National Quality Forum
Renal Measure Evaluation Spring 2022 Cycle Web Meeting
Thursday, June 30, 2022

The Standing Committee met via Videoconference, at 2:00 p.m. EST, Lorien Dalrymple and Renee Garrick, Co-Chairs, presiding.

Present:

Lorien Dalrymple, MD, MPH, Fresenius Medical Care
North America, Chair
Renee Garrick, MD, FACP, Westchester Medical
Center, New York Medical College, Chair
Andrew Chin, MD, University of California, Davis
Medical Center
Annabelle Chua, MD, Duke University
Rajesh Davda, MD, MBA, CPE, Cigna Healthcare
Gail Dewald, BS, RN, CNN, Gail Dewald &
Associates, LLC
Stuart Greenstein, MD, Montefiore Medical Center
Mike Guffey, Patient/Caregiver Perspective,
UMB Bank
Lori Hartwell, Patient/Caregiver Perspective,
Renal Support Network
Fredereick Kaskell, MD, PhD, Children's Hospital at Montefiore
Myra Kleinpeter, MD, MPH, Tulane University
School of Medicine
Alan Kliger, MD, Yale University School of
Medicine, Yale New Haven Health System
Mahesh Krishnan, MD, MPH, MBA, FASN, DaVita, Inc.

Karilynne Lenning, MHA, LBSW, Telligen
PreciousS McCowan, ESRD Network
Andrew Narva, MD, FASN, University of the District of Columbia
Jessie Pavlinac, MS, RDN-AP, CSR, LD, FAND, Oregon Health & Science University
Jeffrey Silberzweig, MD, The Rogosin Institute (New York Presbyterian)
Michael Somers, MD, American Society of Pediatric
Nephrology, Harvard Medical School, Boston Children's Hospital
Cher Thomas, Patient Advocate
Jennifer Vavrinchak, MSN, RN, CNN, National Dialysis Accreditation Commission
Bobbi Wager, MSN, RN, Patient/Caregiver Perspective, American Association of Kidney Patients
John Wagner, MD, MBA, Kings County Hospital
Center
Gail Wick, MHSA, BSN RN, CNNe, Consultant, GWA

NQF Staff:

Peter Amico, PhD, Consultant
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Matilda Epstein, MPH, Associate
Paula Farrell, MSHQS, Director
Katie Goodwin, MS, Senior Director
Oroma Igwe, MPH, Manager
Gabby Kyle-Lion, MPH, Analyst

Also Present:

Vahakn Shahinian, UM-KECC

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(2:01 p.m.)

Welcome and Introductions

Ms. Farrell: Good afternoon, everyone, and thank you again for joining us on Day 2 of our Renal Spring 2022 Measure Evaluation Meeting. I'm Paula Farrell, and I'm the director for the project. And I just wanted to provide a brief recap on the Standing Committee's discussion that we had yesterday.

We did discuss and vote on four measures. And all four of the measures were not recommended for endorsement. And so today we have two measures that we're going to be discussing. One measure is a new measure, and the other measure is a maintenance measure.

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

Chair Dalrymple: Thanks, Paula. I'll just briefly start. Thank you all for joining us again today. Yesterday the discussion was really productive, and we really appreciate the engagement. We recognize eight hours by video, that is a big ask.

Today we're hoping to keep it under three hours. We will be reviewing two measures. We want to give them their full review and due. So we really appreciate you all rejoining us today to make sure we can have thoughtful and deliberative conversations and decisions. So thank you all.

Chair Garrick: Thanks again. This is Renee, and a special thanks again to our patients who have joined us. Their input yesterday was terrific and really very helpful. So we're glad to have Precious and Bobbi, I hope, back with us today. And thanks, and feel free to jump in any time. So thank you.

Ms. Farrell: Great, thank you. So today I'm just going to start with a few housekeeping reminders as

we did yesterday. So we are again on a Webex meeting with audio and video capabilities. So if you're able to, we do ask that you please turn your video.

Please also remember to always keep yourself on mute if you're not speaking. And we do encourage you to use the chat box. And you can message in the chat box to the NQF staff individually if you're having an issue or a question, or you can message all the meeting attendees through the chat box if you like.

We also ask, during the discussion today, like we did yesterday, to please use the raised hand function so that you can be called upon by the co-chairs when you'd like to speak so that everyone has an opportunity to talk.

And finally, if you're having any technical issues or have any other questions, please also feel free to reach out to us at our project inbox which is at renal@qualityforum.org.

Next slide, please. All right, today the project team that was with you yesterday is also here today to assist you. I did want to mention though that Poonam Bal is attending another projects measure evaluation meeting today. So I'd like to introduce Katie Goodwin. She is the senior director that's going to be on our call today to assist us.

Next slide, please. All right, so our agenda for today, we'll do roll call to ensure that we have attendance to hold the meeting. We are going to conduct another voting test to ensure everyone has the link and access to Poll Everywhere and is able to vote.

The Standing Committee will then have their discussion on the remaining two measures and vote on those measures. And then we'll discuss any related and competing measures as applicable. We'll allow time for NQF member and public comments,

and then we'll discuss next steps and adjourn the meeting.

And as a reminder, you should have received an email yesterday with the voting link that you'll need for today's meeting. If you need us to resend that to you, please let us know if you could send in a comment in the chat or send us an email to renal@qualityforum.org to let us know. We'll get that link out to you.

Next slide, please. All right, so now I'm going to turn it over to Oroma, and she is going to do our roll call for today.

Ms. Igwe: Great, thank you, Paula. So at this time we're going to go through a general roll call. The names will be featured on the next slide. And when I call our name, please just let us know that you're here, state your presence.

And today, we will not be going through disclosures of interest, of course, unless an attendee or an anticipated attendee who was not present yesterday happens to arrive today. So when I call your name, just feel free to state your presence.

Okay, we'll start with Lorien Dalrymple.

Chair Dalrymple: Present.

Ms. Igwe: Renee Garrick?

Chair Garrick: Present.

Ms. Igwe: Stuart Greenstein?

Member Greenstein: Present.

Ms. Igwe: Frederick Kaskel?

Member Kaskel: Present.

Chair Garrick: Myra Kleinpeter?

(No audible response.)

Ms. Kyle-Lion: Paula, I think we might have lost Oroma.

Ms. Farrell: I think we have lost Oroma. Let me check to see where she was. I think she was on Myra Kleinpeter.

Ms. Kyle-Lion: Yes, that's correct, Paula.

Ms. Farrell: Just wait one moment to see if she responds.

Next is Alan Kliger?

Member Kliger: Present.

Ms. Farrell: Thank you. Mahesh Krishnan?

Member Krishnan: Here.

Ms. Farrell: Thank you. Karilynne Lenning?

Member Lenning: Present.

Ms. Farrell: Thank you. Jessie Pavlinac?

(No audible response.)

Ms. Farrell: Okay, Jessie is not on. Jeffrey Silberzweig?

Member Silberzweig: Silberzweig, present.

Ms. Farrell: Silberzweig, sorry. Next we have Michael Somers.

Member Somers: Yes, I'm here.

Ms. Farrell: Thank you. Next is Jennifer Vavrinchak?

Member Vavrinchik: Present.

Ms. Farrell: Next is John Wagner, John Wagner?

(No audible response.)

Ms. Farrell: Okay. James Michael Guffey?

Member Wagner: I'm on.

Ms. Farrell: Oh, John Wagner, you're on?

Member Wagner: Yes, thank you.

Ms. Farrell: Okay, sorry. Thank you. James Michael Guffey? James Michael Guffey?

(No audible response.)

Ms. Farrell: Andrew Chin?

Member Chin: Present.

Ms. Farrell: Thank you. Annabelle Chua?

Member Chua: Present.

Ms. Farrell: Thank you. Rajesh Davda?

(No audible response.)

Ms. Farrell: I think he advised that he wasn't going to be on the call today. So I'll move onto Gail Dewald.

Member Dewald: Present.

Ms. Farrell: Thank you. Gail Wick?

Member Wick: Present.

Ms. Farrell: Thank you. Lori Hartwell?

(No audible response.)

Ms. Farrell: I think she also advised that she wasn't going to be on the call today. Lori Hartwell?

(No audible response.)

Ms. Farrell: Okay. Precious McCowan?

Member McCowan: Present.

Ms. Farrell: Thank you. Cher Thomas?

Member Thomas: Present.

Ms. Farrell: Thank you. Roberta Wager?

Member Wager: Present.

Ms. Farrell: Perfect, thank you. And Andrew Narva?

Member Narva: Here.

Ms. Farrell: Perfect, thank you. Team, wondering if there's anyone that we need to check conflicts of interest today that were not on the call yesterday? I believe it is the same folks, but if someone could --

Ms. Kyle-Lion: That's correct, Paula. Everyone was here today.

Ms. Farrell: Okay. So no need for conflicts of interest, all right. Thank you for going through the roll call. And now we'll go on to our next slide. And I'll turn it over to Gabby, and she's going to do a quick voting test to ensure everyone has access to the link. Gabby?

Ms. Kyle-Lion: Hi, everyone. We sent out an email last night with the voting link for today. So if you need us to resend that to you, let us know. I will go ahead and pull up the poll. Also if you're having any issues voting via Poll Everywhere, feel free to send me a message via private chat on the Webex platform like we did yesterday.

There are 19 people on this call, so we are expecting 19 votes. And like I said, if you're having any issues, please go ahead and speak up now, and we will either send you the polling link via chat or have you vote via chat.

Okay, we're at 13. We're just waiting for a few more. We need at least 16 to continue. Okay, we're at 16. I'll just give it a couple more seconds to see if we get anymore votes, but 16 is quorum. So if that's all we have, we will move forward.

Okay, I did receive a couple private chats. And we can resend the link to the Committee. I'll send it after we finish this vote. We do have 18, so I'll send the link again to the last person who was unable to vote. But for now, I'll go ahead and close the poll.

So the poll was is a hot dog a sandwich? And options were A for yes, B for no, and voting is now closed. And 53 percent of you said yes, and 47 percent said no. So a little contentious there, consensus not reached. All right, I'll pass it back to Paula.

Ms. Farrell: All right, thank you, Gabby.

So next slide, please. As I mentioned earlier, we have two measures that we're going to be reviewing today. And the Standing Committee's going to following the same structure as our call yesterday.

So to begin with, I will hand it over to our Co-Chair lead that's been assigned to lead the discussion. And the first measure we're going to review is NQF Measure Number 3695.

The developer will then be providing an opportunity to give their introductory remarks, and then the co-chair will turn it over to the discussant who will begin with the first criteria which is evidence. And they will provide the summary of the submitted evidence, the pre-evaluation comments, and the Committee pre-evaluation survey results.

And the Standing Committee will also discuss the evidence. And during that discussion, Co-chairs and NQF staff will keep track of any questions that come up for the developers. And then once the Standing Committee has completed their discussion, we'll allow time for the developers to address any questions that have come up.

The Standing Committee will then vote on evidence, and once voting is completed we'll then move on to the next criteria which is performance gap, and

follow the same structure. So with that, I am going to turn it over to our Co-chair lead, Lorien, to facilitate our discussion on our first measure, NQF Number 3695, Percentage of Prevalent Patients Waitlisted. Lorien?

3695: Percentage of Prevalent Patients Waitlisted (PPPW)

Chair Dalrymple: Thank you, Paula. Well, I will just briefly introduce the measure and highlight that Measure 3695 is the percentage of prevalent patients waitlisted. This is a new measure. It is outcome measure. The level of analysis is the clinician group or practice. The setting of care is outpatient, and source of data is registry data and claims.

And with that, I'd like to ask the developer, Dr. Shahinian, to present a brief overview of the measure.

Dr. Shaninian: Thank you, and good afternoon, everybody. So again, I'll keep this very brief since we've gone through a number of these measures yesterday. We're talking about the percentage of prevalent patients waitlisted which assesses overall waitlisting, in other words, any kind of waitlisting, regardless of active or inactive status for patients on dialysis.

In that sense, you could think of this as a super-set of the measure we discussed yesterday which was waitlisted in active status. Like that measure, it's a prevalent measure, and it captures both new placements on the waitlist at any point after the initiation of dialysis but also assesses maintenance of patients on the waitlist, including maintenance of waitlisting that was initiated prior to dialysis.

So the motivation for including this in addition to one that specifically looks at just active status, really came about because of discussions we had during the Technical Expert Panel and in particular

motivated by points that were raised by our patient members of the TEP.

And that had to do with potential benefits of waitlisting regardless of active status. So the idea is that even for patients not immediately ready for transplantation, waitlisting may still be beneficial as it can serve as a motivation to start a search for living donors, take action to achieve improvements in health that are needed to achieve a point of being able to be actively listed.

In addition, they described that waitlisting may provide psychological benefits providing hope for patients on dialysis. So those were some of the reasons to include an overall waitlisting measure beyond one that was restricted just to actively listing.

So I'll stop there. And thank you all again for your consideration of all of our measures.

Chair Dalrymple: Thank you, Dr. Shahinian. So with that I will hand it over to the lead discussant who will be Andy Narva. And supporting discussants today will be Andy Chin and Jessie if she is able to join us subsequently. So, Andy Narva, let me let you begin on review of evidence.

Member Narva: Thank you. Good afternoon. The evidence and the comments for this measure are quite similar to 3694 which we discussed yesterday and which were really well summarized by Michael Somers in his discussion.

There were two Technical Expert Panels that were in favor of the development of all of the measures that targeted waitlisting. The developers provided a logic model that outlined the steps in the transplant evaluation process and asserts that being waitlisted is an outcome because it represents a desirable change in health status for the patient. There was some discussion about whether it was actually a process measure.

They cited empirical support for the value of waitlisting and the association between processes under dialysis practitioner control and waitlisting. The developers cited several studies that provided strong support for the association between processes under the dialysis practitioner control including a correlation between ranking and referral ratios, and waitlist rates, and a number of studies showing the positive effect of patient education on transplant listing and transplantation.

