National Quality Forum

Consensus Standards Approval Committee

Measure Evaluation Meeting (Spring 2021 Cycle)

Wednesday

December 1, 2021

The Committee met via Videoconference, at 10:00 a.m. EST, Melissa Danforth, Chair, presiding.

Present:

Melissa Danforth, Chair; the Leapfrog Group
John Bulger, DO, MBA, Vice Chair; Geisinger Health Plan
Dan Culica, MD, MA, PhD, Texas Health and Human Services Commission
Dana Cyra, MA, CPHQ, Inclusa
Lisa Freeman, Connecticut Center for Patient Safety
Kevin Kavanagh, MD, MS, FACS, Health Watch USA
Rebecca Kirch, JD, National Patient Advocate Foundation
Laura Pennington, Washington State Health Care Authority
Leslie Schultz, RN, BSN, PhD, Premier Safety Institute
Jeffrey Susman, MD, Northeast Ohio Medical University

NQF Staff:

Poonam Bal, MHSA, Interim Senior Director
Tricia Elliott, MBA, CPHQ, FNAHQ, Senior Managing Director
Elizabeth Flashner, MHA, Manager
Elisa Munthali, MPH, Consultant
Matthew Pickering, PharmD, Senior Director
Dana Gelb Safran, ScD, President and CEO

Also Present:

Constance Anderson, BSN, MBA, Renal Standing Committee Co-chair
Dale Bratzler, DO, MPH, Primary Care and

Chronic
Illness Standing Committee Co-chair
Donald Casey, MD, MPH, MBA, FACP, FAHA, FAAPL,
DFACMQ, American College of Medical Quality
Robert Dickerson, Mathematica
Tom Heymann, Sepsis Alliance
Joe Messana, MD
Sean Townsend, MD
Iona Thraen, PhD, ACSW, Patient Safety Standing
Committee Co-chair
Donald Yealy, MD

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Proceedings

10:02 a.m.

Welcoming Remarks and Recap of Day 1

Ms. Elliott: Okay, welcome everyone. Thank you for coming to Day 2 of our consensus standards approval committee. We look forward to more robust discussions today. And to those who were participating in the call yesterday, we thank you for your time for a very productive meeting.

Next slide please. Just a quick welcome. So welcome back to everyone. And once again, we truly appreciate the time and energy that folks put in to both the meeting, as well as the NQF team for the meeting preparations to get us here today.

Next slide. We'll go through some housekeeping reminders.

So once again, this is a Cisco Webex meeting with audio and video capabilities. When you're not speaking if you can place yourself on mute to minimize any background noise.

And we encourage participants to use the following features on the platform. There is a chat box. You can message the NQF Staff or the group or everyone on the call if you have any questions or issues.

There is also a raise hand feature. That can be accessed if you have the participant list open and see your name. You can hoover over your name and there is an option to do a hand raise.

Or at the bottom there is a function, at the bottom of the screen of Webex, there is a reactions button, it has a smiley face. If you click on that you can also find the raise hand feature there as well.

And there will be opportunities throughout the meeting for member and public comment opportunities. The committee members have been

sent the link to the voting poll everywhere. So please make sure that that's working. We'll be doing a test vote in just a minute.

And lastly, if you're experiencing any technical issues please send a message to the NQF Staff, either through the chat box or the email. And the email is csac@qualityforum.org.

Next slide please. Our agenda, we got, have completed part of our welcome. We'll be doing a quick roll call to make sure that we have all of our committee members on the call today.

Today we'll be having a discussion and vote on three topic areas. Renal, patient safety and primary care chronic illness. And we'll have an opportunity for public comment at the end of the day, prior to discussing next steps. And we'll be adjourning at 12:00 p.m. eastern time today.

Next slide please. Okay. At this point we'll be completing a roll call. And if you were not able to join the call yesterday as a Committee Member, please provide any disclosures.

So if you can state your name, your organization, and then if you have any disclosure for us today.

So I'll start with our Committee Chairs. If you attended yesterday and offered your disclosures you can just say present or here.

Missy Danforth?

Chair Danforth: Here.

Ms. Elliott: John Bulger?

Vice Chair Bulger: Here.

Ms. Elliott: Dan Culica?

Member Culica: I'm here. Good morning, everyone.

Ms. Elliott: Good morning. Thank you, Dan. Dana

Cyra?

Member Cyra: Here.

Ms. Elliott: Welcome. Lisa Freeman?

Member Freeman: I'm here. And I have no disclosures.

Ms. Elliott: Excellent. Thank you, Lisa. Kevin Kavanagh?

Member Kavanagh: Here.

Ms. Elliott: Thank you. Rebecca Kirch? Okay, we'll circle back. Laura Pennington?

Member Pennington: Here.

Ms. Elliott: Thank you. Leslie Schultz?

Member Schultz: I'm here.

Ms. Elliott: Thank you. Ed Septimus has informed us he will not be attending. Jeff Susman?

Member Susman: I'm here. Thank you.

Ms. Elliott: Excellent. Thank you, Jeff. And I believe Kelly Trautner will not be joining today. Just to double check if Kelly is on the call. I do not see her. Okay.

And I'll circle back. Has Rebecca Kirch joined?

Member Kirch: Good morning. Yes, I have. Sorry, I had technical issues. Good morning.

Ms. Elliott: No problem. Excellent. We can hear you now perfectly. Okay. So, for the record, we have eight of ten members, and we have quorum, so we can proceed.

Or no, ten of, sorry, numbers are wrong. Ten of 12. So I think we're good, correct, team? Just checking in the team.

Chair Danforth: Yes.

Ms. Elliott: All right. Excellent. So our next slide is we're going to do a quick voting procedure reminder, so I'll hand things over to Beth.

Ms. Flashner: Good morning, everyone. So, as we did yesterday, we will vote on each topic area after the discussion is complete.

For today we have three topic areas. Only one will we offer the vote, the block vote, because we have, we'll have to, because of disclosures we have to do separate votes for all the patient safety measures.

So I'm going to do a quick test vote. You should have received an email from this morning with the link. This is only for CSAC Members.

And so, I'll share my screen. Oops, other screen. It worked so beautifully yesterday. I'm trying to pull it over. There it is.

All right, so --

Ms. Elliott: Beth, we're seeing your SharePoint site and not the vote.

Ms. Flashner: All right, let me stop sharing and try this again. My screen just went completely black on me.

All right, let me try this again. All right, I apologize. Let's try this again. Are you now seeing the vote?

Ms. Elliott: Yes, we are.

Ms. Flashner: Oh, good.

Member Susman: But not on the poll, everywhere.

Ms. Flashner: Right. I will active this now. So, just a test vote. Did you travel for Thanksgiving, A, yes, B, no?

I'm seeing seven votes, eight votes. Nine, ten. I believe that's all CSAC numbers, so I will close the vote and see what happens. We had three people

travel and seven people not. We had ten votes total, so very good.

Is there any questions about voting before I turn it back to Tricia? I will turn it back to Tricia. Thank you so much.

Ms. Elliott: Great, thank you, Beth. And next slide please. I want to just hand it over to Missy and John for any opening comments and welcome remarks.

Chair Danforth: Thanks, Tricia. Welcome back everyone. Based on how efficient we were yesterday I suspect we may have the same success today.

I wanted to welcome Lisa today. We missed you yesterday and happy that you are able to join us today. And thank you again everyone for your time. John?

Vice Chair Bulger: Thanks, Missy. I think you might have just jinxed us but I agree with Missy that we were pretty, very efficient yesterday and hopefully that continues. And I appreciate everyone taking the time this morning.

Ms. Elliott: Excellent. Thank you both. I appreciate your leadership and chairmanship of these calls, much appreciated.

And so, I think if everybody is ready we'll kick things off with renal. So, John, I'll hand things back to you.

Vice Chair Bulger: Great. Thank you, Tricia. And so, do we have Constance?

Ms. Bal: Connie just messaged that she is having some difficulty unmuting. Are you able to unmute, Connie?

Ms. Anderson: Okay. Yes, I finally was able to get unmuted.

Vice Chair Bulger: All right.

Ms. Anderson: I'm here, thank you.

Vice Chair Bulger: Great. Thanks, Connie. And Poonam Bal too I believe.

Ms. Bal: Yes.

Vice Chair Bulger: And the primary discussants are Laura and Jeff, correct?

Member Susman: Correct. At least for me.

Vice Chair Bulger: Yes. Laura is primary, Jeff is secondary. Okay, great. So we'll turn it over to Poonam, direct of the renal team, to start us off.

CSAC Discussion and Vote: Renal Spring 2021

Measure Review Cycle

Ms. Bal: Perfect. Thank you. Next slide please. Perfect.

So there were two measures under review, renal measures, for the spring 2021 cycle. Those measures did go to the SMP and did pass SMP on reliability.

However, neither measure was recommended for endorsement. Measure 3615 and 3616, which was unsafe opioid prescriptions. And then both measures were at different levels. These measures did not pass on evidence.

Next slide please. The main concerns around the evidence, which we've listed here as overarching issues for renal measures, is that the evidence must directly represent the measure focus of interest as specified.

The primary evidence that was provided by the developer focused on reduction of unsafe opioid misuse by primary care providers rather than patients receiving hemodialysis.

It also focused mainly on reduction of pain as the primary symptom. And so the standing committee

questioned whether the measures should focus on appropriate pain management rather than reducing unsafe opioid use.

So that was the main rational for not passing the measure on evidence. If you can go to the next slide.

There were other rationales that were provided to the developer that the standing committee felt was important to highlight for these measures. Mainly around reducing unattended consequences.

Part of the evidence did support that patients receiving hemodialysis have very little pain relief options. And so by reducing the opportunity to provide an opioid use, the opioids to those patients, that might have unattended consequences whether or not actually able to fully manage their pain.

There was also concerns that the accountability entity, oh, as written, would be nephrologist regardless of who had prescribed that medication. And so, nephrologists would be held accountable, regardless, as long as one of their physicians had given the opioid prescription.

So, due to that they felt that nephrologists would be inappropriately attributed to that concern and that the measure should focus on primary care physicians or someone, or the clinician that actually prescribed the opioid.

Next slide please. And so, we did receive four comments. They were all unsupportive of, I'm sorry, they were all supportive of the standing committee's decision, but not supportive of the measure.

Due to the same concerns that were outlined by the standing committee. And the four members that did send the expressions of support also stated that they did not support these measures to move forward.

And with that, I'll see if Connie wants to add anything else.

Ms. Anderson: Thank you, Poonam. I think that was a great summary of our discussion.

