and posits that being waitlisted is an outcome as it represents a desirable change in health status for patients on dialysis. And there's empirical support for the value of waitlisting and for the association between processes under dialysis practitioner control and waitlisting.

The developer has cited several studies that provide support for the association between processes under dialysis practitioner control and waitlisting, correlation analysis between ranking on referral ratios and waitlist rates in several studies on education and transplant.

The Committee comments on evidence. Several questioned, again, whether this is an outcome since listing is a process. However, the measure was generally accepted. It was generally accepted that the evidence supports the measure, including several studies on education and transplant.

There were some objections that listing is done by the transplant center and not through referring physician, and this is addressed by Dr. Shahinian, and that there's not adequate attention to the fact that not all patients are suitable for transplant or choose to undergo a transplant.

The preliminary rating was pass.

Co-Chair Dalrymple: Andy, just to clarify that, preliminary rating was the NQF staff preliminary rating, correct? Okay.

Was there any public comments related specifically to evidence that the Committee needs to hear a recap of?

Member Narva: Well, there was some comments from the, I think, KCP. There was nothing new there that I saw.

Co-Chair Dalrymple: Okay, thank you, Andy. Would you like to hand it to the support discussants for evidence or anything else from your perspective?

Member Narva: I have nothing further to offer.

Co-Chair Dalrymple: Okay, the supporting discussants for this measure are Cher Thomas, Andy Chin and Stuart Greenstein. Would any of you all like to add additional comments or perspective related to the evidence for this measure?

Member Thomas: I would like to just make a comment that it's probably not appropriate in the evidence, but I would certainly like to see some direction put towards maintaining active participants on the waitlist. What I'm saying is that we're focusing

on having a ratio, but there are lots of people that are inactive on the waitlist. I would just like to see more focus put on getting those people reactivated instead of making it just a larger number of eligible transplants. That's what I want to say.

Member Narva: I think that 3694 addressed active -- people who are active on the waitlist, and that was not endorsed in the last discussion.

Co-Chair Dalrymple: Correct. And, Andy, just to the point of clarification, the Committee only endorsed the measure that include inactive and active in the numerator, and the measure that focused on active.

But to your point, Cher, this one does include both inactive and active in the observed is my understanding.

Andy, is that your understanding this would be all waitlisting in the observed count?

(Simultaneous speaking.)

Co-Chair Dalrymple: We might need to ask, and I'm supposed to be taking notes, so I will. But when a new event was described, I don't think I saw anything that said the new event had to be an active waitlisting, for example. I think we're all presuming this is waitlisted active or inactive in the observed.

Member Thomas: Okay. If we could get some clarification, that would be helpful.

Co-Chair Dalrymple: Yes, Cher, I will take note so that after the Committee is done discussing, we can go back to the developer. Thank you, I will capture that.

Member Thomas: Thank you.

Member Chin: And I don't have anything additional to add.

Member Greenstein: I don't either. I think that it's

important from my point of view as a transplant surgeon, the first step is always getting the patients referred from the nephrologist that they see. I understand the comments about why isn't this being placed on the transplant programs, but the first step is you got to get patients to us. So if we can't get them to us, we can't even do a due diligence.

Co-Chair Dalrymple: Thank you both, Andy and Stuart.

I would like to open the discussion to the broader committee, specifically on evidence.

Michael, I do see your hand.

Member Somers: Yes, I just wanted to confirm from my view of that algorithm that to meet the evidence criteria, we just have to have data that demonstrates the relationship between the outcome and some structure or process, right?

Co-Chair Dalrymple: Correct.

Member Somers: It's a rather general and potentially not very high bar to pass to be evidence, correct?

Co-Chair Dalrymple: I agree with that interpretation, and I think, Andy, you referenced this. I will give the guidance you gave last time to the Committee.

NQF makes a determination with the measure developer what type of measure this is, and the decision is that this is an outcome measure. Michael, what you're highlighting is the algorithm is a pretty straight flow for an outcome measure. There's a simple question you ask yourself, and the answer is yes, then the measure passes.

Unless Matt or Leah, someone tell us differently, the evidence will be assessed as an outcome measure, and we should follow that algorithm with respect to that question.

I think, Matt, in the past, there's been debate as to

whether this should be an outcome, but we will review it as an outcome measure today, correct?

Dr. Pickering: Yes, that is correct. It's in front of us as an outcome measure.

Thanks, Lorien, as well as Michael for a great question.

Correct. As an outcome measure, we are looking for an empiric association to the outcome. Something that an intervention or a structure that the accountable entity can do to improve on that measured outcome. We want to see that as an empiric association through evidence that developer can provide.

If there is a lack of that empirical information, there is a way to grant exception to the evidence as well. So if the Committee feels that there's really not that strong empiric association that you're seeing from the evidence that's been presented, or even in the body of evidence that you may also know of but you still find there's value in having this measure and really there's no other measure that could be in existence, you can give an exception to the evidence.

I just want to make that known because we're talking about options here related to evidence assessments. There could be an exception. In order to do that, the Committee has to vote -- more than 60 percent of the active Committee voting need to vote insufficient, and then we can move to the question on whether or not you want to grant exceptions to that evidence.

However, if more than 60 percent of your votes do not go to insufficient, then we'll just assign whether it's -- excuse me, not insufficient. But if you do feel like that there isn't sufficient evidence, we'll go to the exception vote, excuse me.

I do also want to just let you know that there's also a judgment on whether or not there are unintended consequences, and if the benefits of this measure or

measuring this outcome outweigh any potential unintended consequences based on your knowledge and experience of evidence related to any practices or any types of structures that would be needed to achieve the outcome.

So if you know that there could potentially be a significant amount of unintended consequences as a relation to what's happening with the measured outcome, that's something to consider with evidence as well.

Again, when I mention the insufficient rating, sorry for any confusion there, if the Committee feels like there's insufficient evidence here, we can move to an exception to the evidence. But if you feel confident enough that the information in front of you is enough to give a rating of pass or no pass, you're able to do that as well.

Co-Chair Dalrymple: Thank you, Matt.

I'm looking for any other hands from the Committee before we move to vote on evidence. I will --

(Simultaneous speaking.)

Co-Chair Dalrymple: -- an opportunity to answer the question. I'm sorry, I heard a voice, and I see --

Member Hartwell: Lorien, hi. It's Lori Hartwell, and I'm on my iPad, and I'm very efficient at this at all.

I just wanted to specify. I have struggled with this. I'm just making a comment is that as somebody who has four kidney transplant, understanding the process and understanding how patients make choices, there are a ton of reasons why patients don't choose the transplant as had been noted.

But the biggest issue is the geographical area in financial concerns. So we're going to run into the same problems with physicians, although as a patient when somebody says, I can't talk to a dialysis facility.

So I do believe the physician is my advocate, period. I've always thought that. There's staff that turns over, but I pick my nephrologist. So it's a tough one because of just the geographic disparities. And we created a transplant dashboard that took all the STR (phonetic) website to help the patients be able to navigate this.

And I do agree with Cher. I just want to make a comment to the committee of as a patient, and Cher and I are the only patients on this call, it's really hard to keep track of all these measures and all the nuances, and it takes a lot of time.

But I did want to specify that. Transplant is very important right now. People are getting a three to four-month wait to get into a transplant center.

My only concern is we just need to make sure with transplant centers being so overloaded, and they are, please specify if I'm wrong, especially with managed care coming into the market, the network adequacy is so horrific for some patients in whatever insurance managed care one day and go into UCLA. The next one, you're going to Cedars.

That's a whole other issue, but how do you -- I mean, it's an important issue. I just wanted to bring those issues to light because it is important that the doctor talk to the patient about transplant, period. Now, how that's measured is another story.

Member Thomas: I'd like to also jump in, if I could, just to add onto what Lori said because obviously she and I both being patients, she and I both being transplant recipients. I've had my transplant now for almost 24 years. I am eternally grateful for what the transplant community has done for me.

But for 20 years, I have driven five hours to go to my transplant care for follow up. Thank goodness during COVID, I was able to do some telehealth visits, which helped remove some of the financial constraints that I was incurring, but COVID is now getting lighter.

Like Lori said, people are having to wait three months to get into a facility, and this is all a result of fewer and fewer healthcare providers available, and I see that this could be a potential problem in that people are going to even have to wait longer.

In my situation, I actually tried to move my care to Houston. I've been getting my care in Dallas all this time. I've tried to move it to Houston where I could be closer. And because I'm so far out, that wasn't an option for me. So even if a patient wants to make another choice, it might not be an option to them, and it will add another barrier. It's just something that should be considered. Thank you.

Co-Chair Dalrymple: Thank you, Cher.

Alan, I know your hand is up. Would you like to go next?

Member Kliger: Thanks.

I'd just like to again raise the question about patient choice. The denominator here does not exclude patients who clearly tell us that they do not want to be considered for transplant patient.

Everybody should be educated, obviously. Everybody should have access to a transplant center evaluation. There are more than a small number of patients who say, that's simply a choice I do not choose to follow.

So I'm concerned that a measure that gives the rate in this fashion will pressure care teams and patients to refer to a waiting list when the patient clearly says, I have absolutely no interest in going on the waiting list.

It seems to me it's really important to honor patients and their choices in this process. Let me just also just quickly say both patients just now talked about the problem of the clogged pipeline, and that with transplant centers being so busy and evaluations taking so long in some geographies, that a push to

get more and more evaluations done, particularly if they're for patients who choose not to be evaluated, might cripple the system.

Those are just some potential unintended consequences.

Co-Chair Dalrymple: Thank you, Alan.

Jeff, I see your hand up?

Member Silberzweig: Thanks, Lorien.

I just wanted to make a couple points based on what Alan just said. One is that I've heard some concerns from patient groups particularly that in the face of the COVID pandemic, there may be some patients who are afraid to get listed because they're concerned that further immunosuppression may in fact worsen their outcomes if they developed COVID. That's one point that I think needs to be further studies.

The second point is I do worry about negative consequences that this measure could have in terms of that it may prompt more physicians to refer patients for listing, as Alan said, patients who are not interested or for whatever other reason may not be candidates so that it may clog the system further for those patients who are candidates for transplant.

Co-Chair Dalrymple: Thank you, Jeff. I do not see any additional hands. Oh, I heard a voice, so maybe, Renee, you'd like to say something?

CO-CHAIR GARRICK RENEE: Lorien, I apologize to the group for having technical problems. I can't seem to get the hand raise function, for some reason, to work. But I just wanted to thank Lori and Cher for their comment since they reiterated this concern about the problems of waitlisting, and they're really quite real because the transplant centers are very congested at the moment.

And to have that be a marker for the quality of the

care being rendered by the nephrologist is, again, quite complicated because those are elements that are completely out of the control. And this issue, by the way, of the impact of managed care and accountable (audio interference) Medicare Advantage Plans has really added to that.

Again, I think that has to factor in our overall discussion when we get there. I apologize. They're trying to fix my computer, so sorry.

Co-Chair Dalrymple: Thank you, Renee.

I don't see any other hands -- oh, I see one now. Stuart, would you like to go next?

Member Greenstein: Yes.

I personally think that's two separate issues. Yes, the transplant programs can get overwhelmed, but again if the patient doesn't get to the transplant program, they're not going to get on the list. Let the transplant programs then deal with the overwhelming aspect of it afterwards.

That's a separate issue. I agree 100 percent that that's what going to happen. And the fact about patients refusing, so those should be excluded from this measure as one of the exclusions.

If a patient specifically says, I don't want to consider transplantation, then the nephrologist should not be dinged for. I agree 100 percent. But again, there are plenty of patients who don't show up or not told to show up for many, many years, and that's wrong.

Co-Chair Dalrymple: Thank you, Stuart.

I am not seeing other hands at this time, and we do have two more steps to take before we get to voting.

One, Matt, I want to give you an opportunity to provide a synopsis of public comment before we get too far into voting. And then, two, I would like to go to the developer just to clarify the question posed by

Cher that I took note of.

So, Matt, would you like to share a public comment before I go to the developer? Because then we will move to vote, unless I see hands.

Dr. Pickering: Great. Thanks, Lorien.

Just to add onto what Andrew had mentioned about the public comment from Kidney Care Partners not adding anything new. I'll just summarize just for the record as well that we didn't receive a public comment on this measure from Kidney Care Partners.

We did a public comment on this measure from Kidney Care Partners. It was non-supportive. There are three areas that the comment focused on with concerns with this measure.

One was attribution, recognizing the comments objects to attributing the successful and unsuccessful placement on transplant waitlist to individual clinician or group practices and believes that's a fatal structural flaw.

The KCP does mention the KCQA has developed dialysis facility level transplant access measure sets, which pairs referral rate metric in a measure assessing the waitlisting rates specifically among those patients who were referred by a facility within the preceding three years.

It further attests that because KCQA waitlist measure denominator is limited to those patients specifically intended as appropriate transplant candidates and deliberately referred by a dialysis facility within a defined time period, facilities have considerably more agency over the measure than less precise metrics like the PSWR, the measure in front of us today.

The other areas of concern were the variation in transplant center eligibility criteria. They note that the criteria indicating a patient as not eligible for

transplant patient can differ by geographic location.

And the degree to which some of these differences influence waitlist placement must be accounted for in the model for this measure to be a valid representation of waitlisting. So that's more of a concern with testing, validity testing.

And then the last area of concern with measure reliability. The KCP raises concern that the overall reliability was 0.56 is questionable, and adding that the reliability statistic was not stratified by facility size, so very difficult to discern how well the reliability scores look like across various different practice sizes.

So that's really coming into play with reliability. And like I mentioned, the variation concern was really coming into play with validity. I just wanted to touch on those comments. I'll just also remind the group that as you go to vote, I know there's been a lot of discussion about patient choice and things of that nature.

Keep in mind that the vote really is getting at is their evidence really showing there's an association, there's structure or process that can improve the outcome being measured.

So the questions around some of the accounting for attribution or accounting for things like patient choice really start getting into areas where you're questioning whether the measure is truly valid.

So evidence is really assessing is there evidence here to show that something can be done to improve on this metric by the accountable entity. Just wanted to add that as well.

Sorry, Lorien, I've taken up a lot of air time there, but handing it back to you.

Co-Chair Dalrymple: Thank you very much, Matt.

And Karilynne, I see your hand.

Member Lenning: I'm so sorry.

This is Karilynne Lenning, and I did just join the meeting. I had an appointment, so I was told that as soon as I joined, I did need to disclose, so I wanted to do that before we got into the voting. So I do need to disclose that I work for an organization called Telligen, which is a subcontractor with CMS and CMMI on the Kidney Care Choices model.

Co-Chair Dalrymple: Thank you, Karilynne, and we appreciate you letting us know and going through your disclosures. I don't believe you're recused from any of the measures, is that correct? I see staff nodding their head.

Dr. Pickering: That's correct.

Co-Chair Dalrymple: Thank you.

Mahesh, I see your hand.

Member Krishnan: Just had a point of clarification just based on the last comment.

I don't think we're debating whether or not we should try to improve transplant waitlisting. I guess the question we're really debating is, per the last comment, is how much can the nephrologist influence the actual waitlisting versus the transplant center.

I know we've talked about coach and the athlete model. And maybe for the measure developer, a question. Would it be reasonable to have the same measure apply to both coach and athlete, and that would actually allow us to harmonize these two issues that have been raised or not?

Co-Chair Dalrymple: Yes. Mahesh, we are about to move to questions for the developer, so I will go ahead and let them answer your question first, and then I will pose Cher's question.

Dr. Shahinian, would you like to answer Mahesh's

question, and I'll pose Cher's.

Dr. Shahinian: Sure.

In our analogy, the athlete is the patient, and the judges are the dialysis practitioners. So by including a fairly robust set of comorbidities in the adjustment, in effect we're adjusting for patient level factors. And we feel a lot of the remaining predominant accountability sits with the dialysis practitioner.

And as we mentioned, we do recognize that there's some variability across transplant centers in their judging, but we do include an adjustment for a couple transplant center factors that we think are particularly relevant.

Member Krishnan: So maybe to extend your analogy, then. Coach, judges, governing body. You're saying the transplant centers are the governing body. Are you saying that you believe the adjustment you're doing statistically is adequate for assuming that the transplant centers are also aligned for the waitlisting criteria? Or we will be better served to have the same metric for transplant center practitioners as well as dialysis practitioners?

Dr. Shahinian: To me, I think the issue of whether transplant centers should have some kind of quality measure attached to them. We think that's a distinct question. We think that this measure is reasonable and appropriate because dialysis practitioners hold such an important component of this.

The reasoning behind our analogy is the fact that -- the transplant centers mostly are doing is evaluating what comes to them. They're not capriciously deciding who's a candidate or not. It's not about them. It's about who presents to them. And we --

(Simultaneous speaking.)

Member Krishnan: Who's referred to them, right? Like, who is referred to them?

Dr. Shahinian: Yes. Well, referred, but also in what health state and what state of preparation. So it's not simply referral.

Member Krishnan: I see. So your intent with this is not just to encourage referral, but also to ensure that the dialysis practitioners do as much as work as possible to ensure that the patients are well-suited? Because that's what the transplant center or the governing body will use to make the decision.

Dr. Shahinian: Right.

Member Krishnan: Okay, that's an interesting interpretation. Thank you.

Co-Chair Dalrymple: Dr. Shahinian, I'm going to ask Cher's question, and then there are two other hands up, and I don't know if those are questions for you or for the Committee, so let us finish this loop, and then we may come back to you.

Cher's question, specifically. Does the observed count of, I think what you described as new events, included both a new active or inactive waitlisting? Would both of those count as an event as long as it was new?

Dr. Shahinian: Correct. They both count. We additionally living donor transplant events as well in this for the unusual cases where people essentially go directly to that without a significant period of waitlisting.

Co-Chair Dalrymple: Okay, thank you. Maybe stay on camera because maybe additional questions.

Renee, I saw your hand first and then Lori's.

CO-CHAIR GARRICK RENEE: Thanks. I'm hope I'm off mute.