The Committee comments prior to this meeting, there were a lot of folks who supported this. There was concern with this, as well as with all of the other transplant listing measures about unmeasured confounders, patient preference, and that listing of, they assert that the listing is really under the control of the transplant center solely.

And some responders did kind of react to the assertion that some patients would receive preferential treatment in order to be optimized for listing and that all patients should be medically optimized. And I'll just stop there, since we've heard a lot of this evidence already.

Chair Dalrymple: And, Andy Chin, would you like to add anything else to that review?

Member Chin: No, I think that was very thorough and nothing new to add.

Chair Dalrymple: Thank you. I'll open it up to the Committee to discuss. Does anyone have anything they would like to discuss related to this evidence, recognizing we did have a discussion yesterday. So I just want to offer that opportunity.

Alan, I see your hand.

Member Kliger: Yeah, again, Andy, similar to the question I asked last time, was there anything in the evidence that was different than we looked at with the other measures when we considered the

evidence?

Member Narva: You know, I didn't see any. I tried to compare them. And I think the same literature was used. And I did not see anything significant. I don't know if Andy Chin saw anything that I didn't see.

Member Chin: No, I think the basis of the evidence for this measure is the same body of literature as the previous one.

Chair Dalrymple: And I'm just looking to see if there are any other hands or if anyone has any questions for the developers before we move to a vote on evidence.

Okay, with that I think we can move to vote on evidence.

Ms. Kyle-Lion: Okay, give me one moment to get the poll pulled up. All right, voting is now open for Measure 3695 on evidence. The options are A for pass or B for do not pass. Again, there are 19 people on the call, so we are looking for 19 votes.

And we're at 17, so I'll just give it a couple more seconds to see if we get those last two. Okay, we're at 18. Give it one more second to see if we get the last one. We're still at 18, so I'll go ahead and close the poll, because 16 is our quorum.

Voting is now closed on Measure 3695 on evidence. Just give me one moment to get the results pulled up, please.

Okay, there were 13 votes for pass and five votes for do not pass. Therefore the measure passes on evidence. And I'll pass it on to Lorien.

Chair Dalrymple: Thank you, Gabby. We're now going to move to a discussion of performance gap. So again, I'll let Andy Narva start the discussion and then ask Andy Chin to contribute any additional thoughts before we open to the broader committee.

Member Narva: Thank you. 2019 performance scores for all dialysis practitioner groups that had a least 11 patients at a mean value of 19.1 percent. The interquartile range was 9.1 percent with the bottom quartile of dialysis practitioner group practices having 14.2 percent or less of prevalent patients waitlisted versus the top quartile where 23.3 percent or more of prevalent patients were waitlisted.

There were some racial differences. Waitlisting performance was highest for Asian Pacific Islanders at 28 percent and lowest for Alaska Natives and American Indians at 12.3 percent. There was not a significant Black/White difference, and the Committee did note that only 3.4 percent of providers actually fell below the expected level. So it's similar performance to what we saw with the previous measure, slightly different but very similar.

Member Chin: And I will just add that the developers, the gap in both provider performance between racial and ethnic groups was presented. But they didn't find that --- the evidence did not support --- that performance on the measure is more significantly linked to transplant centers than to treating providers or provider groups.

Chair Dalrymple: Thank you, both. Would the Committee like to discuss performance gap, or does anyone have any questions for the developers?

And, Renee, I see your hand.

Chair Garrick: Thank you. So I just have a question, maybe not necessarily for us, maybe for the developers. But in terms of it as a quality measure and thinking of performance gap, I think that there was something like out of 2,276 units, facilities, or providers, I apologize, as to a practice level measure, so out of 3,276 providers there were only 109 that performed worse than worse than expected.

So thinking about this in terms of the power of a quality improvement measure, or outcome measure, I was interested in that. Because it's such a small number out of the 2,200 provider groups evaluated.

Chair Dalrymple: Thanks, Renee. So we'll gather those questions for the developers. And it looks like, Michael, you have your hand up?

Member Somers: I just wanted to comment that I think sometimes though that they performed as expected, but that doesn't necessarily mean that what is expected is good, right. So, you know, since the data showed that the mean was only 19 percent, I think perhaps part of the rationale for having a quality measure is to be moving the bar upward, right, so that what you'd have to achieve to actually perform as expected would get higher over time.

Chair Garrick: I think that's a great point. I think that's part of the challenge here, that this is, again, a wait-listing measure, not a referral measure. Because it's easier to push that envelope and push the metric as a referral metric. I certainly agree with that.

Chair Dalrymple: And, Alan, I see your hand.

Member Kliger: Yeah, the developers did address this yesterday, I think, well in that they said that the bar that's set for the outliers at either end are variable. You can choose where to set that bar.

And they've chosen to set it at a, you know, five percent basically up or down level which would mean that people who are performing better than the average do it exceedingly well. And people who are judged to be below the standard are clearly different than everybody else.

But, you know, that's not part of the measure itself. That just is where you set the bar to look at what

you can always change. And as the developer said yesterday, they wouldn't and I wouldn't recommend changing that either. That just simply gives you assurance that if you really are very good or very bad that it identifies it that way but is not intrinsically part of the measure, really, as Michael suggests.

Chair Dalrymple: And I think just to add to that, Alan, at least when I think about performance gap, I heavily weight variation. So I do look at quartiles and distributions. And I think, arguably, there is variation that is meaningful across groups and practices. And there are disparities.

Chair Garrick: And this traced to this group for a second. Has there ever been a try at evaluating that gap for referral to transplant?

Chair Dalrymple: I mean, I don't understand the question, Renee. I don't know if others did.

Chair Garrick: I was just curious whether there's ever been the creation of a measure that maybe didn't pass about looking at whether nephrologists or facilities refer patients for transplantation waiting list. I just wondered if we knew about that.

Chair Dalrymple: Alan?

Member Kliger: Like you, Lorien, I've been on this committee for about 55 years, and I don't remember a measure coming to us on the referral.

Chair Dalrymple: And I think I will also say, based on the guidance we were given yesterday, and I think it's important, our responsibility really is to evaluate the measure before us on its --

Member Kliger: Thank you.

(Simultaneous Speaking.)

Chair Garrick: I was just interested, thanks. And I'm so much younger than you, Alan, right, ha, ha, ha,

by about two years, right.

Chair Dalrymple: And me, Renee. Because I've been on the committee for at least 55 years, ha, ha, ha. We've all been together for a very long time.

So does anyone else have questions for the Committee? Because, Renee, we could still give the developer the opportunity, again, to see if they concur with how Alan, and I, and Michael kind of think about gap versus your question about, well, who does this really flag? Do you want us to give them that opportunity just to get that question addressed?

Chair Garrick: I think we're okay.

Chair Dalrymple: Okay.

Chair Garrick: I think they would say pretty much what Alan recapped from yesterday. I think it's just an issue that the bar is set where it is. So it's only few in a number of facilities that look like they are real outliers.

Chair Dalrymple: Okay, great. And, Stuart, I see your hand up.

(Simultaneous Speaking.)

Member Chin: Oh, sorry. I just want, again, I mentioned it earlier, but I just want to again point out that the developers noted that there was no evidence, that there is a performance gap, but there's no evidence to show that the gap is more significantly linked to the transplant center than the dialysis provider. And this is a measure that is basically on the provider level --

(Simultaneous Speaking.)

Chair Dalrymple: So, Andy, maybe I can ask you a question.

Sorry, sir.

Is your thought that maybe the disparities are not attributed to the group in clinical practice? Is that the point you're trying to make? Although disparities are present the accountable organization may not, and in this case the accountable organization is the clinician group, is your concern that the disparities do not result from their practices but instead the transplant center practices?

Member Chin: It seems to not be more the transplant center than the providers, so maybe equally related to the gap. But this measure is attributing -- it's really, the onus is on the provider only. So I just want to bring that up. Because, again, that was important part that was mentioned, you know, by the developers. And again, this is a measure that's at the provider level.

Chair Dalrymple: So what I would recommend for that, Andy, if you're agreeable, and it looks like Dr. Shahinian would like this opportunity as well, we'll let the developer respond to that. Because I think it's an important point, and important to let them have the opportunity to respond.

But before we go to the developer, Stuart, you're up.

Member Greenstein: Give me one second, all right. Actually, let me answer this call to a donor.

Chair Dalrymple: Of course, please take the call.

So I think to be efficient, Dr. Shahinian, we actually are going to give you the opportunity now to respond to Andy's point regarding disparities, and if you can shed additional light on what we do or do not understand about the cause of those disparities, and where those are principally attributed to, whether it's the referring providers or the transplant centers.

Dr. Shaninian: Yeah. So I think, so number one, just going back to, you know, I think a lot of the

points that were made in defense of the performance gap we certainly agree with. I would say that it's important to remember that when you're talking about 100 practices, you are still talking about thousands of patients that are cared for by those practices.

So, you know, again, as was noted, the cut points can be changed in terms of how it's actually utilized. But even 100 practices is representative of care for a lot of patients. And that's just one thing to bear in mind.

The point about the, you know, the variation we're showing is that those are derived from the models which include adjustment, as we discussed before, for transplant center effects. And so these are variations that persist after adjustment, you know, for a range of patient characteristics but also transplant center characteristics and the transplant center random effect.

So, you know, I do think that it is getting at variation that is predominately attributable to the group practice.

Chair Dalrymple: Maybe I can just ask a follow-up question, and Andy Chin may have one as well. I do recall the transplant center characteristics you reviewed with us, the fixed effects and then there's a random effect. Is your perspective that those adjustments would, to some degree, account for bias that may occur at the transplant center?

I felt like those adjustments accounted for many things. I'm just not sure on this particular issue.

Dr. Shaninian: I mean, I think it's, you know, to be fair I think it is difficult to know exactly what that adjustment will be able to account for. But it is essentially looking at, to the extent that patients that, you know, again the flow in terms of the assignment from patient to transplant center is based on where the patient lives and where,

typically, people who live there, which transplant center do they predominately go to.

And what this is adjusting for is their propensity to be waitlisted as a function of the transplant center to which they are going. So if certain transplant centers have higher rates of waitlisting, then that's going to be adjusted for when you're looking at what the actual waitlisting rate of the practice that the patient was attached to.

So it is adjusting for essentially what is the, you know, the transplant center's behavior with respect to waitlisting patients that live in an area where typically that center would see such a patient.

Chair Dalrymple: Thank you, that's helpful.

Did anyone else have questions for the developer, although the hands raised may be for the developer.

Stuart, I'm definitely going to come back to you but, Renee, do you have a question for the developer before I go back to Stuart, or are we back to Committee?

Chair Garrick: I do have one for the developer. But if Stuart has one as well, he could go first.

Member Greenstein: No, Renee. I just wanted to make a comment.

Chair Garrick: Thanks. So based on the comment you just made, I just wanted to ask a question regarding this issue of where the patients usually go from the dialysis provider or nephrologist to the transplant facility.

So in metropolitan areas, patients can choose to go to one of many transplant units. So depending on which part of the country you're in, there may be ten transplant units you may choose to go to. And there are lots of reasons why patients choose to go those units.

So are the characteristics of each transplant unit so similar that the reflection back on the nephrologist includes the waitlisting would be synonymous, regardless of whether they go to one in even their own state? Because obviously in metropolitan areas people cross state lines all the time and go to transplant facilities that aren't even in my state.

And the other question I had that you raised, which made me just wonder, you mentioned about the fact that the fallout units could be a lot of patients, I was just curious. And we don't have to take too much time, but there were only, like, 112 fallout units or something. I wondered if you looked at the characteristics of those units.

You made the comment that it was lots of patients, and I was curious. Are they all large facilities and large groups of providers? Or are some of them, is there a large splay in the characteristics of those units that were in the low provider group? So thank you.

Dr. Shaninian: So in terms of the assignment, basically we're limited to -- and I agree with you that technically in areas where there's a high, kind of, population density, and there are several transplant centers, this can be a bit trickier.

But it's essentially looking at, predominately within a given ZIP code, historically where do those patients predominately end up, kind of the, you know, what is greatest proportion of patients that reside in that ZIP code, where is the greatest percentage, which transplant center they go to.

So it is based on the predominant transplant center which is likely to be a reflection of where the predominant flow is for patients that are part of that facility that are in that particular ZIP code. So it's not going to be perfect. You're absolutely right. But that is kind of mechanically, that's how it's done. We look at where they are. Yeah.

Chair Garrick: I'm really interested in that. Do you get those data from UNOS? I mean, I happen to live in New York where we have lots of centers. So would you know where the patients from a particular practice list routinely?

Dr. Shaninian: We don't. So again, what we know is we can look at waitlisted patients and see where or which ZIP code they live at. So we can say, by ZIP code, which transplant centers have the, you know, for a given ZIP code, let's say ZIP Code A, historically what percent of the patients, where do the majority of those patients, which transplant center do the majority of those patients ultimately end up waitlisted at.

Chair Garrick: Thank you. I mean, it's interesting because, again, this is a reflection, this measure is going to reflect not on the transplant center but on the nephrology provider.

So if a nephrology provider happens to live in area that has 15 transplant units, which may have very different waitlisting characteristics, depending on each transplant unit, what I guess I'm listening to is that, regardless of where the patient goes or regardless of what the criteria are any given unit, which may or may not be at all similar, and you don't know where they went, it reflects back on the nephrologist. Am I getting that right?

Dr. Shaninian: Can you state that, sorry, can you say that again?

Chair Garrick: Well, yeah. I mean, like, in New York we have 10 or 15 different transplant centers. And they're not just in New York. They're in New York, New Jersey, Connecticut, and patients list routinely, they go to Pennsylvania. Because some, like, you know, have family there.

So I'm just trying to figure out, since there's no line of sight to where the patients go, other than the ZIP code. And the ZIP code in New York might, in one

ZIP code, might have four transplant. That's a black box.