I think also as we looked at the evidence, we went through the evidence algorithm and did not feel that the evidence supported the measures and therefore it did not pass on the evidence.

Vice Chair Bulger: Great, thanks, Poonam, thanks, Connie. So we'll go to the CSAC discussions. And, Laura.

Member Pennington: Thank you, John. I think you covered most of my points, but what I will add is that the standing committee did agree that this is a really important topic. That an appropriate opioid use and prescribing are a major problem in the country. And that appropriate pain management is critical. So I'll just point that out on top.

But I agree the evidence was a really good deciding factor. And kind of, there seem to be a confusion about the intent of the measure.

I think you mentioned in your opening remarks that, for example, the evidence focuses on reducing unsafe opioid misuse rather than for patients receiving hemodialysis.

Which it states that patients with end-stage renal disease report pain as their primary symptom and report higher rates of pain than the general population. Which is where that unattended consequence comes in about if they implement a measure like this could it potentially reduce the options for patients with end-stage renal disease and limit their options for pain management.

The other thing I'll mention that was not previously mentioned is there is some concerns over the exclusions. For example, the committee questioned why the measure does not exclude people with sickle cell disease and cancer. And yet they were adjusted in the risk model as complex conditions.

So, the developer did address that stating that they limited the exclusion criteria to patients that are enrolled in hospice in any point in the reporting period. They choose to be a bit more specific in the inclusion criteria and to use that the risk adjustment strategy so that they could have a more broadly applicable measure to the patient population.

And then the last thing I'll say is the risk adjustment, the committee felt the risk adjustment is insufficient to meet population and the provider needs. They expressed concern about the scientific acceptability and risk adjustment that were not satisfactory and the measure will not improve dialysis care or outcomes for patients or providers. I'll stop there.

Vice Chair Bulger: Okay, great. Jeff, anything to add?

Member Susman: Yes. I think one of the important issues that this measure raises, beyond what's already been said, is accountability for outcomes. And in this case, appropriate use of opioids, pain control.

And a dialysis patient is a good example where a primary care clinician may have a significant role in their care, but they have a very specialized health care need and dialysis. So, who should be accountable and how do you measure that in a way that is fair to each of the providers providing care, as well as reflecting what their optimal outcome is.

And unfortunately these measures did not really address that challenge successfully. But I think it does raise the larger issue of, were there multiple providers providing significant amounts of care, how do you attribute outcomes.

And we could think of other examples. Patients with complicated neurological conditions, like MS that might seek neurologists and primary. Or folks who are in end-stage heart failure and they're in a heart failure program and have a primary care clinician.

So, that's something that's a broader issue that NQF might want to think through more on a cerebral level. Bottom line though, I agree with the committee's recommendations for all the reasons that have been stated. Thank you.

Vice Chair Bulger: Great. Thanks, Jeff. Other comments from CSAC members? Questions?

Member Kavanagh: I have one. And I'm sorry, I don't know how to raise my hand.

Vice Chair Bulger: Go ahead, Kevin. I see your hand.

Member Kavanagh: Okay. I don't mean to blend in, but I haven't figured out how to work the computer yet.

I disagree with the standing committee's conclusions on two basis. One is that opioid usage is not indicated for chronic pain treatment outside of treatment of cancer. It basically doesn't work.

You get addicted to the opioid. And as you increase dosage then to try to handle pain, the pain really doesn't go down, but yet your opioid consumption goes up.

And so, that this is a very important metric. It's a very important metric to get data on what's going on in a dialysis group.

The second thing is, is I really think we need to separate out whether or not the metric is valid and will be useful, versus how it will be used in its intent.

We don't know what that is. Now, granite you can worry about that, that's not part of the submission process. I don't think NQF should be involved in who's going to get penalized, how the metric is going to be used, et cetera, but whether or not that metric is going to be found.

If we are going to be involved in that, then that should be one of the submission criteria, and we

should have that information up before us as one of the, you know, criteria for improvement. Regardless of who is going to be held responsible knowing the rate of addiction, of opioid addiction in chronic renal patients, will serve as a basis for research to get them on effective pain control management.

This is a very important subject. It's a very important metric. If the metric is valid, and this is such an important topic where these opioids are being misused, and again, I don't feel the committee has a appreciation that chronic opioid use is really not an option in managing chronic pain because it doesn't manage it. It does not control it.

And I would recommend sending this, actually, I would recommend approving the metric. But seeing how the CSAC cannot do that, not approving the standing committee's recommendation, sending it back to the standing committee for reconsideration.

I just, again, feel that this is a way of perpetuating the system because we're not getting data. If you don't have data, you can't manage the system.

Who gets penalized is a separate issue. And unless that's written into the metric in part of our submission criteria, I don't think it should interfere with us approving or disapproving this important metric. That's a separate issue that they can fight out with CMS.

(Simultaneous speaking.)

Member Kavanagh: That's all I have.

Member Susman: Could I respond?

Vice Chair Bulger: Sure. Go ahead, Jeff.

Member Susman: Okay. And just briefly. I respectfully disagree. I believe that accountability measures need to be attributed appropriately. That there are some fatal flaws within this measure.

Regardless of how you feel about opioid usage and the options, which are very limited for patients undergoing dialysis. I'll just leave it at that.

Vice Chair Bulger: Thanks, Jeff.

Member Kavanagh: Well, to re-retort, again, I don't think this is an option. And I really think that if we're going to have, as a approval criteria how the metric is going to be used, that should be information then that's submitted on the front end to NQF. I mean, we should have that as a major criteria.

I don't personally think it's appropriate. I think we should be approving metrics based upon the validity of the metric and the importance of gathering the data, rather than looking at how that data is going to be used.

If you are going to look at that, that needs to be a submission criteria and needs to be submitted on the front end.

Vice Chair Bulger: Great. Thanks, Kevin. And there's clinician information for people to see that it should be a very important topic, but the measure needs additional work. Lisa, do you have your hand raised?

Member Freeman: Yes. I just want to say, I agree with what Kevin is saying but not with his conclusion. I don't think the measure is, should be passed right now.

I think there is a big problem when it comes to issues around pain control from a patient's point of view. And I also, having talked to so many different people who are experiencing pain from a patient's side of it and view of it, the quality of life is sometimes a hell of a lot more important than things like addiction or whatever. Especially in end-stage disease.

I think that we need to make sure that the measure is considering safety. There's a broader way to look at safety than just whether a person gets addicted.

And I understand, I am very familiar with addiction and I've seen it caused by mis-prescription of opioids. So, I'm very sensitive to that too.

But I agree with the committee, I don't think this is developed well enough. I don't think that it's considering things. Effects of the measure in a broader perspective.

And I think at NQF we need to look at what's important to patients as well as what is defined by the medical community as being important to patients. Thank you.

Vice Chair Bulger: Thanks, Lisa. And other comments? I don't see any other hands, but other CSAC Members that would like to make a comment?

Okay, hearing none, are there any public comments?

Okay, hearing none we'll turn it over to --

Dr. Messana: Excuse me, Dr. Bulger, I had my hand raised.

Vice Chair Bulger: Yes.

Dr. Messana: My name is Joe Messana, I'm a clinical nephrologist at the university and I'm the principal investigator on the CSM contract that developed these measures.

I appreciate the CSAC's discussion of this and the perspectives. I would only make two points about the measures.

There are two measures here. One is directed at the prescribers. The second measure is directed at the MCP practitioner.

Now, if you're talking about the attributability of outcome, the prescriber measure I think covers that build. That's why there were two measures put up because the TEP that was used to help develop these measures included a number of nephrologists who

didn't feel that attributability for safe opioid prescriptions practices was in their wheelhouse.

And so we developed two separate measures. One for the actual prescriber and one for the so called MCP position.

So, I'm not sure that all of the arguments that I've heard apply equally to both of the measures.

The second point that I will make relates to the safety issue and the patient concern issue. These measures were developed, not to create absolute thresholds for individual prescribing, but to look at the physician or the groups prescribing practices as a whole over the year, and to compare them to their peers. To all other organizations.

The measure, as submitted to both measures, as submitted to NQF, only flag extreme outliers based on cumulative results for the group. So, you'd have to have either an extraordinarily different practice that is not adjusted for the case mix measures, or extraordinarily different prescribing practices, or both, to be flagged on this measure.

And so, I believe that the measures, as submitted, do take into consideration individual patient needs, provide flexibility for almost all prescribing scenarios, and then do address the small number of outlier practitioners or groups.

And so, I'll stop there. Thank you very much for your time.

Vice Chair Bulger: Great, thank you. I appreciate the comments.

So there is a comment in the chat from Rebecca saying, Lisa's emphasis on impact for patients end life quality is paramount. I appreciate her well-stated reminder for this group and thoughtful points of being discussed. And I'm just reading the chat because I know some people can't see the chat.

Any other public comment? Okay, hearing none I'll turn it over to Beth to run the voting.

Ms. Flashner: Hopefully this will go smoother than the test vote. Activate the vote.

So the first vote is, please select how you would like to vote for the two renal measures. A, is to vote for both measures at once, B, is to vote on them individually.

If even one member of the CSAC choices to vote individually, we will vote, the CSAC members, will vote individually. I'm seeing seven votes, looking for ten votes. Ten votes. It looks like everyone has voted. I will close the vote.

Okay, that doesn't look right, but -- whoa, whoa, whoa, stop sharing.

Vice Chair Bulger: Yes, you had it back there.

Ms. Flashner: Yes, I didn't know if that showed who voted which way, so that's why I wanted to quickly --

Vice Chair Bulger: It was 9-1, I did see that.

Member Susman: Yes, 9-1 is --

Vice Chair Bulger: -- the voting.

Member Kavanagh: I think you all can figure that out, so just --

(Laughter.)

Ms. Flashner: Well, I want to, you know.

Member Kavanagh: I mean, now come on.

(Laughter.)

Ms. Flashner: Plus the threshold is only one person voting to say to vote individually. November CSAC, and we're on renal. We'll go to the first specific

measure. And I will activate this.

So, please select your vote for NQF 3615, Unsafe Opioid Prescriptions at the Prescriber Group Level. A, is to uphold the standing committee's recommendation not to endorse the measure. B, is to do not uphold the recommendation and instead return it to the standing committee for reconsideration.

I'm seeing eight votes. Ten votes. I'm going to send the vote, lock it. Oh good. Oh, now it's percentage. But it's ten people so it should be 9-1.

Vice Chair Bulger: It's easy math.

Ms. Flashner: Yes. So the vote, the measure NQF 3615 is not endorsed on the vote of 9-1.