My question is raised to the developer. Stuart Greenstein and the others have mentioned the patient's choice should be included in this measure,

and I think that that was touched on as well just now by yourself. I don't see that anywhere as an exclusion criteria for patients that don't want a transplant. Is that --

Co-Chair Dalrymple: Renee, I'm going to ask that we defer that to validity. I do think we are crossing over into validity discussions in evidence, so can we hold that question, Renee? I will note it because I captured it for Alan as well. When we get to validity, we will address that with the developer.

Lori, I see your hand is down, but did you have a question for evidence or do you want to wait for future --

(Pause.)

Co-Chair Dalrymple: Okay. I see John's hand. I will say we are close to wrapping up on evidence just because I'm watching time. So if anyone has comments, I will ask you to make it brief.

John, you're up next.

And you're muted, John, so we're not able to hear you.

Member Wagner: Sorry about that. Hear me now? Yes, good, okay.

How do unintended consequences get factored into the evidence discussion? I understand we're crossing into validity and reliability questions, but how should we factor in unintended consequences?

Co-Chair Dalrymple: Matt, I'm going to let you respond to that for NQF. Go ahead.

Dr. Pickering: Yes. Obviously, we want to ensure that there is evidence to support the measure. But if the Committee feels that there's evidence of potential unintended consequences that have not really been considered within this measure submission based on how the measure is structured and the outcome

that's being achieved, that is up for Committee's consideration.

We want to ensure that obviously these measures are not going to cause any unintended consequences. That does come into play in the evidence discussion. It also comes into play in usability when the measure is being used.

But factoring that in to say how the measure is structured, its intent of what it's trying to capture and measure, achieving that, will that lead to any potential unintended consequences, especially from your knowledge of evidence that is out there in existence. And then you can discuss and factor that into your consideration for a measure.

Co-Chair Dalrymple: Given Matt invited additional discussion, I will allow the Committee if they have any comments based on that clarification. I'm looking for hands.

Dr. Shahinian, I do see your hand, and we will give you an opportunity to speak before we go to vote, but I need to let the Committee finish their discussion first.

I don't see hands from the Committee. Dr. Shahinian, I would respectfully ask brief comments as well before moving to voting.

Dr. Shahinian: Sure. It's mostly a bit of a question back relevant to the unintended consequences because I am a little concerned that there's been a discussion of unintended consequences relating to patient choice and things like that. I appreciate that that's a validity concern. We agree.

But there's been a lot of discussion about that. And given that there's a -- what we're hearing is that people may take into account unintended consequences. I'm wondering whether we should be tackling that if people are taking into account things like whether or not patient choice is there as an

exclusion as an unintended consequences in their evidence vote.

Co-Chair Dalrymple: Matt, I think I'm going to let you provide counsel to the Committee.

Dr. Pickering: Yes.

If the Committee is feeling like there is concern related to any potential unintended consequences related to the evidence, it should be discussed just because we do want to be able to provide a rationale as to -- if the Committee votes the measure down or does not pass on evidence, we do have to have a rationale as to why.

Again, keeping in mind that there is evidence to show, there are interventions that can be put into place to improve on this outcome. Does that outweigh or are the benefits of that outweighing any potential harm? Is there enough evidence that exists around the harm that the Committee can fall back on and justify?

Some of these concerns around patient choice, as we discussed, and potential concern are more of the validity discussion and included it in the validity as it could be potentially biasing the measure. But in this case, is there evidence out there as well that point in the other direction? Showing that it could be harmful to this type of intervention through (audio interference) this type of outcome.

So just keeping that in mind as a way to open up discussion if there is because we do want to ensure that there is some rationale to explain if the Committee voted a certain way or not.

If there is evidence here to show that the outcome can be improved, empirical associations established that are well, and there's not really any known unintended consequences from that, then I think the Committee can take that to consideration and vote the way they choose to, or you feel there's not

enough association for you to actually pass the measure.

Some of that discussion would be helpful just so that we can clearly understand if there are concerns and Committee votes a certain way, we'll be able to have the rationale to support that.

Co-Chair Dalrymple: Yes, so what I might try to do here, Matt, to address that and the developer's concern is Andy Narva.

I'll bring it back to you as lead discussant and ask a very specific question. Are you aware of any evidence in this area that would suggest harm that should be considered?

Member Narva: I am not. Actually, I was about to make a comment because maybe I've lived a very sheltered existence, but I can't think of any patients who have been listed for transplant against their will.

I think actually it's incumbent upon -- because it's such a preferable treatment modality that it's imperative that providers be very enthusiastic and supportive and proactive in getting people listed.

But given that what's involved in getting listed, including a psychiatric evaluation, I can't imagine how anyone could get through that process and get listed if they actually were not willing or interested in being transplanted.

So I just can't imagine that, but there are people here who have wider and deeper experience than I do in transplant.

Co-Chair Dalrymple: Thank you, Andy.

Alan and Cher, I see your hands, but I would like, because this is going back through rediscussion, to give the original support discussants an opportunity. So, Cher, that will be you, and it will also be Andy and Stuart. I'm sure since your hand is up as a supporting discussant, I'll let you go next, please,

and then Andy and Stuart a few comments.

Member Thomas: I would like to add that with the Renal Support Network, one of my responsibilities is interacting with patients and listening to what they have to say.

And we have a regular participant at Support Group right now that was until recently listed for a transplant, and she had been offered a transplant four times in a row, declining it every time because she was literally scared to death. Scared to death.

They ended up taking her off the list. She's the prime example of how somebody who gets on the list might not have been put there in the first place. And mentally, she's not ready for it. And depending upon on where a patient is on their life stage and whether or not they're going through a divorce, things come up. Things change. And it is something that is not always easy to predict.

Co-Chair Dalrymple: Thank you, Cher.

Andy and Stuart, and then it will go to Alan.

If you have anything to add, Andy and Stuart. I just want to, since we're rediscussing this.

Member Narva: I don't --

Co-Chair Dalrymple: Sorry, it went Andy Chin. My apologies to Andy.

Member Chin: So sorry.

I do think a lot of this will kind of come up in validity. I think if the discussion at this moment with evidence is on unintended consequences, which is kind of where I think we're at right now. I agree with Dr. Greenstein that this is sort of a separate issue than the overload for a transplant provider.

However, it can affect the patients that are actually good transplant candidates and delaying their work

sometimes several months back if there is. There are more patients being sent in for potential evaluation.

I know a lot of transplant centers have initial screening questions or criteria that automatically make them not candidates, and it dissuades providers from referring them if the patient meets certain exclusion criteria for the transplant center. But even that, I have seen it myself that patients get referred.

We do sort of know that they're not a great transplant candidate. And four months later, they get the denial letter. But I always think, well, what other patients were actually delayed because of this person being referred?

And our efforts to truly try to do our best job of getting everybody who -- even a potential transplant candidate in. I just want to point out observationally that, again, I think I'm sort of getting into validity, so I'll maybe make my comment a little later on.

Co-Chair Dalrymple: Thank you, Andy.

Stuart then Alan. Again, Stuart, just if you have something to add before we go to vote.

Member Greenstein: I think the issues have been addressed. In terms of the patient that was four times called and turned it down, patients don't get listed unless they actively say they want a transplant. We don't get any buy-in by putting a patient on a list who's not going to transplant.

But patients do get scared once they are active, and that is their choice. And, yes, after four times if they still seem like they don't want it, programs do take patients off the list. It does slow the whole process down.

Co-Chair Dalrymple: Okay.

Alan, you will be our last comment before we go to vote on evidence. Thank you.

Member Kliger: Very quickly. Other than validity, the question does need to be raised of unintended harm. Andy's right that there are few patients who get listed who don't want to be listed. That's because there is no pressure on clinicians to get enough patients on the list so that they fall within the usual instead of being called out.

I'm concerned of the potential unintended consequence of clinicians referring patients and then getting patients listed who are clearly unwilling or unable to get a transplant. You're right. The transplant center will find that out and will sort that out, but the patient has to go through that process when they've said they just don't want a transplant. That is the potential harm.

Co-Chair Dalrymple: Matt, the developer has their hand up. I'm going to defer to NQF staff if we take one more comment from the developer because I do feel we need to vote on evidence, unless NQF staff disagrees.

Dr. Pickering: It may be worthwhile just one last comment from the developer, but I'll just, again, hear that. There definitely could be concerns about unintended harm, but what we're also considering here is evidence to support that.

So there are also concerns about unintended harm that could come into usability criterion as the measure is being used. Here, we're trying to also consider, yes, there's evidence to show that there's something that can prove the outcome, but do you know of evidence that you can justify the other direction?

If there is harm. If there is a potential harm, that means -- potential means if the measure is used, so that is coming into play around usability. So here, we're trying to say that is there evidence that's currently existing that you know and is not currently listed in here that's pointing in the other direction around obviously some harm?

Some of the Committee members had said they're not aware of any. I just wanted to make that known. Patient choice, things like that, validity considerations that we'll get into. And potential harm if the measure is used, that comes into the usability criterion.

In the evidence piece, if you know there's evidence that's showing the other direction, that something that can happen that's harmful because there's evidence to show that, that's where we wanted to have that discussion. But from what I'm hearing from some of the members, they don't know of any.

I just wanted to raise that just to remind the group about what we're really trying to assess here with evidence when you're thinking about any potential harm over benefit. So we want to say there's evidence there to show that there's harm. Potential harm if the measure is out there is not use and usability, and we'll go into those discussions later on if the measure proceeds.

Member Kliger: Thank you, Matt. I believe that helps to clarify it. Thank you.

Dr. Pickering: Well, thank you. I know that evidence is a very important criterion, and I know there's a lot of discussion that goes into evidence, a lot of things to consider. I just wanted to clarify that because a lot of really great points in discussion.

I just want to make sure that the Committee is going to focus on what really we're asking. And so just keeping that mind, is there evidence to show that there's harm versus if you feel that this could potentially lead harm. It's about the measure being used, and that comes through use and usability later on.

Co-Chair Dalrymple: Matt, what I would ask of the NQF staff is can you please pull up the algorithm for evidence because there'll be one question that the Committee is asked to answer.

And while you're doing that, Dr. Shahinian, I'll give you an opportunity for one final comment before we vote on evidence.

Dr. Shahinian: Thank you, and I'll be very brief.

I just wanted to re-emphasize at this juncture that what we have as the overwhelming empirical evidence is that people who can benefit from transplant are not getting to the waitlist. Overwhelmingly, that is the current concern. I think these concerns about coercion, I think at this point, are mostly theoretical.

There isn't a very large body of evidence that suggests this is a commonplace thing. What is clear is that overwhelmingly, there are many people who could benefit from transplant that aren't making it to waitlisting. I'll stop there. Thank you.

Co-Chair Dalrymple: Thank you.

We don't see the algorithm up yet, Matt. Is it possible, Gabby or others, for us to at least put up the voting algorithm for evidence?

Because, Michael, you alluded to this earlier, but it can be helpful for us all to be looking at the same thing. And then I would propose that we move to vote on evidence.

Dr. Pickering: Yes, we'll pull up the algorithm. So sorry, here we go.

Lorien, was there something you specifically wanted to draw attention to in the algorithm or just have it screen-shared?

Co-Chair Dalrymple: I think it can be helpful just to screen-share, but just to point out that the answer to Question 1 is, yes, that is not a question that we as a committee decide; that is decided by NQF staff and developers. This is an outcome.

So the second question for the steering committee

does the steering committee that the relationship between the measured outcome and at least one healthcare action, structure, process, intervention or service is demonstrated by empirical data?

If the answer to that is yes, then you would vote to pass. And if the answer for a committee member was to be no, then that would be no pass. But this is what we are now voting on. I just want to make that clear because I do think as Matt summarized, the discussion at times was focused more on validity and use and usability. So for this vote, I would ask that we vote only on the evidence using the NQF criteria.

So with that, Gabby or who will be assisting today with the voting process.

Mr. Barone: Hi, Lorien. That will be me now. My name is Nicholas.

Co-Chair Dalrymple: Great, Nicholas, thank you.

(Simultaneous speaking.)

Mr. Barone: Yes. I'll walk through the voting going forward now.

Before we proceed, if anyone has any difficulties voting moving forward, just please reach out to me via the chat, and I can help you with that. But for now, we'll move into the voting for the evidence here, so I'm going to go ahead and share my screen.

Okay. Let me just look for it here. I think it's that one. Okay. All righty. Can everybody see the screen?

Dr. Pickering: Yes.

Mr. Barone: Okay. All right.

All righty. Voting is now open for Measure 3719 on evidence. The options are A for pass and B for no pass. We are looking for 18 votes this time.

Dr. Pickering: Anybody having difficulty voting? It

looks like we've got 15. Looking for 18. Again, you're using the same Poll Everywhere link we used previously, so we got 16. Looking for two more. There's 17. One more. Anyone having difficulty?

Member Krishnan: Was your previous job in auctioneering? You're doing a good job.

(Laughter.)

Dr. Pickering: Thanks.

Member Chua: I think I got logged out.

Dr. Pickering: Who is that, I'm sorry?

Member Chua: It's Annabelle Chua. I got logged out. I'll just send it to you.

Dr. Pickering: Okay, yes. You can direct message me. I'll drop it in for the team.

Annabelle, were you able to send your vote to me?

Member Chua: Yes.

Mr. Barone: Yes, Matt, I was able to get it.

Dr. Pickering: Oh, you got it. Okay, great.

Mr. Barone: All right, I'm going to go ahead and lock the poll now.

All right, so it looks like we got 17 votes for pass and one vote for do not pass here. Therefore, the measure passes on evidence.

Co-Chair Dalrymple: Thank you, Nicholas.

So we will now move on to discuss the next criterion. We will go in the same order as before where Andy Narva will lead the discussion, and then Andy Chin, Stuart and Cher will support that discussion.

Our next criteria for discussion is performance gap.

Member Narva: Okay.

The PSWR performance was evaluated for all groups with more than 11 patients, and at least two expected events. The mean value is 103 percent. Interquartile was 63 percent. And disparities were demonstrated between races and sexes. The Committee comments in general supported that a gap in care exists and disparities exist. That was true even from members of the committee who don't accept the way the measure was actually described. The preliminary rating from the NQF staff was moderate.

Co-Chair Dalrymple: And then, Cher, Andy, Stuart, I would just offer you all the opportunity to add any additional information.

Member Chin: Let me just also under performance in terms of disparities. I find it interesting that disparities read like the survival ESRD. I don't know how the developers felt if there were disparities or not.

This to me really represents the survival on dialysis for race and ethnicity, so I don't know the presented data on disparities, whether it was to show that there disparities or simply that this reflects the best survival on the ESRD. And I was just going to have maybe the developers comment on that.

Co-Chair Dalrymple: Great, Andy. I'll take that question. So after the Committee discussions, we'll go to the developer, but I think you are asking for clarification on how they interpret the finding with respect to disparities.

I'll just take this opportunity to add my question to your question which is there's also some striking differences between means and medians and other factors that we could probably get additional thoughts from them on how they had hoped the Committee would interpret that data. So we'll take that question to them after committee discussion.

Cher, would you like to go next as one of the

discussants?

Member Thomas: I would, thank you.

I just want to state as a patient that really I don't even know that we can begin to cover all of the disparities and then close it. There are just so many things, even like I said, on paper as a patient, you might look perfect, and then a life event happened.

A spouse died. A divorce. A loss of job. And there's just so many things that are economic, emotional that I just -- honestly, I can't see this measure taking everything into account. I agree with creating this ratio on its premise.

I just see lots of problems in the mixture, in the recipe and putting everything in there. I think that this is something that we have to be very, very, very careful that we aren't clogging the system with people who have all the best intentions of getting a transplant. But whenever it comes right down to it, are clogging the system on an already overburdened healthcare system? Especially within transplantation.

Co-Chair Dalrymple: Okay, Cher. So as I interpret your questions, I heard questions both about risk adjustment and exclusion. I think I will take those notes for our validity discussion, if that's acceptable to you.

Member Thomas: It is.

Co-Chair Dalrymple: We will take those back to the developer once we reach validity on both those topics.

Member Thomas: Okay, thank you very much.

Co-Chair Dalrymple: Thank you.

Stuart? Anything to add before we go to the broader committee on performance gap?

Member Greenstein: Let's face it. There's no measure

that's going to be perfect, and I think that if we try to make a perfect measure, we're going to have more imperfections. I hear what everybody's saying. The measure from my point of view is whether or not the patient gets referred and will go to a transplant program.

If there is a gap in terms of what patients are getting referred based upon race, and that goes into the whole socioeconomic differences that we all know about in this country. So I think, yes, you have to admit there is a gap. How we're going to correct it? That's a different discussion, I think.

Co-Chair Dalrymple: Okay, Stuart, so I hear you saying there's both a gap, and as we know from the Committee, there's also consideration of disparities which you feel they've also demonstrated through the data.

Member Greenstein: Yes.

Co-Chair Dalrymple: And I know, Andy Chin, we're going to give the developer another opportunity to walk us through their disparities data, but that's my recap of your perspective, Stuart.

I'd like to offer up for the rest of the Standing Committee discussion of performance gap and disparities before we ask measure developers additional questions on gap.

I am not seeing any hands.

Renee will -- Leah, if I'm missing hands, but I don't currently see hands. So I think I'd actually like to take this opportunity to ask the developer to walk us through the data. I think in particular as it relates to disparities, for example, I invite you to perhaps walk us through Table 2.

And, Andy Chin, would that help with some of the questions you raised? I know that's the table I was hoping for a lot more clarity on. So Dr. Shahinian,

would you be able to walk us through Table 2?

And you may be muted, and we can't see your camera yet.

Dr. Shahinian: Yes. Hi, everyone.

Couple of things in terms of what we were trying to do. Obviously, number one, we were trying to show that overall that there is a substantial variability over practitioner groups in terms of performance on this measure, and that's kind of indicated in Table 1 with respect to looking at the deciles of performance.