So the measure reflects did my patient get waitlisted, and I don't have necessarily control over that. I send them to the transplant facility. So I'm just trying to get a better handle on this concept of the geographic distribution and how that's really factored into the measure in terms of places like New York where patients could go to many, many different transplant centers, each of which may have their own criteria for the ultimate outcome if this measure which is waitlisting.

Dr. Shaninian: It's based on, within a ZIP code, if there were multiple transplant centers, if a ZIP code had multiple transplant centers, we would essentially assign a patient that lives in that ZIP code to where, if we looked at where patients from those ZIP codes, which transplant centers they'd go to.

So, you know, let's say there's three transplant centers. So we could look historically at a ZIP code and say, historically, 40 percent go to transplant center A, you know, and then 30 percent to transplant center B, and 30 percent to transplant center C.

We would essentially attach the effect to the one that carries the plurality or the majority of the patients. So we are essentially, you know, adjusting for the predominant transplant center that patients that live in a certain area would go to.

So we are, in effect, being able to identify that, within a ZIP code, if there are multiple transplant centers, we can identify which ones typically see, are most likely for the patient to be waitlisted at and, therefore, make the adjustment for that transplant center's characteristic.

Chair Garrick: Okay, I think I'm wandering from gap to validity, so I'll be quiet.

Member Greenstein: Can I ask the --

Chair Dalrymple: Stuart, you're up.

Member Greenstein: Yeah. Why the developer never really raised the question of referrals, as everybody's trying to get to, rather than patients being waitlisted. If you don't get referred, you can't ever get waitlisted. And yes, it's true, in the transplant programs we control who gets waitlisted at the end of the day. But if they don't get a referred to us, we cannot get them waitlisted.

And the other point I want to make is that depending upon where you live, like for instance, I'm in the Bronx, so we get most of the patients from the Bronx. They can't go out of state, because many of them have Medicaid. And so they cannot go out of state.

Whereas Cornell patients will get patients from all over. So you're not going to -- the ZIP code is not going to be effective really to look at for the transplant center. It's really the ZIP code of where the patients live themselves. And they then go to a specific program based upon, honestly, if they have money and things like that. But I really think that the issue really is the referral rate.

And years ago, they changed the whole practice of wait time on the transplant list from you got your time based upon when you started dialysis. And the reason why they did that was they found that there was a disadvantage to many patients who were not coming forward, for whatever reason, whether they were being referred, or because they didn't have the money, or they were scared to come for a transplant.

So now, if you're on dialysis for six years, you get six years of waiting time versus -- even though you just came today versus somebody who came five years ago and is not dialysis yet, but has the GFR to allow them to be on the wait list, they only have

five years.

So wait time now has changed based upon the basis that we recognize that there are patients who are not getting on the list because they're not being referred, or they're afraid, and things like that. But it's the referral, and that's the only way you're going to get around this whole issue.

I mean, if you have 100 patients in a dialysis unit, I would never expect all 100 patients to get referred. Because they're going to have patients who should not be referred. But I've always said if you want to really look and make sure that everybody's getting referred, you send me the names of every patient, and a little brief history.

And let me, as the transplant program, tell you, you know what, this 85 year-old, we can't list. Let us decide. It's a lot more work on the transfer programs, but that's the only way you're going to get around whatever bias there's going to be about referrals.

Chair Dalrymple: And, Jeff, I see your hand up.

Member Silberzweig: Yes. I just had a bit of concern. Like Renee and Stuart, I live in New York. Stuart, I do see patients at Cornell, by the way. But I worry that this measure could negatively impact patient choice, because in New York City, patients do have choice of transplant centers. And the nephrologists are being measured based on whether patients are actively listed.

So a patient may have a preference for one center over another, but the nephrologist may push them to go to the center that is more likely to get them listed even though, say, they may get all of their care at another center and have all of their providers there. So I worry about the unintended consequences a bit.

Member Greenstein: That's why referral is the key.

You've got to get referred. As long as you're referred, it doesn't make a difference which program.

Chair Dalrymple: And I do see the developer has their hand up.

I do think we need to move towards voting on performance gap. I know other topics have been raised, such as validity, and usability, and unintended consequences. But does anyone else have discussion as it relates to performance gap? Because I will give the developer one last opportunity to respond. And then we will move to vote.

Okay. Dr. Shahinian?

Dr. Shaninian: Yes, thanks. I'll just quickly respond to some of the points raised. So one thing I wanted to clarify is if the patient's ZIP code of residence, so if a given ZIP code leads to a transplant center outside that ZIP code, we account for that. So that issue is not an issue.

If you're waitlisted, you're waitlisted. You know, we're not looking at waitlisting at specific centers. So if you're waitlisted, you're wait-listed. It doesn't matter where. That's how the measure is structured.

You know, the referral thing, there is no national mechanism to capture referral. That's number one. So we don't have the current ability to look at referral nationally. That's number one. But the other issue is that this is a point that also was discussed. We've thoroughly discussed a referral measure, the idea of it at the top.

And, you know, it is important to remember it is not a panacea. It is, as others have noted on this call as well, that there's a lot of attrition that happens beyond referral. A lot of the work of getting people waitlisted happens after the referral.

It's a very low bar, and many people have raised the issue of unintended consequences if a referral measure is places that, you know, everyone --- it's such a low bar that all patients will simply be referred and not much will be accomplished.

It's waitlisting that involves the careful evaluation, preparation of patients. And so I think, number one, I think certainly if referral was available as data, that incorporating it somehow into a measure makes sense. But it is not the panacea. And I think that waitlisting and incorporating waitlisting will always remain important. So I'll stop there. Thank you.

Member Greenstein: Can I make a comment?

Chair Dalrymple: Yes, Stu, please go ahead.

Member Greenstein: And then Renee and Jeff may know this, but isn't there a Form 2827, or something like that, that has to be filled out where it says that you've discussed with the patients their options about transplant? So to some degree, there is that form that has to be filled out physically in the dialysis units. And if that's the case, then that's the start.

Member Silberzweig: You're right, Stu, that there is a 2728 form that has to be filled out. And it does include a question about discussing options. The only issue with that is that that's done at the start of dialysis, not once the patient's on dialysis. So if discussions are held after that point, you know, it won't capture that.

Chair Garrick: But that's a really great point that maybe is for later in the discussion. We could bring up more about the 2728 and how it is utilized, probably under other areas of topics and gap.

Member Greenstein: Well, the point is that sometimes those forms are signed when probably the patients didn't have much of a discussion to let

them know that they really have that option. I've heard that.

Member Narva: That would be an understatement.

Member Krishnan: I think the policy there though is that that reflects --

Chair Dalrymple: We can --

Member Krishnan: --- the, well, never mind.

Chair Dalrymple: Sorry, Mahesh, did you have your hand up? I may have missed it. Is that you?

Member Krishnan: No, never mind.

Chair Dalrymple: Okay. I am mindful of time. Because we do have to get through two measures today. And it is really important that we complete that work today. I think you will probably see Renee and I, you know, try to move discussions along to make sure everything gets reviewed. So I would like to move to vote on performance gap unless anyone has last words they feel strongly they need to share with the Committee.

Okay, Gabby, can we move to performance gap vote, please.

Ms. Kyle-Lion: Yes, we can. Let me just go ahead and get my screen pulled up here. Okay, voting is now open for Measure 3695 on performance gap. The options are A for high, B for moderate, C for low, and or D for insufficient. And again there are 19 people on the call, so we are looking for 19 votes here.

We are currently at 15, 16 votes. We're on 18, just waiting on one more. So I'll just give it a couple more seconds.

Okay, we are still holding at 18, but that's okay, because 16 is quorum. So I will go ahead and close the vote. Voting is now closed for Measure 3695 on

performance gap. Just give me one moment to get the results pulled up.

Okay. There was one vote for high, 14 votes for moderate, three votes for low, and zero votes for insufficient. Therefore the measure passes on performance gap.

I'll pass it back to you, Lorien.

Chair Dalrymple: Thank you, Gabby. We're next going to move to scientific acceptability. As a reminder, this measure was reviewed by the SMP. We do have an SMP rating on reliability that the Committee can vote to decide to accept or not accept. If we do not accept the SMP vote, then we would move to have our own vote.

In terms of validity, SMP did not reach consensus, therefore, that will be a criterion we vote on. So if I can, Andy and Andy, ask you all to present a brief summary of reliability. And then we can decide if we would like further discussion or to vote on whether to accept the SMP decision.

Member Narva: Sure. The numerator statement, first I'll just briefly go over the specifications. The numerator was the adjusted calendar patient months in which the patient at the dialysis practitioner group practice was on the kidney transplant waitlist as of the last day of each month of the reporting year.

The denominator is all patient months for patients who are under the age of 75 in the reporting month who were assigned to the dialysis practitioner group practice according to each patient's treatment history. The exclusions include people over 75, nursing home residents, people in hospice, and people with dementia.

The developer calculated an IUR of 0.94 for the measure which, as you know, indicates that over 94 percent of the variation in the measure can be

attributed to the between facility differences on six percent to within a facility. The SMP passed on reliability with a score of four high, four moderate, zero low, and two insufficient.

And Andy Chin may want to add something to that.

Member Chin: I don't have anything to add. Thank you.

Chair Dalrymple: Would the Committee like to discuss reliability before we take our first vote which is to decide whether to accept the SMP rating?

Okay, Gabby, I'm going to ask you to put up our first vote on reliability, please.

Ms. Kyle-Lion: Sounds good. Just a reminder, if this vote doesn't pass, I'll move straight into the second vote which is asking your own vote reliability.

Okay, voting is now open for Measure 3695 on whether you all, as the Standing Committee, accept the Scientific Method Panel's rating for reliability. And as a reminder, the SMP's rating was a high soft moderate. And I believe we're looking for 18 votes now. Because somebody had to step away for a meeting.

And we are at 18. So I'll go ahead and close the poll. Voting is now closed for Measure 3695 on whether you all, as the Standing Committee, accept the Scientific Method Panel's rating for reliability. Just give me one moment to pull the results up.

There were 18 for yes and zero votes for no. Therefore the Standing Committee accepts the Scientific Method Panel's rating for reliability. Back to you, Lorien.

Chair Dalrymple: Thank you, Gabby. So we will now move to our discussion of validity, again starting with Andy Narva.

Member Narva: Okay. The validity of this measure

was tested by the Association With Mortality and Transplant. At the dialysis practitioner group level, average mortality was 17.9, 18.2, and 19.2 deaths per 100 patient-years for each of the three tertiles based on their performance on this performance measure from highest to lowest.

And the dialysis practitioner group level average transplant rate for the three tertiles was 5.3, 3.9, an 3.1 transplants per 100 patient-years for the three tertiles respectively.

And it's noted that the higher performance on this measure was correlated with higher transplant rate. And the relationship with mortality was also as expected by the developers and statistically significant with numerically lower mortality with higher performance on the measure.

In terms exclusions, 28.6 percent of patients were excluded, and there was a fair amount of variation in the percentage of patients excluded across practitioner groups.

The risk adjustment model uses age, area deprivation index, which we did talk about yesterday, dual eligibility status, diabetes status, comorbidities at the SRD incidence, prevalent comorbidities based on claims and transplant center fixed characteristics, as well as the random effect.

Statistical analysis showed that 75.29 percent of the pairs of patient-months that were discordant with respect to the response rate were correctly ordered by the model.

The patient, I'm sorry, the developer tested SDS factors including sex, race, and ethnicity, Medicare/Medicaid dual eligibility, and ADI as social characteristics in the risk adjustment model.

And Medicare and Medicaid dual eligibility and ADI factors were significantly associated with the outcome of the waitlisting and included in the final

risk adjustment model on a clinical and conceptual basis. And that was supported by the expert panel.

After adjustment, 3.4 percent of dialysis group practices performed better than expected, 4.8 percent performed worse than expected, and 91.8 percent performed as expected.

And there were some concerns, there were a number of concerns from the SMP including the non-independence of patient-months in the model, the use of patient-months. That was a concern because the status of any one patient on two or three consecutive months does not really seem to be independent of each other.

There were questions whether this was a process measure rather than an outcome. There was a lot of discussion about the inclusion of social risk adjustment in the model. This was, as we mentioned yesterday, motivated by a desire to reduce disparities. And it was posited that the factors had a conceptual basis and that they are proxies for financial and social resources that can affect success following transplant.

There was one rather strong statement by one of the members of the SMP which I will read. "The measure is a classic example of when not to adjust for social risk factors. It is a process measure for which social factors are in the quality pathway. This is a process measure accordingly.

"The selection of risk factors must be extremely well justified to avoid magnifying bias by adjusting for factors that are in the quality pathway. It may be appropriate to adjust for functional factors that interfere with transplant eligibility, and for major medical comorbilities.

"However adjustment for social risk factors, such as ADI and dual eligibility when severe disparities on these factors are so well documented, is shocking and unconscionable."

And then he refers to KVO 2020 guidelines as well as ASPE reports on social risk factors. And KVO does not recommend de-prioritizing patients for transplant based on area deprivation or dual eligibility.

The only, this is still in the statement from the SMP member, "The only medically legitimate reasons for deferring or declining wait-listing belong in," oh, I'm sorry, "only medically legitimate reasons for deferring or declining wait-listing belong in the risk adjustment model."

The SMP did not reach consensus on validity. The scores were high, zero, moderate, five, low, four, and insufficient, zero.

The Committee comments were that exclusions were reasonable but perhaps insufficient. And there were some very -- people shared a range of perspectives on the adjustment for social risk factors and questions about whether this was needed in addition to the previous measure.

I will take maybe one minute just to report my own experience with a population that had very limited access to transplant, and that was American Indians. And I was able to oversee that through the Indian Health Service.

And contrary to, when we looked at it in a fairly rigorous way, we found that the barriers to transplant were not willingness to be referred, despite traditional beliefs. It was primarily completing the evaluation.

And I think the reason that I have argued that this is an appropriate measure for the nephrology group is that I do believe that the nephrologists can have a large impact on how rapidly people treat evaluation.

