National Quality Forum
Patient Safety, Spring 2021
Measure Review Cycle
Post-Comment Standing Committee Meeting
Wednesday, October 13, 2021

The Standing Committee met via Video Teleconference, at 2:00 p.m. EDT, Ed Septimus and Iona Thraen, Co-Chairs, presiding.

Present:

Ed Septimus, MD, Co-Chair
Iona Thraen, PhD, ACSW, Co-Chair
Joel Bundy, MD, FACP, FASN, CPE
Elissa Charbonneau, DO, MS
Curtis Collins, PharmD, MS
Theresa Edelstein, MPH, LNHA
Jason Falvey, PT, DPT, PhD
Robert Green, MD, MPH, MA
Bret Jackson
John James, PhD
Laura Kinney, MA, BSN, RN, CPHQ, CPHRM, CPMA, CPC
Arpana Mathur, MD, MBA
Raquel Mayne, MS, MPH, RN
Anne Myrka, RPh, MAT
Nancy Schoenborn, MD
David Seidenwurm, MD, FACR
Geeta Sood, MD, ScM
Donald Yealy, MD, FACEP

NQF Staff:

Matthew Pickering, PharmD, Senior Director
Tamara Funk, MPH, Director
Erin Buchanan, MPH, Manager
Yemsrach Kidane, PMP, Project Manager
Hannah Ingber, MPH, Senior Analyst
Sean Sullivan, MA, Coordinator
Jesse Pines, MD, MSCE, MBA, Consultant

Contents

Proceedings

(2:15 p.m.)

Attendance and Disclosure of Interest

Participant: -- conflicts to disclose.

Ms. Buchanan: Thank you.

John James?

Member James: John James, Patient Safety America. I have no conflicts to report.

Ms. Buchanan: Laura Kinney?

Member Kinney: Laura Kinney, Teledoc Health, and I have no conflicts to report.

Ms. Buchanan: Thank you.

Arpana Mathur?

Member Mathur: Arpana Mathur, CVS Health, Medical Director. I have no conflicts to report.

Ms. Buchanan: Thank you.

Raquel Mayne?

Member Mayne: Raquel Mayne, Hospital for Special Surgery. I have no conflicts to disclose.

Ms. Buchanan: Thank you.

Anne Myrka?

Member Myrka: Anne Myrka from IPRO. I also have no conflicts to disclose.

Ms. Buchanan: Edward Pollock?

Jamie Roney?

Nancy Schoenborn?

Member Schoenborn: Nancy Schoenborn from Johns Hopkins University School of Medicine. I have no conflicts to disclose.

Ms. Buchanan: David Seidenwurm?

Member Seidenwurm: David Seidenwurm. I'm Sutter Health. No new conflicts since my disclosure.

Ms. Buchanan: Thank you.

Geeta Sood?

Member Sood: Hi. I'm Geeta Sood, Hospital Epidemiologist at Johns Hopkins Bayview.

Ms. Buchanan: Okay. David Stockwell?

Don Yealy?

Member Yealy: Hi. I'm from the University of Pittsburgh and the University of Pittsburgh Medical Center, and I will be recused from the 0500 sepsis standard.

Ms. Buchanan: Thank you.

And Yangling Yu?

Okay. Was there anyone who joined while we were going through names or that was unable to unmute themselves? Please speak now.

Co-Chair Septimus: So what's the total number then that's on right now?

Ms. Buchanan: We have 18 members total. I'm confirming with the team, but I believe we have -- yes, we do have a quorum.

Ms. Funk: We need 16 for a quorum today, and we have 18. So we are good to proceed. Thanks, Erin.

Co-Chair Thraen: Does that also include those that have to exclude themselves from voting later, the two that had to exclude themselves?

Ms. Funk: Yes. So there is one recusal on 3501e, the measure that we'll be voting on. So that comes out of our denominator as well.

Co-Chair Thraen: Seventeen. Okay.

Ms. Funk: Yes.

Co-Chair Thraen: All right. Thank you.

Ms. Buchanan: No problem. So as you all know, this cycle there were six measures under review related to sepsis, pressure ulcers, falls, radiology, and medication use. And as we've mentioned already, we'll be voting on the consensus not reached measure, and the rest of the measures were recommended for endorsement by you all. And we'll be discussing any comments received on any of the measures today.

Voting Test

Next slide. And I think I'm turning it over Sean for the voting test.