We will move to the next vote. And I will activate this. Please select your vote for NQF 3616, Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level. A, is to uphold the standing committee's recommendation to not endorse the measure. And, B, is do not uphold the recommendation and instead return it to the standing committee for reconsideration.

I'm seeing ten votes. I will close the vote and lock the vote. And show the responses. Again, that should be a 9-1. NQF 3616, Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level, is not endorsed on a committee vote of 9-1.

I will turn it back to John.

Vice Chair Bulger: Great, thank you. Beth, and I appreciate, Connie, your work on this, and Poonam, and Laura and Jeff and the rest of the members for the good discussion. Thank you.

So the next --

Ms. Elliott: John, before we move on to the next topic --

Vice Chair Bulger: Go ahead.

Ms. Elliott: Elisa Munthali would like to make a comment.

Vice Chair Bulger: Okay.

Ms. Elliott: Are you off mute, Elisa?

Ms. Munthali: Can you hear me now?

Ms. Elliott: You're very faint.

Vice Chair Bulger: Very faint.

Ms. Munthali: Let me try and increase my volume. Is that better?

Vice Chair Bulger: Not much.

Chair Danforth: Not really.

Ms. Munthali: I'm sorry, I'm using another computer today and so I hope you can hear me. I just wanted to thank the CSAC, again, for a very thoughtful conversation as you think about these measures that you're endorsing and the attribution of the measures.

We wanted to clarify, while we don't consider a particular use in a particular specific program. So, the measures that we endorse, as we're endorsing them, their use agnostic.

The issue of its use for quality improvement and for accountability is very much in play as committees are evaluating these measures and the CSAC is looking to endorse these measures.

So, it is a little murky, but use is important. It's one of our major criteria. A must pass criteria.

But the particular program use is one of, that's where we draw the distinction. And it's not part of the evaluation of the measures.

So we just wanted to put that out there as we

continue your evaluation and endorsement of the measures that are in front of you.

Vice Chair Bulger: Thanks, Elisa.

Member Kavanagh: To clarify, what you're saying is that it is used, it's important, but how exactly it is used is not a criterion?

Ms. Munthali: Exactly. So you should be thinking very broadly at its use for accountability and its use for quality improvement, but not for a particular accountability application. If that helps.

Member Susman: Yes, but in the use/usability criteria, if I'm not mistaken, there is a criteria that it's been used in publicly-reported programs or some such language for a maintenance measure, is that correct?

Ms. Munthali: Yes, that's it. That's exactly it.

Member Susman: Okay.

Member Kavanagh: But how it's used isn't a criteria.

Ms. Munthali: For a particular program.

Member Kavanagh: For taking over --

(Simultaneous speaking.)

Member Kavanagh: Because it could be used by multiple agency's institutions. Research could be used, opioid prescription data could be used by many entities. Publicly reported, et cetera. Could be used by research entities.

Although you may have one entity, a government entity, that penalizes people you don't think should be penalized, it's a separate issue. These are very important data to get during an opioid pandemic.

Vice Chair Bulger: Okay, great. Thanks, Elisa. Any other discussion on that particular topic at the moment? Okay.

Well, we'll move to the next committee. Which is patient safety. And to make sure we have everyone, we have Matt, we have Iona. We have Matt Pickering on?

Mr. Pickering: Yes. Hi, John.

Vice Chair Bulger: Yes. Great. Hi, Matt. And, Iona?

Dr. Thraen: I am here.

Vice Chair Bulger: All right. And I see Dale. And the discussants, my other sheet here, are Leslie and Nate. So, Leslie, you're prepared?

Member Schultz: I am prepared.

Vice Chair Bulger: Excellent.

Member Schultz: Yes.

Vice Chair Bulger: All right. So let's go. Matt, over to you.

CSAC Discussion and Vote: Patient Safety

Spring 2021 Measure Review Cycle

Mr. Pickering: Great, thanks, John. And hello everyone. Good to see you again for day two.

This time I'm not the last one to go. I think there is one more committee that stands in front of our adjournment today.

But I do have a lot of measures to discuss with you all today. So thank you all very much in advance for your time and consideration of the measures up for discussion.

So I'll be going over the patient safety spring 2021 review cycle. And Iona, who is on the call today, is our co-chair.

Ed Septimus is another co-chair. Obviously he's not on the call today or unable to participate in the CSAC

proceedings this cycle. But I want to thank both Iona and Ed for all of their time and leadership of this standing committee. Especially for the spring 2021 review cycle.

So going to the next slide, there were six measures up for review for the patient safety standing committee for spring 2021. You can see those listed there. Four were maintenance and two were new measures.

So those measures included 0500, which is the severe sepsis and septic shock, or also called the SEP-1 measure. This is a composite measure.

We also have 0674, which is the percent of residents experiencing one or more falls with major injury.

And 0679, which is the percent of high risk residents with pressure ulcers.

Then there is 3389, which is the concurrent use of opioids and benzodiazepines.

And 3501e, an e-measure. A hospital harm measure specifically for opioid related adverse events.

And then lastly is 3621, which is another composite measure. This is the composite weighted average for computerized tomography exam types. So you can see those listed there. So, computerized tomography or CT exams.

Four measures were reviewed by the scientific methods panel. Three of which passed on reliability and validity. And those were 0674, 0679 and 3501e.

One measure did not reach consensus on validity from the scientific methods panel. That was 3621. So that's the composite weighted average CT exam types.

So the SMP didn't reach consensus on this measure for validity. They questioned the level of analysis for this measure. So being clinician group versus

facilities.

Specifically whether faced validity, as this is the new measure. And face validity is an acceptable form of validity testing for new measures.

The SMP questioned whether face validity was conducted at the commission or facility level of analysis or at both levels of analysis. So consensus was not reached based on that.

The measures validity was through consensus documents from a wide range of professional advisory regulatory organizations. And the use of the measure has significantly increased over the past two years, indicating wider acceptance of this measure by clinicians.

And the developer clarified both for the methods panel, as well as the standing committee that had to re-vote on this measure, that the measure was conducted at both levels, that testing was conducted at both levels of analysis. That face validity testing. And ultimately, the committee passed the measure with a 16 yes and a 2 no vote.

So going to the next slide there was a couple of overarching issues this past cycle. One was related to the importance of evidence. And this really focused on 3501e, which was the hospital harm measure, 3621, that CT measure, and 0500, which is the sepsis measure.

So for 3501e and 3621 and 0500, the standing committee raised concerns regarding whether evidence showed that the process has a clear association, would relate to desired health outcomes.

So there are process measures, and sort of indicators within some of these composites, that according to our evidence criteria there should be strong evidence to link those two beneficial outcomes. Or to improve patient outcomes.

For 0500 specifically, some concerns were raised as to whether all elements of the composite sepsis measure were associated with outcomes. So there was some discussion during the event measure evaluation proceedings, including the post-comment call, that some of the elements were clearly associated with improved outcomes while others were not. Or based on some expert consensus.

And so, there was some discussions that continued in the post-comment, which we'll talk about on the next slide.

But for 3621, there was concerns raised whether the radiation dosing itself had truly been linked to any outcomes beyond some of the older evidence that had been presented, and that high radiation levels are harmful.

And lastly, for 3501e, there were concerns raised whether naloxone administration was a true indicator of an opioid overdose rather than whether it was being used for other reasons. Such as naloxone as a diagnostic tool, for example.

But the standing committee recognizes these measures are important and add more benefit than risk. And ultimate did pass these measures on the evidence criterion. And ultimately recommended all three of those measures for endorsement.

The second overarching issue was on performance gap concerns. And this related to 3501e, 0679 and 0674.

For 3501e specifically, the standing committee had discussed whether there was a four-fold difference and performance gap was sufficient in the naloxone measure for opioids. Particularly using a small sample at six hospitals and the conditions in which the outcome was relatively rare.

So consensus was not reached during the measure evaluating meeting based on this concern. But during

the post-comment meeting the standing committee did review the comments that had been submitted. Largely by the developer.

Which provided comments that since the spring 2021 discussion, data had been gathered from 13 additional hospitals and showed that there was even a larger performance gap varying from .11 to .61 percent. Which was a six-fold increase.

In considering this information, the standing committee did pass the measure on performance gap for this measure. And also, we recommended it for endorsement.

For 679 and 674, the standing committee did focus on the need for performance gap be established during maintenance measures. And in particular, for these measures as these are longstanding measures, such as these measures, which have been placed in public programs and for a long period of time. And so they really wanted to see strong performance gaps still there for these measures, since our maintenance have been used for a long period of time.

And that was the case. So the standing committee agreed that there was still considerable performance gap for both of these measures and decided to pass them on performance gap and recommending them for endorsement.

The next slide we'll talk about public comments. And this is where it gets a little bit more meaty.

So there were 15 comments received for across all of these six measures. So ten were in support of the measures under review. Including some for 0500, 3501e, 3621 and 3389.

And then four were not supported due to concerns about evidence and unattended consequences. Specifically for 0500 and 3501e.

One was not supported due to concerns about

clinicians' choice of protocol. And this was for 3621.

And you can see six NQF members provider expressions of support and non-support for three measures under review. Two members expressed support for 0500, two expressed non-support. One expressed support for 3501e and one expressed non-support. And then lastly, two members expressed support for 3389.

So I'm going to circle back and talk a little bit more about the non-supportive comments for the measures that I mentioned. I'll start with 3501e, for the hospital harm.

A commenter expressed concerns related to the unattended consequences of the measure, as well as the performance gap. Which was in discussion during that measure evaluation meeting like I mentioned.

I mentioned also that the developer did respond through public comments with some additional evidence related to 13 additional hospitals that they did testing on performance gap. And did indicate that there is a good, a gap in performance varying from .11 to .61 like I mentioned. So that was, equates to a six-fold difference.

In considering that information, the standing committee re-voted on that criterion because it was consensus not reached. And did pass it on performance gap. And ultimately passed it, or recommended it for endorsement.

Moving to 3621, this was the CT exam. There was one comment that was raised about the physicians choice of protocol and its inclusion of only single-phase, so not double-phase scans. And the concerns were related to a lack of overall evidence to support that higher phase protocol provides better diagnostic utility.

So in response to this, the developer explained that single-phase scans represent about 75 percent of

overall scans. And that the developer described additional work that is in process to examine the indication for the exam.

A standing committee member asked about whether there was multiple-phased scans would be considered in the future. And the developer did state that additional work needs to be done to examine the variation in dose length product with those computed scans. Computed tomography scans.

So the standing committee considering this did not have any additional questions or concerns with those comments and their responses, and that measure is recommended for endorsement.