And it may not be their direct action. But certainly, if making a difference in a dialysis unit with people

who have decreased access to transplant means having an extra social worker FTE or half a social worker FTE to help patients who need more help completing the process, it seems unlikely that anyone but the nephrologist is going to advocate for that. That is not probably going to come from the dialysis organization.

You know, I just personally see it as part of the advocacy that physicians should manifest for their patients. And I realize that I have a different experience and different perspective than many people. But I don't think the nephrologists need to work harder or necessarily refer people more.

I do think that the barrier for many people in rural settings and who have decreased access to healthcare in general, or decreased health literacy, or decrease health numeracy, is assistance in completing the listing process. Once people get listed it's sort of out of our hands. I'll stop there.

Chair Dalrymple: And, Andy Chin, do you have anything to add?

Member Chin: This may be more for, perhaps for the developer but maybe for this group is, you know, when we talk about the criteria for waitlisting, and is there a difference between transplant centers, here in northern California we know that there is, because the transplant centers, I'm in Sacramento which is in kind of the central northern part of California. And it's a different OPO than the transplant center in the San Francisco Bay Area.

And we know that the transplant centers, three centers in that OPO in the San Francisco Bay Area, they have a variance with UNOS. So what they consider waitlisting is slightly different than what we consider waitlisting at our transplant center here at the University.

And I know it's been brought up multiple times that

each transplant center has perhaps a slightly different criteria for waitlisting. But there are some glaring examples of dramatically different criterical waitlisting. And how that affects this waitlist measure, I think, needs to be perhaps explored.

Because again, it comes down to the dialysis providers who are really not able to change these waitlist criteria. And again, I think that's really important that we don't take the transplant centers out of it and assume that waitlisting is waitlisting across the nation.

I think there are vast differences in what perhaps certain centers call waitlisting versus others. And again, I will just say I'm not a transplant nephrologist. And so, you know, little details may -- - I may not be aware of certain other details.

Chair Dalrymple: So, Andy, we will hold that question. And we will give the developer the opportunity to respond to as whether the characteristics there, including of transplant center, including the two factors they put in, what they think that's really measuring and how close it's getting to waitlisting behavior at the transplant centers.

Member Chin: Right. And I understand that they're putting in these, you know, adjustments for the transplant centers as part of the adjustment. But, I mean, does it really get to that degree of difference at times. I don't know.

Chair Dalrymple: Yeah, so if you find it acceptable, we'll let them talk through the two specific characteristics. And I think the northern California example is a very useful one. Because of the number of transplant centers and the difference in behavior may have some parallels to issues that were raised in the New York region. So it may be helpful to kind of further understand how those characteristics do or do not address the concerns that are being raised.

So we will hold that for the developer at the end of our discussion. So we'll repeat that. But if you can keep it in mind as well, that would be very helpful.

And, Renee, then Stuart, then Gail.

Chair Garrick: I'll be really brief. I just wanted to go back to the 2728 issue, because someone raised it. So just in point of how that works, when a patient's first enrolled in dialysis, a 2728 form is filled out. And it contains comorbidities about that patient.

One of the issues is that that form is a static moment in time, and it never updated. Things change and the patient's world after that form is filled out. And Stuart and others raised some very legitimate important concerns.

Because that form is done that day, and then you go forward with the rest of your life. And the only new information that anyone ever gets about how I'm doing would come from a claim form.

And those have all kinds of different risks around them, because the completion and the quality of claim forms we're all very familiar with. So that has always been a concern of everyone's, because it's not necessarily a fair assessment of how the patient really looks.

And the other issue is that the people who fill out the 2728 form always really know that they have to be very thorough. And they may just pick one or two main topics that that patient had without thinking about can the patient transfer with all of the other comorbidities they have.

So there's always worry about the completeness of the 2728 in terms of how it actually reflects a patient's true being. And that goes to Alan's comment yesterday about a patient's ability to decide if a transplant's appropriate for them. Because they may have a lot of other issues that aren't well captured on that form. So thank you.

Chair Dalrymple: Stuart?

Member Greenstein: I just wanted to bring up the issue that Andy brought up about transplant programs. Every transplant program does have different criteria for who they will and will not transplant. Some of that is based upon the risk aversion of some transplant programs versus others.

And for instance in the New York area, most of the programs in the New York area are very, very aggressive programs. They will transplant people that other programs in other parts of the country won't transplant.

And I think that you cannot look at the transplant criteria of the transplant programs, because that's not going to be, you know, that's going to be an individual thing of the transplant programs. They're going to say we can put you on the waitlist, because we think we're going to transplant you. Whereas another program may say we won't put you on the waitlist.

I mean, for instance, one of the big issues in the New York area is BMIs. How big is too big for a person to be transplanted? And, you know, that's going to be an individual program decision. So I don't think you can use the transplant program's criteria.

I think, you know, what we're trying to do is get on more patients referred so that theoretically they can get transplanted. We're not even looking at the bigger issues that even if we get them referred, there aren't enough organs out there to transplant them no matter what. So, you know, that's a different issue for them to cite.

But what you want first is to get them referred. Let the transplant programs decide if they think they are transplantable. And yes, it's true, you're going to have different transfer programs saying yay or

nay. But let them get referred.

Chair Dalrymple: Gail and then Mahesh. And you're on mute, so we're not able to hear you, Gail.

Member Wick: The discussion is really great and all, but what I keep coming back to is that the developer has an outcome measure holding the practitioner accountable for obtaining that outcome. And I just don't, whether they go on the waitlist or not, it's the transplant program not the practitioner? So the attribution to me is incorrect. And I hear that from some people, but not from others. So I don't know where to go with this.

Member Krishnan: Really, my comment was going to be a more broader comment. Maybe, you know, that addresses it. Because I'm just listening to the conversation and the fact that we didn't approve any measures yesterday, and we've had a hard time approving measures in the past, I think we might be holding ourselves to too high of a standard, right, which is I don't think there's any measure that's going to be perfect, right.

Like we all our anecdotes and, you know, what happens in this area of the country or that area of the country. It ain't never going to happen, right? There's never going to be a perfect measure. But I guess the question I have is, and I think Joe Messana said this yesterday, or somebody said this yesterday, is there some potential for, say, a physician to help?

Right now they have to go from zero to 100, but could they go from 20 to 45, right, or could they go make something of real benefit. And so I just wanted maybe for the Committee, if we should think through what success looks like.

Because I don't think you're ever going to find a perfect measure. And if we continue to hold ourselves to this standard, I don't think we'll ever get any measures, which will not be helpful.

Chair Dalrymple: I do see two more hands up. It will be Bobbi followed by Alan. After that we will need to move to vote, if at all possible, because we're mindful of time, and the remaining criteria, and additional measure we have to evaluate.

So Bobbi and Alan, I'd like to give each of you an opportunity to speak. Please make your remarks as brief as possible so we can move to vote.

Member Wager: Sure. I'm going to say something in regards to Dr. Narva. And I think we all have to take in consideration when we do this, these measures, when they talk about waitlists, we found, like, they're referred and then they're put on the list.

We are forgetting that these patients are on dialysis and that they're in the center there three days a week. There's two days left in that week, so then they go get tests done to get onto these lists.

It may take them six months to even a year to get waitlisted, okay. I just wanted you all to know the patient perspective. It's not as easy. And it's just a comment. We all talk about, well, who's responsible, the practitioner or the facility? Where is patient-centered care? When in the heck is a patient accountable in this process. Just my thoughts. Thank you.

Chair Dalrymple: Thank you, Bobbi. And, Alan?

Member Kliger: So I just want to remind, we're talking here about validity. And in addition to the SMP's concerns that we heard discussed, I continue to have a concern which is a fundamental problem in validity in this measure which has to do with the exclusions.

And that is that patients choosing not to get on the transplant list clearly should be excluded. I know it's difficult, and it's not a matter of just a check box. I think that the fact that it's a difficult thing to do

doesn't mean it's not a central law in the reasoning here.

We are excluding people who are hospice, or have other significant medical problems. But to me, the major thing is the patient makes a decision that she or he is not interested in being wait-listed. That clearly needs to be excluded. So I think that it's a flawed metric without attending to that.

Chair Dalrymple: We did plan to give the developer an opportunity to respond to some of the questions raised, including the ones that I wrote down were the questions you first raised, Andy Chin, and then also if they wanted to make a comment about claims for comorbidity adjustment, since I believe there's 64 prevalent comorbidities adjusted for in this model after the 2728. But we will ask, your comments to be brief so that we can move to vote. So Dr. Shahinian?

Dr. Shaninian: Okay, thank you. Yeah, I mean, again, in terms of variation, all we can say is we're making adjustments. The two fixed variables are one looks at essentially the transplant rates within those transplant centers that gets at issues of, you know, how quickly they can move through that process to get people transplanted as well as issues of organ availability within that transplant center's purview.

Similarly, we adjust for transplant waitlist mortality which is a proxy for the sickness of the kinds of patient you get onto their waitlist. On top of that, we're adjusting for a random effect which effectively gets a kind of what's unique about that transplant's particular, you know, waitlisting tendency in the patients that end up going to it from the ZIP code that they get the patients from.

So I do think that there's an adjustment that accounts for some of the variability that exists across transplant centers. But we are accounting for that, at least to, you know, I think that.

The following comorbidities, you know, all I can say is that this is, you know, I would push back, I guess, and say that there are a number of very well validated prognostic models that are based on Medicare claims. It is not, you know, these aren't useless to look at.

And many measures, a lot of research is founded on comorbidity identified in claims. And so I think that, you know, what we're doing is absolutely up to the best standards available today for risk adjustment, so I'd say that.

The only other thing I'd say, just to Dr. Narva's point about our decision about social risk factor adjustment, I agree, it's an incredibly difficult issue. But this was a huge point of discussion at the top that they felt strongly, I think unanimously, that we adjust.

And a lot of that is driven by the fact that issues of finances, social support, and things like that are allowable and used by transplant centers and decisions about waitlisting. So we felt like that is something that, if we were going to hold dialysis practitioners accountable to, that we at least needed to account for adjustment. I'll stop there. Thank you.

Chair Dalrymple: And I just had one question for clarification. Is it 64 prevalent comorbidities, or can you please remind us how many prevalent comorbidities come from the claims data?

Dr. Shaninian: It's 64. And again ---

(Simultaneous Speaking.)

Chair Dalrymple: Okay. Thank you. I see Andy's hand. And, Andy, I will yield, because you're the lead discussant. But after your comments we will move to vote.

Member Narva: Sure. So I've looked at ESRD in

Washington, DC, which has the highest rates of any state. And DC has looked at, Department of Health has looked at social determinates of health and mapped those along with race.

And the geographic mapping of race, and income, and employment, and education, and all the social determinates of health, they're identical. They all fit exactly right over each other. So in reality, I mean, you are looking at race. You may be looking at, say you're looking at income, but they're so congruent it's shocking.

The second point I would make is just a few minutes ago we talked about how heterogeneous transplant centers are. And maybe I'm naive, but my patients sort of go to transplant centers that I sort of encourage them to go to.

And if there are differences in the way you're prescribing the transplant center to the patient, and the differential between transplant centers is a factor that may have a significant impact on whether the patient actually gets listed, I definitely saw that with BMIs where some places, you know, our patients were very heavy, and some places had a BMI that excluded almost all of them, and some didn't.

There were, although our patients were covered by Indian Health Service and Medicare/Medicaid, unless there was a guarantee of certain kinds of financial guarantee's, they wouldn't be accepted at that transplant center.

So, you know, those decisions are largely in the hands of the referring nephrologist. And I don't know how big a factor that is elsewhere, but again, I just find it a little bit disingenuous to say it's out of our hands.

Chair Dalrymple: Andy, thank you for being the lead discussant. And, Andy, for being the supporting discussant. We are going to move to vote now on

validity if, Gabby, you can bring up the poll. I appreciate the Committee's extensive discussion and thoughtfulness on this topic. I think, again, it reinforces the importance of transplantation and that clearly our Committee takes transplantation very seriously. So thank you all for your comments.

Ms. Kyle-Lion: Okay. I will get the poll pulled up. Just give me one second.

Okay, voting is now open on Measure 3695 on validity. The options are A for high, B for moderate, C for low, and D for insufficient. And again, I do think we're looking for 18 votes here, as I believe someone stepped away. We're at 17 right now, so I'll just give it a couple more seconds.

Okay, we're holding at 17, but that's okay, because 16 is quorum. So I'll go ahead and close the poll. Voting is now closed for Measure 3695 on validity. Just give me one moment to pull up the results.

Okay, there were 12 votes, I'm sorry, zero votes for high, 12 votes for moderate, five votes for low, and zero votes for insufficient. Therefore the measure passes on validity. I'll pass it back to you, Lorien.

Chair Dalrymple: Thank you, Gabby. So we will now move to a discussion of feasibility. Andy and Andy, I will ask for brief summaries, because we have one more measure to review after this.

Member Narva: Sure, wow. I didn't think we'd get this far. That's a delight.

Feasibility, the only elements are generated, and are reflected, and used by healthcare personnel during the provision of care, there were not significant concerns about feasibility.

Member Chin: I have nothing more to add.

Chair Dalrymple: And is there any Committee discussion on feasibility or any questions for the developers?

I see no hands. We will move to vote on feasibility. Gabby, you're up?

Ms. Kyle-Lion: Okay. Give me one second to pull up the poll. Okay, voting is now open for Measure 3695 on feasibility. The options are A for high, B for moderate, C for low, or D for insufficient. I believe there should be 18 votes, but again quorum is 16. So we'll just see where we get to.

We are at 16 votes now. Just give it a couple more seconds, see if we get the other two. We're at 17. Okay, it looks like we're holding at 17 votes, oh, 18. Perfect. So I'll go ahead and close the poll. Voting is now closed for measure 3695 of feasibility. Just give me one moment to get the results pulled up.