Going from the lowest to the highest decile, there's a very large variation if you, for example, look at the median values go from PSWR of 0.31 up to a PSWR of almost 2.0 going from the lowest to the highest decile of performance. So there are substantial differences in performance as a function of practitioner groups overall.

The other thing we wanted to show, obviously, was relating to various groups. And we presented on race, ethnicity and sex. There's a couple things we're trying to show if you kind of think about Table 2 versus Figure 1.

What we're looking in Figure 1 relates to looking at are those performance gaps also existent within the strata of the various characteristics. Are we seeing performance gaps within strata of sex, ethnicity and race? And we certainly do see that.

And then separately within Table 2 if we look at the medians, we see disparities in terms of the achieved performance considering each strata kind of on its own. So not necessarily comparing different practitioner groups to each other, but just looking at performance within strata. And so there are disparities evident by sex and race.

Co-Chair Dalrymple: Dr. Shahinian, what I hear you saying, and I think at least when I was reviewing this,

I wanted to understand better from your perspective, is you're asking the Committee to focus on the medians. Because when you look at the means, there's clearly something very different happening that may lead to discordant conclusions about disparities, correct?

Dr. Shahinian: I agree. I think the median makes the point the clearest.

Co-Chair Dalrymple: Okay.

Andy Chin, have we gotten at what was underlying your question, or do you have additional follow-up questions for Dr. Shahinian?

Member Chin: Maybe I'm kind of getting confused when I don't look at this table but look on the worksheets, the percents that were given for race and ethnicity and how that truly translates into this table.

Am I just misinterpreting when I look at in the worksheet under disparities, the percent waitlist is obviously quite different for different race and ethnicities. How do we interpret this percent as opposed to the what looks like we should focus on on Table 2, which is the median. Maybe it's just my ignorance and I have a disconnect there.

Dr. Shahinian: Sorry, I'm just trying to orient myself to specifically what piece you are asking about.

Member Chin: Oh, well --

(Simultaneous speaking.)

Dr. Shahinian: Not at the table, but something else?

Member Chin: Right. It's in the worksheet that we were provided, Page 8 of our worksheet.

I don't know, Lorien, if you're able to pull that up and just help me understand. Because the data is going to come out as the PSWR, and I want to look at those

actual numbers and see how that actually translates into the Table 2 that you presented.

Yes, that's it.

Co-Chair Dalrymple: Yes, I think I just found it as well.

Dr. Shahinian, I think this is SMRs (phonetic) being read out as percentages perhaps? So instead of 4.37, it's being read at 437 percent?

Dr. Shahinian: Yes.

Co-Chair Dalrymple: Andy, like you, I tend to convert this back to the ratio. It's something that I think a lot of us think about ratios as one, two, three, four. So this is essentially the ratios being written using the percent --

(Simultaneous speaking.)

Dr. Shahinian: That's right. That is right. Yes, I think honestly the best numbers to look at to make the point would be Table 2 medians. I think that is the clearest.

Co-Chair Dalrymple: And I think the problem is those were likely coming from the means, right, Dr. Shahinian?

Dr. Shahinian: Yes.

Co-Chair Dalrymple: Because I saw numbers like 437. So I do think the means lead to different conclusions than the medians, which makes this table very difficult when we're trying to think about disparities. So it's helpful, I think, for us as a committee to understand which part the developers thought lended itself to the most invalid inference.

Member Chin: Yes. I guess my question then is if we kind of go back to kind of what we see on the ratio or the percentage, is there a disparity based on the characteristic of those on dialysis that potentially

could get waitlisted? That's what I'm trying to understand between the table and the ratios presented here on the worksheets.

Dr. Shahinian: I would say based on the median values, there are disparities.

Co-Chair Dalrymple: I think the NQF staff has the sheet, if we could go to Table 2. Thank you so much.

So for example, the PSWR is lower in people who are, if we look at medians, who are black, Asian-Pacific Islander, Native American or Alaska Native are classified as other. Also, the median is lower in those who identify as Hispanic and in it looks to be males, although I'm not sure how significant that difference is going to be. I'd have to look at some overlapping intervals. Is that how you are asking us to interpret it, Dr. Shahinian?

Dr. Shahinian: Yes.

Co-Chair Dalrymple: I think we will talk more about this once we get to reliability and validity, so I won't bring in this discussion now. But median's a zero, as you can imagine, are kind of challenging for the Committee, at least for me, because the performance is so shockingly -- so sometimes it's easier for us when it's 0.3 or 0.4 versus 1, but I think you're asking us to recognize that the median value is quite low when you stratify and look at groups. And so your conclusion that disparities do exist based on race, ethnicity and gender. Is that correct?

Dr. Shahinian: I agree.

Co-Chair Dalrymple: Does the Committee have other questions before we move to a discussion or voting, I should say, on performance gap?

I do not see any hands, so I would propose we move to vote if, Nicholas, you can assist us with that.

Mr. Barone: Thank you, Lorien.

We'll now move to vote on performance gap. I'm going to go ahead and share my screen.

Okay, can everybody see the screen?

Co-Chair Dalrymple: Yes, thank you.

Mr. Barone: Okay. Voting is now open for Measure 3719 on performance gap. The options are A for high, B for moderate, C for low or D for insufficient. I believe we are looking for 18 votes again.

Dr. Pickering: That's correct.

Annabelle, were you able to get back into the Poll Everywhere link?

Annabelle, did you hear me okay?

Co-Chair Dalrymple: Annabelle, you might be muted. I think they just want to confirm you're able to vote.

Member Chua: Sorry. I could not even get to my Zoom screen.

Yes, I was, thank you.

Dr. Pickering: Great.

Member Chua: My computer is threatening to reboot, and I'm trying to keep it from rebooting.

Dr. Pickering: Is that 18?

Mr. Barone: Yes, it looks like we're now at 18 votes, okay.

Sorry, I'm just looking for the pause screen-share button.

And then we'll get the counts there. It looks like we got two votes for high, 14 for moderate, 2 for low and then zero for insufficient.

Co-Chair Dalrymple: Thank you, Nicholas. We will proceed with our discussion. We are going to move

to scientific -- right, unless --

(Simultaneous speaking.)

Dr. Pickering: Yes, sorry, Lorien. We just have to capture it for the record. As Nicholas was reading, it was at 2 votes for high, 14 for moderate, 2 for low and zero for insufficient. Therefore with 16 votes for passing votes, the measure does pass on performance gap.

Co-Chair Dalrymple: My apologies, Matt.

Dr. Pickering: No worries.

Co-Chair Dalrymple: We're trying to stay on schedule. We're falling a little bit behind, but we will stay efficient.

So we're going to move to scientific acceptability. We'll first discuss reliability. And so same as before, Andy Narva, can you lead the discussion of reliability, please.

Member Narva: Sure. The numerator is described as the number of prevalent dialysis patients in the practice group waitlisted or receiving a living transplant within the year.

The denominator is the expected number of waitlist or living transplant events in patients less than 75, adjusted for age, comorbidities, previous transplant, dual eligibility, ADI, which is Area Deprivation Index, and transplant center characteristics, which reflects the variation in cut offs that various transplant centers use. That's how I understand it.

The exclusions in the denominator, in addition to age over 75, include admitted to a skilled nursing facility, in hospice, or with dementia. Reliability testing showed an IUR of 0.56, reflecting that 56 percent of the variation can be attributed to between practice groups differences, which is consistent with moderate reliability.

The Committee comments were in general agreement with the assessment of the NQF staff. There was one issue with whether infants less than 10 kilograms should also be excluded. I can't comment on that. I don't know how significant an issue that is.

The preliminary rating by the NQF staff was moderate.

Co-Chair Dalrymple: Thank you, Andy.

And I think, again, unless the NQF staff directs us differently, we'll probably move the pediatric exclusions to a validity discussion, I believe, and Matt's nodding. So, I'll add that as a question for validity.

So, I'd like to invite Andy Chin to share, and Stuart to add, any additional comments, if they have them.

Member Chin: I don't have any additional comment.

Member Greenstein: I don't have any additional comments, either.

Member Thomas: Thank you. I do not.

Co-Chair Dalrymple: Okay. Well, I do have a question for the discussants, and we may have to defer this to the developer. But we are trying to adhere to this process where, first, the Committee has their discussion before we move to the developer.

I was trying to understand the numerator counts. And what I mean by that is, I believe this is a three-year measure. You can have a patient who moves across physician groups in those three years. Do we understand how these events work?

And what I mean by that is, is this a new event or an existing event? Do you all have an understanding of how we're doing the counting in the numerator, if that makes sense?

And I'll just pick a patient who switches from group A to group B in year one, stays in group B year two, and then, goes to group C in year three, and is actually listed by group A -- I know this is getting difficult, but just bear with me -- is listed when they're still with group A.

Do we, as a Committee, have a strong understanding of how the counting works in that scenario? I, personally, struggled to be competent about how events were being counted as people moved and how they related to the timing of the event.

So, in other words, is it a durable event or a one-time event when you're with this group? And if so, what happens, then, to all the other groups that care for you?

And I think if other Committee members are struggling with this question now, we probably would bump it to the developers pretty quickly, because our discussion, you know, I think is going to be dependent on making sure we really understand how the numerator, and what I mean by the denominator, how they expect it as being calculated if you've already had the event and can't have the event again.

So, Dr. Shahinian and I can make up another example. Or if you thought that one was a reasonable one, you can go with that one. But can you kind of help us just walk through how numerators get attributed over the three-year period? Assume the groups are moving, and assume that the waitlisting event happens early in that three-year period. Like maybe that's a good starting point for us.

Dr. Shahinian: So, this is structured like a time to event. So, at any given time, people at risk are kind of included in the denominator. So, the denominator at risk is just people over any given period, when looking at it, that are not currently waitlisted. So, once people are waitlisted, they are not kind of part of this evaluation, essentially.

So, this is just looking at one-off events, although people can contribute time if they've previously been waitlisted, come off the waitlist, and are not on the waitlist during the period of evaluation.

Co-Chair Dalrymple: So, I think in the scenario I made up, group A is going to have an observed waitlisting event, because the patient is newly waitlisted while under group A's care. By the time that individual moves to group B or group C, they are no longer in the denominator, nor are they counted in the numerator. They're, essentially, removed from the whole pool.

Dr. Shahinian: Correct. Yes, you're really only at risk for this -- you know, you're in the denominator at risk if you're not currently waitlisted. So, this measure focuses on, essentially, new events only.

Co-Chair Dalrymple: And I may be crossing into validity, which I am really going to try not to do, but I just want to make sure how counting works. And I see Alan laughing. I mean, we do try really hard, but it's tough.

Does that mean, if I have really high waitlisting rates, that over time I can't perform -- well, I'll just say, I'm a provider group with an average waitlisting rate of 45 to 50 percent. Are all of those patients coming out of the denominator, and really all who's left at risk are a very, I'll call them, potentially, a different case mix, which you're now trying to handle through adjustment measures? Is that what's happening; that I have a very high waitlisting rate, so therefore, may have subsequent low event rates?

Dr. Shahinian: I mean, I appreciate that concern. I mean, you're right --

Co-Chair Dalrymple: Well, I just want to make sure. Is that how this works?

Dr. Shahinian: Yes.

Co-Chair Dalrymple: Okay. Is that fair, that that's how it works, that you keep people in your pool?

Dr. Shahinian: Yes, but, I mean, the measure is calculated. I mean, it's calculated -- you know, there's three years, but it's calculated kind of on stacking each individual year. So, the comorbidities for a given period of time are assessed in the prior kind of six months. So, the population does get kind of, essentially, reset or readjusted for as you go.

So there is that adjustment happening.

Co-Chair Dalrymple: Okay.

Member Greenstein: So, does that mean if a patient removes himself from the list, and then comes back (audio interference) if he changes the nephrologist, he's going to be a new event for somebody else?

Dr. Shahinian: Yes, he could be, correct. I mean --

Co-Chair Dalrymple: Oh, wait. I think I want to follow up on that. If they're on the waitlist and change to a new nephrologist, that new nephrologist cannot have any attribution to the event?

Dr. Shahinian: That is correct.

Co-Chair Dalrymple: You might have been asking about someone who's been removed from the waitlist, and then, goes on it. If they're removed, then when they get put back on, that's a new event? Was that the question you --

Dr. Shahinian: Yes, that's what I understood.

Co-Chair Dalrymple: Okay.

And, Andy Chin?

Member Chin: Yes, thanks.

I'll ask another question along those lines because this measure also includes the rare event that, if the individual received a living donor transplant -- so, it's

sort of on the same scenario that Lorien provided. If a patient receives a transplant with group A, and then, moves to group B, that also falls off the books, if you will, once the attributable nephrology group is no longer caring for that individual?

Dr. Shahinian: Yes, this is directed at patients who are on dialysis. These are dialysis practitioner groups. So, certainly, if they were to get a transplant, they would not be here anymore. So, the group that helped them do that would get the credit, and then, they would no longer kind of be part of this evaluation.

Member Chin: Okay. But if the patient remains with that group through the three years, then that patient just remains counted for that group if they got transplanted on year one? Or are they taken off the books completely once they get a transplant?

Dr. Shahinian: They're taken off the books. I mean, over the evaluation period, once it happens, they've got the credit, and it's one and done.

Member Chin: One and done? Okay.

Dr. Shahinian: I mean, the only exception to that would be whatever -- they somehow return to the waitlist over the evaluation period, get re-waitlisted. That could potentially happen.

Member Chin: Got it. Thank you.

Co-Chair Dalrymple: And I'm sorry, I didn't see the order, but I believe it was Renee next, followed by John, followed by Cher.

Co-Chair Garrick: Thanks.

So, I confess to being confused. Can we go back to the question that Lorien raised? If the patient, again, is in group A and gets waitlisted, and moves to, then, provider group B, and they've already been waitlisted by A, does A continue to get the credit for that waitlisting? Is it by patient month or does -- what

happens? Even though they're no longer caring for the patient, are they in the pool and counted since they're on the waitlist? Is patient A's wait assessed and do they count patient months, since the patient (audio interference) group A for the patient, even though they're not caring for them anymore?

Dr. Shahinian: This is a one-time event. So, it's not an ongoing thing. So, unlike, for example, the PPPW, which looks at waitlist status month over month, this is just over the period. In a group of people who are not already waitlisted, did they get it? So, it would go into that numerator once, as appropriate, over the evaluation period.

Co-Chair Garrick: Over a three-year period?

Dr. Shahinian: Yes.

Co-Chair Garrick: So, my other question which I think might be more -- I don't want to wander out into validity. So, I'll just hold my other question.

So, it's a one-and-done. That also does raise the question, which, again, might be more validity, that if you are a practitioner that waitlists a lot of patients, and you have preemptive patients waiting -- or patients who come into your facility who are waitlisted early on, and you have 45 percent of your patient population is waitlisted, you don't have much room for improvement. Because what's left in your denominator is maybe a patient population that's not a great candidate for waitlisting or doesn't choose one. I'm trying to decide if that's a reliability question, a validity question. And I'll let you --

Co-Chair Dalrymple: I think it's validity, Renee. And I'm the one who made that error. I'm going to look at Matt to see if he agrees. I think that is going to be a validity.

Co-Chair Garrick: Okay.

Co-Chair Dalrymple: We're struggling, and I think we

really want to understand the numerator and denominator in reliability. So, we're asking these questions just to make sure we understand numerator/denominator. But I agree with you, Renee, I think we have to bring that question back at validity, unless it's us trying to understand how counting works or what's in the numerator and what's in the denominator.

Dr. Pickering: Yes, that's exactly it, Lorien. And this is Matt again.

So, part of reliability is looking at the specifications to make sure they're clear and precise. And part of that is understanding how the measure is constructed, right? So, understanding how it's constructed is part of validity -- or excuse me -- reliability questions. But if there are concerns around including certain patients or not including certain patients, like exclusions, that's starting to get into the validity.

So, if you have concerns related to whether or not or how a patient is being attributed, or if patients are excluded, the concerns there should be more applied to validity. But if you have concerns that the specifications are not clear, and you're just trying to understand those specifications, that's part of reliability we can discuss. I just wanted to make that distinction.

So, concerns around inclusion/exclusion, or how a patient is attributed, is more getting into the validity, and reliability around specifications is like, are these clear; can you really understand, and are the specifications precise? So, it's a good conversation and discussion to ensure that you understand the construction of the measure. But any concerns with patients being included or things like that is more validity.

Co-Chair Garrick: Thank you very much. Very clarifying.

Co-Chair Dalrymple: And I still see three hands up. So, I'm going to assume these are reliability-related questions. And I think, at least on my queue, it shows it's John, then Cher, then Michael.

So, John?

Member Wagner: Yes, thanks.

I guess I have two questions. One is, the exclusion of 11 patients or less, does that apply to 11 patients who are on dialysis assigned to the practice or 11 patients who are waitlisted in the practice?

And also, I guess the other question that just occurred to me is: if a patient is preemptively transplanted, does the dialysis physician get credit for that patient the moment they go on dialysis because they now have a waitlisted dialysis patient?

Dr. Shahinian: Should I address that?

Co-Chair Dalrymple: Yes, please, Dr. Shahinian. Yes, I think straight to you.

Dr. Shahinian: So, just to start with the last point first, I mean, this measure is focused on the vast majority of patients that don't get preemptively waitlisted. So, you know, it's only including patients who've already started dialysis and are not already waitlisted. And the exclusion is for 11 patients, total dialysis patients, at risk in the denominator or two expected waitlist events. So, either a small number of expected waitlisted events or just a small number of patients in the denominator at risk.

Co-Chair Dalrymple: And Cher?

Member Thomas: So, I'm unclear. If it's mostly dialysis patients, are preemptive patients included the ratio or not?

Dr. Shahinian: They are not.

Co-Chair Dalrymple: And Michael?

Member Somers: I guess I'm just trying to read the numerator and denominator statement to make sure that I understand the context of what we've now discussed. So, you know, my understanding of the numerator was the number of prevalent dialysis patients in a group that had been listed or received a living donor transplant in the calendar year being considered. Now, is that correct? Is that really what --

Co-Chair Dalrymple: Michael, can you restate that one more time? Because at least there was one part that threw me off. Can you say that again?