Lastly, 0500, which is the severe sepsis and septic shock measure. And so that's the SEP-1 measure.

There were several comments from groups expressing concerns about this measure. And I do want to list some of the names of those organizations because there was quite a few. Both for this measure and also not supporting this measure.

Dr. Thraen: Matt?

Mr. Pickering: So those --

Dr. Thraen: Matt? Matt? Matt, I want to interrupt you. Do you have a slide that's relevant to this?

Mr. Pickering: No, we do not, Iona.

Dr. Thraen: Okay. Great. I just wanted to make sure that we weren't supposed to be progressing on the slides. Sorry.

Mr. Pickering: Nope. Sure. Sorry about that.

So, I do want to just mention some of the organizations that were both pro and not supportive of the 0500 with comments that came in. So, for those that were not supportive those organizations included the Infectious Disease Society of America,

the American College of Emergency Physicians, the American Hospital Association, the Society for Healthcare Epidemiology of America, Society of Hospital Medicine and the Society of Infectious Disease.

So there were a good number of organizations that raised concerns related to the burden of chart abstraction of this measure considering that a considerable effort is involved in reporting the measure.

There are also concerns regarding the potential for the unattended consequence of including both sepsis and sepsis shock in the measure to differing evidence that supports the clinical actions required NQF 0500.

And there were also additional concerns from these organizations raised regarding the quality of evidence for including serial lactate measurements as part of the measure.

Now conversely, there were several groups that provided support of comments. And I'll just name some of those. The Sepsis Alliance, the Alliance for Aging Research, Americare CSS and Americare Incorporated Home Care Association of New York State, The Leapfrog Group, MoMMA's Voice Coalition, Peggy Lillis Foundation and the Society to Improve Diagnosis in Medicine.

So you can see both sides there was quite a few organizations that were both for and also had concerns for this measure.

For those that were for the measure, or at least have supported the measure, these commenters expressed strong support for this measure due to timely diagnosis and early treatment of sepsis.

The comments thank the standing committee for re-endorsing the measure and cited studies to show the association between this performance metric and patient outcomes, such as decreased risk, adjusted

sepsis mortality, increased hospital level of compliance with the mandated public reporting.

So even with all of that information that was submitted during post-comment, during the standing committee discussions for this measure, a standing committee member stated that the degree of scientific rigor, included in the measure, is insufficient. So specifically, there were concerns that the components of the measure do not meet NQF's criteria for evidence.

And it was also noted that during the surviving sepsis campaigns recent review of the evidence at that time, supporting many of these components was reported to be low quality of evidence.

Concerns were also raised about the unattended consequences or harm to patients. Another standing committee member during the post-comment meeting brought forth another study that examined these unattended consequences and found that the SEP-1 was associated with increased broad spectrum antibiotic use across 111 hospitals.

The concern here was that the SEP-1 requirement to immediately administer antibiotic therapy to all patients with possible sepsis leads to increase use of unattended antibiotic use, antibiotic resistance.

In relation to sepsis versus sepsis shock, the commenter states that while timely administration of antibody use can reduce mortality for septic shock, mortality is not similarly reduced in the case of sepsis.

So it was also mentioned that the measure may be out of step with current recommendations for a wait and see approach. In some specific septic patients, without giving antibiotics to patients who are not septic in the current surviving sepsis guideline.

So the developer did provide a series of responses to a lot of the commenters concerns. And also was on

the call and provided some responses to some of the standing committee concerns trying to clarify that these matters were fully addressed and that the comments that they provided to the standing committee, through the public comment period. In addition to the measure, is consistent with current sepsis guidelines.

And the developer further stated that NQF permits a moderate level of evidence to support the measure.

And during that, the standing committee discussions, a member stated that the developer, and speciality societies, were interpreting the evidence in a fundamentally different way. And so there was some back and forth on that interpretation during the standing committee proceedings during the post-comment call.

Ultimately, a standing committee member wished to pursue the options of reconsidering the measure. To reopen the measure to review the evidence that had been submitted through post-comment.

Including this evidence around antibiotic use across those 111 hospitals. Which had not been discussed previously during the measure evaluation meeting that had occurred.

NQF had articulated that there is that option to reconsider or reopen the measure if the standing committee is presented with any new evidence that they feel needs to be considered. That is part of what is expected of standing committees to thoughtfully consider the comments, and may adjust any recommended as needed based on the evidence or any analysis that's been submitted through post-comment.

So our standing committee co-chair confirmed that the standing committee member had rationale for the new information was available since the time the standing committee's review, including that new guidelines, as well as other evidence. And the

standing committee member requested the standing committee to vote to reconsider the measure in light of this information.

So following all of that discussion, and I thank you all very much for your patience as I went through that, a reconsideration vote was conducted for 0500. And based upon the rationale in the new guidelines of that evidence, that was also considered, the standing committee decided to not reconsider or reopen the measure for further discussion.

So there was a reconsideration vote in which there was a 38 percent voting yes and only 62 percent, and 62 percent voting no. So the reconsideration vote was to not proceed because you need more than 60 percent to vote yes, and only 38 percent voted yes.

So that concluded the proceedings for the post-comment meeting and the consideration of all of those comments and evidence for 0500. As well as the other measures.

And I'll stop there as that, I believe that's the last slide before we go to the project team. But I'll turn it to Iona, who is on the call as our co-chair, to see if she has any additional remarks to share. Iona.

Dr. Thraen: Thank you. First I want to thank Matt for that summary. That's a very, that's a mouth full to cover a lot of process conversations that took place around, particularly around the sepsis measure. And I think he accurately represented that process.

I think there is good news here. I think that what NQF is in the position of, which I think is actually a plus, is trying to manage the tension between an efficacy sector, a clinical experience sector and the research sector.

And often, not often, but at times those sectors are out of sync with each other. And I think that's part of the reason why you saw so much dialogue around 0500, in particular.

Particularly with this, is a bundled measure. And so with bundled measures there's lots of layers underneath that have to be considered. And there is some disagreement of opinion about some of those layers that are then bundled up into this final measure.

So I think that there was some concern that from a clinical experience perspective, and from the societies that Matt has mentioned, that the experience is indicating differences of opinion from what the research is indicating. And so, the committee, as a whole, listened to those arguments.

I think we did have some opportunities for process improvement. We gave that feedback to the NQF project team, and some of those efforts are under consideration. But as a whole, the committee re-voted and voted to recommend, to continue to recommend this measure.

One other comment and then I'll be quiet, is I think as we get into maintenance measures, and bundled measures in particular, you're going to see this kind of contention and intention in that conversation as we move forward, whether or not the research is the most recent up to date research with what the clinical experiences is and are.

So I think that you can anticipate in the future that there might be other opportunities like this.

I was actually happy to see that renal had some struggle as well, so it's not just a patient safety issue. There was differences of opinion in the renal measures prior.

So with that, I'll turn it back to Matt. Matt, you're talking but I think you're on mute.

Mr. Pickering: Thank you. Thank you. I was just saying thanks, Iona. And before I turn it to John I also just want to recognize, again, Iona, for your

leadership, as well as Ed, through this process as there was a lot of information to consider with the standing committee.

And also recognize the team as well at NQF. There was a lot of back-end work leading up to these proceedings and ensuring that the standing committee had all the information available to them to consider. So thank you.

John, I'll turn it to you for CSAC discussion.

Vice Chair Bulger: Great, thanks, Matt. So, Leslie, you are the primary discussant, you're up first.

Member Schultz: Okay, thank you. Matt and the patient standing committee thank you. That's a lot of work. I'm sure it was lively.

Iona, thank you for your eloquence. You did a marvelous job.

So, I'm going to go a little bit out of order here. Just some observations or comment on the opioid harm related measure.

If you read all the details in the report this now has a new measure steward who took it over. And I think did an admirable job of addressing all the feedback that came out of the last time this measure was before the committee.

So they've addressed the timing, they're addressed the, let's only include people who ever got an opioid during this hospital stay. So I think they did a very nice job with that.

And I think if we think of a naloxone rescue within a certain time period after a procedure or a surgery,

it's a very good measure. It could become a leading indicator. So it gets it started. And I appreciate the measure and the work that the steward did.

If we move on to the radiation one, it was nice to see another radiology safety measure come back into the portfolio, potentially. We have very few. And it's been a long time since we've seen anything, other than a pediatric one.

So again, it may not be perfect but if we get it endorsed then we can beat up on it a little bit more and see how it really works in the real world. So I also applaud that measure steward for being great and coming forward with that.

Some measures are not going to come in time, but then that leads us to my favorite, 0500. And so, I can only imagine the discussions were lively, robust.

Maybe sometimes they might took out a little less collegial than one might like, but I think this, the whole process, and it sounds like the process was tested. The entire CDP process was tested thoroughly with this one.

We see the importance of the post-comment regrouping by the committee to reflect. And I think we also see where having an option of an ad hoc review, as more evidence comes in because evidence is more nimble than some of our processes, I think that will become very valuable. And I'm sure that someone might pursue that venue in this case.

I can believe that the discussion and the back and forth was very passionate. Yes, very passionate, on all parts. And I think everyone wants to do the greatest good for the greatest number of people.

And then, back to Iona's eloquence of balancing the practicality of the real world versus the research arm, versus the reality of what is the lowest common denominator of capabilities across all hospitals that

ever see sepsis.

Not everybody can do everything. But there are some of the components that every hospital can. And I almost would wish that a new measure steward would step up to the plate an unpack that bundle and show us, here is a component and here is the relationship to an outcome and get us beyond a composite of process measures where nobody really knows.

And I think people have a gut feeling, the clinicians do, of which ones are more important. But we don't know that right now. So, unless they bring us the data we'll never know that. So enough with that.

I think the committee did an admiral job. I'll be interested to see what the next step is. But that's about my summary of it. John?

Vice Chair Bulger: Great. Thanks, Leslie. And I don't have a whole lot to add other than that, I do really appreciate Iona's comments. I think, and I appreciate your comments, Leslie, about this went through the process.

And I really do believe, as you said, I think the process worked as it went through this. And there were a bunch of different checks and balance points.

And in the end, I think there is this need to balance between a bunch of different stakeholders. Be they the advocacy groups or scientific groups or research groups.

And I think, as is important with anybody, is patient groups. And I think that was done as part of this. I mean, if the committee didn't have a chance there is, this is probably the most dense that I've seen the, just the back and forth on this measure and the comments from different groups and the developers response to those comments.

A lot of those are based off of a IDSA paper, physician

paper, on the topic. And kind of point, counterpoint.