Okay, there were ten votes for high, eight votes for moderate, zero votes for low, and zero votes for insufficient. Therefore, the measure passes on feasibility. Back to you, Lorien.

Chair Dalrymple: Thank you, Gabby. We will now move to usability and use. We will first vote on use. We will subsequently vote on usability.

So, Andy and Andy?

Member Narva: Sure. This measure is, it's a new measure, as you know. It's not currently publicly reported or used in any accountability program. The planned use is as a measure in public reporting and likely in a quality payment program.

I did not see any potential harms identified. And the only question was whether, and this, I guess it goes to the next thing, whether this in the previous measure are both needed. But the previous measure, it looks like they're not going to proceed. So that no longer, that's moot.

Chair Dalrymple: And Andy Chin?

Member Chin: Yeah, I'm just kind of briefly looking through the Committee revaluation comments. And

again, I think this has been brought up, but one of the comments stated that there are multiple factors that determine if the patient is an appropriate candidate for transplant, many which are out of dialysis practitioner's control. But I think this is not related to feasibility. I don't see anything in the comments that particularly deal with feasibility.

Chair Dalrymple: I would open it up to the Committee for discussion for those of you who would like to discuss. If you feel there are unintended consequences, this would be the time to do that. I know in the past I asked for us to wait until we got here. We do need to keep our discussion brief, but if anyone would like to say anything on that topic, this would be your opportunity.

And, Alan, I see your hand.

Member Kliger: Yeah, I mean, if this is ascribed to the nephrologist, and if it's a measure of the total numbers of their patients that are going to be on the waitlist, I believe a potential harm is the pressure for that nephrologist to convince patients that, even if they've chosen not to be evaluated, that they just go and get evaluated, go through this so that my numbers look better.

I think that the potential harm to patients is a discussion against their choice and against their will. And I think that that's a substantial problem.

Chair Dalrymple: And Andy Chin?

Member Chin: Yeah, I agree. I think this is something, maybe not to the point of coercion, but it's going to be a lot of pressure put on really good transplant candidates from a physical perspective path, for and age perspective, who really just don't want transplant at the moment, to be pushed towards getting at least an initial evaluation.

Because the likelihood of these younger, healthier

individuals to get waitlisted is rather high, despite them not wanting to consider transplant, even with the correct amount of education and, you know, reasons to do transplant. Again, that makes it no longer a patient choice thing.

And I also want to say that, you know, as Dr. Greenstein mentioned, it sounds like he would love to have list of dialysis patients and go through and look at it himself. There are a lot of transplant centers that are already overwhelmed in terms of the number of individuals being referred that are backlogged for over two years.

And I can tell you, our center is one of those centers. We do 350 transplants a year. And our workup list is at least a year and a half now. And I can imagine that, if this becomes a measure at the provider level, that there may be individuals that nephrologists know, I know, that aren't going to be really good transplant candidates.

But maybe, just maybe, the transplant center will take them. And I'm going to send them in. They're going to go through the workup. They're going to be denied waitlisting but, you know, the transplant center gets a few extra 100 of this every year. And the patients who are truly appropriate and want a transplant are now in a long queue. And their workup is potentially delayed. I see that as a potential consequence.

Chair Dalrymple: And, Stu, I see your hand. I have been reminded by the NQF staff we should actually vote on use before usability. So is this is in regards to unintended consequences versus use, we may go ahead and proceed quickly with the use vote and then come back to this discussion.

Member Greenstein: Sure.

Chair Dalrymple: Is your comment related to unintended consequences?

Member Greenstein: It's in response to Andy's comment just now. I just wanted to respond to that. But let's do the vote first.

Chair Dalrymple: Okay, yeah. And thank you, Paula. So we'll vote on use which I don't think there's additional discussion on. And then we will come back to usability and unintended consequences.

So, Gabby, can we vote on use?

Ms. Kyle-Lion: Yes. Give me one second to pull up the poll. Okay, voting is now open for Measure 3695 on use. Your options are A for pass or B for no pass. And we are looking for 18 votes here. We are at 16. Just give it a couple more moments for the last two to come in. Seventeen, just give it one more moment. Okay, we're at 18.

I'll go ahead and close the poll. Voting is now closed for measure 3695 on use. Give me one moment to pull up the results. Okay, there were 17 votes for pass, and one vote for not pass. Therefore, the measure passes on use. Back to you, Lorien.

Chair Dalrymple: Thank you, Gabby. And we can now resume our discussion of unintended consequences under usability. My apologies for that.

Stu, I want to let you have a chance to respond to Andy, and then Mahesh will go next.

Member Greenstein: Thanks. So my only comment would be that what we want, I mean, if what we do in our program is when patients get referred, we get brief summaries. And by reading that, we will automatically tell them, you know, what patients are not going to be considered candidates. And we shouldn't waste the patient's time nor our time.

And then what I'm going to suggest is that at that point in time you write a letter to the referring doctor saying the patient's not a candidate. And this way it takes the onus off of that referring doctor so

that they shouldn't say, oh, you're not referring your patients.

So there are ways to get around this whole problem. And I agree with you that there are too many patients that need, would like to come forward. And we can't transplant everybody. But there are ways that we can adapt to this.

And, I mean, I would like to go back to ask Renee and Jeff, how could we make it a better system such that the patients are referred early enough so that we can see more about the patient on a little brief summary, and then we can make a decision. Because the bottom line is otherwise the patients are not referred for many, many years. And that's the problem that we're trying to avoid.

Chair Garrick: I will go first and just sort of say I'm really sorry, I would love to have the conversation. But because of time, and because we have another measure to get through, Stu, I'd love to talk to about it. But probably we have to wait and do it a different time. But thank you, it's a great topic.

Chair Dalrymple: And Mahesh? You're muted, Mahesh.

Member Krishnan: I think there's always going to be some probability of a bad scenario, right. Like, it could be that someone says I'm going to refer all my patients. But that assumes that the way that the measure will be used is binary, right, like it's 100 percent or zero percent.

I guess, if I think about this, the probability of that happening seems low, right. It seems like people swore an oath, right, what they should do for their patients. It seems like we said yesterday they're going to be rational actors. It just seems to me like there could be adverse use cases, but the probability of that is low.

So I guess when we say there could be an adverse

event, and we discuss this with the Committee, I'd love to get some of the people's perceptions of is that low probability, and we don't tolerate that, or is that high probability, in which case we ought to address it.

(Simultaneous Speaking.)

Chair Dalrymple: I'll let you respond, and then we will move to vote.

Member Kliger: Very quickly, it's not binary. I'm just talking about the pressure on the clinician to do what patients make a clear choice not to do. Whether that happens with three people or 30 people, it's an unexpected, unintended consequence. And if we're not excluding patients who clearly choose not to be transplanted, that's a flaw for this measure.

Member Krishnan: Yeah, I totally hear you, and I totally agree, Alan. I think that really makes sense. But that's true of every single measure we evaluate, right. And if there's not a, maybe it's iterative, right, maybe we have to say there's something we can do now and something we can do in the future.

But if that's the criteria that we apply, that there needs to be a data element, it's essentially patient's choice. But I totally agree with you. We should work on it. I don't think any measure will pass.

Member Kliger: I apologize. But transplant is one that is really different than other best -- you know, how you treat bone disease, or what you do with anemia is different than the role of the patient in making a life-choice about not choosing dialysis if they so choose. It's different than the other measures.

Member Krishnan: Yeah, although we have the same discussion around fistualas and access, right.

Chair Dalrymple: So I so see that the developer has

raised their hand. I would ask for a very brief comment, Dr. Shahinian, and then we will move to vote.

Dr. Shaninian: Yeah, I mean, I just want to raise, you know, just to address some of that concerns. Again, I think the issue, as we know, as people have discussed, that rates of waitlisting are, in absolute terms, are already low. The bar is already set where most people who could potentially benefit are not getting a crack at it.

So somebody who's feeling pressure has lots of patients, good patients, to choose from before they would have to actually take the unethical stance of having to pressure and coerce people. There is plenty of people that they could workup who would be appropriate candidates. So I'll just say that. Thank you.

Chair Dalrymple: Okay. Gabby, can we move to vote on usability?

Ms. Kyle-Lion: Yes. Give me one moment to pull up the poll, please. Okay, voting is now open for Measure 3695 on usability. The options are A for high, B for moderate, C for low, or D for insufficient. And again, we are looking for 18 measures, sorry, 18 votes here. And we are at 18, so I'll go ahead and close the poll.

Voting is now closed for measure 3695 of usability. Give me one moment to pull up the results, please. Okay, there were three votes for high, ten votes for moderate, five votes for low, and zero votes for insufficient. Therefore, the measure passes on usability. Back to you, Lorien.

Chair Dalrymple: Thank you. I believe we now move to our final vote which is overall suitability for endorsement.

Ms. Kyle-Lion: Okay. I'll go ahead and get that pulled up as well.

Okay, voting is now open for Measure 3695 on overall suitability for endorsement. The options are A for yes or B for no. And again we're looking for 18 votes here. We're at 17, just waiting on one more. Okay, we are at 18 votes, so I'm going to go ahead and close the poll.

Voting is now closed for measure 3695 on overall suitability for endorsement. Just give me one moment to pull up the results. Okay, there were 13 votes for yes and five votes for no. Therefore, the measure is recommended for overall endorsement. Back to you, Lorien.

Chair Dalrymple: Thank you, Gabby. I will now hand it over to Renee who is going to lead the discussion on 2594.

2594: Optimal End Stage Renal Disease (ESRD) Starts

Chair Garrick: Thanks. Just to unmute, so our last measure is 2594 which is the

Optimal End Stage Renal Disease (ESRD) Start measure. This is a maintenance measure. It's being presented by Permanente, Kaiser Permanente.

Briefly, we're going to have our discussion, talk in more detail, but it's a process measure. The level of analysis is population at clinician group and practice facility health plan. It's an integrated delivery system, a focused measure, the setting of care is the ambulatory in-patient/out-patient and hospital services. Data source is our registry, and claims, and other electronic health records.

And as I mentioned, it's a maintenance measure which can influence the things we vote on if we choose to do that. And I'll begin by having our developer from Permanente, Dr. Leo Pravoverov, take over and walk us through some thoughts about the measure.

Dr. Pravoverov: Good afternoon, thank you for giving me the opportunity. So the optimal ESRD measure was developed by Kaiser Permanente in early 2000s and adopted by all regions of Kaiser Permanente in 2012, 201.

The measure is actually a composite outcome measure for peritoneal care and counts of what are the best outcomes that peritoneal care can deliver. And the best outcomes for transition to ESRD are considered to be transplantation, starting with home dialysis or initiating hemodialysis with function physiograph. And the presence of subcutaneous catheter is considered to be a marker of insufficient or inadequate peritoneal care, patient education, and engagement.

The measure was endorsed by NQF in 2015. Since 2015 we developed a few modifications that were mentioned in our submission. And now we are applying for re-validation or re-endorsement. And we'll be happy to answer any questions.

Chair Garrick: So one of the questions in terms of our upcoming vote would be whether or not there's any new information or evidence that you'd like to share about the measure.

Dr. Pravoverov: The few changes that we incorporated in the measure are removal of graft ceiling or there was a ten percent graft, involved ten percent of graft starts would not be counted. The initial thought was to avoid unintended consequences of increasing, disproportionately, grafts in this population.

However, the evidence that came since this measure was adopted, our internal evaluation and the literature did not show that this measure promoted overuse of grafts. And KDOQI guidelines, the recent KDOQI guidelines of hospital access supported our decision.

Another change that we promoted and incorporated

in Kaiser Permanente was to address patients with potentially low survival and those who benefit from trial dialysis and high comorbidities. So we incorporated removal of patients who transition to hospice or died within the first three months, to remove them from enumerator. So that was recommended to address potential overuse, unintended consequences of steering patients who are not a good candidate for chronic dialysis into some of the surgeries.

As well, as use of inclusion of patients who, say, we transplant, and returning back today I was -- so we started counting those patients. Because we felt that inclusion of those patients and making sure that they are well prepared to be starting back on dialysis, are well incorporated and well taken care of prior to transition to dialysis.

Chair Garrick: Thanks. Two quick clarifications. One is, I think you may have said that it's a composite outcome measure. But I think actually it's listed as a process measure. I just wanted to clarify that.

Dr. Pravoverov: Sure.

Chair Garrick: Okay. Because we are evaluating this as a process measure, not as a composite outcome measure.

Dr. Pravoverov: Oh, you're right, it's a process measure.

Chair Garrick: Thank you. And the other issue is I might have missed this, but are patients with acute kidney injury who start dialysis for support and then recover and are removed, how are they dealt with?

Dr. Pravoverov: So they're just removed from preliminary.

Chair Garrick: Okay, so those ---

(Simultaneous Speaking.)

Dr. Pravoverov: Yeah, they are just removed.

Chair Garrick: Thank you. Okay, so I think we could then turn to our main discussants. So that's Jeffrey Silberzweig. Jeff, if you'd like to lead us on a discussion that would be great. And our supporting discussants are Myra Kleinpeter and Bobbi Wager.

Member Silberzweig: Thanks, Renee. If I might, I'd actually like to start with a point of clarification for the NQF staff. So this measure is going to be graded for integrated practices rather than dialysis providers or general nephrology groups. Am I understanding that correctly?

Chair Dalrymple: So, Jeff --

Chair Garrick: That would be a question for the developer.

Chair Dalrymple: Yeah. So, Jeff, I do think we need to clarify that before the discussion starts. And for the developer, what our Committee received was multiple different potential levels of analysis. So we do need clarity on what the level of analysis is, if it is an integrated delivery system, health plan, or something other.

Dr. Pravoverov: It is most suitable for integrated care delivery systems, large practice groups, large nephrology groups. It's not suitable for individual dialysis providers, dialysis units, or small practices.

Chair Dalrymple: And what level was all of your testing conducted at? Because we would want to align with that level.

Dr. Pravoverov: The level of testing was conducted on the level of large medical centers and large Kaiser regions.