Member Somers: Well, I thought that what the numerator said was that in the numerator was the number of prevalent dialysis patients who had been listed or who had received a living donor transplant in the calendar year under consideration.

Co-Chair Dalrymple: That is how I understood it. We'll ask Dr. Shahinian if we're interpreting it wrong.

But I think, Michael, at least for me -- and I don't know if this helps you -- it's, you know, we thought about so many of these measures in patient months. This is very different. It is not patient months. It's an event. So, it has to be like a new event in that calendar year.

So, I start the year -- and again, if we get this wrong, we'll ask the developer; you know, we will definitely come back to you. But you start the calendar year. You can't have been preemptively waitlisted or previously waitlisted. You're actually out of the denominator. So, you are not waitlisted. You're a prevalent patient in that practice. And to get a count in the numerator, you have to have a new event of waitlisting or living donor kidney transplantation.

Member Somers: So, does that mean you actually have to be on dialysis? What I don't understand is that calendar year, right? Because like, say, you start dialysis in March, but you were preemptively listed in

January. It's still the calendar year, but we don't look at anyone --

Co-Chair Dalrymple: Your exclusion, yes --

Member Somers: -- unless they're already on dialysis, right.

Co-Chair Dalrymple: Already on dialysis, not waitlisted; none of the other exclusions -- you know, age, nursing homes, hospital --

Member Somers: Right. Yes, yes. Yes, yes, yes, yes.

Co-Chair Dalrymple: And then, you have to have an event in that timeframe.

Member Somers: All right. Okay. Thank you so much.

Co-Chair Dalrymple: And, Lori, you had a question?

Member Hartwell: I did.

I'm curious, if people who are getting -- or if it was a physician, and the ideal is preemptive transplant. Everybody hopes for that. So, would that incentivize not to preemptively transplant -- I don't want to be on the dark side -- but in a practice? So, I just wanted to ask the developer that, if they gave any thought to that.

Co-Chair Dalrymple: And, Lori, if I could, could I take that question down and us discuss that in validity? Because I think it's a concern about exclusions and who is getting excluded or not getting excluded.

Member Hartwell: Okay. Sure. That would be great.

I'm sorry, I think a note to everybody is that, you know, Cher and I and other patients, we try to live in this data world and we live in the patient mindset. So, I appreciate everybody's patience, and it can be sometimes challenging because we're off into thinking about things, and it may not fit the right discussion.

Co-Chair Dalrymple: Yes, Lori, I think we all struggle, quite honestly. Everyone on the Committee is trying to find the right time to talk about really critical points. And I do think the preemptive discussion is critical, but for the reliability, we'll need to vote on it.

There is no reliability issue that has not been addressed to my knowledge, before we move to vote, that I would like to ask about.

The Developer, did you look at smaller physician practices? I think many of us noticed this reliability is sitting kind of on the cusp. And so, whenever we see reliability numbers like that, we can become concerned. Well, what if you're a small physician practice; is the reliability much lower? Do you all have data to provide us on how reliability is a function of physician practice size? And how many groups are we talking about that are smaller in size?

Dr. Shahinian: So, I mean, we did not look at reliability. I mean, it would be expected to be lower. That's just the way the calculation works.

And, you know, we do have the exclusion for very small practices or practices that are expected to have low waitlist events.

Co-Chair Dalrymple: Okay. I think we will be moving to vote.

Would the NQF staff like to provide any guidance before we move to vote on reliability?

Dr. Pickering: Thank, Lorien.

I'll just restate again, so any concerns you had about including certain patients or excluding certain patients, or things like that, please that's more validity. Whereas, we're looking at, are the specifications clear and precise, and the testing. So, the testing, as it was reported out as a score level, and we had discussions just now about the testing results. So, you can make your vote accordingly on

that.

But, again, how the vote categories work: if you have enough information available to you, you assign a voting category of high, moderate, low. The insufficient is available to you if you feel that there is not enough information for you to actually assign a vote. That is also available as well.

And I will say, we're running behind schedule, as we were going to be breaking at 12:30. We're going to keep going to continue this measure. But if we could try to continue through the discussions a little bit quickly? The next measure developer for the next measure we have up, they have a hard stop at two o'clock. At least one of the presenters has a hard stop at 2:00. So, we wanted to see if could try to get to that measure discussion in a timely fashion.

So, thanks, everyone. We'll vote on reliability.

Mr. Barone: Thank you, Matt.

Okay. We'll go ahead and vote on reliability now. I'm going to go ahead and share my screen.

Okay. Voting is now open for Measure 3719 on reliability. The options are: A for high, B for moderate, C for low, or D for insufficient.

And then, I believe we are looking for 18 votes again for this one.

It looks like we're already up to 14 votes, 15 votes. We're looking for 18 votes here. One more vote.

And we're up to 18 votes. We'll go ahead and close this.

It looks like we got zero votes for high; 14 votes for moderate; 3 votes for low, and 1 vote for insufficient. This one passes on reliability.

I'm going to go ahead and pass it back to Lorien now.

Co-Chair Dalrymple: Thank you.

So, we will move on to our discussion of validity. And as has been mentioned, we will try to be concise in this discussion.

And so, if, Andy, you can start please?

Member Narva: Sure.

The validity of this measure was tested by evaluating the association between the practitioner group performance and subsequent mortality and overall transplant rates among the patients attributed to that group.

The hypothesis tested was that, for higher PSWR scores, transplant rates would be higher and mortality would be lower.

The developer tested the relationship between tertile groups and practitioner group level outcomes. The dialysis practitioner group level average mortality was 17.7, 17.5, and 18.1 deaths per 100 patient years for each of the three tertiles.

The average transplant rate was 4.7, 3.8, and 2.6 transplants per 100 patient years for each of the three tertiles.

So, PSWR did correlate with the higher transplant rates and with mortality as expected by the developer, though it was not statistically significant.

The measure's exclusions did not significantly change the scores.

Risk adjustment, the model had 24 variables. The expected probability for events for each patient was based, though, on age, comorbidities, previous transplant, dual eligibility, ADI-6. And sex rates and ethnicity were not included because they could reinforce disparities.

So, this was discussed at length in the spring -- or

let's see, it is the spring -- in the fall, or last time we discussed this, whenever it was, of last year. And it was clear that doing that would just reinforce existing trends.

The meaningful differences between groups: 4 percent of dialysis practitioner group practices had a PWSR that was better than expected with a mean score of 2.19; 94 percent of practitioner groups were as expected with a PWSR of .93, and 2 percent had a PWSR that was worse than expected of 0.18.

Expected physician groups, on average, had observed waitlist and living donor transplant rates, or PWSR, more than double that of expected, while worse-than-expected dialysis practitioner groups had rates there were less than one-fifth of what was expected. So, I think there weren't large groups of providers that were either above or below, but those groups' differences were significant.

The Committee's comments on validity were, in general, that transplant was associated with listing and inversely associated with mortality. Some issues were raised with the measure, and again, that physicians aren't necessarily responsible for listing, or the practitioner groups aren't responsible for listing.

Threats to validity were discussed. The exclusions were felt to be appropriate. Once again, there was a question whether ADI and dual eligibility should be included in the adjustment. Missing data was not addressed.

The preliminary rating by the NQF staff was moderate.

Co-Chair Dalrymple: Thank you, Andy.

Additional comments from the additional discussants?

Cher, Andy, and Stuart.

Member Chin: Yes, I'll just add to that excellent summary that, you know, the introduction by the developer suggests that this measure, the aim was really twofold. It was primarily to get more patients into a transplant, but also with the idea that, as nephrologists get patients better prepared for transplant, that this would somehow make the patients have a potentially better outcome.

And I do want to point out that the mortality by tertiles was not significant, even though it was numerically different.

And I also want to point out that, in the pre-evaluation comments, there was some concern about diagnosis of cancer and receiving chemotherapy/radiation. I believe the developer does have this as being controlled with claims data, not just the initial 2728 form, and correct me if I'm wrong there, but I do believe that that is updated and I believe the cancer diagnosis was part of the adjustment. So, I do think that is being looked at because, clearly, that's an important part of waitlist eligibility.

Those are my only comments.

Co-Chair Dalrymple: Thank you, Andy.

Cher or Stu, any comments before we open to Committee that weren't already covered?

Member Thomas: Lorien, you had a couple of comments that I had that were going to go towards validity. And I'll go ahead and stick with those comments. I may add something, but I just wanted to remind you about them.

Co-Chair Dalrymple: Yes, perfect, Cher, and I will take all of those questions to the developer. There may be a few more that come out of discussion.

Member Thomas: Okay.

Co-Chair Dalrymple: Stu?

Member Greenstein: No comments.

Co-Chair Dalrymple: Okay. I'd like to open it up to the broader Committee then. If you've already made comments that relate to validity, I do believe we have captured those, but I can summarize them for the group, if that would be helpful, so people feel comfortable that their ideas have been captured. Would that work for everyone if I just try and capture what I think some of the discussions on validity have been?

And so, what I've heard throughout our discussion is there have been concerns raised about exclusion, so exclusions that are included and those that are not included. So, what I mean by that is, I think we have heard from a number of people that excluding preemptive waitlisting may not be an ideal measure of practice. But, today, as the measure is constructed, preemptive waitlists are excluded from the measure.

There were comments regarding not excluding pediatric patients, or at least very small pediatric patients, due to the surgical challenges that relate to small size, and since we are excluding those that are 75 and older, why aren't we taking into consideration younger age ranges?

I think Alan and others have emphasized the importance of patient choice, and that today there is no exclusion related to when patients choose not to be waitlisted, even after having been informed and having that opportunity.

And then, some of what I captured throughout the conversations included really a focus on risk adjustment. And the way I interpreted that is, is the risk adjustment adequate? There's always this challenge not only of unmeasured confounding, but unobserved confounding. And does the risk adjustment model take into account all the factors needed to give confidence that it's really calculating that expected number correctly?

Those are the notes I previously captured about validity. Do the Committee members have other concerns not captured or questions for the developer?

Alan?

Member Kliger: Just quickly, looking at the tertile testing, I just want to emphasize Andrew's point that there was no difference in mortality.

Second, that the differences in the groups of waitlisting was really small. So that, overall, they're really grouped very closely together.

Co-Chair Dalrymple: Thank you, Alan.

And it did remind me that I did not recap one other comment that I do think is appropriate for validity, which is, for group practices that have very high waitlisting rates, is there the potential that they actually would not look particularly good on this measure? And I think that's going to be an important one for the developers to be able to respond to, but, again, is this a valid measure? And if somehow, inadvertently, the rules created a construct where high-performing groups look like they provide poor quality, that would, obviously, be pretty concerning to the Committee.

So, I think, if everyone feels comfortable with us now giving the developer an opportunity to respond to those different validity issues, we could move to that response. Any other questions for the developer?

Okay. Dr. Shahinian, if you could respond to those? I'm happy to repeat some of them, but I think you know the general words we're focused on now.

Dr. Shahinian: Yes, I'll try to tackle what I have in my notes. But, certainly, let me know if I haven't adequately addressed something.

So, one thing was about the preemptive listing, that exclusion. Obviously, there are some practical

difficulties in being able to carry those over. Sometimes groups, you know, the responsible groups, change from prior to dialysis to after dialysis. And I think the idea is that, at least with current practice, the vast majority of transplants and waitlisting are occurring after people start on dialysis, and therefore, I think this is an appropriate focus for the measure.

With respect to some concerns about whether this could disadvantage certain groups that are very affected, again, it's a small portion of the population that's ultimately going to be waitlisted for transplant preemptively. And on top of that, we are including what we believe to be fairly robust adjustment for underlying comorbidity. So, to the extent that the healthiest patients have been transplanted, these groups will be extant as a function of the perhaps less healthy group that they now have. So, the adjustment addresses, we believe, a lot of that concern. So, that's one thing.

Quickly, about the pediatric concern about the weight, I think, clinically, that's not an unreasonable concern. Our general approach here in terms of exclusions was to really tackle things that are likely to be relatively common and likely to be imbalanced across dialysis practitioner groups fairly commonly. And I think the older population is much more common than the very young population. So, our basic strategy was to focus the exclusions on the scenarios that are relatively common and more likely to be clearly, potentially, imbalanced across the dialysis practitioner groups.

I think, with respect to the patient choice issue, I mean, there's, I think, a lot to unpack there. But one is that, you know, I think it's very difficult to capture patient choice, practically. We know there are difficulties. It depends heavily on how it's presented, the interaction that takes place between the practitioner and the patient in terms of their decision.

A perfect example of this is the discord that's been demonstrated between the checkbox on the 2728 about informing about transplant and actual perceptions from the patients' perspective of what took place.

So, it is challenging to tackle, and I would restate the issue that I think we've already gone over it: the fact that the overwhelming issue here is people who should potentially have access to the transplant not getting it, rather than a concern about coercion.

The associations with mortality, we agree they're modest. They're numerically --- you know, at least the first tertile versus the last tertile are in the expected direction, but the fact an association with mortality is modest, I think, in general, in terms of those kinds of associations, it can be challenging to show a clearly demonstrable effect on mortality, just because it is inclusive of so many things that can go into it. So, it is challenging to demonstrate it. So, we're not necessarily too surprised to find the inability to do that, but we do find a numerical trend that's consistent with what we would hope to see.

There was a question. Dr. Dalrymple, you mentioned a concern about high-performing groups doing badly on this. Now, I wasn't sure I understood your question there.

Co-Chair Dalrymple: Yes. Yes, I think that was a recap of the prior discussion where we tried to give this example: imagine a physician practice group that has 45 to 50 percent of their patients waitlisted, which, by national standards today, would be quite good, I think we would all agree.

But, in this measure, what's really be evaluated is their subsequent patients who have a new event. And I think you tried to address that with the hope is risk adjustment kind of accounts for the remaining 50 percent of people who may not be candidates. But at least I have this concern and I think others have it. Is it possible that, actually, very high-performing

physician groups could not look very good on this measure? And that would be unfortunate to capture them as lower-quality if, in reality, they performed well above average.

Co-Chair Garrick: Before you --

Dr. Shahinian: Yes, I mean -- sorry.

Co-Chair Garrick: Can I just add a clarifying piece to that, if I could? And I apologize for interrupting, but I just want to make sure I understand.

So, the patient is listed for a transplant, CKD-5, and then, they don't get that transplant. They don't have a living donor and they're on the deceased donor waitlist. And then, they start dialysis. Could you clarify how that individual is handled in terms of the validity of this measure?

Co-Chair Dalrymple: Renee, that is preemptive waitlisting. So, they are excluded from the measure. They will neither be in the denominator nor the numerator.

Co-Chair Garrick: Right.

Co-Chair Dalrymple: And so, I think --

Co-Chair Garrick: That answers that. And just again to the developer, additionally, we've made many conversations about how the ongoing care of the patient is important for their continued waitlisting, and we certainly agree with that.

If I'm following this, because the patient changes practitioners and is waitlisted by practitioner A, and practitioner B or C continues to take great care of that patient, you continue their waitlisting status. The way this measure is constructed, the validity of this measure, they would not get credit for their ongoing care of this patient that would have allowed them to be waitlisted, because it, then, happened under the care the first practitioner A, is that correct?

Dr. Shahinian: That is correct, but, you know, I'll remind the Committee that there is another measure that this Committee endorsed that does capture that. And so, I think the idea here is we're focusing this measure on an important population and an important aspect. We're focusing it on dialysis patients because the vast majority of patients arrive to dialysis not having been waitlisted.

And then, the other feature that is distinct from the PPPW that does look at continuation and maintenance on the waitlist is ensuring rapid attention. This is why it's structured as a time-to-an-event measure, to try to incentivize rapid attention to getting patients waitlisted, because that's been associated with better outcomes, particularly amongst those who do eventually get a transplant.

With respect to the concerns that Dr. Dalrymple has articulated, I mean, I think, ultimately, we're going to come back to the argument we made for the preemptive waitlisting: that we are adjusting for comorbidity on an ongoing basis, along with other risk adjustments, to try to say, for a given population at risk, you know, who is expected to get rapidly waitlisted within that denominator at risk at any given time. So, we believe we're adjusting for that.

Co-Chair Dalrymple: And if I can just offer a brief follow-up question to that, and then, John will go next.

Did you, by chance, do any analyses you could share with us where you did go look at high-performing groups -- or some definition, whatever definition you would like -- and how they performed on this measure to reassure us? You know, did you have the opportunity to maybe test that to make sure that is how this plays out?

Dr. Shahinian: We have not done that.

Co-Chair Dalrymple: Okay. Thank you.

John?

Member Wagner: Yes, thank you. I have two different questions.

One is, I was wondering about the adjustment-for-center effect. If you could just review that for a moment?

And my second question is on the theme of the preemptive patient. Although the numbers may be very small in what has been reported in the past, I think we have to recognize that the payment models that are now deployed are incentivizing changes in practice behavior. So, what was may no longer be the case, either now once we collect the data and understand it or in the near future. So, how would that potentially impact this measure?

Dr. Shahinian: Should I go ahead with a response?

Co-Chair Dalrymple: Yes, please. Thank you.

Dr. Shahinian: Just to the last point, there is ongoing measure review, and that's something that could be examined with respect to the proportion of preemptive waitlisting to potentially look at the impact of evolving patterns of care with respect to that.

With respect to the adjustment for transplant center characteristics, this was, essentially, assigned based on where the patients lived, the ZIP code of residents. We looked at historical rates of where those patients residing in a certain ZIP code get waitlisted in order to kind of identify a dominant transplant center. So, that each patient gets, essentially, through their ZIP code of residence, assigned to a potential transplant center.

And then, we use that to adjust for a couple transplant center characteristics. One was waitlist mortality, which we see as a proxy for kind of the aggressiveness with which they're willing to waitlist

patients, meaning that if they're more willing to take on sicker patients onto the waitlist, they're going to tend to have higher waitlist mortality. So, in a way, it gets at an aspect of what kinds of patients the transplant center is willing to transplant.