But I think it does clearly show, from what I see, a very professional process that went through what needed to be done. And I think the great part about all of this is this is all iterative. So we are where we are today, and where we are tomorrow or two years from now may be difference than where we are today.

But I don't have any other, and I agree with Leslie's comments on the other measures. It's great to see these patients safety measures continue to be developed and to evolve.

So, I don't have anything else to say. Other CSAC Members have comments? Jeff, is your hand raised?

Member Susman: Yes, please.

Vice Chair Bulger: Yes, go ahead, Jeff.

Member Susman: I will just confine my remarks to 500, sepsis. I read through the comments in detail and I agree the process was robust and it seems to have reached a reasonable conclusion.

Nonetheless, I saw in the re-vote that it was 38 percent, the committee had concerns about this being reconsidered or wanted it to be reconsidered. And I think when the third, or more than a third, of the group had substantial concerns. And there is a number of very detailed, and I think appropriate remarks about this measure.

And clearly the data elements within the measure, some are closely tied, some are not very closely tied at all to an outcome by evidence, that really the Full Committee should reconsider this. And I don't say that lightly because I know it's already been a bear for them, but there was such substantial disagreement within the field and within the committee itself.

I don't think we're doing quality improvement a good

service by continuing to perpetuate this as a ongoing measure, but rather, somebody needs to start to look at refining it and improving the measure to more accurately reflect what the field believes.

I think the, it's too controversial, in my mind, to have as a beneficial part of the portfolio. Is it better than nothing, yes, probably, I'll give you that. But I think we should do better. Particularly as measures are coming back for maintenance.

Vice Chair Bulger: Thanks, Jeff. Lisa --

Dr. Thraen: This is Iona. I'm sorry.

Vice Chair Bulger: Go ahead. Iona?

Dr. Thraen: Oh, I'm sorry.

Vice Chair Bulger: Go ahead.

Dr. Thraen: I don't disagree with your assessment on this issue. I think that because of the rules we're bound to following those rules.

Absolutely agree that the passion and the concerns that were expressed were legitimate concerns. But the 60/40 rule voting rule is a 60/40 voting rule. And yes, 38 percent is like two points below, but there is a marker there.

And unless those rules get changed or rethought about or thought through differently and are reapplied, I think we felt like we were bound by those rules to --

(Simultaneous speaking.)

Vice Chair Bulger: Right.

Member Susman: That's makes a little sense. I think then it becomes CSAC's job to occasionally, in fact rarely, suggest that well, maybe we need to really readdress this at the committee level.

Vice Chair Bulger: Yes. Can Staff clarify for

everybody what the threshold for reconsideration is, please?

Mr. Pickering: Yes. Hey, John. So more than 60 percent of those voting were eligible to vote, need to vote yes to reconsider.

Vice Chair Bulger: Correct. And what was the vote by the committee?

Mr. Pickering: Yes. Six voted yes, which of those voting during the call, that was only 38 percent.

Vice Chair Bulger: So in another words, this was not within two percent of being reconsidered, it was actually 22 percent, or 42 percent, I'm trying to do the math quickly. It needed to have 60 percent of the vote and only had 38 percent of the votes.

It didn't need 40 percent to be reconsidered, it needed 60 percent to be reconsidered and it got 40, is that accurate?

Mr. Pickering: Yes. And just, it needed more than 60 percent so it didn't meet that, correct.

Vice Chair Bulger: Correct.

Mr. Pickering: It only had 38 percent voting yes.

Vice Chair Bulger: Okay.

Member Susman: My point still stands. I mean, I think --

Vice Chair Bulger: No, I know your point still stands, Jeff, but I --

Member Susman: And yes, I appreciate you clarifying.

Vice Chair Bulger: -- when I heard the previous one, the comment was like it was two percent off, it wasn't really.

Member Susman: Yes. And I appreciate the --

Vice Chair Bulger: You didn't make that comment, so. Other, Lisa, I think you had your hand raised?

Ms. Elliott: Lisa, if you're speaking you're on mute, if you could un-mute yourself.

Member Freeman: Thank you. I think this is why what we do is so important. I think, particularly, when there are measures that are controversial, and sepsis has long been controversial, I think it's very important to have this process and to have the ability to reconsider the numbers. And, you know, you can always slide the percentage. But I think that, you know, 60/40 is, to me it's reasonable.

But what I do want to say is, again, and I'm going to probably become a broken record over the course of time, but particularly in a situation with sepsis, it's so important too to consider if we're not measuring it in some way.

And frankly there is a lot of good data out there. I don't know exactly, you know, whether it was all built into the Committee's work, but the consequences to patients, the loss of limbs, and all those other terrible things that come about when it's not treated fast enough, it makes it so much more urgent to have a standard. And maybe we need to tweak it a little bit or change something. But it's just critical that we have a measure like this.

And I know my experience here in the state of Connecticut is that, up until just a couple of years ago, it was very limited awareness even of sepsis. So I really commend NQF for following through on keeping this measure in place. And if it's not perfect, let's hope that it refines itself and gets better, which it should. But it's so important to have something like this from the point of view of the patient. Thank you.

Vice Chair Bulger: Great, thank you. Are there other comments, I don't see any other hands raised, other comments from members of the Committee?

Dr. Thraen: Donald Yealy has a comment, but he's uncertain of whether or not he should.

Vice Chair Bulger: We'll have a public comment here in a second, after the Committee, and he should during that, absolutely.

Any other Committee members? Okay, go ahead, Donald.

Dr. Yealy: Hi, thanks very much. I was part of the committee that reviewed this measure. And actually, as scheduled today, I'll be following Iona as one of the co-chairs of the Committee.

Secondly, sepsis has been in the area of not only clinical but investigative interest of mine for a long time. I led the largest trial that impacted, eight years ago, this same measure when it was under consideration. Our data came out in between steps of the measure consideration process.

And at that moment in time, I was not a Committee member. I was asked to just publicly comment about what did our information show and how might it affect the measure as it stood at that moment in time.

Because of that activity, which I announced to the Committee, even though it was not the current measure, I was conflicted out of all the conversation about this measure, although I was a participant and listened throughout the entire meeting.

So I think that you've heard that there was lots of input, lots of vigorous conversation. The biggest concerns I think you're fairly aware of. And that's that the question is not is having a measure better than not having a measure. It's is this measure, does it meet all of the standards, even for renewal, that NQF and then eventually if CMS adopts it. Does it need all of those standards, particularly as information, insight, and aggregate experience, you know, is gained.

And that's where there's concerns. I don't think anyone was arguing that there shouldn't be a sepsis measure. And the question is, is this measure, at this time and place, delivering on the hope and the needs as existing.

And the concern is noted. And I will just speak to that. I share the concerns that multiple steps within the measure lack evidence. And the stewards offered that there would have to be evidence of harm in order to take away the lower evidence.

Probably if nobody actually studies the application of the measure in an intended population, that simply doesn't happen much. And so you're asking for evidence of something that's not been under the direct purview.

I think that while many organizations and individuals were supportive, I have never seen a measure with this high level, consistent concern about does it deliver on improving the outcomes for our patients. We have the largest group of emergency physicians, infectious disease physicians, hospitalists involved. And then the most recent surviving sepsis guidelines actually have very much similar concerns noted in them.

And so whether this was a 62/38, you had a couple of people conflicted out that not only couldn't vote but actually couldn't discuss. They were the experts on the topic. I think that you have an opportunity, as was noted here earlier, to ask is moving forward the smartest thing to do. You're not bound solely by numerics. If you were, there would be no need for this Committee.

So I think that there are real questions about what's the best way to get a sepsis measure that works for all. And is approval of this, as it stands now, going to achieve that goal? I think this is an opportunity.

I'm speaking now because of the request. I recognize Dr. Townsend believes that this is conflicted out. I'll

share with you what my conflict was. Having done research and having commented on the measure previously, I have no other involvement with the measure.

Vice Chair Bulger: Thank you.

Member Kavanagh: Kevin here, Kavanagh here.

Vice Chair Bulger: So, yes, hold on, Kevin. Let me just make sure I have people in the order I get in the chats.

Ms. Elliott: Don Casey, then Jeff Susman, John.

Vice Chair Bulger: Yes, agreed.

Dr. Casey: Hi, can you hear me?

Vice Chair Bulger: Yes.

Dr. Casey: Don Casey. I'm from the American College of Medical Quality. I'm speaking as an individual. I'm an associate professor of medicine at Rush in Chicago, been working on sepsis for many years.

I think it's easy to lose sight of the main purpose of measures that come through the NQF endorsement. I've chaired the Care Coordination Joint Committee for 12 years and am on the Patient Experience and Function Committee. So I'm well aware of everything that goes on structurally within NQF.

The notion of NQF endorsement really is related primarily to its use for public reporting and potentially incremental payments based upon differences in measures.

And this is an excellent example of where the science of guidelines is subsequently informed by additional evidence generated through the use of the guidelines and then additional new evidence past that, for example, during COVID, the notion of the emergence of resistant organisms.

I think the other important thing here is sepsis is not a homogeneous population. You can simply divide the notion of patients who present to the hospital door present on admission with signs of sepsis as one category and the other of patients who are in the hospital and get sick, you know, during the hospitalization and are noted to be septic at the bedside, non-POA. And those are primarily, for the most part, fairly different populations.

And so I think that the last thing I'll mention is structurally my experience is votes occur only with Committee members in attendance more often. I know that staff sometimes circles the wagons, but there's sort of been some uncertainly about how to handle the live in vote.

I'm not suggesting that this be re-voted, I'm just pointing out that there are different interpretations that I've seen about what constitutes a quorum for voting.

And then the last thing I will say is, actually, for the present on admission, no one is asking the question how did they get to the door. And I think, for the purposes of sepsis, we're not answering that question. I do not think that having publicly reported measure means that no one's paying attention to sepsis.

I disagree with one of the speakers, because people are working on this problem hard and fast, day in and day out, unfortunately, only within the hospital. So I'll leave it at that. But thank you for allowing me to speak.

Vice Chair Bulger: Thank you, Jeff.

Member Susman: Yes, thank you very much. The issue here, I think, is broader related to what we should expect for maintenance measures. And as new evidence accrues, and as the field moves forward, we should expect measurement to move forward with that.

And I feel as if NQF as a whole, not in great specifics but as a whole, we tend to slide maintenance measures through and allow them to continue, because they are better than nothing for sure.

And talking about sepsis is better and measuring septic outcomes or outcomes of sepsis is better than nothing. But I think in this case most people would say that maybe we could do a little better yet. And I'm not sure that we've asked for that. I'm not sure we've demanded that of the field.