Member Silberzweig: So it was conducted in Kaiser regions, so in an integrated health plan, if I understand correctly.

Dr. Pravoverov: Right.

Member Silberzweig: Yeah.

Member Krishnan: And, Jeff, your confusion might be that when we first approved this it was definitely set up, as we had mentioned, in an integrated care system measure. But it has since been adapted in some way, shape or form, to another use, other use cases in the real world.

(Simultaneous Speaking.)

Chair Dalrymple: Yeah, what I would suggest, oh, I'm sorry, Jeff, is on the submission multiple levels of analysis have been submitted. I think we need to agree, before we proceed, how we are assessing that measure.

And unless the NQF staff overrules me or the developer strongly objects, I suggest we review it as an integrated delivery system, given the data we've been provided and for clarity.

Let me ask the developer if you feel comfortable with that, and the NQF staff if they have a different perspective.

Dr. Pravoverov: I mean, it all depends on what integrated healthcare system and how it's defined. I know it's used in multiple group practices nowadays. It's, I think, intended to be used in KCC models as well and are used as a sort of measure in practices that utilizing intentional and multi-disciplinary care team approach of --

Member Silberzweig: I think that's absolutely right. But the point is the KCC model is to develop integrated plans. So it is being used essentially in integrated plans there as well.

Dr. Pravoverov: Well, then it's integrated healthcare plan. So just wanted to make sure that we end up on the same page again.

Chair Dalrymple: Yeah, and I think what we're concerned with is the level that the testing was conducted at. Because that's what we'll be asked to vote on. So, Paula, are you comfortable with us agreeing that for now we will evaluate it at the level of an integrated delivery system based on this discussion? Or is further discussion needed?

(Simultaneous Speaking.)

Chair Dalrymple: I think you're muted.

Ms. Farrell: Sorry, I was trying to come off --

Chair Dalrymple: I think you're muted.

Ms. Farrell: Yes, I was trying to come off mute, I couldn't get my mouse to move. I'm going to ask Katie Goodwin, our director, to help us out with this question.

Ms. Goodwin: Yes, I do think that makes sense. If the developer would like to, and agrees, we can even have them make the change to the submission during the comment period if that would help ease the standing committee's mind at all to the level of analysis.

But I do agree with what you're proposing. And I think that makes sense.

Chair Garrick: And so the analysis was done at that level? Back to Lorien's question?

Dr. Pravoverov: Yes.

Chair Garrick: Thank you.

Member Silberzweig: So, Renee, are we okay to go ahead and discuss evidence then?

Chair Garrick: I'll yield to the NQF Staff given what we've just discussed so, Paula.

Ms. Farrell: I'm sorry, was that a question to vote on evidence?

Chair Garrick: To go ahead and, like, we're okay with reviewing the measure with the changes that were just proposed.

Ms. Farrell: Yes. And per Katie's response that's fine. Yes.

Chair Garrick: All right, thanks. So to Jeffrey, yes.

Member Silberzweig: Thank you. So the developer provider a systematic review of the evidence, building on the evidence presented in 2015, with the evidence supporting the concept that optimal ESRD starts improve outcomes and saves money.

In the 2015 review they noted the Canadian Stark Trial which showed that optimal starts were associated with a savings of almost $24,000 per patient over the first six months of kidney replacement therapy. It also presented Kaiser Permanente data, which showed an average savings of $47,000 per patient in the first six months and 14.1 fewer hospital says during that period.

In terms of changes to the evidence since 2015, there is a new KDIGO clinical practice guideline on the evaluation and management of candidates for kidney transplantation that I think has been referred to in our discussions over the past couple of days which supports kidney disease education for all patients, but grades the evidence for that as very low.

The European Society for Vascular Surgery recommends an AV fistula as a primary option for vascular access. And the vascular access for hemodialysis recommends a fistula as a first choice, an AV graft as a second choice, and a tunneled catheter as a third choice. And their evidence was graded as strong expert recommendation and high indication of study design, directness of evidence and consistency of results.

Finally, the Canadian Society of Nephrology

recommends a radiocephalic fistula as the preferred vascular access and suggests it should be created when a patient's eGFR is between 15 and 20.

The developer cited a systematic review with 21 studies involving 29,000 subjects supporting peritoneal dialysis as an optimal treatment option for ESKD patients.

In terms of analysis, the rating for evidence is high based on the guidance from the evidence in algorithm. So I'll stop there, and happy to have any discussion.

Renee, do you want me to turn to Myra and Bobbi for any comments they might have?

Chair Garrick: Thank you. So, Myra and Bobbi, anything you'd like to add?

Member Wager: No. He took it just from my notes.

Chair Garrick: Okay. So, thanks to all of you. I think that at this point we have an option, since this is a maintenance measure, and as with a maintenance measure with no new evidence, now that we've had a discussion, we can just go right to a vote of accepting the prior evidence. Am I right about that, Paula?

Chair Dalrymple: I'll just make one correct, Renee, because new evidence was submitted. But we can still vote to accept the prior decision recognizing we've reviewed and discussed the new evidence.

Chair Garrick: Great, thank you so much.

Chair Dalrymple: Unless Paula tells me I'm wrong.

Chair Garrick: Right.

Ms. Farrell: Correct. Yes. Yes. That's correct. And this would be an informal vote. The Committee can either decide if they want to accept the renal committee's prior vote or if you'd like to have a

further discussion and yourselves vote on evidence.

So it would be up to the co-chairs. Do you want to just do a hand raise if you want to accept the previous vote or how would you --

Chair Garrick: I guess I'd feel comfortable, since we're kind of changing it now to, if I have this correct, we're looking at this measure now as an integrated delivery measure, maybe we should have the vote so we're all clear that we're accepting the evidence for the measure under our current conversation. Maybe that's the cleanest way to proceed.

Ms. Farrell: However the Standing Committee would like to vote.

Chair Garrick: Yes.

Ms. Farrell: Okay.

Chair Garrick: So if people are comfortable with that we can ask Gabby.

Ms. Farrell: Okay. Gabby said we'll move forward with a full vote on that --

Chair Garrick: Yes.

Ms. Kyle-Lion: Okay, give me one moment to get that pulled up please.

Chair Garrick: Thank you.

Ms. Kyle-Lion: Okay. Voting is now open for Measure 2594 on evidence. Your options are, A, for high, B, for moderate, C, for low, and D, for insufficient.

And we are looking for 18 votes here. We do have two coming in through the chat now so that's probably why you'll see a discrepancy in the numbers on the screen versus what I will announce. Just so we're clear.

We are at 17 votes. Just give it another moment to see if we get another one. Okay, we're holding at 17 votes so I'll go ahead and close the poll.

Voting is now closed on Measure 2594 for evidence. Give me one moment to pull the results up. Okay, so there were four votes for high, and 13 votes for moderate, and zero votes for low, and zero votes for insufficient, therefore the measure passes on evidence. Back to you, Renee.

Chair Garrick: Great, thank you very much. So, Jeff, if you and your team could proceed with looking at gap.

Member Silberzweig: Sure. So, in terms of performance gap, the developer submitted Kaiser Permanente data, which showed improvement in the number, in the proportion of optimal starts from December of 2015 to December of 2020 from 57.1 percent to 58.3 percent. But a decline in 2021 during the pandemic to 56.5 percent.

They noted that in the eight regions of Kaiser Permanente the range of optimal starts was 42 to 65 percent. They also looked at data from the USRDS and the CMS official, the first program, which showed estimates of only 30.4 percent optimal starts in 2017, the latest year for which data was available.

It also noted some disparities with higher rates of optimal starts in Asian and Pacific Islanders and Whites compared to Hispanics and Blacks. So that was the performance gap data.

Chair Garrick: Thanks. Any comments from our additional reviewers?

Member Wager: Nothing to add.

Chair Garrick: I'm sorry, you were cutting in and out, and I apologize, I think it might be my mic. So if there are --

Member Wager: I'm sorry. This is Bobbi, nothing to add.

Chair Garrick: Okay, great. Thanks, Bobbi. So with no other comments I think we could accept the prior reliability evaluation of the measure when it was first introduced, is that acceptable, or since we voted on evidence do we have to vote again?

Chair Dalrymple: So, Renee, we are going to vote on gap. So gap we must vote on.

Chair Garrick: Okay, thank you.

(Simultaneously speaking.)

Chair Dalrymple: -- vote.

Chair Garrick: Thanks. So we have to have our own gap vote, so thank you.

Chair Dalrymple: Yes.

Ms. Kyle-Lion: All right, so we're ready to move to vote on gap?

Chair Garrick: Yes, please.

Ms. Kyle-Lion: Okay, perfect. Let me go ahead and pull up the screen. Okay, voting is now open for Measure 2594 on performance gap. The options are, A, for high, B, for moderate, C, for low, and D, for insufficient.

And we are looking for 18 votes here again. Okay, we are at 18 so I will go ahead and close the poll. Voting is now closed for Measure 2594 on performance gap.

Give me one moment to get the results pulled up. Okay, there was zero votes for high, 18 votes for moderate, zero votes for low and zero votes for insufficient, therefore the measure passes on performance gap.

Okay. Back to you, Renee.

Chair Garrick: Great, thank you. So that brings us then to scientific acceptability, with the first issue being reliability. Jeff, would you like to review that and decide, along with our standing committee, if there is a need for the discussion and vote?

Member Silberzweig: Sure. Thanks, Renee.

Chair Garrick: Because it's a maintenance measure.

Member Silberzweig: So as the developer pointed out, the numerator is the patients who initiate outpatient kidney replacement therapy with either a preemptive kidney transplant, home dialysis or outpatient in-center hemodialysis with official or graft.

The denominator is all new in-stage kidney disease patients, including those who received a preemptive kidney transplant. There were no exclusions and no risk adjusters.

In terms of reliability, the specifications appear to be pretty clear and precise, according to comments. As the developer noted, in terms of changes since 2015 they've removed the ten percent of new hemodialysis patients that have AV grafts.

And included failed allografts, which they estimate makes up about three percent of the denominator. So, I'll stop there on reliability.

Chair Garrick: Thanks. Myra or Bobbi, anything you'd like to add to that?

Member Wager: No, ma'am. This is Bobbi.

Chair Garrick: Okay, great. Thanks. So with regard to that, if the Committee is comfortable accepting the reliability measure as discussed on the first vote, since again, it's a maintenance measure, we do not need to repeat that vote. The preliminary rating by the staff was moderate. So if we're comfortable with that we could move to validity if we're comfortable with reliability. So, Alan,

comment.

Member Kliger: No, it's not a comment, it's a vote.

Chair Garrick: A vote, okay. Another vote. How about, we can all put our hands up if we're comfortable with the reliability measure.

Chair Dalrymple: Renee, I actually have a question.

Chair Garrick: Oh, thank you.

Chair Dalrymple: That's why my hand was up.

Chair Garrick: Okay, thanks. I didn't see that hand. Sorry, Lorien. I apologize.

Chair Dalrymple: That's okay. And this may be for the developer. I had two questions. I wanted to understand how the, I know you didn't describe them as exclusions, but we might describe it as an exclusion, how the changing dialysis modality impacts this measure?

And probably more important, my question is, where does the minimum member of 50 come from? It was unclear to me the minimum of 50 new ESRD patients as a lower threshold.

Dr. Pravoverov: The modality change would not be applicable with the measure, the measures, this first allocation dialysis treatment or date of transplant, if they have a transplant. So whatever was the first therapy on the first outpatient day, that's what goes into measure so that it shows modality would not be applicable to that for that measure.

Chair Dalrymple: Yes. And I am referencing a section in the measure where it says, clarification of denominator. And it's patients changing dialysis modality.

And, Jeff, you may be able to get there quicker than I can as lead discussant, but it's where the, you know, removed from the denominator, patients who

recovery in 90 days. There is this change in dialysis modality.

But I also had difficulty understanding how that worked given how the measure was constructed. So I was trying to make sure I understood that clarification.

Member Silberzweig: I am not a hundred percent, Lorien, but my thought is that that relates to patients with failed kidney transplants in that 90 day window.

Chair Dalrymple: Did the developer want to confirm?

And do you know the page, Jeff? You might find it quicker than I do. Or I can keep scrolling. Or if any other committee members have found the denominator clarifications.

Dr. Pravoverov: Yes, I would need to --

Chair Garrick: Yes, I thought that was in part the, that's why I asked the AKI question earlier, but maybe I was just confused.

Chair Dalrymple: I think the AKI falls within the recovery of 90 days.

Chair Garrick: Right.

Chair Dalrymple: And I can --

Member Silberzweig: Yes.

Chair Dalrymple: -- read it. I'm sorry, I finally found it. It's determined denominator, eliminate patients who do not meet the denominator definition.

Eliminate patients who recover kidney function by day 90. Eliminate patients who previously were on dialysis 90 days or more who then recovered kidney function, then later restarted dialysis.

Eliminate patients changing dialysis modality. And

that's the one I just, I just wanted to make sure I understood what that meant. And maybe that means they're not really in-center, they're just switching modalities and you want to make sure --

Dr. Pravoverov: Yes.

Chair Dalrymple: -- people don't pull them into the measure somehow, could they move in-center?

Dr. Pravoverov: That's is correct. So it's only applicable to the patients who start in dialyses new. For new ESRD patients. And the new additional was the patients who were failing transplant, who had the transplant before, and start the new either preemptive transplant or new dialysis, must be included.

But the switch modalities of the patients was hemodialysis of which the peritoneal dialysis were received, you know, was the dialysis received, transplant would be not be counted in this measure.

Member Silberzweig: If I might Lorien. I think that this also helps with the patient, who for example, might have started training on PD and then for whatever reason discontinued that, switched to in-center hemodialysis and had a catheter. If I'm understanding the developer correctly, that patient would be excluded from the denominator so the plan would not be penalized for that kind of effort.

Chair Dalrymple: So failed training, in home dialysis takes you out of the denominator and the numerator? Home training failures come out of both?