Co-Chair Septimus: Well, you all should have gotten a separate link at the last email that gave you the link to voting. Did everybody get that?

Okay. I guess let's try it. Let's hope it works.

Ms. Ingber: I'll just remind everyone (audio interference).

Co-Chair Thraen: Hannah, we're having a hard time hearing you.

Ms. Ingber: Can you hear me better now?

Co-Chair Septimus: Yes, that's better.

Co-Chair Thraen: Yes.

Co-Chair Septimus: So you have the question up, right?

Which candy do you prefer on Halloween? Does everybody see that?

Co-Chair Thraen: Yes.

Co-Chair Septimus: Okay. So is it open for voting?

Let's do it.

Member Jackson: I object that you can't choose both.

Co-Chair Septimus: Oh, I was hoping you'd ask who's going to win the World Series.

(Test vote.)

Ms. Funk: We're still waiting for one.

Just bear with us a second. We're working on the screen-sharing component to make sure that we can do that for the actual voting for you, too. There's always got to be at least one technical hurdle, right?

Co-Chair Septimus: Yes, it always slows us up.

(Pause.)

Ms. Ingber: All right. Thank you for your patience, everyone.

Co-Chair Septimus: So it says only 17. Aren't there 18 of us? I don't want to stop. I'm just saying, aren't there 18 of us?

Ms. Funk: There are, you're right. So we're missing one vote.

Is anyone having trouble with the link or did not receive the link? Or does not like either of these candies and abstained from voting?

(Laughter.)

Member Green: It's Rob Green, and I voted once, I

thought, but now it's showing up again and I can't click on either one. Maybe the poll is closed?

Ms. Funk: Hannah, is it closed? You're shaking your head. Okay.

Ms. Ingber: I see your vote, Rob.

Member Green: Okay. Oh, I'm looking at your shared screen. Sorry. Yes, I voted.

Ms. Funk: Should we try this one more time?

Co-Chair Septimus: Yes, I think we'd better.

Ms. Funk: Eighteen. Yes, I'm sure everyone wants to see that they're counted.

So, Hannah, if you don't mind clearing? And we'll just do it one more time.

(Test vote.)

Co-Chair Septimus: Here we go.

Ms. Funk: Okay. Now we're waiting on two. We've lost one.

Co-Chair Septimus: Oh, gosh.

Ms. Funk: Okay. Has everyone -- oh, 17.

Co-Chair Septimus: One more.

Ms. Funk: Well, we have more than our quorum minimum received.

Ms. Ingber: It looks like we have 14 votes for Twix and 3 votes for Skittles, for a total of 17. Thanks, everyone.

Co-Chair Septimus: Why don't we just keep going on? Let's keep going.

Okay. So, Matt and Tamara, are you going to take us through the preliminary stuff on 3501e, consensus not reached?

Ms. Funk: Yes, thank you, Ed. I'll give an introduction for this measure.

Co-Chair Septimus: Right.

#3501e Hospital Harm - Opioid-Related

Ms. Funk: And Sean is sharing again. Great. Thank you, Team.

So we'll be starting with 3501e, Hospital Harm - Opioid-Related Adverse Events. We have just this one measure that we'll be voting on today on the performance gap criterion.

So a reminder that there's no gray zone here. So that more than 60 percent of the Standing Committee must vote high or moderate for this measure to pass on performance gap. And if the measure does pass on performance gap, the Committee will, then, be voting on overall suitability for endorsement. Similarly, the measure must, then, receive greater than 60 percent yes votes to be recommended for endorsement.

So I'll remind the group of what happened previously related to the discussion around performance gap. Erin will provide a summary of the comments received related to this measure, and then, we'll turn it back to you, Ed, to lead the Committee discussion.

Before I begin, let me check if there is someone from the developer team, from Impact International, on the line today.

Ms. Hall: Yes, we have our team here. This is Kendall Hall. Thank you.

Ms. Funk: Okay. Thank you, Kendall.

So the developer is on the call, if the Committee has any specific questions that the developer can answer. So thank you to our measure developer here.

So this is a new measure. This measure assesses the proportion of inpatient hospital encounters where patients aged 18 years of age or older have been administered an opioid medication; subsequently, suffered a harm of an opioid-related adverse event, and are administered an opioid antagonist, naloxone, within 12 hours. This measure excludes opioid antagonist naloxone administration occurring in the operating room setting. Again, consensus was not reached on performance gap.