And as an example, if there is a bunch of elements within this composite, and we know that perhaps, and I'm making this up, four of them are the most important, which we could find out through a variety of investigations or statistical methods. I mean, this isn't rocket science. It would take some further study. But that's really what we should be expecting with measurement, in my mind.

So, you know, we're here today to consider the measure we have before us. Is it better than nothing, is it going to cause great harm? I don't think so, personally. Would I vote for approval? Yes. But I think we really deserve better. Thanks.

Vice Chair Bulger: Great, thank you. Kevin?

Ms. Elliott: Actually, John --

Vice Chair Bulger: Yes.

Ms. Elliott: -- if I can interrupt. We have a very active chat going on. I'd like Matt Pickering to step in to address some of the comments in the chat before we proceed.

Vice Chair Bulger: Okay.

Mr. Pickering: Yes, thanks, Tricia. I think there's been some concern about certain Standing Committee members, such as Don Healy who was originally recused from the measure evaluation proceedings, participating. Since he was recused, Dr. Healy did not

participate in the discussions of this measure during the measure evaluation proceedings, as well as post-comment. So he also was not voting as well on this measure.

However, since this is an opportunity for members of the public and others to provide comments for the 0500, this would allow for other Standing Committee members, as well as, including Dr. Healy, to provide comments during the public comment period, which is not part of that measure evaluation.

So this is just providing some clarity on that, since there is now public comment for the measure, that was able to allow Standing Committee members, as well as Dr. Healy, to provide any comments related to the measure.

Vice Chair Bulger: Thanks, Matt. And Sean Townsend, who's commenting on the chat, who is that, or Sean Townsend wants to speak?

Mr. Pickering: Dr. Townsend is one of the measure stewards.

Vice Chair Bulger: Okay.

Dr. Townsend: I am one of the measure stewards. And I think we followed the process appropriately. And these discussions were held in committee. And twice we voted, and the evidence was supported for the measure. And so much of this discussion we can have again in committee. And there is an ad hoc process, and there's a way to have this discussion again.

But I don't think it's appropriate for a member of an NQF panel to suddenly decide that they're a member of the public and then start making comments at the level of CSAC --

(Telephonic interference.)

This process has actually seen a lot of testing of how good we are at being able to vet a measure. And

that's because of the complexity of it. It won't be resolved here, but we may be able to have additional debates and arguments at the committee level.

So I just point out that twice, and a panel member of the NQF voted to approve this on the evidence, and yet we continue to rehash it at an angle to come back at it again. I don't know what else to say besides we've appropriately followed the process, and I just want to move forward.

Vice Chair Bulger: Understood, Dr. Townsend. My only rebuttal to that is part of the NQF process is the process we're following right now. And I believe we're still following the process. So I do appreciate your ability to comment during the public comment period.

I would encourage you to be as professional as possible when entering comments in the chat or commenting publicly. And I think, you know, what you just said was very professional. So I appreciate your comments.

So I'm going to go back to Kevin.

Member Kavanagh: Yes. I've got some experience with this measure, and I think it is flawed. We, at one point were working with an investigative reporter from a major news outlet trying to report sepsis and, you know, adequacy of managing sepsis with major healthcare facilities around the nation with the sepsis reporting.

And basically, the data was not good, because it centered upon the necessity of prompt treatment of sepsis versus waiting for a lactate. And many of the facilities wouldn't get the lactate test to wait to where they'd have to begin treatment. They would go on ahead and begin treatment on the front end.

Because that delay, again, even in hours, a significant amount of people were dying. And if you're in septic shock, their feeling was you don't need a lactate test. And they weren't getting it within their

decision parameters.

And so you had some very high functioning facilities that were getting marked very low on the metric. And needless to say, the investigative reporting from this major news outlet just evaporated, because the data was inadequate because of how the metric was designed.

So it may be better than nothing. I think at this point I would still personally vote for the metric, although I'm conflicted at this present time. But from personal experience, it wasn't generating discriminative data.

And the main problem was, was the requirement for a lactate test in a patient that's obviously crashing from sepsis, you go ahead and treat, and the lactate test isn't gotten. And that would result in a non-compliance. And so the data couldn't be used.

Vice Chair Bulger: Thank you.

Member Kavanagh: And that's all I have to add to your comment, I'm sorry.

Vice Chair Bulger: Okay, thanks, Kevin.

Tom Heymann? I see your hand's up.

Mr. Heymann: Thank you. Yes, we really have a dearth of patient perspective happening in this conversation, and I want to correct that.

My name is Tom Heymann. I'm the president and CEO of Sepsis Alliance. And I think we are forgetting about the patients.

One in three people who die in a hospital are dying of sepsis, 270,000 people are dying in hospital. Another 80,000 are going to hospice. These are real people. These are our relatives. These are our friends. These are our community members.

And we know that the SEP-1 measure is going to need to continue to evolve as we learn more about

sepsis. It's largely a black box right now. But we do know that SEP-1 saves lives. And, you know, I appreciate the work that's being done here, that has been done to investigate this. And we know that SEP-1 will continue to evolve.

But as an organization that represents more than two and half million people each year, founded by a doctor who had never heard of sepsis, who lost his perfectly healthy 23 year-old daughter, we represent these patients who are coming into hospitals, many of whom are now much more attendant to the idea that this patient could have sepsis. And we owe that to SEP-1.

You know, there's 14,000 new amputees each year, thousands and thousands of cases of post-sepsis syndrome. And, you know, the numbers are even worse in medically under-served communities. So I think it's really important to remember that these are real people.

And I, for one, would sure want my hospital that I go to, or that I take a loved one to, to have SEP-1 versus not having SEP-1. It can make an incredible difference in time to treatment.

And are there some false positives, yes. But I wouldn't want to be the one in that ED where they're saying let's wait two days to get a blood culture back. So I really encourage this committee to keep an eye on the ball. And that eye on the ball is the eye on the patient.

And I thank you for the work you're doing. I appreciate it, but let's please remember that these are about real people coming into your institutions, you know, who are compromised. And they need you to be thinking about sepsis. It's the most commonly occurring thing that's coming through your doors.

And we need, whether this is perfect or not, we need to be held to account that this is happening. And we have an incredibly high mortality rate, and people are

dying, people are losing limbs. And, boy, to take our foot off the gas right now, I think, would be a huge, huge mistake. Thank you.

Chair Danforth: John, you're on mute.

Vice Chair Bulger: There's a comment from Robert Dickerson in the chat that wants to make sure that it's understood, because there seems to be an assumption that the measure is not evolving with the evidence, and that that's not the case.

There's a comment from CMS that wants to make sure the members of CSAC are aware, since it hasn't been mentioned, that there was a CHEST study published in August which shows strong evidence the SEP-1 measure showed a significant mortality reduction in beneficiaries.

Are there other comments from the public? I don't see any hands raised. Are there other --

Mr. Dickerson: John, this Bob Dickerson. I wasn't able to figure out how to raise my hand.

Vice Chair Bulger: Yes, got it.

Mr. Dickerson: So I just heard the comment. I think one of the things that tends to be a little bit of disconnect between what NQF and the committees are reviewing, and what is actually happening with the measures, is that because of delays in the ability to obtain data, run the analysis on the data when we're submitting -- and for full disclosure, I work for Mathematica, was contracted under CMS to help support maintenance of the SEP-1 measure.

So we actually end up submitting data that is a couple years old and is based upon not the most current version of the specifications for the measure.

So what I can say is the version of the measure upon which the data is based is not necessarily an outdated version of the measure, but it also may not be reflective of updates that have been made to a

measure based upon the most recent evidence.

And an example with SEP-1 is, in the version of the measure on which data is based, the crystalloid fluid requirement to meet the measure is 30 mils per kilogram for every patient that's eligible for fluids. Now, every patient in the measure is not eligible for fluids, so there's not a requirement that every patient receive them. But if they're eligible, it needs to be 30.

The more recent version of the measure has allowances for less than 30 mils per kilogram of crystalloid fluids if there's clinician documentation that they have concerns about detrimental flux to the fluid, such as fluid overload or maybe congestive heart failure. The patient may not be able to handle it.

So there's an example of where I think we need to kind of balance a couple things. But there's no data from the measure being in place with those current specs, because the data has not been submitted. And we've not been able to gain access to it yet. So that was the one thing that I wanted to point out.

And then there was one other thing regarding the antibiotic use. There seemed to be a lot of concerns about giving the antibiotics, getting those started right away, and adverse events associated with that.

And the area that this seems to be really unclear is whether those adverse events are actually happening versus are they theoretical in nature.

We know that there is evidence out there regarding delays in the antibiotics increase mortality risk. And every hospital should have an antimicrobial stewardship program.

And so what the measure is really looking at, the measure is looking at the first dose of antibiotic. It's not looking at then when cultures come back, should the antibiotics be different, or de-escalation that

antimicrobial stewardship would look at.

So I think that there things that we need to take into consideration about what a measure actually does and focuses on versus some of the theoreticals that could be problematic. But the evidence is not real clear on it. And thanks very much for the opportunity to comment?

Vice Chair Bulger: Thank you.

And I have a question for staff to clarify what the role of the CSAC is at this point. Because there's a lot of stuff going on in the chat about what are the possibilities of what we can do. And I'll lead in with that to say I think we can uphold the Committee's decision or we cannot uphold the Committee's decision.

Once we not uphold the Committee's decision and send it back to the Committee, we are able to provide guidance to the Committee or further guidance. But we would first need to not uphold the Committee's decision if that was what the CSAC chose to do. Is that accurate and fair, or is there a clarification needed to that?

Ms. Elliott: That is correct. Matt, is there any clarification we want to add to that?

Chair Danforth: Well, this is Missy. I think an important area to clarify is the specific regions that CSAC would be able to not uphold the Committee's decision.

I think we, as a committee, need to be consistent in that specific decision and where we've made it in the past, which has been totally focused on significant questions we've had about whether or not the process was followed.

I'd be very concerned if this Committee moves in that direction, given the length to which Iona and Matt have described the process being followed, I think,

quite specifically.

Vice Chair Bulger: Correct, yes. So we need to --- I agree with that. We need to specifics of why, you know, what is our decision based upon. I want everyone -- it would be good, I think, to remind everybody of that.

And then it sounds like the process though is then, you know, we vote based on those criteria. And then we could get into a secondary discussion if, based on those criteria, the CSAC decides not to uphold the Committee's decision. But that's the first decision that needs to be made before we get into a discussion of what are other options, I think, as Jeff has laid out in the chat.