And then, the other piece is the transplant rate amongst the transplant centers, which can get at aspects of kind of regional organ availability and transplant center practices with respect to, again, how aggressively they try to find living donors or how well they're able to convert patients to a transplant. So, that's how we did the transplant center adjustment.

Co-Chair Dalrymple: Thank you.

Member Wagner: Could I have a follow-up on that?

Co-Chair Dalrymple: Well, John, what I will say is we are short on time, and I am getting reminders by the NQF staff.

So, I think what I would like to ask the Committee -- and so, John, you may take advantage of this -- are there critical questions that need to be answered by the developer or discussed by the Committee before we go to vote on validity?

I do think this is an important discussion. So, Annabelle, I still see your hand up. And so, I do think, you know, if there are critical discussions we need to have, so you can vote appropriately, I want us to have those. But we need to be timely.

Member Chua: Yes, I just wanted to say, I put it in the chat, but it, basically, just goes to the pediatric patient, the left ventricular. While it's not an overwhelming number across the country, for pediatric centers, it could be a good number of our center rate in terms of the left ventricular child who is not able to get transplanted. And the transplant center may or may not even consider doing their workup or get them listed at that time, especially

since their time now accumulates from the time that dialysis started; it's not from the time that they had their eval rate. So, some people don't feel the need to refer those patients early and get them in active listed. So, I'm really concerned about that piece not being part of this measure.

And then, to the social aspects that Lori commented on as well.

Co-Chair Dalrymple: And if people haven't had an opportunity to see the chat, I think it is important. I know we're trying to do a lot of things at once.

Annabelle, can I just ask you one question? For pediatric groups, is the thought that, because it's an entire group being abrogated, that you would not suppressed with the less-than-11 rule? So, you would still be in, but you'd have a significant number of small children.

Member Chua: Yes, there are still, even though some centers may fall into that less-than-11-year-old, there are some bigger pediatric centers that have a lot of those intents for young children. Especially nowadays, people are getting better with keeping these neonatal AKI, CKD babies alive. So, it's becoming a bigger number for these centers.

Co-Chair Dalrymple: Okay. Thank you, Annabelle.

And, John, is there something you want to discuss? I don't want to cut off discussion. We're just against the clock.

Member Wagner: No.

Co-Chair Dalrymple: You're okay?

Okay. I, unfortunately, do have one last question for the developer. This will be our last question before we go to vote.

I want to give you an opportunity to clarify one of the tables that was submitted in the measure under

validity for exclusion. And that's table 6, "The Distribution of Patient Months Excluded." Can you just succinctly explain to us why the patient months is, I'm going to say, 180 to 190 thousand, which is not much higher than the total number of patients excluded? This is a little bit different than what we're used to seeing for patient months exclusions, and this may be related to the way the model is being constructed. But if you could just quickly clarify that table 6 and table 5 for us, that would be great. So, we can vote on validity.

Dr. Shahinian: Sorry, I'm trying to pull it up.

Co-Chair Dalrymple: Yes, and I'm sorry, in a PDF reader, it shows it's page 41 out of 65. That might not be the page number on the bottom. I think it is, though. I think it is page 41 of the PDF.

And it's just help us understand why the patient months exclusions look quite a bit lower than I would expect, based on the patient number. I think this was in the validity section. So, we just want to make sure we understand this before we vote.

Co-Chair Garrick: Lorien, while we're getting there, just to call attention, as your Co-Chair, there are some comments in the chat box in case people did not see them there. There are several comments there that we could call attention to.

Co-Chair Dalrymple: Thank you, Renee. I do think that's important to review those.

I don't know if it's possible table 6 is mislabeled, but the numbers don't quite line up with table 5. But I think the specific question is, why are the patient months excluded so close to the patient number? Does that make sense to you all?

Dr. Shahinian: Sure. I'm trying to clarify with our team for a moment if there's a mislabel.

Co-Chair Dalrymple: Okay.

Dr. Shahinian: Sorry. So, our team is saying it's patients.

Co-Chair Dalrymple: Okay. Thank you. Okay.

So, I think that number is slightly different than what's listed in table 5. So, we'll go with the table 6 numbers as number of patients excluded. Okay.

With that, I would like to move to a validity vote.

I do not see any objection. So, we will move to vote on validity.

Ms. Kyle-Lion: Thanks, Lorien.

And I'll be taking over this vote because Nick's experiencing some technical difficulty. So, just one second to get that up.

Co-Chair Dalrymple: Thank you, Gabby.

Ms. Kyle-Lion: Yes, no problem.

Okay. Voting is now open for Measure 3719 on validity. Your options are: A for high, B for moderate, C for low, or D for insufficient.

And because Mahesh had to step away, we're looking for 17 votes here.

We're at 15 votes. So, we're just looking for -- oops, 16. So, we're just looking for one more.

We're still at --

Member Hartwell: I'm sorry.

Ms. Kyle-Lion: Oh, go ahead, Lori.

Member Hartwell: I'm sorry, I have to go find the link because I'm going to the chat. So, sorry, I've got to find the link.

Ms. Kyle-Lion: Okay. I'm sorry, does that mean you're chatting your vote, Lori? Apologies. I just want

to be clear.

Member Hartwell: Well, I did find the link from there.

Ms. Kyle-Lion: Oh, okay.

Member Hartwell: My computer's not cooperating. So, I found it. Sorry.

Ms. Kyle-Lion: Okay. No, you're fine. Take your time.

Okay. We're at 17 votes. So, I'm going to go ahead and close the poll.

Voting is now closed on Measure 3719 on validity. Just give me one second to pull up the results.

Okay. There was 1 vote for high; 4 votes for moderate; 11 votes for low, and 1 vote for insufficient. Therefore, the measure does not pass on validity.

And I will pass it back to Lorien.

Co-Chair Dalrymple: Okay. So, validity is a must-pass criterion. So, I believe we stop discussion here, is that correct, Matt?

Dr. Pickering: Yes, that's correct.

Co-Chair Dalrymple: And so, I think the question for the NQF staff is, originally, we were scheduled to take a lunch break. We, obviously, are behind. I would suggest that we have some brief break for the Committee. What's the time that you would like us to come back?

Dr. Pickering: I know we all have to protect our kidneys, right? We have to go relieve.

Co-Chair Dalrymple: Yes.

Dr. Pickering: A little humor.

All right. So, I know the KCQA, we have them on the line. They have a hard stop at 2:00, but I believe they

can come back at 3:00. So, you can see on our agenda we have like another hour break from 2:00 to 3:00. I'm just going to confirm that with KCQA.

Are you on the line? Is that correct, that you have to leave at 2:00, but you'll be back at 3:00?

Ms. Lester: Yes, and I apologize. This is a standing conflict that I could not move, but we can definitely come back at 3:00 and finish whatever we need to on that rate measure before we start the retention measure.

So, thank you for that.

Dr. Pickering: Okay. Thank you.

So, if I could propose, maybe we can take a 15-minute, brief break for the group, just to stretch, a bio break, maybe grab some quick food.

We'll pick up with the next measure, the KCQA measure, and then, at two o'clock, we'll just stop, and then, we'll have an hour break, and then, just pick up where we left off when we reconvene and close out the remaining criteria of the measure, and then, close out that last measure of the day. Does that sound okay with the group? Any objections?

So, we'll reconvene at 1:15 p.m. to pick us up with the next measure.

And thank you again to UM-KECC for being on the call and being attentive to the questions.

We'll see you all at 1:15.

Co-Chair Dalrymple: Yes, Matt.

And I'd just like to reiterate your thanks to the developer. We really appreciate the discussions and clarification and time and commitment. So, thank you.

(Whereupon, the above-entitled matter went off the

record at 12:59 p.m. and resumed at 1:15 p.m.)

Dr. Pickering: Okay. So, hi, everyone. Again, Matt Pickering here.

I have 1:15 p.m. on the Eastern side. So, we're going to kick things back up. If we could, I just wanted to check in to see if our KCQA representative is on the line.

Kathy, are you there?

Ms. Lester: I am. Thank you.

Dr. Pickering: Great.

Ms. Lester: And I have my colleagues as well.

Dr. Pickering: Okay. Excellent. Thank you.

All right. And then, Renee, I think we heard you earlier, but you're good to go? Renee, are you there?

Member Narva: She's muted.

Dr. Pickering: She's muted. I see. We were just hearing you, Renee. We can't hear you. We can't hear you now for some reason. No, sorry, we may have to try to see if we can get your line to work again. We were just hearing you.

Yes, maybe we can proceed, just so that we can kind of take up the conversations. I think we can at least start out maybe with the developer overview and see if we can get Renee's audio working.

Okay. So, if we go to the next slide? Great.

3722 Home Dialysis Rate (Kidney Care Quality Alliance [KCQA])

So, the next measure up for discussion is NQF No. 3722. It's the Home Dialysis Rate Measure. The developer for this measure is the Kidney Care Quality Alliance.

As you can see, the description of the measure is: the percent of dialysis patient months in the measurement year in which the patient was dialyzing via home dialysis. Modality, the measure type here is process. The level of analysis facility, and the setting of care is ambulatory. They have home care, outpatient services, and postacute care. The data source here is electronic health data.

And with that, I'm going to go to our developer, Kathy Lester, to give a 3-to-5-minute overview of the measure to kick us off.

So, Kathy?

Ms. Lester: Thanks.

I'm Kathy Lester. For those of you who don't know, I'm the consultant to the Kidney Care Quality Care and Kidney Care Partners. I have a JD from Georgetown University and my master's in public health from the Johns Hopkins School of Public Health. My background is in the HHS General Counsel's Office, as well as doing health care issues in the United States Senate.

I will be joined today by my colleagues, Dr. Lisa McGonigal, who serves as primary staff to the Kidney Care Quality Alliance, as well as Dr. Dave Gilbertson, who leads our team on the testing and is the Co-Director of CDRG and co-investigator for the U.S. Renal Data System, as well as Dr. Shuling Li, who is a Senior Service Researcher at CDRG and Director of Health Policy and Biostats.

And, Matt, just to clarify, we are looking at this measure at the HRR level, rather than at the individual facility level. And I'll get into that a little in my opening comments.

Dr. Pickering: Okay. Thank you.

Co-Chair Garrick: No problem.

On behalf of KCQA, I really want to thank NQF for the

opportunity to submit our home dialysis measure for endorsement consideration and the Renal Standing Committee for its thoughtful and thorough review of our measures.

The intent of this measure set is -- and we'll talk about retention next -- is to grow overall home dialysis utilization. To do so effectively, both new prescription and efforts to retain new and existing home dialysis patients must be incentivized.

To that end, the measures create a counterbalance of incentives. Assessment of home dialysis rate, which we'll talk about now, will incentivize increased adoption of home modality, while an assessment of home dialysis retention will serve as a counterbalance, prioritizing the selection of appropriate candidates, recognizing patient choice, and each patient's desire to select home dialysis modality, and the provision of appropriate patient education, preparation, and support to minimize treatment failures and recidivism.

We appreciate the Standing Committee's preliminary questions and comments, and I'll try to touch on a few now, but we also welcome the opportunity to answer others during the Committee's deliberation.

In terms of the priority, KCQA is committed to eliminating health care inequities for individuals living with kidney disease. Currently, nearly 60 percent of dialysis are non-white, but only about 11 percent of home dialysis patients come from communities of color.

The Biden-Harris Administration has prioritized improving access to home dialysis, and they deployed the ESRD Treatment Choices Model in January 2021 as part of this initiative. KCQA developed the home dialysis measure set specifically to support the ETC program. Moreover, the patient and patient advocate members of the KCQA asked for these measures to be prioritized.

As a threshold matter, and in response to some of the comments that we received, today there is no relevant clinical practice guidelines, systematic reviews, or published RCTs addressing home dialysis utilization. As such, we are currently limited to observational studies and expert opinion, but both of these sources support that home dialysis therapies are at least equivalent to in-center dialysis in terms of clinical outcomes and superior in terms of patient-reported outcomes on physical and mental health-related QOLs. Referring to NQF's evidence algorithms, and consistent with the staff's preliminary analysis, this scenario allows for a moderate evidence rating.

In response to comments about the measure's lack of an exclusion for patient performance, we note that home dialysis utilization remains remarkably low in the United States compared to other developed economies. And most members of the kidney community acknowledge that the home dialysis rates could increase substantially without infringing upon patient choice.

In fact, research in this area suggests that the opposite occurs more frequently. Patients are initiated on in-center hemodialysis, despite a patient's preference for home therapy. This concern was the driving force behind KCQA's decision not to incorporate an exclusion for patient preference.

Our clinical experts and patient members alike agreed that an exclusion for patient preference or refusal could easily perpetuate the status quo in home dialysis, providing facilities with a simple means of, in fact, opting out of the measure and letting them off the hook for ineffective or inadequate education.

As we will discuss in the next presentation, the retention measure addresses this concern of patient preference by penalizing facilities that would seek to place as many patients on home dialysis as possible,

regardless of their choice, while also eliminating an easy out for facilities that may not support patient choice to receive home dialysis.

One Standing Committee member commented and raised concerns about the number of patients involved in our process, and I'd just like to clarify. Overall, patients were roughly 15 percent of the KCQA Steering Committee and Work Group. Additionally, patients comprised 40 percent of our follow-up face validity panel.

We also received another comment suggesting that the measure should specifically exclude patients based on social determinants of health that can have an impact on outcome. KCQA members agree that the use of exclusions and/or risk adjustments to address SDOH would perpetuate existing health disparities and inequities, potentially setting lower standards of quality for those patients who are more socio-demographically vulnerable.

To address this concern, KCQA chose to stratify performance by these categories to facilitate quality improvement and focus resources on disparity-reduction strategies, while still creating a level playing field in terms of payment and penalties.

And finally, we want to speak to the use of the hospital referral region level of analysis. If adopted into the CMMI ETC model, which is KCQA's intent, CMS would aggregate the scores of the individual facilities that provide home dialysis into their CMS-determined HRRs.

The reliance on HRRs by CMS and KCQA recognizes that the delivery of home dialysis is not at the facility level, but, rather, at a regional level. Dialysis organizations of all sizes in a local area will designate one or two facilities to specialize in the delivery of home dialysis and send the home dialysis patients to this home dialysis facility.

This structural practice means that a patient who

may start at facility A, selects home dialysis, will be transferred to the organization's home-dialysis-specific facility. Facility A may appear to have zero home dialysis patients, but that is only because those patients receive their treatment in a different commonly-owned facility. This practice of cohorting home dialysis patients is common among all sizes of dialysis organizations, including medium and small organizations.

Thank you again for your time and consideration. We recognize that there were some other comments specifically related to reliability and validity testing that we will be happy to respond to during the Committee's deliberation.

Dr. Pickering: Great. Thank you so much, Kathy.

Renee, I'm just going to check to see -- I think I heard you.

Co-Chair Garrick: Can you hear me?

Dr. Pickering: Yes. Yes, we can.

Co-Chair Garrick: Okay. Great. Thank you.

Thanks so much and thanks for that introduction. And, Dr. Lester, thank you for your comments.

I just have one quick comment that I wanted to make sure that we clarified. But the NQF staff has clarified for us that this measure will be and must be reviewed as a free standalone measure. And so, we will be reviewing this measure as a process measure using the 2021 evidence report, and we will review it solely as a freestanding measure, not as a paired measure.

And with that in mind, as you just heard, the intent of the measure is to incentivize prescription and preparation for home modalities for all clinically appropriate patients in accordance with their preference.

And so, thank you for the introduction, and I think

we can turn it over to our lead discussant, who is Dr. Kliger.

Then, I do think we have a number of people who are recused. So, we should probably just clarify that we have returned from lunch with a vote. That was just with a meeting and a voting quorum.

We do have a quorum?

Dr. Pickering: Yes. So, we should still have a quorum. So, with the recusals being absent, we look like we still do have a quorum, yes. So, we can proceed to going to voting.

Co-Chair Garrick: Right.

Dr. Pickering: Mahesh is back as well. So, that gets us back up to our quorum numbers.

Co-Chair Garrick: Okay. Thanks.

And so, Dr. Kliger is our lead discussant.

Member Kliger: Hi. So, first, we're, obviously, tasked with looking at the evidence. You've already heard the definition, which is basically the percent of all facility patients dialyzing via home modality. You've heard the definitions of the numerator and denominator.

The level of analysis, as submitted to us, was at the facility level, although it sounds like a regional level is what you're hoping to do through the CMS alteration.

And most importantly, it's a process measure. And so, the way that we're going to look at the evidence algorithm is different than the last one, which was an outcome measure. So, we're going to look at this as a process measure.

The developer's statement about importance to measure I think is an important place to start to look at the evidence. The measure is intended to

incentivize prescription of and preparation for home modalities for all clinically appropriate patients, in accordance with patient preferences.

And we heard that the patient preferences and appropriate patient designations are in the second measure. Yet, we're being asked to look at this one as a freestanding one. So, I just want to put that out a moment as we review the evidence.

Again, the developer is saying, increasing home dialysis rate is a major objective. It was an objective of the Advancing American Kidney Health Initiative, and subsequently, CMS's ETC Payment Model.

So that the focus of the measure is to increase home dialysis rates to accomplish the 2019 Presidential Executive Order that directed HHS to take bold actions to transform how kidney disease is prevented, diagnosed, and treated. And that included a move to substantially increase transplant and to increase home dialysis. Also, the measure is to take advantage of the ETC Payment Model that, in 2021, was put in place.

Before I discuss the evidence in-depth, I'll report the preliminary opinions we gave before the discussion.

Nine of us said there was sufficient evidence to rate this evidence as moderate and pass on the evidence. Some of those noted that only empirical data were presented.

Four of us said that there was either tangential or insufficient evidence to support passing at the level of the evidence.

Okay. So, it seems to me that there are really three major questions about the evidence that we need to address.

First is, what is the evidence that a measure of percent home dialysis at the facility level will incentivize prescription of and preparation for home

modality? That is, will the measure, if it succeeds, succeed at the goal that the developers have given us?