Can you go to the next slide, please?

So during the measure evaluation meeting, the Standing Committee didn't reach consensus on performance gap. The measure was tested in six hospitals with measure rates ranging from .11 to .45 percent. The Standing Committee discussed whether a performance gap was truly present because the absolute rate was low, but Committee members also noted that there were four-fold differences across the sites tested. The Committee also discussed whether the number of events, which was low, truly showed a difference across sites.

I'm going to hand it to Erin to summarize the comments received for this measure.

Discussion of Comments Received

Ms. Buchanan: Hello, everyone. So as we noted, there were four comments for this measure, two of which were supportive. One from a member organization was overall supportive, but they did note a few points that we felt that the developer should respond to.

The comment, as I said, was overall supportive, but encouraged additional care in the development of endorsement of the measure in meeting a performance gap while minimizing unintended consequences. You can find the full text of the comment in your meeting materials.

In the developer's response to this comment, which can also be found in your meeting materials, they note that the comment may be referring to a different version of this measure when it was managed by a different developer. And since this developer has taken over, there are now no exclusions for the use of naloxone within two hours of procedure, nor does the measure address the use of doxapram or any other respiratory stimulants.

They note that measure testing is de-identified in chart data from six hospitals within two EHR systems, not state-base data, which is mentioned in the comment, and clarifies some of the points that the Committee made during the call.

In addition, the developer provided additional evidence for the performance gap.

I'll turn to the developer to see if there's anything else they want to add that was missing from this overview of their comment for their response.

Co-Chair Septimus: Before they start, Erin, this measure started, what, in 2019. I want to make sure I understand the timeline. When did this developer take over the measure? Am I correct about that, it was 2019?

Ms. Hall: Yes, this is Kendall.

We took over the measure a month before we presented it to you in 2019.

Co-Chair Septimus: Okay.

Ms. Hall: So it had already been submitted by the previous contractor.

Co-Chair Septimus: Got you. And what about when it was presented this time?

Ms. Hall: This is all us, and we took your comments to heart from the 2019 review, and then, made our changes. And this is all Impact International.

Co-Chair Septimus: Okay. Okay. So some of these exclusions that were removed, did we just not look at this correctly or did we have the wrong version? I'm confused now.

Ms. Hall: No, this was a version that we were not a part of. It was not submitted to us back in 2019, when we took over the contract. And I believe in our summary, our response, our comment response, we have in there the changes that were made from that 2019 version.

Co-Chair Septimus: Okay. Well, that's helpful. Thank you.

Ms. Hall: Yes.

Co-Chair Septimus: Any other comments you'd like to make before we see if any of the Committee would like to comment?

Erin, you're finished here?

Ms. Buchanan: Yes.

Co-Chair Septimus: Okay. Okay.

Go ahead, Kendall.

Ms. Hall: Oh, sure.

Anna, do you want to just restate the specific support and the comments?

Ms. Michie: Absolutely. Thanks so much, Kendall.

So I just wanted to highlight that, among the four public comments that we received, there were some supportive comments that I just want to highlight the specific support.

In particular, there were favorable comments in support for the performance gap and that it meets NQF criteria for Leapfrog. And there was also indication from both AHAP and Cynosure that this measure is addressing a gap in medication safety

and responsible opioid use. So I wanted to point that out to the Committee.

Thank you.

Co-Chair Septimus: Okay. Any other comments from the developer?

Ms. Hall: I believe that is it. Thank you.

Co-Chair Septimus: Okay. So, again, I think everybody understands that this is a must -- again, NQF Staff, correct me -- this is a must-pass measure, and there's no gray area on the performance gap. And if it passes, we go for suitability for endorsement. Did I get that correct? Yes or no?

Ms. Funk: That's correct.

Co-Chair Septimus: Okay. Good. After 10 years, you'd think I'd get it right.

(Laughter.)

Okay. I guess you can raise your hand or use the chat box. So anybody who would like to comment? Because we've had some clarifications about the measure. Does anyone have their hand raised? I can't see everybody at once.

You all know how to use the Hand Raise function?

Ms. Funk: I don't see any hands.

Co-Chair Septimus: Yes.

Ms. Funk: I'll keep looking, though.

Co-Chair Septimus: Yes. You go down to the bottom where it says Reaction, and then you can see it says Raise Hand. Sometimes it's confusing from one platform to another.