Member Susman: Could I just ask the CSAC staff, is there any option for us to recommend something, even if we approve the Committee's recommendation? In other words, I think the process was done elegantly, maybe messy, but it did exactly what it was supposed to do.

I do have concerns though, and we've already discussed those. So can we come back and say let's take a look at this with these specific questions over a time period? Or is that out of our purview?

Vice Chair Bulger: Reena, I do see your hand, but I'd like the staff to comment on that.

Ms. Bal: Tricia, you're on mute.

Ms. Elliott: Oh, once a day it has to happen. So thank you, Jeff, for your question. We need to stay true to the CSAC process just as if the processes were followed in terms of the measures coming forth in front of CSAC, and if the Standing Committee applied the criteria appropriately.

So I think, you know, kind of based on some additional comments from Missy and John, if upon the voting, if it's recommended to not uphold, then

offering the reasons why it's not being upheld. But we have to stay true to that decision process.

Member Susman: I'm fine with the decision process up to that point. But let's do -- confirm, yes. The process was appropriate, we approved the Committee's recommendation. Do we have any flexibility in what happens next, or is it maintenance as usual?

Ms. Elliott: Yes.

Member Kavanagh: Just a comment. I think we need to be careful of degenerating to the point where we're just sort of making a clerical decision on what happens. It kind of makes the Committee irrelevant. Even though you have an approval or disapproval vote, I still think you can have reasons for the vote, in other words, pro and negative, to go along with that vote.

I don't think, you know, to express ways of making things better for the next go around is something that would help patients. And I think that's something that's within the purview of the Committee. I agree with Dr. Susman on that. Because otherwise we degenerate just to a clerical function. We can have a secretary look at the check list and just vote it up or down and be done with the meeting in a minute.

So I think this type of discussion's beneficial. I think it's important for the developers. Myself, you know, I would suggest that the change that under SEP-1 it would be, instead of initial lactate level measurement, just have initial lactate being drawn.

Vice Chair Bulger: Thank you, Kevin.

Member Kavanagh: That, I think, would allow it to go on ahead. And I think that would be beneficial to put in with an approval vote.

Vice Chair Bulger: Thank you, Kevin.

Mr. Pickering: Sorry, I was just going, this is Matt.

Jeff, thanks for your question. So CSAC can make recommendations. If those recommendations mean that the measure needs to come back for review early, there needs to be clear rationale as to why, you know, the rationale for any of these recommendations as to why that's the case, if the measure is, say, voted to move forward to uphold recommendations.

So any of those recommendations need to have some rationale to support those recommendations as to why CSAC would want something different to come to them or be seen with the measure.

Vice Chair Bulger: Thanks, Matt. Lisa, you have your hand raised.

Member Freeman: Yes. I just want to -- I kind of, my thoughts fall in between everybody's here. And what I'd like to say is just that I think that the measure probably could be, you know, improved. As we learn more, we can add more.

But I don't think, to my understanding, that this Committee is trying to refine measures. So I would like the ability to look at the process and our discussion. I mean, we're a bunch of well-informed people who have really read into everything here.

I like the idea that we can send back some overarching comments as Kevin has suggested. Because I do think we can add things to it. But I don't think the process right now should be changed either.

I don't think that the timeframe for maintenance measures should be altered but just that, you know, measures should be evolving all the time. I mean, you know, the world is spinning around us very fast.

So I would just like to say that it would be nice to be able to approve that the process was followed or disapprove that it was not followed. And if we do have comments that we would like the measure developer to consider, and the Committee to keep in mind, you

know, for when it comes back, that that be noted somewhere, it not get lost. But I think basically the process works, and it's been working.

Vice Chair Bulger: Thank you, Lisa.

Member Kavanagh: What about having it come back in two years to incorporate the data regarding fluids? And that was another problem that we detected, and also with the lactate, and have it on a two-year cycle.

Vice Chair Bulger: Thank you, Kevin. I think you got to share your concerns. Any other questions on the process from CSAC members?

All right, thank you. And I think we've exhausted public comment. So I am going to turn this over to Beth to run the voting.

Ms. Flashner: So as we mentioned before, because there are some recusals on some of the votes, we are going to vote on each measure individually. And hold on a minute.

Okay, so the first vote will be on the sepsis measures, so I'll just open it. So please select your vote for NQF 0500, Severe Sepsis and Sepsis Shock Management Bundle.

A is to uphold the Standing Committee's recommendation and endorse the measure. B is do not uphold the recommendation and instead return it to the Standing Committee for reconsideration.

I'm seeing eight votes. We need ten votes on this one. I'm seeing ten votes. I'm going to close the vote and lock it.

Let's see. On this vote, the vote is ten to zero to uphold the Standing Committee's recommendation and endorse NQF 0500.

We'll go to the next vote. And I'll delete this. Please select, yes, please select your vote for NQF 0674, Percent of Residents Experiencing One or More Falls

with Major Injury (Long Stay).

A is to uphold the Standing Committee's recommendation to endorse the measure. B, do not uphold the recommendation, instead return it to the Standing Committee for reconsideration.

I see nine votes, looking for ten votes.

Vice Chair Bulger: Sorry.

Ms. Flashner: No problem. Ten votes, let's close the vote. NQF 0674 is endorsed on a vote of ten to zero.

Next vote, I'll activate this. Please select your vote on NQF 0679, Percent of High-Risk Residents With Pressure Ulcers (Long Stay).

A is to uphold the Standing Committee's recommendation and endorse the measure. B is to not uphold the recommendation, instead return it to the Standing Committee for reconsideration.

Seeing ten votes, I'll stop the vote. NQF 0679 is endorsed on a vote of ten to zero.

Next vote, please select your vote for NQF 3389, Concurrent Use of Opioids and Benzodiazepines (COB).

A is to uphold the Standing Committee's recommendation to endorse the measure. B is do not uphold the recommendation and instead return it to the Standing Committee for reconsideration.

Seeing ten votes, close the vote. Stop the vote, show responses. NQF 3389 is endorsed on a vote of ten to zero.

The next vote, I believe, is one with a recusal. I believe Missy is recused due to a conflict of interest on this vote. So we're looking for nine votes here.

Ms. Elliott: Beth, correction. It's Kevin Kavanagh that is recused on this measure.

Ms. Flashner: Oh. I apologize, Kevin Kavanagh is recused on this measure.

Ms. Elliott: So we're expecting nine votes. Thank you.

Ms. Flashner: Nine votes. Kevin, please do not vote on this one. Activate the vote. Please select your vote for NQF 3501e, Hospital Harm - Opioid-Related Adverse Events.

A is to uphold the Standing Committee's recommendation and endorse the measure. B is do not uphold the recommendation, instead return it to the Standing Committee for reconsideration.

Seeing nine votes, which is what we're expecting, I'll close the vote. Responses, NQF 3501e, Hospital Harm - Opioid-Related Adverse Events, is endorsed on a vote of nine to zero with one recusal.

And our last vote of this group, we had to abbreviate a little bit here, because of limited text availability in system. But I will activate the vote. This is the one Missy is recused on. I apologize for the ---

Chair Danforth: No problem.

Ms. Flashner: I'll activate this vote. NQF 3621 Composite Weighted Average for CT Exam Types: Overall Percentage of CT Exams for Which Dose Length Product is at or Below the Size-Specific Diagnostic Reference Level for CT Abdomen, Pelvis with Contrast Single Phase Scan, and CT Chest Without Contrast Single.

Looking for nine votes. A is to uphold the Standing Committee's recommendation to endorse the measure. B, do not uphold the Standing Committee's recommendation and send it back for reconsideration.

I'm seeing eight votes. Looking for nine votes. Kevin, you do vote on this one. I can't see who's voted. I just see the eight people in it.

Member Kavanagh: Yes, I'm in on this one.

Ms. Elliott: We've got nine votes --

Ms. Flashner: I see nine votes.

Ms. Elliott: -- so we're good. Yes --

(Simultaneous speaking.)

Ms. Flashner: I see nine votes. I'll close the vote, and responses. NQF 3621 is endorsed with a vote of nine to zero with one recusal.

Thank you so much. I will pass it back to John.

Vice Chair Bulger: Okay, great. So just a quick thank you to Iona and Matt for all the work from the Committee, and appreciate the work on that. Also, thank you to Leslie.

I have a quick question about -- so the minutes of this meeting are transcribed, and then the chat ends up being transcribed as well. Is that true?

Ms. Elliott: Correct, we do capture the chat.

Vice Chair Bulger: And then so Jeff's suggestion that's in the chat will go to the Committee, correct?

Ms. Elliott: It will be captured, yes.

Vice Chair Bulger: Correct. Okay, great.

And I want to pass it really quick to Dana who wants to make a comment.

Dr. Safran: Thank you, John. I know that we've run long, so I promise I'll be brief. I just want to acknowledge the challenges that the Standing Committee have been through and our really robust discussion here today.

Really appreciate the professionalism maintained here. I mean, that's always of utmost importance. Someone said it very well today, you know, we all are

trying to accomplish what's best for patients, and there can sometimes be different points of view about what that is, even very strongly held differences. So maintaining that professionalism is so critical to this dialogue. So I thank everyone for that.

I thank the Standing Committee, the staff, and the CSAC for the really intentional focus, excellent work over weeks here, and want you to know that part of my commitment coming into this role has been that we will take a very close look at the endorsement and maintenance process and undertake a robust redesign in the early part of next year.

That's something that, you know, many data points suggest important questions that need to be visited and revisited. Some of them were aired today. So I've really appreciated the opportunity to hear the dialogue and to take some of this input.

At some point, I think we will come to CSAC to interview you, so to speak, about your perspective about the priorities for redesign. But rest assured, you will be involved in this process. But mostly, I want you folks to know that it will happening and how much I appreciate the work and the dialogue that we've seen here today and in weeks leading up to this. So thank you all.

Vice Chair Bulger: Thank you, Dana.

Dr. Thraen: And I just want to say thank you. You guys had a mini experience of what it's been like to deal with the particular issue. So I think you have tons of empathy for how that Committee struggled with the particular measure. So thank you very much for that.

Vice Chair Bulger: Thank you, Iona.

Ms. Elliott: I believe Missy has the last group.

Vice Chair Bulger: Yes.

Ms. Elliott: But just by way of correction, John, I just

want to capture two comments in the chat, just so it actually is in the transcript as well.

So Jeff Susman mentioned, basically is suggesting that the measure holder, CMS, specifically look for parsimony and more focus on evidence as the field evolves.