The second evidence question is, what's the evidence that home dialysis provides better outcomes than in-center dialysis for all patients, not only those choosing home therapy? Remember that the denominator is not patients who choose to go home, but the denominator is all patients, with some exclusions for medical condition. It does not exclude patients whose homes cannot easily accommodate home treatment or whose family structures would be adversely affected by home therapies, or any of the many potential unintended consequences of incenting home therapy. So, again, is there evidence that home dialysis provides better outcomes than in-center dialysis?

And then, finally, is the Presidential Executive Order or a payment model favoring home dialysis sufficient to approve the measure if the science does not support its superiority? I raise the third only because it was brought into the rationale for putting the measure together.

So, I want to talk about each of those three questions.

So, the first is, is there evidence that a measure of percent patients in a facility dialyzed at home will provide an incentive to increase prescription and preparation for home dialysis?

As the developer nicely outlined for us, there haven't been any evidence-based guidelines or any previous attempts to answer that question. So, the developers agree that there are currently no data to answer that question.

So, while some might hypothesize that public reporting of percent home therapies will incentivize more home treatment, there's really no evidence to support that hypothesis. There's no evidence to

counter that hypothesis, either. There's just really no evidence in that here.

So, on its face, there's as yet no evidence to support the importance statement, but let's for a moment presume that evidence to support the hypothesis can be developed in the future. The underlying question is the hypothesis that home dialysis is superior to in-center dialysis; that it provides better outcomes.

The developers in their application make two interesting statements that on their face would appear to contradict each other. They don't, but let me just tell you what the two are.

The first is the statement that says, "Home dialysis will reduce cardiovascular risk, mortality, hospitalization, cost, and will increase the quality of life."

The second statement says that, "Peritoneal dialysis, which is the predominant form of home dialysis, yields similar short- and long-term survival for patients with kidney failure."

So, on the one hand, there's a statement that home dialysis reduces risk, mortality, and hospitalization. And the second is that peritoneal dialysis yields similar short- and long-term survival for patients with kidney failure.

The developers also, I think correctly, say that peritoneal dialysis has been associated with preservation of residual kidney function. They say it enhances patient autonomy and quality of life. And then, they say that home hemodialysis is associated with improved blood pressure controls, regression of left ventricular hypertrophy, shorter recovery time from dialysis treatment, normalization of phosphate levels, improved pregnancy outcomes, and better health-related quality of life.

So, these are all the statements that I'd like to examine, as we make a decision about the evidence.

The developers are right that home peritoneal dialysis, the dialysis modality that's the most common one used, is not superior to in-center hemodialysis for short- and long-term survival. Actually, early data suggested that some subgroups, like diabetic patients, had worse outcomes on home PDs than in-center hemo, but more recent studies suggest they really have equivalent hard outcomes. What's important is that the data don't support a superior physical outcome for home peritoneal dialysis patients.

Well, but, then, the developers are also citing home dialysis compared to in-center hemodialysis showing improvement -- better blood pressure control, better phosphate control, and regression of left ventricular hypertrophy.

So, I know about these studies because I was the study Chair for the NIH-sponsored randomized controlled studies looking at more frequent hemodialysis compared with standard treatment. Our publications did, indeed, show that more frequent treatments, whether in-center or at home, did improve blood pressure, lower phosphorus, and reduce left ventricular hypertrophy.

The studies were not powered to examine mortality, but post-hoc studies were interesting. There was a clear signal that, for in-center patients, more frequent dialysis may have improved mortality. Interestingly, in contrast, our home hemodialysis study showed a signal for lower survival among home patients treated with more frequent dialysis than in-center conventional therapy.

Now, these mortality figures clearly need additional studies because both of those studies were underpowered to look at mortality. But if you're just looking at what signals were there, the signals for home therapy did not suggest that mortality was lower in home hemodialysis patients.

So, I guess what I'm saying is, if we're looking at the

predominant form of home dialysis, which is peritoneal dialysis, there was not any good evidence that the physical outcomes were any different between in-center and home.

The observations about home hemodialysis, and particularly around more frequent dialysis, are differentiating frequency, but not site of place where the dialysis is performed. So, I don't think that those findings are particularly relevant to the discussion here about evidence of home being a superior therapy to in-center.

Now, there are many observational trials or observations that were made and published. There are dozens of them that suggest that there may be some advantages of home therapy in terms of many of these physical outcomes, but they are observational and are confounded by who chooses to go home or who doesn't. And so, the randomized controlled studies that I'm quoting here I think are really the ones that we need to pay attention to.

If there are no convincing data showing the superior outcomes of home dialysis compared to in-center, then how about the developer's arguments that the observational studies show better quality of life for patient-reported outcomes than in-center treatment?

Can we put up the logic model that the developer showed us? I just want to show everybody sort of the logic model that the developer used in order to make this argument.

Matt or somebody? Oh, thank you.

So, come down, yes. So, can you make that just a little bit bigger for us? That's great. Thank you.

So, you'll see here in the logic model that the logic is, if we identify the populations, implement process intervention, increase home dialysis, that we will get these improved outcomes; that we will get reduced cardiovascular risk, reduced mortality, reduced

hospitalizations. Well, I believe the evidence does not support improved outcomes with home therapies for any of those first three -- cardiovascular risk, mortality, or hospitalizations. But how about quality of life?

Clearly, several observational studies report that home dialysis patients have a better measured quality of life than in-center patients. The problem with these observational studies is that the two groups they compare are very different. Patients who choose to go home for dialysis and succeed in home training are a very select group of patients. They're likely healthier, more motivated, have different social and financial resources than those who do not choose to dialyze at home.

It seems likely that those very motivated patients, motivated to go home, are much more likely to report better quality of life, not so much because they're home -- it's not home that's creating a better quality of life -- but, rather, people who choose to, and succeed at, training at home are just more likely to be healthier and more likely to have a sense that they have a better quality of life.

Now, we don't know that because that hasn't been tested, because there are no randomized controlled trials of people going home or not going home. I wouldn't want to have one. I mean, how can you randomize patients who would want to go home to either go home or randomize to stay in-center? So, those studies will really never be done.

I guess my point, though, is that claiming that improved outcomes from going home include improved quality of life is really not necessarily because of getting them home, but more likely because of who they are that choose to go home.

So, when we look at all of the potential improved outcomes, of the five that are listed in this logic model, the one that I do think is real is reduced cost. And there are several studies out looking at real cost

of home therapies, whether that be home hemo or home peritoneal dialysis, and it is likely that, for any given population of patients, that costs will be reduced for patients who choose to go home.

Our NQF guide asks us to answer several questions about the evidence. So, let me just quickly go through them.

One, they ask, what's the relation between this measure and patient outcomes? I suggest the current data do not clearly support that this measure will improve patient outcomes. It may or may not. There's just no evidence right now to suggest that that's the case.

The second question the NQF guide asks us is, is the evidence directly applicable to processes of care being measured? That is, increasing the rate of home dialysis uptake. So, is there evidence that we've reviewed that the work that will be done will increase the home dialysis uptake rate? I don't see any evidence that that is so.

The third, is there evidence of a systematic assessment beyond the developer? And I know this is a question that KCQA considered because they convened a panel of nine people, including a patient, five clinicians, and other stakeholders, to help develop this measure, in the absence of clear evidence for the utility.

And the developer, they did develop those measures, and the developers unanimously endorsed the measures. So, they did believe that there was a systematic assessment beyond the developers and they came, and then, endorsed the measure.

I'm not convinced that this relatively small panel represents a systematic assessment. The careful analysis of evidence that I just discussed was not provided, at least in the paperwork we got from the developers.

Is it acceptable or beneficial to hold providers accountable without empirical evidence? The NQF asked us to ask that question. Well, in this case, the developers are, indeed, the providers. So, I can only presume that it would be acceptable to them.

I must say that I wonder what their main objective was, and whether it really perhaps was influenced by the wish to conform with the Presidential Executive Order and the new payment model, and perhaps more so than examining critically the evidence to support superiority of home therapy for all comers.

There's no question that home therapy needs to be more available to people who choose it, and that it is a wonderful thing that needs to expand. The U.S. has very low uptake. We were asked to look at the evidence that home therapy for all is a better outcome, and I believe the evidence is not there to support that.

But let's look at the evidence algorithm that we're asked to use in terms of assessing this evidence.

So, could you put up the evidence algorithm, please?

So, I know you've all seen this because we used it in our initial evaluation. But here, just to go down as the Committee did before us: does it measure performance on the health outcome? And the answer is it doesn't. So, we go from box 1 to box 3.

And here, for the measures that test performance as an intermediate clinical outcome, process, or structure. And, yes, that is the case for us.

"Is it based on a systematic review and grading of the body of empirical evidence?" And the answer to that is no, because there was no systematic review of the grading and no grading of the body of that. And so, we have to go down to box 7.

So, 7, then, asks us: "Is the empirical evidence submitted, but without systematic review and

grading?" And the answer to that is yes.

So, in box 8, "Does the empirical evidence that is summarized include all studies in the body of evidence?" Well, this is an area that I've worked in for years, and there are some papers that aren't cited, but I don't think that matters. I think that they did a very good job at citing all of the relevant evidence. And so, I think we have to answer "yes" to that.

And then, that goes, therefore, to box 9, and here's the critical one. It asks us, "Does the Subcommittee agree that the submitted evidence indicates high certainty that the benefits clearly outweigh undesirable effects?" And this is a different bar than we've looked at in terms of potential adverse outcomes than in the outcome measure we talked about in the last few hours.

Here, in this process measure, we are asked to say that we have a high degree of certainty that the benefits clearly outweigh undesirable effects. Here, I think we have to say that, first of all, the evidence suggesting that home therapies are superior is shaky. There is no clear evidence; that is true for all patients.

Now, it might be different if the denominator we were asked to look at were that group of patients who were anxious to go home or who wanted more information about going home, or chose to go home. But here, the definition we're given is that that denominator is all patients, all the dialysis patients.

And there are, potentially, questions of undesirable effect. Many patients don't have a conducive home environment for dialysis -- not enough room to store supplies; family members who are unhappy with home treatment; financial and social effects of home treatment every night that might cause anger, pain, mistrust.

There are many reasons that we might think that

clinicians who are pushing hard for patients to go home and pressuring them to go home might, indeed, bump into some of these negative outcomes. Now, we don't have evidence of those negative outcomes, but we're asked here to say that we have a high degree of certainty that the benefits outweigh the undesirable effects. And for me, anyway, when I'm asked that question, I can't have that high degree of certainty.

So, on the algorithm we see, we're asked, then, to rate the evidence as either moderate or low. And based on my uncertainty of that last question No. 9, I would have to rate it as low.

It was interesting to me to go through all of the evidence carefully: what is the evidence supporting superiority? Something I hadn't done when I did my preliminary rating, I must admit, but something I spent some time doing in order to really ask the question about the evidence. So, that's the way that I see the evidence laid out.

And so, let me, then, ask you, Renee, to then turn it over to others for their discussion.

Co-Chair Garrick: Can you hear me now?

Dr. Pickering: Yes.

Member Kliger: Yes.

Co-Chair Garrick: Okay. Great. Thank you so much.

So, Alan, before we turn to the other discussants, were there any public comments that you wanted to share with us before we turn to the other panel members?

Member Kliger: Yes. There was one and it was supportive of the measure.

Co-Chair Garrick: Thank you.

And our other discussants are Gail Dewald and

Annabelle Chua, Karilynne Lenning.

So, if we could have some comments from our co-discussants?

Member Dewald: This is Gail.

And I think Dr. Kliger was very eloquent in his points. I think home therapy has a big place for our patients, but I'm thinking the denominator should not include every patient at the clinic. There are some, I know there will be some measures -- or this measure will probably exclude some of those. But there are many patients that just have fears about going home, and then, once they get home, once they have a problem, they return to the clinic.

So, I think nursing-wise, staffing for home therapies has been very difficult. And we're seeing in some clinics that they're training people out on the hemodialysis floor for home therapies because they have four or five at a time that need training. So, I'm not sure they're getting the best training that way, but it's not against the regulations. So, we're going to see that occur.

Thank you.

Co-Chair Garrick: Thank you.

I think, Dr. Chua, do you have some comments you would like to add?

Member Chua: I don't really have too much to add. I think Alan really summarized that very nicely and very systematically.

You know, as somebody who, in pediatrics, we really do push home peritoneal dialysis on all our patients, and anecdotally, see the benefits. But I agree -- and this is getting towards validity -- but I think, just in terms of the evidence, you know, it really is there are going to be patients that really are a challenge to get on PD, no matter how much we want to do that.

And so, I agree that, even though there is, I guess, empirical evidence, based on what Alan was saying, you know, the true benefit isn't really demonstrated in the literature currently.

Co-Chair Garrick: Thank you.

And I think Karilynne Lenning is on the call as well. Do you have some comments you would like to add?

Member Lenning: I don't have anything additional to add. Thank you.

Co-Chair Garrick: Okay. Thank you.

And thanks very much, Alan, for leading a very robust background.

So, we can open it up now to the Committee members at large, if there are other Committee members that have anything they would like to add. I will look for hands.

And since I don't have a Co-Chair, if someone else sees a hand, please shout it right out.

Dr. Pickering: Yes, John Wagner.

Member Wagner: Yes. Hi.

Co-Chair Garrick: Right.

Member Wagner: Thanks, Alan. That was a wonderful review. Just a couple of questions.

One, is an outcome of lower cost a valid reason to say we have evidence that this is a measure to endorse?

And secondly, just to round out the rationale that was given by the developers, I think there was also a comment that 30 percent of patients said that they might have felt that they were not given the information that they might have wanted regarding their choice of in-center modality versus home.

So, is the kind of low-bar kind of evidence that might say, well, we have a process that we can influence because we can give those patients information and have them go home, if that's what they wanted?

Dr. Pickering: And so, maybe we can hold that question.

I do also want to remind the group of a time check. At two o'clock, our developer has to leave for an hour.

So, if there's still a lot of questions that are raised for the developer and we're not ready for a place to vote, I don't think we would be able to get through all of that in about six minutes and have the developer respond adequately.

So, may I propose this? If the Committee does have questions, please write them down or keep them in mind, because I do feel that we're probably going to have to break at two o'clock and reconvene in an hour at 3:00, because I don't think we'll have enough time to really get into questions with the developer. And we don't really want to go forward with the voting if there's still questions for the developer that they can respond to for the Committee. So, I'm proposing that because I don't think we can actually get to doing any of that by two o'clock.

Renee, what are your thoughts? Would you be okay with that, if we hold off, keep questions, and then, we'll reconvene at 3:00 and pick this back up?

Co-Chair Garrick: I think that probably makes the most sense because there's no point in our having a conversation. We don't have a lot of opportunity, I think, to talk to the developer. So, it would be better for us to take a break now and come back.

Will they be able to have a hard restart at 3:00?

Dr. Pickering: I'd look to Kathy for that.

Ms. Lester: Yes.

Dr. Pickering: Okay.

Ms. Lester: Yes.

Dr. Pickering: Great. Okay. Thank you.

So, let's do that. I think we at least got introduced to the measure.

And, Alan, thank you for that great overview of the evidence assessment.

For those who do have questions related to the evidence, please write them down or keep them in mind.

We'll reconvene and start from that top there, John, probably with you with yours. Also, I think Andrew has his hand raised, too. So, we'll go to him next.

But we'll reconvene at 3:00 p.m. Eastern. So, if you didn't get any food, now we have a little bit longer time to do so. So, we'll reconvene at 3:00 p.m. and pick up here with evidence for 3722.

So, thank you all very much. We'll see you at 3:00 p.m. Eastern.

(Whereupon, the above-entitled matter went off the record at 1:56 p.m. and resumed at 3:00 p.m.)

Dr. Pickering: All right, so we have 3:00 p.m. here on the Eastern side, so we're going to kick back up. It sounds like we have our stakeholders here with us, and I don't believe we were expecting anyone to not come back at 3:00.

I do know that we have, I believe, one of our members stepping away at 4:00, but I still think we would still maintain quorum because we aren't aware of anyone else stepping away at that time. So, with that, let's go ahead and get back to our discussions.

So, if I could, Isabella, would you mind putting back Measure 3722 on the screen? So, just a refresher of

what measure we're talking about, we went through the developer's opening remarks and some discussion already about the evidence from our lead discussants and discussants.

I will say that now we get into the full committee discussion, and as we've done previously, if there are questions for the developer, we'll capture those and then turn to the developer after the initial committee discussion with those questions.

I do want to just recognize again that we have this measure and another measure to try to finish before 5:00 today, so if we can try to keep the conversations concise, and if there's no new information or no new questions that you have, we'll just try to keep this moving forward just to see if we can get the remaining two measures done today.

So, with that, Renee, I believe John was the first person we were going to go with, and I think Andrew was after that, so I'll turn it to you, Renee, to open that up.

Co-Chair Garrick: Great, thanks so much. And I think just for a quick recap, Alan gave an overview of the evidence behind the measure and walked us through the logic model, looking at the five areas of reduced cardiovascular risk to mortality, reduced hospitalization and improved quality of life, and reduced costs, and I think his commentary suggested that the evidence at this point is low based on his review, and we're about to now have an internal conversation among ourselves and then back to the developer for their comment.

So, I agree, Matt. I think it was John and then maybe Andrew. Both had their hands up. And Alan, if you needed to add anything, feel free. I know we had a pretty long break in between. All good? Okay, thank you. So, I think, John, you're next.

Member Wagner: Yeah, I guess, so I had asked two questions. One was if an outcome is reduced costs,

is that something that is considered to be sufficient evidence in support of the measure?

And the second question was how do we view the reference that the developer made to the fact that 30 percent of dialysis patients state that they don't believe they have adequate information about modality choice?

Again, it's observational, but is that something that is added to the evidence pile in a more compelling way than the other evidence that you've discussed?

Co-Chair Garrick: John, is that something you'd like to go to Alan to comment on or is that for the developer?