If there are no comments, I think we should go on to the vote then.

Ms. Hall: Ed, I'm sorry to interrupt. Is there a chance -- I'm sorry, one of my teammates just wanted me to add another point, and I'm sorry to interrupt, but before you hit the vote.

Co-Chair Septimus: Is this Kendall?

Ms. Hall: This is Kendall, yes. Sorry.

Co-Chair Septimus: You know what? I'm getting to know your voice. Go ahead.

Ms. Hall: Sorry.

Bo, do you want to talk about your additional analysis? Thanks.

Mr. Feng: So, Kendall, can you hear me okay?

Co-Chair Septimus: Yes, we can hear you.

Mr. Feng: Very nice. Thanks, Ed.

Thanks, everyone. First of all, I'd like to thank you for the great discussion we had back in June. Our team definitely appreciated the value of constructive feedback. And, in fact, we acted upon your feedback and we'll provide a few new findings in a minute. And I'd also, again, like to thank the support comments from AHAP and Cynosure.

With the limited time, let me just focus on the areas that the Committee did not reach consensus, and that is performance gap. Three points that I'd like to emphasize. Of course, our detailed responses are in the public domain, and I encourage the members to read them.

Point No. 1, we assessed the measure's performance gap by teaming up with a large healthcare system and quality measure reporting service provider who has access to many rural hospitals across the country.

So our testing data shows that it ranges from 1.1 to

4.5 per 1,000 qualified admissions. Again, this is a four-fold difference, and it indicates room for quality improvement.

The second point, since our June discussion, we collected, based upon your feedback, additional data from another 13 hospitals. By inputting those data, our measure range now ranges from 1.1 to 6.1 per 1,000 qualified admissions, and that performance gap has widened by, roughly, 40 percent.

In our formal response to the public comments, we also provided a data visualization to demonstrate clearly the pattern of variation in performance gap across difference hospitals. As you can see here, several hospitals' rates are significantly higher than the system-wide average and some are lower than that.

The last point, just to get a sense of what will be the total number of harms we could see across all hospitals in the United States, we conducted a very simple extrapolation exercise by pairing our data with data from AHRQ's National Inpatient Sample. And we estimate that close to 62,000 adult inpatients who have suffered this harm event, and that is a number by no means trivial.

So, overall, I want to emphasize that all of our data clearly confirms that the performance gap across an even larger number of facilities is clinically meaningful, with enough power to discriminate across facilities.

I'd also like to remind the Committee that this measure's absolute performance gap is similar in magnitude to many of the currently endorsed NQF-endorsed patient safety measures, and it translate into a great opportunity for us to improve care by preventing up to 60,000 adverse events every year.

Overall, we have really appreciated your consideration of this measure. Thanks.

Co-Chair Septimus: That's terrific. It's exactly what we love to see between the constructive dialog between the measure developer and the Committee. So thank you for that update, and thank you for doing that extra work.

Okay. I'll ask one more time now, since we had another comment, has anybody raised their hand? Or else, we will go to the vote.

I don't see any hands.

Ms. Funk: I don't see any.

Co-Chair Septimus: There's nothing in the chat box.

Ms. Funk: Ed, can I jump in quickly?

Co-Chair Septimus: No.

(Laughter.)

Ms. Funk: Nicely? Just to give the Committee a reminder of what we're looking at for performance gap before the vote. So a reminder that according to our criteria we're looking for a demonstration of quality problems and an opportunity for improvement, meaning data that's demonstrating considerable variation or overall less-than-optimal conformance in the quality of care across providers and/or disparities in care across population groups.

Co-Chair Septimus: Thanks, Tamara.

Ms. Funk: That's all. Thank you.

Co-Chair Septimus: All right. Okay, everybody, get your voting thing out. Let's prime the vote.

Remember, there's no gray area here. This is a must-pass criteria.

I don't see it up yet. Here we go. Okay. Remember, it has to be greater than 60 percent moderate or high. Let's vote.

(Vote.)

We've only got 16. Seventeen. We need one more. We seem to be stuck on 17. Oh, here we go, we've got 18. Okay. Okay.

And the results are? We're holding our breath here. It's not displaying, for whatever it's worth. Can you see the results on your end?

Ms. Ingber: Yes.

Co-Chair Septimus: Well, if you can't get the display, you have to read it out loud anyway. So why don't you tell us the results then.