Dr. Pravoverov: Home training would not take you out of the denominator if the patient had a meaningful exchange. So if the orders were written so the patient becomes, let's say peritoneal dialysis, so the order was written in a meaningful exchange as defined by Medicare was conducted, that would be considered to be first day of treatment. So those

would be included.

Chair Dalrymple: Okay. Yes, so I think those are in, Jeff. I read this as maybe people want, I think your intention may have been to be clear. It's not first day of modality, it's first day of ESRD.

Dr. Pravoverov: That's correct.

Chair Dalrymple: And you were worried people were confusing those two things so you wrote this.

Member Silberzweig: But I wonder if those patients should be excluded, because as Alan talked about yesterday, for a program that has a high rate of attempting to get patients home on perineal dialysis and gets well inpatient who then are unsuccessful on PD training, for whatever reason it is, they may have to start in-center hemodialysis by a catheter because the plan was to have that patient treat by perineal dialysis. And it seems to me that the plan should not be penalized for that.

Chair Dalrymple: And they wouldn't be, Jeff. That person would be in the numerator and the denominator.

Member Silberzweig: Okay.

Chair Dalrymple: Unless the developer disagrees with that statement. But that would not be a penalty, that would be considered a success. Day 1 was PD.

Member Silberzweig: Okay.

Dr. Pravoverov: Yes.

Chair Garrick: Are we understanding that correctly? For the developer.

Dr. Pravoverov: I think if I understand it correctly. So if the patient was prepared, if the question is, if the patient was preparing for PD planning for PD but something unexpected happened and patient had to

start with a center hemo with catheter, on the current definitions, no, the patient would be counted as non-optimal. Because again, the first --

Chair Dalrymple: Well, this scenario is they actually do PD for, let's say, 15 days and then convert to in-center. If you do PD for 15 days are you optimal if your very first treatment is PD?

Dr. Pravoverov: Yes.

Chair Dalrymple: So you don't get penalized because they fail on PD if you start on PD?

Dr. Pravoverov: No.

Chair Garrick: Okay. Thanks for that clarification. So as long as you start and you're on PD for a bit then come off, even if you started hemo with a catheter it's not viewed as a sub-optimal start, correct?

Dr. Pravoverov: That's correct.

Chair Garrick: Thank you so much.

Dr. Pravoverov: It's a first patient dialysis treatment. That's when the determination happens.

Chair Garrick: And back to the other question on reliability. The number 50, needing patients for this to reliable data?

Dr. Pravoverov: This is something that we came up as a sort of the learning curve. It becomes very, if it's 11, 50 patients in the group or medical center, the statistics become very difficult. It should be at least 50 starts in the measurement period to become meaningful. To make some adjustments or to kind of judge the programs successful in the ESRD care.

That's why we promote it as a more of organization and integrated health care system measure. Because it requires large number of patients, large number of new starts.

Chair Garrick: All right, thank you. So I need some guidance maybe from the, from our experts from NQF. That conversation then about the applicability of the measure would go to use and usability, is that correct? How it would be applied?

Because if we need to have a large number of starts is obviously, as you mentioned earlier, Doctor, it's not a measure for a smaller number, it's not a measure for small dialysis facilities, it's a measure for integrated delivery systems, correct?

Dr. Pravoverov: Yes.

Chair Dalrymple: Size is usually reliability discussion, Renee.

Chair Garrick: Okay. Thanks.

Chair Dalrymple: And like the 50 came up here because typically --

Chair Garrick: Yes.

Chair Dalrymple: -- that's what's most impacted by small versus large is unstable reliability.

Chair Garrick: So I guess where I'm struggling though is that if it's, I understand that. But if we need 50 people, 50 new starts for this to be a reliable measure, that would apply to any unit, any facility, any practice group, which is any, right? If I'm understanding this. Is that correct? To the developer.

Dr. Pravoverov: I don't think it's applicable to individual dialysis facility or individual practice just because of the small number of potentially involved patients.

We found that at least 50 starts per the measurement period, and the measurement period is a year, to be reliable. And statistically reliable.

I don't think it's applicable to individual facilities.

And I think the definition of integrated health care delivery system usually means larger size.

Chair Garrick: Okay, thank you. We do have another question from the standing committee. Precious, I think your hand is up?

Member McCowan: You all have answered my question. Thank you so much.

Chair Garrick: Okay, great. Are there other questions to the developer at this point, other wise we could go back to where we were, which was to have a conversation about voting or the need to vote on reliability?

So, Jeff, back to you. Would you like to enter the group? We could have a vote on reliability or accept the prior vote when the measure was first introduced?

Do I have a sense of whether you'd like to have a vote on reliability from the Committee? We can have a hands, show of hands, or should we have our own vote?

So let's put up our hands if we'd like to accept the prior vote on reliability, which it did pass. At that time I think was a moderate degree of reliability.

I can't count that fast but it looks like all the hands are going up. To my NQF Staff friends it looks to me like we are very comfortable moving ahead with the current vote on this maintenance measure.

And then moving to the second part, which would be validity. So, Jeff, back to you.

Member Silberzweig: Thanks, Renee. So the measured data elements are considered accurate.

The data presented by the developer indicated that the denominator is 96 percent accurate, the numerator is 87 percent accurate. And the total data element match rate was 83 percent.

The developer presented a positive predictive value to identify true optimal starts at 0.94. And a negative predictive value for non-optimal starts of 0.79.

The changes since the last submission, as noted, are removal of AV graft limits. And the addition of failed transplants. And the developer states that those have no impact on the data.

Exclusions are anybody less than 18 years old. Anybody who is not a member of Kaiser Permanente at the start of dialysis, and anyone who recovered renal function by day 90.

There were no risk adjustments. And the only missing data were that preemptive transplants are not attributed to dialysis facilities. So that's what I have on validity.

Chair Garrick: Thank you. Anything to add Myra or Bobbi? Myra or Bobbi, anything you'd like to add?

Member Wager: Nothing to add.

Chair Garrick: Okay. So, again, because it's a maintenance measure, if we are comfortable that there is nothing new on validity and we're comfortable, then we don't need to have further discussion. And I'll ask my colleagues from the NQF if we have to have a vote on validity at this point?

Ms. Farrell: It would be the same thing, where you would accept, if you would like to accept the previous --

Chair Garrick: So --

Ms. Farrell: -- on validity or you can have your own vote.

Chair Garrick: So we can do it with a show of hands again, right?

Ms. Farrell: Yes.

Chair Garrick: Is that correct? So let's do that.

Ms. Farrell: Yes.

Chair Garrick: Thank you. It seems to work well. All right, I counted the hands. I think we have a clear agreement that we can move ahead and accept the prior vote of validity. Thank you, Mahesh, I was waiting for that.

Which then brings us, Jeff, Myra and Bobbi, to feasibility.

Member Silberzweig: So the developer notes that they have an integrated care model and electronic health record that allows for consistent data collection and reporting. But does note that there is a lack of consistency so the data has not yet been reported publicly. And I know that public reporting gets to use in usability.

But the data elements are all available in their EHR. And on the 2728 forms. So the developer says they have not had any problems in capturing the data.

Chair Garrick: Okay. Bobbi and Myra, anything you'd like to add to that in terms of the feasibility of this measure as it's now being prescribed as a measure for integrated delivery system and its maintenance measure?

Member Wager: Sure. They did mention that if there was any inconsistences then they just got a hold of the renal care coordinator to get those taken care of.

Chair Garrick: Yes, I saw the same thing. Thank you. If they had trouble tracking down the data they were able to, in their integrated system, find the right people and get the data.

Member Wager: Correct.

Chair Garrick: Okay. I believe we do need to vote on feasibility. So if we can, Gabby, have that

opportunity?

Ms. Kyle-Lion: Yes.

Chair Garrick: Okay.

Ms. Kyle-Lion: I'll get that pulled up for everyone.

Chair Garrick: Unless there are any other comments, I think we can move to the vote.

Ms. Kyle-Lion: Okay, I'll go ahead and pull that up. Okay, voting is now open for Measure 2594 on feasibility.

The options are A, for high, B, for moderate, C, for low, or D, for insufficient. And I do think we'll have 19 votes now, as I think the person who left is back.

Right now we're at 16. We're at 18. Okay, it does look like we're holding at 18 so I'll just go ahead and close the poll because that is over quorum. Voting is now closed for Measure 2594 on feasibility.

Give me one moment to get the results pulled up. Okay, there were four votes for high, 14 votes for moderate, zero votes for low and zero votes for insufficient, therefore the measure passes on feasibility. Back to you, Renee.

Chair Garrick: Great, thank you. And that brings us to another usability and use. So discussing first use, Jeff and Myra and Bobbi. Jeff, if you want to lead us on that conversation?

Member Silberzweig: Sure. Thanks, Renee. So the data is not currently publicly reported and is not currently used in accountability program. But Kaiser Permanente does have a plan for it.

It is used by the Permanente foundation and benchmarked against the U.S. average. And they plan to submit it for consideration in federal programs.

There were several outside commenters on it. The American Society of Nephrology described Measure 2594 as the only metric specifically addressing advanced chronic kidney disease and kidney replacement planning.

And they stated that there is no aspect to the practice of nephrology in greater need of quality improvement and that this is the step in the right direction.

Kidney Care Partners called the measure appropriate but only feasible in fully integrated delivery care systems or large physician groups and not applicable to dialysis facilities. They noted that 40 percent of patients have not seen a nephrologist at the time of dialysis initiation and suggest that the measure should exclude patients with limited life expectancy, as well as those receiving an unlimited trial of dialysis and patients with AKI.

They are concerned about potential unattended consequences, including misrepresentation of an optimal start. And that it may damage, lead to damage to immature AV fistulas if they are cannulated before they're really ready for us, it could potentially damage them for long-term use. They also expressed concern that it might penalize facilities caring for more patients with lower socioeconomic status.

Finally, the Nephrology Care Alliance calls high-value care for chronic kidney disease a front line solution.

So, I'll stop there. Happy to hear any further comments.

Chair Garrick: So, to our co-discussants, Myra and Bobbi, any thoughts that you'd like to add?

Member Wager: No, nothing to add.

Chair Garrick: Okay. Alan?

Member Kliger: Just a question. If we're looking at use, any measure of use outside of Kaiser?

Member Silberzweig: Alan, the only use outside of Kaiser that's been described is the retrospective analysis of USRDS and CMS fistula first data. There is no other use outside of Kaiser that I am aware of.

Chair Garrick: Yes. So, we've obviously had some, you know, all of us agree that having optimal starts and having patients have well planned entry into ESRD and advance EK is very appropriate.

I think one of the unattended consequences that I think Kaiser is working hard to help us understand is that this is really meant to be an integrated delivery system measure because none of us would want it to be that people who are not well prepared for dialysis and haven't had a good optimal entry into dialysis, we would never want those people to be refused entry into some dialysis unit with the old express of cherry picking. So that would be a serious unattended consequence, which is why I think --

(Simultaneously speaking.)

Chair Garrick: I'm sorry, Rick, you want to, is that Rick Kaskel? I'm not sure if Rick was talking to us or not, but if others have other comments that they want right now, this is a, in using Kaiser largely. Lorien, some clarification?

Chair Dalrymple: Yes. And again, I'll have Paula or Katie correct me, but my understanding for maintenance measures is they're expected to be in an accountability program. And we've clarified that's a federal accountability program within three years, and publicly reported within six years.

So in terms of use and what is expected of a maintenance measure, I do not believe this measure meets either of those criteria.

We did ask the NQF Staff if we, as committees, can make exceptions to that, or discuss exceptions to that, if we believe there to be a credible plan working towards that goal. So I do think, and again, Katie or Paula interject here, but I do think we have to be transparent in that the current use guidance for measure, maintenance measures, is not met. Is that correct, Jeff?

Member Silberzweig: That is correct, Lorien. Yes.

Ms. Goodwin: So this is Katie. I just did want to clarify. Apologies for any confusion. It does not have to be a federal accountability program.

So, we just require that the results are used in at least one accountability application. And that it is reported publicly.

Chair Dalrymple: Okay. So, Katie, I think that's a really important clarification from before. So it does not need to be federal.

So, would Kaiser internal accountability meet at least that criteria because it is used internal to Kaiser?

Is the accountability criteria met? You might be muted, Katie, none of us can hear your response.

Ms. Goodwin: Yes. Sorry about that. Yes.

Member Silberzweig: But it is not publicly reported?

Chair Garrick: It is not publicly reported.

Ms. Goodwin: Oh, okay, then -- okay.

Chair Dalrymple: But that's okay, Katie. We're just asking if three year accountability application can be internal use. My understanding, and Jeff, I want to clarify this with you as lead discussant, we can always go to the developer, it is used internally to Kaiser now for regional accountability, that this measure is looked at and reviewed.

And we may ask for clarification. It sounded like components of it were publicly reported, but I did not fully understand that, Jeff. And you may have greater insight into that.

Member Silberzweig: My understanding is the same as yours, Lorien, that it is used internally, it is not publicly reported. At least not as an entire measure. Whether there are elements that are publicly reported that was clear to me.

Chair Garrick: If there aren't other questions or comments, our developer has his hand up so --

Chair Dalrymple: John has his hand up too, Renee.

Chair Garrick: Oh.

Chair Dalrymple: I don't know if you want to give him an opportunity first.

Chair Garrick: That's fine. I didn't see him, he must be on a different page. So, John, do you want to go next? Thank you so much, Lorien.

Member Wagner: Yes, thank you. Yes, I just was curious. On the graph that's shown, I think on Page 100, it doesn't look like, if this is being used, that there has been much moving of the needle.

Of course, the pandemic has altered the care in significant ways, but if you look before 2019 I think there was only one of the markets that indicated an improvement. But what does that say about use?

Does that tell us this measure does not really help us improve the quality in terms of what they're trying to target or, and how does that influence this discussion?

Chair Dalrymple: John, can you tell us the page? I know I have looked at overall performance and seen that it had gone from 57.1 to 60.7 before the pandemic started and then did decline down to 56.5. But that's the national mean.