Member Wagner: Well, I think Alan can handle the 30 percent of the patients question as I don't believe you referenced that particular argument that the developer made, just to round out the arguments that the developer did make, and I think the developer might want to answer the cost issue and perhaps NQF.

Member Kliger: Yeah, so John, I was quoting published data, you know, that did or did not support and the evidence here that did or did not support the argument.

It's awfully disturbing that 35 or 38 percent of patients didn't feel they got adequate information. In fact, I know that that's right from my clinical experience. You know, we know that most dialysis units have no patients on home treatment.

You know, over 50 percent are the ones they looked at, and to me, that suggests that dialysis facilities are not equipped or ready to offer home dialysis except regionally the way the developers described.

And so, I think that is a compelling problem, but I don't see that as evidence that reflects on the appropriateness of this measure. It compels us to do

better getting people home, but I don't see that it reflects on the evidence for this measure.

Co-Chair Garrick: And I will save the other question for the developer. And Andrew, I think you had your hand up before the break?

Member Narva: Yeah, I did. I want to address this to Alan actually. And, you know, health equity is an important goal for NQF in general and for all of us, and it's an aspect of the previous discussion that I hoped to interject, but didn't have a chance.

I'm curious, Alan, given your vast experience and real knowledge of not only the science behind home dialysis, but the pragmatic implementation, what do you think the impact of this measure would be on increasing health equity among people with kidney disease?

Member Kliger: You know, it's a great question, Andrew. My sense is that we, as a profession, have done so relatively little to promote health equity that almost anything that we, you know, that we think of has the possibility of improving access to care that otherwise hadn't been there, and equity in availability of care and level of care.

So, obviously, there's a possibility that a measure like this could compel doctors to speak to their patients more and open that opportunity more. I think that possibility is there.

I restricted this part of the discussion though to the evidence, and if we get there, we can talk about that later, but, you know, we're asked first really just to talk about the evidence behind this model and that's really all that I addressed.

Member Narva: Thanks.

Co-Chair Garrick: I don't see any other hands at this point, so I think we could turn back to the developer for John's specific question about cost and whether

or not the conversation about cost is something that would give us evidence for the creation of this measure.

Ms. Lester: Thanks, Renee. I'm happy to do that, and I also would like, after answering that, if it's okay with you, to address a couple of misnomers that I think came out in the evidence discussion.

But to answer the cost question first, I do think -- and it is something that the KCQA took into account as an important criterion to be considered in measure development.

Obviously, the drive toward home dialysis has, as we believe and the evidence, a lot of ability when those patients who are able to receive home dialysis to really change the economic infrastructure, not only of the Medicare program, but also the workforce and their ability to be more active in their communities and with their families, so we would consider that it would be there.

Just a couple of other points, if I may, I think the evidentiary standard, you know, for ESRD just cannot be prospective trials. You know, earlier today, you talked about a transplant measure, we have vascular access measures, and these measures have been endorsed, but do not have prospective trials either.

And as Dr. Kliger said, it would really be unethical, if I can use that word, to suggest that you can't have a home dialysis measure without having a randomized control trial. We're just never going to go back to that day.

We also stand by the assessment of the observational data and the clinical experts. To be clear, and this is what I wanted to really clarify, KCQA was led by the American Society of Nephrology, the Renal Physicians Association, the Association of Nephrology Nurses of America, several patient groups, as well as dialysis facilities. It is not a provider-only group.

And it was really the patients who drove these measures and drove the decision to establish a retention measure rather than the exclusion for patient choice because of their deep concern the measure would be manipulated.

And as Dr. Wagner pointed out, they are seeing that a third of patients are just not getting the information they need, and it is unfortunate that our patients here are not able to speak today to this measure, but this was a major part of the discussion in our panel and the model.

And so, you know, right now, the ETC model does have these providers being assessed on a rate-only metric. They will begin to be cut and there's no counterbalance that we have there. So, while I know, you know, technically we can't consider the two together, I do think you should be aware that the patients looking at the evidence and looking at practical reality and practice today preference a retention matter over an exclusion. Thank you for that.

Co-Chair Garrick: Thanks so much, and I do want to reiterate that we do need to consider this measure as a standalone measure because that is how it's addressed, and the NQF staff's comment on that, Matt, if you'd like to give us any guidance?

Dr. Pickering: Right, you know, measures sometimes can be deemed as paired, right, so you could have a measure come out and then you recognize that maybe there's a need for another measure for some sort of focus, and that would be a paired measure.

Developers may say that these measures should be paired and maybe used together, but the measures -- your evaluation is separate from any of that pairing relationship. You should be taking the measure into consideration as a standalone item and walking through the criteria and evaluating the measure on its own.

Recognizing if you feel like it is important to have a paired measure or if a developer says that there will be a paired measure, that's great, but it does not influence the endorsement decision for this measure, so you have to evaluate each measure independently irrespective of if there's a paired measure or the need for a paired measure.

Co-Chair Garrick: So, are there any other additional comments that anyone from the standing committee would like to make, Alan?

Member Kliger: Just a quick response, Kathy, to what you said. There are many studies in dialysis that are prospective randomized trials.

They're not nearly as plentiful as in other areas, but I can tell you that's the study that we did nationally, the FHN study, looking at home hemodialysis done frequently. That was a randomized prospective study.

You're not going to be able to study things like the current psychosocial or patient choice issues because the populations are so different.

When you look at people who, you know, have chosen to go home, they're a very different group than the comparator group of people who remain in center. So, you know, that's where the observational studies' vulnerabilities are really clear, so I'm just talking about looking really clearly at the level of evidence that supports what the measure calls for.

Co-Chair Garrick: So, Alan, if I could just ask to reiterate that point, you made a comment that, if I got this correctly, that on the hemodialysis side, the secondary analysis of your trial showed that in-center hemo patients actually did better. Is that correct?

Member Kliger: Yeah, this is -- you know, we published a paper that basically said that raw data show that analysis of mortality, comparing those who are home on frequent dialysis to standard in-center

dialysis, that was the comparison, that the post hoc analysis of mortality showed worse mortality among people at home, but in a study that was underpowered and in a study that was not powered to look at mortality, that our conclusion based on a Bayesian analysis was that there was no evidence of an improved outcome with home.

You know, the raw numbers looked like they did worse at home, but our Bayesian analysis said no, statistically, we don't think we can say that, but what we can say clearly is there's no survival advantage for home hemo patients.

Co-Chair Garrick: And on the PD side?

Member Kliger: We did not look at that in our study, but the literature is clear, as the developer said, that there is equivalent outcomes for hemo and peritoneal dialysis.

Co-Chair Garrick: Thanks for that clarification. I just wanted to recap. Are there other questions or comments from anyone on the standing committee? Are there questions for the developer?

If there aren't, I think we might be prepared to vote actually on the importance of the measure and the evidence. Matt, I don't know who's leading the vote now.

Dr. Pickering: Yeah, I think it's still Nick unless he's still having some technical difficulties, yeah.

Mr. Barone: Yeah, so thanks, Matt. I'll take over the voting again. I got the microphone working. So, I'm just going to go ahead and share my screen.

Co-Chair Garrick: Thank you. The one housekeeping thing I think I'm supposed to remind everyone of is that the highest vote of the evidence under consideration for this measure, I think, is moderate. Am I --

(Simultaneous speaking.)

Mr. Barone: Yeah, so voting is now open for Measure 3722 on evidence and the options are A for moderate, B for low, and C for insufficient, and we're looking for 13 votes this time.

Dr. Pickering: Yeah, and just a reminder for those that have been recused for 3722, you have not participated in the discussions, which is correct, and you are also not voting, so that would be Lorien, Jeffrey, Michael Somers, Lori Hartwell, and Cher Thomas.

Mr. Barone: Okay.

Dr. Pickering: So, we are expecting 13. Anyone having difficulties voting? Anyone else having difficulty voting for 3722 on evidence? We do have quorum for this at 12, but we are expecting 13.

I'm just looking to see, Rick, are you on the line? Rick, are you there? Yeah, I think that's an individual we are missing. It looks like Rick has not returned.

Okay, so it looks like Rick, we're not sure where Rick is, but we do have quorum at 12 for this measure, so we can go ahead and close with that.

Mr. Barone: Okay, so it looks like we got three moderate, seven votes for low, and two votes for insufficient, so the measure does not pass here on evidence. Then, Matt, I'll hand it back over to you.

Dr. Pickering: Okay, yeah, so as Nick had said, it does not pass because moderate was the passing vote. With three votes there out of 12, that's 25 percent, which is less than the passing threshold or the consensus not reached threshold, so, unfortunately, the measure does not pass on evidence, which is a must-pass criterion, so it will not be moving forward further from here.

3725 Home Dialysis Retention (KCQA)

So, that means we pick up with the last measure of the day, which if we could go to the slides? Okay, so

our last measure for the day, and thanks, Isabella, is the NQF number 3725. So, this is the home dialysis retention measure and our measure developer is also KCQA. It is also a new measure. You can see the description here is the percent of new home dialysis patients in the measurement year for whom greater than or equal to 90 consecutive days of home dialysis was achieved.

This measure is also classified as an intermediate clinical outcome measure at the facility level, various different settings of care, and then the data source we had as electronic health data, but I'll see if there's any further clarification on any of that from the developer.

So, the same process as before. The developer will give a three to five-minute overview. We'll then go to the leads, then discussants, and the rest of the committee, capture any questions, and then go to the developer for any responses. So, Renee, I'll turn it back to you.

Co-Chair Garrick: Thanks. I don't have anything to add, so in the interests of time, I'll turn it right over to Kathy. Thank you.

Ms. Lester: Thanks, Renee. Thanks, Matt. So, I think, as you might imagine, you know, we talked a little about this in the previous measure, but the retention measure is part of the measure set, and even on its own is incredibly important given that we do have a non-NQF endorsed measure that is being used and there is no exclusion for patient choice in that metric.

And so, what the dialysis retention measure can provide, right, is a counterbalance, and just to remind everyone, that is prioritizing the selection of appropriate candidates, recognizing patient choice and each patient's desire to select home dialysis modalities, and the provision of appropriate patient education, preparation, and support to minimize treatment failure and recidivism.

So, we appreciate the comments that we received and I'll try to hit on a few of those here. I think you all know from the first discussion that we have an enormous gap in terms of equity with regard to patients who are Black and brown getting access to home dialysis and being able to remain on it.

And so, this was a measure developed specifically to support the ETC program, which as I mentioned before, is using a non-NQF endorsed rate metric to, beginning in June, cut dialysis facilities based on their rate.

So, the incentive, obviously, is to push more patients onto home dialysis than we have today, and there is no counterbalance.

The supporting evidence, again as I discussed earlier, we do not have randomized control trials here and we do stand by the recommendations of the KCQA, which include researchers and physicians who believe that the observational studies and the expert opinion, which I know may differ than some of you on this call, do support that home therapies are at least equivalent to in-center dialysis in terms of the clinical outcomes and superior in terms of the patient-reported outcomes, and in particular with regard to physical and mental health-related QOLs.

Again, we think this does meet the moderate evident rating scenario that the benefits of this measure are protecting against patients being put onto home dialysis who may not want to do that really does outweigh the detriment that might be caused.

Just to remind everybody, this was a measure that very much was driven by patient interest. And I know the patients on this call are not allowed to speak, but I do want to remind folks that patients find this to be a very important measure and one that we are hoping can be endorsed to move forward.

We never talked about this in the last measure, but if we get there, we did receive some questions about

the social determinants of health factors and, you know, again, we do not want to set up a measure that allows facilities who may treat patients with particular SES factors, race, ethnicity, and sex as well, to be able to exclude those patients and then pay attention to their needs.

So, to really allow this to affect and make a dent in the gap that we're seeing, we chose to stratify performance by the categories to facilitate that quality improvement and also address the level playing field for payment and penalties.

We also received some comments about small facility size and the reliability estimates, and to address those concerns, we had actually had this conversation with the SMP in our final submission, which I believe you received as well by CDRG, presented reliability results with a two and a three-year rolling data.

CDRG did not simply double the data in 2021. Rather, they randomly generated new annual data to account for each facility and combine that with the 2021 data to perform the analyses.

And based upon these analyses, the SMP supported the use of the three-year rolling average, which also effectively addresses the concerns about the initial reliability estimates as being potential overestimates.

So, we are not the entity, right, that would ultimately implement this. Hopefully, CMS would be able to adopt that for the ETC program and we would be providing this guidance around the two to three-year rolling data average to CMS for that implementation.

We also received a couple of comments on capturing the 90 days if home dialysis starts late in the year, and for purposes of measure testing, we carried out the numerator consecutive time count forward into a subsequent calendar year for patients who began home dialysis after October 2 of the measurement year.

For example, to determine if a patient who started on home dialysis on November 1 met the 90-day numerator criterion, it was necessary to look through January 30 of the following year. Again, this is an implementation issue and we would recommend the same approach to CMS if it were to adopt and implement the measure.

And finally, I want to reiterate the issues around the HRRs. This is really important because it goes to a fact, and Alan mentioned this in the last conversation, that you do see dialysis facilities with zero. That doesn't mean that that facility did not promote patients onto home dialysis.

What happens in a practical manner is that if you have a dialysis organization with several facilities in an area, they will cohort those patients into a home dialysis facility for a lot of reasons, and that is what is being measured in the ETC program and that is what we measured here.

So, we tested the retention measure at a facility level because dialysis organizations, as I said, with more than one facility will aggregate those patients into a single facility.

If we were to have tested it at the HRR level, however, the data would have been skewed because you would have focused on those facilities with zero, and having them designated as not providing home dialysis would not actually be accurate in the way that dialysis is provided.

We're happy to answer additional questions about this issue, and many of you on the phone work in facilities that do this, so we're happy to hear your comments on that too, but that is why the HRR piece is so important.

Again, thank you for your time and consideration, and we recognize there were other comments, particularly about reliability and validity testing, that the folks at CDRG will be happy to respond to during

the deliberation. Thanks.

Co-Chair Garrick: Thank you. Thanks so much, Kathy, and thanks for that last comment because I do agree that as we move through the measure, we're going to try to keep our comments, and partly for the time, focused on first evidence and then we'll get to later performance gap, reliability, and validity.

So, I think John Wagner is our lead discussant, so, John, if you want to begin this by taking us through the evidence? John, I think you're muted.

Member Wagner: Yes, that works?

Co-Chair Garrick: Yes, that works. Thank you.

Member Wagner: Good, okay. Thank you, colleagues, for allowing me this opportunity.

I have a distinct advantage in that Alan went through a lot of the evidence that was presented and that evidence was, in fact, similar to the evidence that was offered here, although the logic model was different and the measure itself is being called an intermediate clinical outcome measure, whereas I believe 3722 was called a process measure.

The logic model is a little different. It's on page 14 of the handout. And it talks about the facility identifying clinically appropriate home candidates, then providing modality education, identifying the patients who opt for home dialysis and receive training.

The patients who complete training and begin their post-training home modality get ongoing support from the facility. They've achieved 90 days plus of home dialysis and that is, in this logic model, set to provide the same outcomes that we've already discussed at length and critiqued.

But the rationale for the measure is this issue of having a guardrail against overzealous promotion of home dialysis to patients who may not be good candidates and/or who may not receive the resources

necessary to make their home dialysis experience successful.

So, I am struck by the fact that a lot of the references are the same as Alan has already reviewed. There were four references that actually spoke to the issue of home dialysis attrition.

And I was surprised that more effort wasn't expended in describing what the factors that have been identified in mostly observational literature or totally observational literature have been as barriers to successful maintenance of home dialysis status.

So, I think according to the script, the question about whether we should rely on the observational data raises, I think, for me an issue as to whether we should view this measure based on the rationale given in the prior measure or we should view it as the particular rationale given, which is to say is a guardrail measure, and that this is really to prevent patients from being inappropriately placed on home therapies.

So, I think I would like to pause there and see if the developer or anyone has any questions about this.

Ms. Lester: I'm happy to answer, but I'll pause to see if committee members have a thought first.

Co-Chair Garrick: So, let's hear from Cathy first and then the committee may have some other questions.

Ms. Lester: Yeah, I mean, obviously, I do think that this measure has a different rationale than the rate measure, and so we would ask that folks would consider it on the fact that it is meant to be a guardrail that the patient advocates and patients themselves very much wanted to have in place to prevent what you so eloquently described as sort of that overzealous activity that is attributable to a rate measure.

Member Wagner: Okay, Alan? I'm sorry. I'm not the

Chair.

Co-Chair Garrick: Oh, go ahead, John, if you want. Are there other people? Alan, you have your hand up. Sorry, I didn't see it.

Member Wagner: You're muted.

Dr. Pickering: Sorry to interject. I know that, John, you have the lead, but maybe, Renee, we can kind of check in with the other discussants and see if there's any committee discussion and capture the questions first if that's okay?

Co-Chair Garrick: I apologize. I thought Alan was responding to that specific comment, but we absolutely can turn now to the other members of the standing committee for their comments.

So, Roberta Wager, Mahesh Krishnan, and Fred Kaskel are the other discussants if they have other comments they'd like to make. Roberta, or Mahesh, or Fred, anything to add, any other comments that you'd like to make at this point, Roberta? No, how about Mahesh or Fred Kaskel? Did Fred make it back to the meeting?

Dr. Pickering: I do see Rick on the call and then I believe Mahesh was on. I'm not seeing him now though.

Co-Chair Garrick: Okay, if the standing committee members don't have any other comments they'd like to make at this point, we could ask Alan if he'd like to make a comment.

Member Kliger: Just a question for the developers. I'm a little confused about how measuring success through 90 days protects patients, you know, the way that you had described it?

The major reasons for dropout once you've gone home for peritoneal dialysis is peritonitis infection or inadequate dialysis as the renal function deteriorates, so people go on hemo.

Those are the two leading reasons for failure technique in absence of the 90-day periods. So, help me understand how that measure deals with patient choice and with appropriate assignment to home treatment?