There you go. Hey, okay.

Ms. Ingber: Thanks for your patience.

So, again, you were voting on importance to measure and report the performance gap. The vote is (audio interference).

Ms. Funk: Hannah, we can't hear you.

Co-Chair Septimus: Yes.

Ms. Ingber: Oh, I'm sorry, I think I might (audio interference). Is this better?

Ms. Funk: Yes, that's better.

Ms. Ingber: Okay.

Co-Chair Septimus: She just read the top part of the question. So why don't you just go on and tell us the results?

Ms. Ingber: All right. We have 3 votes for high; 13 votes for moderate; 1 vote for low, and 1 vote for insufficient, for a total of 18 results. Therefore, the measure passes.

Co-Chair Septimus: Okay. So now, the next vote will be on suitability for endorsement. And so if we

can put that vote up?

Okay, if you'll all please vote. It's yes or no.

Ms. Ingber: You should now see it on the screen on your end.

Co-Chair Septimus: Yes, we do, but we're stuck at 16. We need two more. Seventeen. One more.

Dr. Pickering: Hey, Ed, Hannah needs to read the question off.

Co-Chair Septimus: Oh, okay. This is suitability. Okay. Go ahead, Hannah. I am sorry, I didn't want to exempt your reading. Okay.

Ms. Ingber: That's okay. Thank you. So the question is regarding the overall suitability for endorsement. Does this measure meet the NQF criteria for endorsement? Your options are yes and no.

(Vote.)

Co-Chair Septimus: Oh, we've got 18. Can I say that, Matt? I can say that, right?

Dr. Pickering: Yes, yes.

Co-Chair Septimus: All right.

Dr. Pickering: So just in case anybody is wondering what the transition is, the staff just confirms the votes. There are double calculations that we do, just to make sure that the vote is consistent. So that's sort of the patience between transition here, just to make sure that the vote is consistent before we display it.

Ms. Ingber: All right. I think we're ready. Thank you for your patience.

Can you all hear me?

Co-Chair Septimus: Go ahead, Hannah.

Ms. Ingber: Thank you.

So on overall suitability for endorsement, we have 15 votes for yes and 3 votes for no, for a total of 18 votes. Therefore, the measure is recommended for endorsement.

Thank you, everyone.

Co-Chair Septimus: Yes, I want to thank the measure development for, again, their working with us, their ability to make changes and improve the measure, and for being here today. So we thank you. And I guess we'll see you again in three years, right?

Ms. Hall: We will be ready.

Co-Chair Septimus: They'll be ready. Okay.

Ms. Hall: We appreciate it. Thank you for your time.

Co-Chair Septimus: Thank you very much.

All right. So Matt and --

Ms. Funk: And there will be a related and competing discussion for this measure at the end of the --

Co-Chair Septimus: That's at the end, right.

Ms. Funk: Yes.

Co-Chair Septimus: Right.

Ms. Funk: Just a reminder.

#3621 Composite Weighted Average for Computerized Tomography (CT) Exam Types

Co-Chair Septimus: Yes, we're going to go to 3621. So who wants to lead the discussion on that from the NQF standpoint?

Ms. Funk: Sure, I'll kick us off.

Co-Chair Septimus: All right.

Ms. Funk: So we will move to the public commenting portion of the meeting. We will be going through comments received for the other measures that were reviewed in June. These other measures did pass. So there's no re-vote needed, like what we just did.

We'll be hearing a summary of the public comments received for these measures. For comments of concern, the developer was given an opportunity to respond to this comments and will summarize that response as well.

As a reminder, the full text of these comments and the developer responses have all been shared with the Standing Committee as part of your meeting materials. So you can find them attached to the meeting invite.

We want the Standing Committee to have the opportunity to have a discussion about these responses and these comments. And there's a proposed Committee response drafted that will be edited after today's discussion to be reflect the Committee's conversation.

So we will lead off with Measure 3621, compose weighted average for three CT exam types. The measure steward is the American College of Radiology.

Let me check and see if this developer is on the call today.

Ms. Burleson: Yes. This is Judy Burleson with the American College of Radiology.

Ms. Funk: Okay. Great, Judy. So the developer is here for this measure as well and if the Committee has any questions to direct their way.

Co-Chair Septimus: I'm sorry, Judy, can you spell your last name for me, please?