Member Silberzweig: Lorien, I think the graph he is referring to is on Page 91.

Chair Garrick: Right.

Member Silberzweig: And it's a line graph showing the eight different Kaiser Permanente markets.

Chair Garrick: Right.

Member Wagner: I think it depends on whether you're using the worksheet version versus the non-worksheet version.

Member Silberzweig: Oh, okay.

Chair Garrick: So would our developer like to comment on John's question?

Dr. Pravoverov: Sure. A few comments. Number one, about the public reporting.

The CMIKCC model reporting optimal start in 2022, so in 2023 you probably will see the data. So public reporting will be extended.

As well as we applied to MIPS program through the CMS for the single application to endorse use of optimal starts in MIPS program. So that the KCC already started reported in 2022. It's a measure period. And it's going to probably, hopefully will be expanded further.

Now about the numbers and performance. In the current definitions that we just discussed for the numerator and denominator, I think there is a maxable, possible achievable ceiling for this measure. You know, if you count the patients with the acute kidney injury, patients with no previous CKD, who never were engaged in any previous dialysis care.

So our discussion within the group was that the probably most achievable is probably about 70. And getting to 60 slowly. So I think there was an initial

rapid increase from average '11 40 percent. In the 2011 and 2012.

And rapidly increased due to the number in the kind of, before the COVID that we were slowly inching to low 60 percent as a program. With a different regional performed in some data, some a little bit worse.

I think there is a lot of opportunities, even with the current definitions. Including home dialysis, peritoneal especially. We can access KDOQI guidelines with a little bit different perspective now on the CDC with completely immunized.

But I think it's overall does continuous improvement to pre-dialysis care and those measures and the problem with developing and any participants which have to be developed to ensure proper chronic kidney disease patient identifications, identification, and engagement in ESRD care. So I think there is a couple opportunities for improvement.

Chair Garrick: Thanks. John, do you have a follow-up question?

If not maybe we could, I think with the clarification it does not have to be a federal measure, I think we could move ahead and have a vote on use and then usability, if people are comfortable with that. If there aren't other comments.

So we do need to have a vote on both usability and use. If, Gabby, we can do that.

Ms. Kyle-Lion: Sure. I will pull up the vote for use first.

Chair Garrick: Thank you.

Ms. Kyle-Lion: Okay. Voting is now open for Measure 2594 on use. Your options are, A, for pass or B, for no pass.

And I believe we are still looking for 19 votes here.

We are at 16. Okay, we're at 18 votes. I'll just give it, okay, perfect, we're at 19. I'll go ahead and close the poll.

Voting is now closed for Measure 2594 on use. Please give me one moment to pull up the results. Okay, there were 17 votes for pass, two votes for no pass. The board measure passes on use. Back to you, Renee.

Chair Garrick: Thank you. And back to Jeff and Myra and Bobbi for the conversation on usability, if you'd like to --

Member Silberzweig: Sure. Thanks, Renee.

Chair Garrick: Thank you.

Member Silberzweig: So, the developer cites that they have used the measure. As the developer just stated, they had seen incremental progress prior to the pandemic.

There are some noted unexpected findings from the developer that moving upstream in CKD management improves outcomes, that there was improved integration with primary providers and improved use of the electronic health record. That there was development of options, such as embedded and IR placed PD catheters. And improved quantification of the value of care. And a better relationship between multi-disciplinary providers.

So that was the information presented on usability.

Chair Garrick: Great. Myra or Bobbi, anything to add?

Member Wager: Yes. The one thing that I loved reading is that in enhanced earlier patients activation and participation.

Chair Garrick: Thank you. Other comments? All right.

If not, I think we could actually move to a vote. And again, this is thinking about integrated delivery systems. And we've had that clarification so it's ready for a vote on usability.

Ms. Kyle-Lion: Okay, I'll go ahead and pull that up for everyone. Voting is now open for Measure 2594 on usability. Your options are A, for high, B, for moderate, C, for low, or D, for insufficient.

We are looking for 19 votes here, and at the moment we have 16. So I'll just pause for a moment longer. We're at 18 votes so I'll just give it one more moment. Okay, we're at 19, I'm going to go ahead and close the poll.

Voting is now closed for Measure 2594 on usability. Give me one moment to pull up the results. Okay, there are three votes for high, 15 votes for moderate, one vote for low and zero votes for insufficient, therefore the measure passes on usability. Back to you, Renee.

Chair Garrick: Thank you. And Jeff, Myra and Bobbi, a summation on overall suitability for endorsement, which again needs a vote.

Member Silberzweig: I think for the right healthcare system this is a really valuable measure. As we've discussed, it can be really beneficial for patients functioning in integrated healthcare systems. And potentially has use for the CKCC model as that roles out.

Chair Garrick: Okay. So I just want to make sure that I understand the clarification that this does not have to be a federal system. Because I think, I just want to make sure I have that right. Is that correct? To the NQF Staff.

Ms. Farrell: Yes, that's correct.

Chair Garrick: Great, thank you so much. Because that's very important for us to understand. Thank

you. Michael has his hand up.

Member Somers: I just wanted to clarify. The results from its use though show that in most of the regions there wasn't a change in the results. Is that correct?

Chair Dalrymple: Michael, if I found the right graph I interpreted that slightly differently. And I interpreted the national mean.

I mean, perhaps Jeff or John, do you want to share your screen so we're all looking at the same graph because it can be a little hard to tell people to go to Page 90 because we're all looking at different numbers.

What I would say, at least the way I thought about this, Michael, it may or may not be correct, is I only looked at pre-pandemic data. I think we all know what the pandemic has done to quality measures, especially ones that take into account these types of outcomes.

And I don't know if Jeff or John are going to share their screen?

Member Silberzweig: I am trying, but apparently I have to change my system preferences to do it, so I'm not sure I'm going to succeed.

(Laughter.)

Chair Dalrymple: That's okay --

Member Silberzweig: It looks like John is sharing his so he's got me beat to it so I'll let him go.

Chair Dalrymple: I can only see the top title, maybe one can see more than that?

Chair Garrick: No. Could you scroll down a bit?

Member Wagner: Hold on. We're working on it.

Chair Dalrymple: We appreciate you doing it on the

fly, John.

Chair Garrick: Very impressive.

Member Wagner: It would be better if I'm successful than you'll appreciate it more. Hold on. Okay. So right now you're not seeing it, is that what you're saying?

Chair Dalrymple: Now we can see it.

Member Wagner: Oh good. Excellent.

Chair Dalrymple: Yes, so, Michael, when I was trying to quickly look at this, as John raised this versus the national mean, if you stop at 2019 Q4. So essentially censure 2020 and 2021 for pandemic.

I mean, a fair number of these lines looked like they were trending up to me. Not all of them. Some were flat and some regressed even a little bit, which again, may suggest there is a ceiling effect.

But the grey, the light blue, the yellow, the orange, the green. I mean, I'd be curious if others looked at this the same way, but does it look like things generally improve prior to the pandemic in a fair number of markets?

Chair Garrick: So I thought, this makes me reflect on what Mahesh said a little while ago. I thought yes to that.

And I thought that since obviously, if we can find a way to improve starts and have optimal starts instead of the catastrophic beginning it would be a good thing.

And I agree, it's not an overwhelming change but it's certainly, for the most part, is in the right direction. And if it's applied to the right group, as we've discussed, so that it's not a federal measure but in the right hands, I thought it looked like it was going up.

Chair Dalrymple: And it was a little easier to see in the national mean --

Chair Garrick: Yes.

Chair Dalrymple: -- but I presume the national mean reflects all these markets. But it did look like the pandemic, almost all of the gains were lost during the pandemic, if not all the gains, if I recall the national numbers.

Chair Garrick: And, you know, this is a quick bias decide on that. I think at some point we're going to have to come to terms with that because dialysis units got moved all around. People lost their home units.

Even the specific data will be very challenged because of what went on during the pandemic and the world of ESRD.

If we're comfortable as a group we could go to the last vote, which is overall suitability for endorsement. If there are other questions or comments.

Otherwise, Gabby, if people are comfortable we could have the vote.

Ms. Kyle-Lion: Okay, not hearing any objections so I'll go ahead and share the poll and get that running for everyone.

Voting is now open for Measure 2594 on overall suitability for endorsements. Endorsement. Your options are A, for yes, or B, for no.

And again, we are looking for 19 votes here. And at the moment we are at 18, so I'll just give one moment to allow for one last vote, which we just got. So I'll go ahead and close the poll.

Voting is now closed for Measure 2594 on overall suitability for endorsement. Give me one moment to pull up the results. Okay. There were 19 votes for

yes and zero votes for no, therefore the Standing Committee recommends to endorse the measure.

Chair Garrick: Great, thanks.

Ms. Kyle-Lion: I'll pass it back to you, Renee.

Chair Garrick: Great, thank you everybody. And I think that concludes our conversation of this measure so I'll pass it back to Paula to have other comments and public comment.

Ms. Farrell: Great, thank you, everyone. So, Erica will go ahead and show Slide 32 please.

We were originally going to have a related and competing measure discussion, but because measure number, NQF Measure 3659 did not, was not recommended for endorsement yesterday we will not have related and competing discussion because it was identified as a related measure to the measure we just discussed, 2594. But since it was not recommended for endorsement we will not hold that discussion.

So next slide please. And before we jump into the next steps, we would like to thank the NQF members and the public and give them an opportunity comment if they like to. So if you're either an NQF Member of part of the public and you wish to comment on the discussion today, if you could please either raise your hand or put a comment in the chat. And I'll just pause for a moment to give folks an opportunity to do that.

Member Lenning: Can you repeat that again please?

NQF Member and Public Comments

Ms. Farrell: Oh, sorry. Yes. This is just our opportunity for NQF Members and the public to provide, give them an opportunity if they would like to comment on the discussion that was had today, they can do so. So I ask that they, either NQF Members or members of the public either raise their

hand or put a message in the chat so that we can call on them if they would like to make a comment.

All right. And I am not seeing any raised hands or anything in the chat, so with that I'll turn it over to Oroma to talk through next steps. Oroma.

Next Steps

Ms. Igwe: Great. Let's proceed to next steps please. Okay. So, as we finish this meeting, next slide please, we'll be taking some subsequent actions here to summarize the evaluation that has been done.

So Staff will prepared a draft report, and that report will detail the discussion across the meetings, as well as the corresponding recommendations. This report will then be released for a 30-day public and member commenting period.

And during that period we will essentially allow the public, and NQF Members, to submit comments on behalf of the decisions that were made.

The Staff will then take those comments and compile them into briefs. And based on the nature of those comments the NQF Staff will decide if a post-comment call is necessary. At that post-comment call the Committee will reconvene to discuss the comments that are submitted.

Staff will then incorporate those comments and responses into the draft report. And then the CSAC meeting will follow. CSAC is considered the final adjudicating body and they will met to endorse the measures for the final endorsement status of those measures.

Following CSAC there will then be an opportunity for the public to appeal the endorsement decision.

Next slide. So here on the screen is a breakdown of the upcoming activities and the overall timeline for this cycle.

We certainly held our follow-up meeting today, so thank you again to everyone. We have successfully completed the entire evaluation.

The official draft report commenting period will be held from August 4th to September 2nd. And then following that, again, we determine the need for post-comment web meeting. Those dates will be provided as well.

The CSAC review will also be determined as well. And the dates for the appeal period will be determined. You all will be notified of those dates.

Next slide please. So then thank you to everyone. The Standing Committee, Developers, NQF Staff and the general public.

We just want to remind you that the project team can be reached via email at renal@qualityforum.org or by phone at 202-783-1300. And of course, to stay up to date on project updates you all are welcome to visit our project page. And for the Committee Members, the materials are always available to you via the Committee SharePoint site.

So again, I just want to say thank you to everyone. And I will now turn it to Paula for some questions and closing remarks.

Adjourn

Ms. Farrell: Great. Great, thank you, Oroma. So we are at the end of our meeting. And I just wanted to provide one additional opportunity for anyone who would like to speak, to have that option. So if you could please let us know. And again, I'll just pause for a bit.

Okay. I don't see any hand raises and I don't see anything I the chat. So I'd like to thank our Standing Committee, our measure developers, NQF Members and the public for their participation.

I'd also like to thank our co-chairs, Lorien and

Renee, for their great work to lead the meetings. And I'll turn it over quickly to our co-chairs so that they can provide their closing remarks.

Chair Garrick: So just, Renee, I wanted to thank everybody. This is obviously my first opportunity to co-chair. And I really appreciated all their support.

And the help from Lorien and the NQF Staff and from the Standing Committee. I think we had a really robust conversation on the measures. So thank you to everyone.

Chair Dalrymple: And this is Lorien. I obviously want to thank Renee for agreeing to co-chair. We know how much work goes into this and I think we all owe her our gratitude.

And I really want to thank the committee. I think we've had a day and a half of very thoughtful debate, discuss and really trying to give great consideration to all of the measures before us.

I know how much work goes into reviewing these measures before we ever come to meet. And then to meet for a day and a half and have such engaged participation and really important discussion. I want to thank you all.

I do want to especially thank our lead discussants and supporting discussants because we know we ask even more of you. And so, thank you to all of our lead and supporting discussants who took it upon themselves to present and summarize all of the data.

And with that, I just want to say what a joy it continues to be to serve on this committee with so many people committed to try and to continuously improve the quality of healthcare in this country.

Chair Garrick: And I'll add my thanks to Lorien and to the NQF Staff for our patient participants. It's really wonderful. We know this is a lot of work for

you as well, so thanks a lot to Precious and Bobbi for joining us, it's really great to have you with us.

Ms. Farrell: All right. And with that, that concludes the meeting. Thank you, everyone, and enjoy the rest of your evening.

Chair Dalrymple: Thank you.

Chair Garrick: Thank you, everyone.

(Whereupon, the above-entitled matter went off the record at 4:57 p.m.)