Ms. Lester: Sure, and I think the way that we are looking at this measure is not retroactive, right. Those are the reasons that today patients come off, but if you have a rate measure, which you do, already in place in the ETC program and could extend to other programs, as you create financial incentives that, as Dr. Wagner said, you know, kind of incite folks to maybe put more patients on home dialysis who may not be the right candidate, who may be doubtful, but are placed on it anyway.

You are overriding patient choice potentially and having a measure that then looks back and says well, was that patient still there after 90 days? It is creating that guardrail to disincentivize the facility from doing the behavior that would lead them forward.

We're not necessarily, you know, looking at infection rates or other reasons why a patient would come off because that may have a whole host of reasons.

What we are trying to do is set a guardrail so if you have something that incentivizes behavior that goes in one direction, we don't go so far in that direction that patients who would rather not be on home dialysis, or who are not good candidates for all of the socioeconomic status reasons and social determinants of health we've talked about, are then sort of trapped and pushed in that way.

The 90-day window is what we thought would be, and the experts on the panel thought would be the right window at which to look to make sure that that behavior was deterred.

Member Kliger: But, I guess, Kathy, my question is when you actually apply the measure and you have

a group of people who leave before 90 days, how do you know if it had anything to do with a guardrail function or a biologic function like developing recurrent peritonitis or having reduced kidney function, or people who decide that it's just not right for me? Home treatment is too difficult. My family is hurting.

So, I mean, I understand the rationale of disincentivizing, but in actually applying the measure, I'm confused that it would accomplish that.

Ms. Lester: Oh, I think it definitely would. I mean, your question is a great academic one, but in the practical world, right, we really do need to look at what is achievable and what can be reported, you know, in terms of what data elements are available and what can be confirmed if you were to audit these measures.

And so, I think we could have an explosion of exclusions here, but the group of experts chose specifically not to do that because as you look at the way the models are implemented, right, you do end up with benchmarks and you do end up with measures that are not 100 percent.

And so, if there were patients who, you know, for a clinical reason are not able to be able to stay on home dialysis, you know, that's going to be built into the benchmarks. The way they do it in the ESRD QIP is based on a national average.

Lisa, you can jump in here, but I think the ETC model is also based in a comparative group between those in the HRRs that are part of the model and those that are not.

And so, the clinical pieces, the folks that might not be attributed, right, to an action by the facility that I think you're talking about, you know, would be ubiquitous across those comparator groups.

Whereas, you know, if you were looking at that

overzealous behavior, you would see it in the HRRs that are part of the model and the ETC and you would not see it in those HRRs where it wouldn't, so that's how it would pick up. Lisa, anything that you would add there?

Dr. McGonigal: No, no, I think that's accurate. That's a good description.

Co-Chair Garrick: Kathy, it's Renee. I have just a question about the evidence regarding the 90 days, and so in the submission, we certainly understand the need for the guardrail, and I wanted to focus specifically on the evidence for the 90-day mark.

So, and the reason is that clinically, many of us have seen patients that want to go home and we really want to support that. We're very big advocates of home dialysis for both hemo and PD.

And so, you try and you give it your all, and they try, and some of them make it a little past 90 days and some don't quite make it to 90 days and they come off, and you feel good that you tried and they feel good, and it's very patient-centered care and it's really doing the right thing, I think, for those patients.

So, I did spend some time looking at those three articles that were listed about specifically the 90 days and the evidence around that choice, and one of them is a PD article from the Netherlands from 2003 to '07, and it did not see a facility effect.

It did support the concept that the first year has about a 25 percent drop in patients overall and the rate did seem to be the highest in the first three months, but it continued on for other months to come, so overall, at the end of the first year, it was 25 percent, although the rate was greater in the first three months.

The second -- and that did not show any specific facility effect. It showed, as was suggested, lack of

patient-related issues, peritonitis, age was a big one, female sex happened to be one that I thought was interesting, and comorbidities.

And then the second article was an article that looked at factors for the discontinuation specifically of hemodialysis and it also did not show a facility effect specifically, and it also showed some of the same things that others have already talked about in terms of family situations and problems with the ability to stay on hemo.

And then the third was actually looking at these for the teleplatform and whether or not teleplatforms could be used to encourage patients to stay on dialysis and be successful.

So, I was interested in the 90-day interval as being the measure of success, as the evidence of the success point of the measure.

Ms. Lester: And if I may, I'm going to turn that to my colleague, Dr. McGonigal.

Dr. McGonigal: Thank you. Yeah, so Renee, you are correct. Again, there's not a lot of evidence around this time frame and we know that going in, and there actually was a good bit of back and forth on our expert committee members and our steering committee about the appropriate time frame for this.

Some of the patients on the group actually wanted to extend this out to a full year. We had some people who wanted to do as short as 30 days, and so really this just came down to a consensus among the experts.

And the bottom line was that this was, 90 days was a moderate and appropriate retention goal that would serve to foster proper investment in patient support and preparation for the transition home, but it's not so formidable a time requirement that it's going to discourage home trials in all but those most ideal candidates.

The providers in particular were quite worried about if we set too long of a time frame, that it really would discourage providers from trying patients on home, so there was a -- this was really about balancing the potential pros and cons of selecting a time frame.

Co-Chair Garrick: Thanks. Are there any other questions or comments on the evidence around this measure for the maintenance of home therapy? Alan, you had your hand up?

Member Kliger: It might be useful to run through the evidence algorithm for this one to see, you know, where that lands.

Co-Chair Garrick: John, as our lead discussant, do you want to run us through that?

Member Wagner: Sure, but Andrew, I think, had his hand up.

Co-Chair Garrick: Oh, I'm sorry. Thank you. There you are. Hi, Andrew.

Member Chin: Hi, thanks. I just have one comment. When I kind of think about this push and pull, that we're looking at this measure to somewhat push against the potential overzealous placement of patients on home, you know, even if we do everything right and try to get more patients on home, you will almost necessarily have more patients failing PD.

And I kind of look at this as the Fistula First initiative. Remember, when that came around in 2006 or 2007, we certainly got our fistula rates higher, but if you look at the surgical literature, there were a huge increase in failed fistulas, and you necessarily have to have that failure that comes along with increasing the uptake of something.

So, because we're not perfect. We can't perfectly predict who is going to succeed in that and I kind of look at it that way, and I'm wondering if we're

appropriately putting patients on PD, I think we will necessarily see an uptick in failures and I would hate to have that significantly counteract a group or a region that's really trying to do right.

But, you know, I hear you, but you need to perhaps have a bit of a push against those individuals who may be overzealous in this process, but I just wanted to comment on the -- I see it as similar to what we saw in Fistula First.

Co-Chair Garrick: All right, thank you. Please, go on. I was just focusing for a second on the evidence specific to the measure. Maybe we could have John walk us through the algorithm, John, if we could put it up?

Member Wagner: Sure, just two comments though. I think, you know, it's important to recognize we don't have evidence that tells us how venality will enter into this equation.

We discussed this morning the fact that we can't convince patients who don't want to have a transplant to be on a transplant waiting list, and certainly the financial incentives are there for practitioners to encourage patients to receive a transplant.

So, I don't know whether there will ever be a study which talks about this, but I think we have to recognize there's an assumption here about human behavior that is not evidence based, but it's just a judgment that one is making that this is going to be a major problem if we incentivize home therapies.

And I think the unanticipated consequence or the -- we've seen in other settings where we might limit access to therapy if we're convinced that someone is going to fail.

We may then be discouraged from running the trials that we just alluded to where we have patients trying it out who we think there's a reasonable chance they

may not make it through the 90 days, but we wanted to have them make that attempt, and this will disincentivize that.

And there is a built-in mechanism in the sense that patients don't count until they reach 30 days, so the patients who are truly not likely to succeed because they really don't want to do it, there is an escape valve that occurs before 30 days where that is not counted as part of this, of the measure.

Co-Chair Garrick: So, maybe we're getting a little into some of the other later conversation about the measure, but if we just want to run through the evidence cascade, this is an intermediate outcome measure, right, so --

(Simultaneous speaking.)

Member Wagner: So, it's box three.

Co-Chair Garrick: Three.

Member Wagner: It's box three. We go to box -- it's based on expert opinion. There was no systematic review as we heard, so it goes down to seven, and then, you know, so really it's a question here, is empirical evidence submitted, but without systematic review and grading of the evidence?

And so, yes, it's submitted, and does it include all of the studies? And I have the same comment that Alan made about 3722. There's a couple of other studies you could find that talk about attrition and what helps patients maintain home therapies, but I think, you know, basically, we have gist of it.

And then we have to decide whether we believe the submitted evidence indicates high certainty that benefits clearly outweigh undesirable effects, and we either conclude that it's high certainty high moderate quality and that this might indicate a substantial net benefit to the patients, and if we don't, then we rate it as low. And obviously, if the NQF staff believes I

misspoke, please feel free to correct me.

Co-Chair Garrick: So, I don't see any hands up for other comments or other questions for the developer. So, if there -- let me just make sure I'm not missing any.

So, if there aren't any, I think we can proceed with a vote for the vote on evidence of this as an intermediate outcome measure, and I think that would bring us to Nicholas.

Mr. Barone: Thank you, Renee. Okay, I'm going to go ahead and share my screen.

Co-Chair Garrick: Oh, I apologize. Did we ask if there were other public comments --

Mr. Barone: Sorry about that.

Co-Chair Garrick: -- on the measure? No, my fault. I think someone mentioned there were no other public comments, but just to be complete and thorough, John, were there other public comments or did the other discussants, the secondary discussants, were there other public comments on the measure besides what we're already covered from the committee?

Member Wagner: I think the one public comment, you know, basically presented the position of the developer, and the -- it's interesting that the comments, the preliminary comments by the group, there were 12, and there were only two that were clearly negative. There were a few that were general and there was favorable or a rating of moderate for, I think, about nine.

Co-Chair Garrick: Great, thanks. I just wanted to be complete on that. So, thanks, John. So, now I think, Nicholas, I think we could proceed, having heard from the public side of things, with the vote. Thank you.

Mr. Barone: Okay, thank you, Renee. Then Matt, I just wanted to make sure we're good to continue with

the voting now?

Related and Competing Measures

Dr. Pickering: Yeah, I would just add, so, John, you're correct. So, Kidney Care Partners submitted comments for this measure as well as the previous measure, which they were supporting the measure.

A lot of the comments that they've expressed in that comment were also what were shared by Kathy in the opening remarks about the importance of this measure as a set and, you know, recognizing some of the efforts that are going on in the ESRD treatment choices payment model, so, and these measures sort of aligning and supporting with those goals and objectives, so very similar comments across both measures, but again from Kidney Care Partners.

And before we go, just a reminder again, this is an intermediate outcome. The voting still would be very similar to how you would assess as a process measure. You will have the highest voting being moderate because of the flow as you saw.

There was no systematic review and grading of evidence, which drops down the rating options to be the highest you can achieve is moderate, so you'll have those options available to you and you're just looking to see if this measure can improve downstream outcomes as what we've been discussing through the evidence that they exist. All right, Nick, let's open it up for a vote.

Ms. Kyle-Lion: Nick, I think you're muted, sorry.

Mr. Barone: Oh, sorry, I was on mute. Yes, so the poll is now activated. You can now go ahead and vote on 3725 for evidence. The options are A for moderate, B for low, and C for insufficient.

Dr. Pickering: And I just wanted to, before we close it, just confirm we do have 12, so that is the quorum number, but -- there we go. I think we were

expecting 13. I think we had an attendee kind of join late for this measure, so great.

Mr. Barone: Okay, we'll go ahead and lock. Okay, so it looks like we got four for moderate, seven for low, and two for insufficient, so we'll just go ahead and calculate real quick. So, it looks like this comes out to 30.7 percent and does not pass on evidence here. I'm going to hand it back to Matt.

Dr. Pickering: All right, so again, that is a must-pass criterion as well, so obviously, the measure will not proceed moving forward because we have to have passing votes or CNR votes on must-pass to continue, so therefore, this measure does not, is not recommended for endorsement by the standing committee.

At this time, I do want to thank the KCQA, as well as KCP who were on the call, for all of your time and attention through the development of these measures and getting ready for the committee's discussion today, and thank you so much for all of your answering those questions as the committee has raised them.

Ms. Lester: Matt, I would just say thank you to you and the whole staff at NQF. It's been a pleasure working with you guys.

Dr. Pickering: Thank you. Thank you very much, same. With that, as you see in our agenda, we have related and competing measures up for discussion.

We will not be having those discussions as only endorsed measures are those that are recommended for endorsement by the standing committee will have related and competing measure discussions.

The standing committee did not recommend any of the measures today or for the fall 2022 measures to be recommended for endorsement, so there's no related and competing discussions.

Therefore, this will be the opportunity for NQF member and public comment, so we'll just pull that up. So, for NQF member and public comment, now is the opportunity for any member of the public, if you're on the call and wish to share any thoughts or comments for the standing committee's consideration, now is the time to do so.

You can raise your hand if you're logging on and wanting to raise your hand. We'll recognize you or you can take yourself off mute. We just ask that you state your name, any affiliation, and then you can just state your comment. So, I'll just pause for a few seconds to see if anyone has any public comments.

Again, this is the opportunity for NQF member or public comment. If you would like to raise any comments for the standing committee about any of the discussions or measures today, you have the opportunity to do so. You could raise your hand or just take yourself off mute and share your comments.

Member Hartwell: Can you hear me?

Dr. Pickering: Hi, Lori, yes.

Member Hartwell: Yeah, I just wanted to say that, you know, I hope that there's more discussion around home dialysis. I'm really sad that these two measures did not make it. As a patient, I do think, you know, it's important to gather some of this data.

I did appreciate the comments about Fistula First and, you know, the unintended consequences of that, and I do think that it's important that we protect patients so they have the right treatment for them.

So, I hope that, you know, more consideration is given to home measures. As somebody who was on it for ten years of PD and home hemo, it's really important, and I just want to thank the work of the group.

Dr. Pickering: Thank you so much, Lori, appreciate the comment. One last call for other public comments. Anyone else on the call for the standing committee's consideration?

Okay, hearing none and not seeing any hands raised, we'll conclude the public comment session. I'll then just turn it over to Nick to walk us through some next steps.

Next Steps

Mr. Barone: Thank you, Matt. So, moving forward, the renal team will begin drafting the meeting summary based off of today's conversations. We're going to communicate all next steps with everybody in the near future. If you have any questions or concerns, please reach out to the team.

And then finally, we will be canceling the February 15 backup meeting that was sent as a calendar event to all of you. Matt, is there anything else that you would like to add or anything?

Dr. Pickering: Yeah, sorry, if we could just go to the next slide, Isabella? We'll just note that we, you know, for the spring 2023 cycle which also kicked off, we did receive 14 measures total.

And as I mentioned earlier on in the meeting when we started off the call, there will be communication to all stakeholders, including developers, around next steps related to the transition. So, there's nothing else there, so thanks, Nick.

So, we can go, I think, to the final slide. Oh, well, there you go. If you had any questions or comments you'd like to share with us, you can reach out to us at renal@qualityforum.org. You can see the project web page there and the telephone number if you wish to just have a phone call.

Any questions? We can go to the next slide, Isabella. Thanks. Any questions from anyone at this point?

Member Kliger: Only a huge thanks for all of the work and expertise that all of you guys at NQF over all of these years have offered and helped us in our work, so thank you so much.

Co-Chair Garrick: Yeah, I would add to that as someone who has been on the committee for several years. We're very grateful for your contributions and your dedication as we are all to patients with renal disease.

It has been terrific working with all of you and with all of the other members of the standing committee. You know, it's a very sad day actually, so thank you all.

Dr. Pickering: And thank you for the kind words and we greatly appreciate your time and expertise. We can't do this work without you. And my minimal engagement with this standing committee since my time at NQF, I've just enjoyed the dialogue and conversations.

It's always been very thorough an just really great dialogue to determine, you know, the value of measures moving forward, and I very much echo that from all of NQF to say thank you for your time and expertise in our work, and like I said, we could not do this without you.

As I mentioned, we will follow up with communications about any of the next steps to stakeholders, so you'll keep an eye out for that, but I also want to thank our two co-chairs as well, Lorien and Renee, for all of the great work that they've done over the past few years as being participants on the standing committee, but then also serving as co-chairs and taking on a facilitation role, which is added work, so thank you both as well.

And to the developers as well as the other standing committee members, thank you for your time. Renee, Lorien, any final closing remarks?

(Simultaneous speaking.)

Co-Chair Dalrymple: Go ahead, Renee, please.

Co-Chair Garrick: I just wanted to thank the patients. You know, the reason why everyone does this is for the patients and to make things better, and your input is so valuable.

And I hope we can continue, with your guidance, keep doing things that make lives better and better, so thank you, because we wouldn't have any of this if it weren't for you guys, so thank you.

Co-Chair Dalrymple: And I just wanted to take the opportunity to also thank the committee. We've worked together for years, some of us more than ten years through NQF, and it really has been one of my greatest professional joys to work with all of you.

I think about how much I've learned over the years and continue to learn every time we meet, and I think it is reflected in the committee's deep commitment to this work, the thoughtfulness of the debate, the time put in. I think it's always really clear when we get together how much time and expertise is contributed to this process.

And then I also think, because we don't know what comes next, Matt, we do really want to thank the NQF staff. We, as a committee, rely on you all heavily, and your expertise, and the amount of time and preparation that goes into this. Renee and I get an even extra view of that. You know, it's really been extraordinary over the years in watching the NQF process evolve.

So, I think I just really want to say thank you to everyone and I think NQF will keep us posted on what comes next, but thank you all for the vigorous discussion and debate, and also to the developers who participated throughout the process today for which we are very grateful.

Dr. Pickering: Thank you, Lorien, and thank you, Renee. Well, with that, it is Friday at 4:00 p.m. I hope everyone has a very nice weekend. I will definitely be in communication through email, but if you have any questions, please don't hesitate to reach out.

Thank you again for your time today and throughout the years in the past. I look forward to what comes down the road in the future. Have a great weekend, everyone.

Adjourn

(Whereupon, the above-entitled matter went off the record at 4:00 p.m.)