Ms. Burleson: Burleson, B-U-R-L-E-S-O-N.

Co-Chair Septimus: I got it. Thank you very much. Sorry.

Ms. Funk: Okay. So this was a new measure. This measure is the weighted average of three CT exam types; overall percent 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, CT chest without contrast/single phase scan, and CT head/brain without contrast/single phase scan.

Let me turn it over to Erin to summarize comments received for this measure.

Ms. Buchanan: Thanks, Tammy.

So there is one comment received for this measure, which the developer did provide a response for. We have some high-level bullets regarding that comment on the slide before you.

Just as a note, they raised concerns around physicians' choice of protocol, and they assert that, because physicians' choice is not taken into account in calculating the measure, known variations in practice associated with differing quality of care will be missed by the measure.

Just as a quick overview of the developer's response, they agreed with the commenter that protocol selection is an important component of radiation dose management, but note that it's not the focus of this measure and should be a separate quality action, due to the level of standardization and the availability of national benchmarks. The developer also notes that they're in the process of developing a measure that looks at the concerns the commenter highlights.

So, Judy, if you would like to provide any additional comments related to your response, you have about three to five minutes to do so.

Ms. Burleson: Thank you.

Co-Chair Septimus: Erin's being really a generous today.

(Laughter.)

Ms. Burleson: I won't take that long. In fact, I don't think I have additional comments besides what we provided in our response to the comments.

I guess just highlighting according to the three bullets you have here, on the first one, that the measure is limited to single phase scans for head, chest, and abdomen-pelvis, but, per the National Council on Radiation Protection and Measurement, those types of procedures account for about 75 percent of all CT exams, and about 11 to 13 percent of those are multiphase scans of those body areas. So the volume is substantial that our measure addresses it.

And then, for the last two bullets, I think to speak to those together, the denominator's population definition again is single phase exams for patients that had those types of procedures. The protocol selection processes at a site, there may be many more multiphase exams that are conducted or done than necessary, which could result in increased radiation exposure, but we see that as a separate measure, that it's a two-prong approach looking at the appropriateness of an exam, and indication-based and radiation dose separate, and that a measure should allow a site to be able to see the impact of both of those variables on the safety of the exam and efficiency of the exam that is provided to a patient.

The work that we are looking towards doing to modify or add to a measure is looking at that indication for exam, but there are a number of challenges to address for doing that. First of all, it's being able to have standardized language to identify the indication. That is a challenge in current

systems. ICD codes may be available that somewhat describe the indication for the exam, but they're not complete as they need to be in several different ways within systems.

There's the interoperability of different types of systems that might contain information that would address the indication, if there was also the need to do a standardization of or being able to assess the level of appropriateness based on indication. So there's some development and testing that would be need to be done in that area.

So those are some of the challenges that we see in implementing the measure that is indication-based, but do see it as an important move forward in the future.

Co-Chair Septimus: Thank you.

As I remember this discussion, there was some discussion about optimization versus designed to decrease radiation exposure. Am I not correct in my recall?

Ms. Burleson: I think you could look at those as the same focus of the measure. The optimization and reducing radiation exposure, if you optimize, then we're going to reduce the exposure. The appropriateness of an exam or protocol would also reduce exposure, but it's more appropriately ordering an exam or conducting an exam that meets the needs of the patient's condition, suspected condition.

Co-Chair Septimus: So, Erin, as I remember here, that we would certainly accept these comments; could have some discussion, and just move on, as opposed to sending it back to the developer. Is that correct?

Ms. Buchanan: Yes, that's correct.

Co-Chair Septimus: Okay.

Ms. Buchanan: I don't know if anyone else on the team wants to weigh in here to clarify.

Ms. Funk: I think if there's any additional recommendations, too, that can get recorded in a technical for the future.

Co-Chair Septimus: Right. Right, but we won't necessarily need to send it back to the developer, if there's not any major problems. Okay?

Ms. Funk: Correct.

Co-Chair Septimus: Okay. So with that, does anybody have any questions based on the comment that we received and the response of the developer? Because I don't think we need to vote on this, right? If there's no other comments, we can --

Co-Chair Thraen: I'm sorry, this is Iona. I had a question.

Co-Chair Septimus: Sure, Iona, please.

Co-Chair Thraen: So is the developer considering -- I think the volume answer that you gave is certainly the appropriate justification for focusing on that single phase -- but are you considering looking at this, the issue that's been raised related to the double-phased -- and I'm out of my domain of expertise here -- for future development?