And Kevin Kavanagh added, "I would suggest re-looking at the metric in two years with changes which are apparently in the works by the developer."

So thank you for offering those comments in the chat.

Missy?

Chair Danforth: Thanks so much, Tricia, thanks, John, thanks, everyone. That was a very robust discussion. **We are going to close it today to focus on primary care and chronic illness.** Is Poonam here?

Ms. Bal: I am on, and our co-chair, Dale, is on as well. Unfortunately Adam did have to log off.

Chair Danforth: Okay, all right. I'm handing it over to you, Poonam, then to get us started. Perfect, thank you.

Ms. Bal: So hopefully this will be a simpler conversation. We have one measure for review in the Spring '21 Cycle. This measure was not reviewed by the Scientific Methods Panel. Measure 3617, Measuring the Value-Functions of Primary Care: Provider Level Continuity of Care Measure, was recommended for endorsement.

Next slide, please. We did have one public comment. It was from the developer during the Standing Committee discussion. The Standing Committee had some concerns about evidence in demonstrating that continued care actually has an impact on outcome.

The developer did provide additional evidence in this comment which they hoped would demonstrate that

the continued care decreases hospitalization, decreases ED utilization, improves primary care utilization, decreases cost, and is valued by patients.

There was no further discussion based off of that public comment. And the measure remains recommended for endorsement. This is a new measure. There were no NQF member expressions of support.

Dale, anything you wanted to add?

Dr. Bratzler: No. I really didn't. The measure is already used in programs like the merit-based consenting payment system, MIPS, for CMS, and some of the AAFP programs. And there was general consensus support for this metric from our Committee.

Chair Danforth: Thank you, Dale. Dan Culica has actually volunteered to be the primary discussant today which is fantastic. Kelly wasn't able to join us. So I'm going to turn it over to Dan.

Member Culica: Thank you, Missy. It's not very much to say maybe some reflections. Can you hear me?

Chair Danforth: Yes, Dan, we can hear you perfectly.

Member Culica: In terms of the main considerations for CSAC, I think the main issue was whether there are any competing measures or alternatives. And there don't seem to be any at this point.

I want to highlight a few aspects in terms of the merit of the measure from my own perspective, if you want. It seems that the evidence that has been presented so far was mostly brought from the Medicare experience in terms of the two studies from the country.

The majority of the other studies were from outside the country. But it seems that there is another set of studies that have been contemplated but maybe not brought in.

But in the sense that there is additional evidence, I think that one aspect I would like to highlight is that in the reference to this evidence they used in the Medicare population is that I represent or I work for a large purchaser of healthcare, which is the Medicaid, for one of the largest states in the country.

And I can see the merit of this measure in the Medicaid population, especially as sort of associated with the primary care as a practice rather than just a physician.

And there are models of care now that are associated with penalty payment models and models of care, accountable care models that are bringing in the entire primary care team as the primary care physician. We are talking about looking more into aspects of health equity and looking into social variables of health and the role of community health workers on the team.

So what I'm trying to say is that it seems that the measure has been designed for primary care physicians, but it's applicable more to the primary care practice. And I would highlight the merit of that.

The other thing is that I think that makes the measure attractive is that it's adding a level of complexity in the sense that the numerator is just not a number, but it's a number based on an index, a continuity of care index. And I think that that's making the measure even more attractive.

And I think that the last thing that I would like to add is maybe for the title of the measure. It says they're measuring better dash functions of primary care. But the detailed title is provider level of continuity of care. Maybe another dash can be introduced between provider and level, and therefore probably make the measure probably more clear to the user when you will be going out into the field.

I know that it currently is in the MIPS program, but I'm thinking it's going to be approved by NQF and is

going to go into the larger use. Then maybe that would be probably better. But it's just a suggestion. It's not something to do expressly. Thank you.

Chair Danforth: Thanks so much Dan. That was excellent commentary. And thank you so much for stepping in on a last minute. We really appreciate it.

(Simultaneous speaking.)

Chair Danforth: Are there any additional questions, comments, or concerns from CSAC members for either Poonam or the Co-chair?

Mr. Pickering: I have no concerns.

Chair Danforth: Thanks, everyone. Beth, I'm going to turn it over to you for our final vote of the day.

Oh, I'm sorry, any public comments? I'm sorry, jumped the gun.

Ms. Elliott: Thanks, Missy.

Chair Danforth: Any public comments on the measure?

Ms. Elliott: Don Casey has his hand raised.

Chair Danforth: Thank you, Don?

Dr. Casey: Yes, good morning. Thanks again, Don Casey from ACMQ speaking as an individual and having spoken before.

The thing that wasn't clear to me on the report, because I hadn't seen this before, is the intersection of so-called primary care, which I believe is a service, not a person, with the rise of digital health and also commercial entities that have a site-specific delivery model, such as Walgreens and Walmart that are evolving.

So I just point that out, because it's not clear to me. I see this index which I actually don't know much

about. I'm sure Dr. Bratzler could give a lecture on it. But I voiced some uncertainty about not having this mentioned in the report. So I just put that out.

Dr. Bratzler: Trying to get my mouse to move to the un-mute button here. Don, we did look at the index itself. There was nice review on medical care not long ago that looked at four different claims-based indices of patient continuity. The Bice-Boxerman Index was one of the ones that was used.

And in general there are, you know, no claims-based measures going to be perfect for looking at continuity of care. But they were felt to be reasonable and validated measures that are reproducible. So this is completely a claims-based measure. And we were comfortable that the index that was used by the Board was reasonable for this particular performance metric.

We did talk about the differences between the measure at the individual position level versus a practice level. Currently the measure is used primarily for individual metrics in the MIPS program and also in a registry program that the American Academy of Family Practice has.

So again, I think for most of the votes we have moderate levels of support. I think the final vote for the metric was 13 to 4 for endorsement.

Chair Danforth: Thank you. Any other public comment? And I apologize, Don, I didn't see your hand up.

Ms. Elliott: Missy, it's Tricia. I don't see any other hands up, and there's no chat either.

Chair Danforth: Okay, thank you. Now I will turn it over to Beth for voting instructions.

Ms. Flashner: Just one measure.

Ms. Elliott: There we go. We can see it now, Beth.

Ms. Flashner: Excellent. I will activate the vote as I read it. Since there's just one vote, we go directly to the measure. I mean, since there's just one measure, we go directly to the measure.

Primary Care and Chronic Illness, please select your vote for NQF 3617, Measuring the Value-Function of Primary Care: Provider Level Continuity of Care Measure. A is approve the Standing Committee's recommendation to endorse the measure. B, do not uphold the recommendation and return it to the Standing Committee for reconsideration.

I'm seeing nine votes, we need ten votes on this one. Ten votes, excellent. I will close the vote. NQF 3617 is endorsed with a vote of ten to zero.

I will turn it back to -- I'm not sure if it's John or Tricia.

Chair Danforth: I think it's me.

Ms. Flashner: Oh, sorry.

Chair Danforth: That's okay, Beth. There's been a lot of minor updates to the agenda, no problem. So thank you, everyone, so much, again, for your time today, also to the project team at NQF and the co-chairs for sitting patiently and waiting for this last vote. We really appreciate that.

Opportunity for Member and Public Comment

At this point, I want to open the meeting up to NQF members and any members of the public for any final comments regarding anything discussed so far today for any of these great projects?

I think I heard someone take themselves off mute. I'm going to wait a second to see if I see a hand raised or anything come up in the chat.

Ms. Bal: Missy, that was me by accident. This is Poonam.

Chair Danforth: Oh, okay.

Ms. Bal: I accidentally hit that mute button.

Chair Danforth: Okay, no problem. Okay, final call for any public or member comments?

Okay. I see none. Thank you all again today. I'm going to turn it back to Beth for next steps and closing remarks.

Next Steps and Closing Remarks

Ms. Flashner: Great. If I could get the next slide, please. Thank you to the CSAC, to members of the public, to CDP Chairs, to the CDP teams, and also the CSAC staff team for our briefing today and all your time and effort.

So the next steps are very -- within the next couple of days we will get out a list of the votes and the measures that are endorsed or were not endorsed.

We will also, in a little bit longer time period, we will be publishing a discussion summary of everything that happened during the meeting. We will also open an appeals period for measures that were endorsed. That will be open from December 7th to January 5th, 2022.

Next slide, please. As I mentioned, I'd really like to thank the staff team, Tricia Elliott, our senior managing director. I'm Beth Flashner, the manager, Mike DiVecchia, our senior project manager, Mary McCutcheon, our coordinator who is done a lot of work on this, as has everyone, Kim Patterson, our executive assistant, and Elisa Munthali, our consultant.

Thank you all for a lot of work to make this happen. You can reach us on our project -- you can view these documents and other information about the CSAC at qualityforum.org/about_NQF/CSAC/consensusstandardsapprovalcommittee, or reach us by email at CSAC@qualityforum.org.

Next slide please. Thank you so much. Tricia, do you have any --

Ms. Elliott: Yes, thanks, Beth, appreciate you covering the next steps and calling out the team. So a thank you to everyone. I just wanted to give one last opportunity. We saw a hand go up and down. Just wanted to pause for a second and see if that person would like to make any remarks before we wrap things up.

Okay, I think we're good. Missy and John, thank you so much for chairing another excellent CSAC meeting. We do appreciate your time and commitment to this process. And I'll hand it over to you for any closing remarks and close this out for the day.

Adjourn

Chair Danforth: Thanks, Tricia, and to the entire NQF staff and the entire CSAC Committee. And, Dana, thank you for your comments. I think all of the members of this Committee put in a lot of time and thoughtfulness in reviewing the reports and the work of the Standing Committee. But I think the recommendations and suggestions they have about potential improvement for the process are important. So thank you for acknowledging them.

And thank you to John for doing an outstanding job, I think, facilitating probably our toughest Standing Committee measure group of the day, Patient Safety.

So thanks, everyone. Have a wonderful holiday. And I'll turn it over to John.

Vice Chair Bulger: Thanks, Missy, and thank you for that. Thank you to you for your leadership and being a part of this. It's been really important just to set the tone of the Committee, how you've conducted things. I appreciate that. Appreciate all the staff's work and everyone's work over the last two days.

You know, this stuff's never easy. I think we all do it because we're looking to make care better for people. I just appreciate everybody taking the time to do what they do. So thank you.

Ms. Elliott: Excellent. With that, I think we're all set. Thank you, everybody, for staying on for 15 extra minutes. Have a wonderful holiday season and be well.

Thanks everybody.

(Whereupon, the above-entitled matter went off the record at 12:15 p.m.)