Ms. Burleson: We can certainly look at that.

Co-Chair Thraen: Do you think there's enough justification, based on the comments that have been made, to do something like that or not?

Ms. Burleson: I think we'd have to do some analysis of the data that we do have with multiphase exams and look at the range of the variation in dose in disease across those types of exams to see if it warrants a measure for accountability.

Co-Chair Thraen: Okay. Cool. Thank you.

Ms. Burleson: Yes, thank you.

Member Seidenwurm: One quick comment regarding the multiphase examination is that there is, and there has been for many years, a measure in the Hospital Compare program for one of the main sources of multiphase examinations, which is with and without contrast. So I think that the sort of residual problem of multiphase examinations for, for example, pancreatic cancer, or that sort of thing, might reach the point of diminishing returns, particularly with the lack of precision that Judy mentioned regarding the coding and the correct assignment of appropriate indication, and even the quantification of the number of phases, and so forth. So will we be reaching the point of diminishing returns, is the point.

Ms. Funk: Sorry, I just need to interject.

David, I think you're recused for this measure for 3621.

Member Seidenwurm: In that case, I apologize.

Ms. Funk: No worries. Just wanted to remind you there.

Member Seidenwurm: Okay.

Ms. Funk: So I'll let you know that, actually, Don has his hand up as well.

Co-Chair Septimus: Don, go for it.

Member Yealy: So, you know, my thinking is these comments are not dissimilar from what we discussed during initiation evaluation. And then, single phase versus multiphase scans, I know, I hate to be a pragmatist, but the measure works on 85 percent of the meat of the issue. And in life, the 85/15 rule works really well. And so I don't have a personal desire to try to have a measure that captures, essentially, one-sixth of a subsection for different purposes. And so what I think is these

comments are entirely consistent with what we already considered.

Co-Chair Septimus: Yes, I think that's correct. In Aggie land, we say it's the 80/20 rule, Don.

Any other comments?

I'm looking through everyone. I don't see any hands. Anybody else see any hands?

If not, I guess we don't vote on this. But if no one has any -- do we have to vote on this or just say we'll just accept the comments and move on?

Ms. Funk: That is correct.

Co-Chair Septimus: That's what I thought. Okay.

Okay. Well, now, it's with great pleasure that I turn this over to Iona, who is going to take us through the 0500, and Don and I are recused.

Co-Chair Thraen: Okay.

Co-Chair Septimus: So you won't have to hear from me for a while. Isn't that refreshing?

(Laughter.)

Co-Chair Thraen: So I just want to point out that, with Don and Ed being recused, the number, the denominator is 16. Is that correct?

Ms. Funk: Let our team just double-check to make sure no one else has joined during the course of the call.

(Pause.)

And we can double-check on that.

Co-Chair Thraen: Okay.

Ms. Funk: Since there's no voting necessary, if that comes up --

Co-Chair Thraen: Okay.

Ms. Funk: -- we'll make sure that the number is straight.

Do you want me to do a quick introduction of this measure for you?

Co-Chair Thraen: Sure. Thank you.

#0500 Severe Sepsis and Septic Shock: Management Bundle (Henry Ford Hospital)

Ms. Funk: Okay. So this is 0500, the Severe Sepsis and Septic Shock Management Bundle. The measure steward is Henry Ford Hospital.

This measure focuses on adults 18 years and older with a diagnosis of severe sepsis or septic shock. It assesses measurement of lactate-obtaining blood cultures, administering broad spectrum antibiotics, fluid resuscitation, vasopressor administration, reassessment of volume status and tissue profusion, and repeat lactate measurement.

Okay. I am going to hand it to Erin again to summarize the comments received for this measure.

Ms. Buchanan: Thank you, Tammy. You can see we've got some high-level bullets here regarding the comments received. We also really want to highlight the dearth of notable organizations who have commented on this measure, both in support and not in support.

So the Infectious Disease Societies of America, the American College of Emergency Physicians, the American Hospital Association, the Pediatric Infectious Disease Society, the Society for Healthcare Epidemiology of America, the Society of Hospital Medicine, and the Society of Infectious Disease Pharmacists all banded together to provide a comment that expressed concerns regarding this measure.

They note the burden of chart extraction; possible unintended consequences of including both sepsis and septic shock in the measure. They note concerns with the inclusion of serial lactate measurements, due to lack of evidence of improved outcomes.

So we also received comments from the Sepsis Alliance; the Alliance for Aging Research; America CCSS, and America, Inc.; Home Care Association of New York State; the Leapfrog Group; MoMMA's Voices Coalition, and NTM Info and Research; Peggy Lillis Foundation, and the Society to Improve Diagnosis in Medicine.

Those organizations wrote in support of this measure, citing studies in support. They also note there are sepsis screening programs at every hospital in the United States, and note that sepsis care is nuanced and no single test is yet sufficient, which is why this measure is so crucial to improving quality of care for the sepsis patient.

So because the latter comments were in support, the developer didn't need to provide a response. However, in the first comment I mentioned, the developer did provide a very detailed response which highlighted areas of disagreements and cited additional evidence. And all of that information can be found in your meeting materials.

And I believe we have the developer on the call today, in the event that they want to give any additional information in three to five minutes.

Co-Chair Thraen: So, Erin, this is Iona. I just wanted to clarify one comment. The first set of provider groups that you identified, I don't believe their position was that they were not in support of the measure. What their position has been, in my reading of the material, is they'd like to see the measure improved, and then, made specific recommendations on how they thought that measure should be improved.

And then, the developer's responses to the rationale for why they wanted it improved provided evidence back indicating, kind of rebutting the arguments that they prepared or they provided for why they wanted to see the measure improved.

So I think it's a little bit different. I think the advocacy groups definitely are in support of this measure because of the need for some focus on this particular issue, but I don't think that the provider groups are saying that they were not in support. They want to see it taken to the next level. That's my interpretation.

Member Sood: This is Geeta.

I'm not sure if the Committee is going to be -- I'm not sure if we're waiting for the developer to speak first, but I guess my interpretation, especially since I was involved in the writing of some of the comments, is not exactly the same as Iona's. But is the developer going to speak next?

Ms. Funk: Yes, let's give the developer a chance to jump in, and then, we can move to the Committee. Thank you.

Member James: Could I ask very quick, wasn't antibiotic overuse one of the concerns from the commenters?

Co-Chair Thraen: Yes.

Member James: Okay. I just wanted to make sure. I didn't see that listed here in the comments.

Co-Chair Thraen: Overuse and adverse events as a subsequent outcome, unintended consequences.

Ms. Funk: And remember that the meeting materials have the full text of all these comments, and the memo has a deeper summary than the slides as well.

Co-Chair Thraen: So is the developer on the line?

Dr. Townsend: This is Sean Townsend. I'm one of the measure stewards. I believe Manny Rivers is also on the line.

Dr. Rivers: Yes, Manny Rivers here, too.

Co-Chair Thraen: Okay. Are there any other additional clarification comments you would like to make beyond what we've already identified?

Dr. Townsend: I don't believe so. I think that our responses are -- you've summarized them, and especially regarding many of the remarks that were made by the combined societies. And so I believe they stand as written.

Co-Chair Thraen: Okay. All right. Geeta, you had your hand up?

Dr. Rivers: I'm sorry.

Co-Chair Thraen: I'm sorry.

Dr. Rivers: This is Manny Rivers. Did you want to mention our manuscript that was published before, that came out after the measure was submitted?

Dr. Townsend: Sure, I will. There was a publication in August after the initial meeting was held about the results of the SEP-1 measure, consistent with some of the documentation we submitted with the measure, the data was drawn from the same dataset, showing reductions in mortality of 6 percent compared to (audio interference). So this is direct evidence from the measure population demonstrating benefits of the measure.

Co-Chair Thraen: All right. Anything else from the developer?

I also think that what's not included here is some of the recommendations -- or some of the concerns/recommendations that were identified by the societies was the burden of extraction and the request for definition of time zero for the measure

as well; all the removal of the serial lactate measures, and then, the separation of sepsis without shock from sepsis with shock.

So go ahead, Geeta. You had a question.

Member Sood: I don't actually have a question; more a few comments, if that's okay.

Co-Chair Thraen: Sure.

Member Sood: So first of all, thank you to Dr. Townsend and Dr. Rivers for presenting these data and being available, and your robust responses to the comments.

I guess I would say, a little bit more generally speaking, I think I'm understanding that almost all the professional organizations that deal with septic patients have concerns about this metric. And I guess my interpretation of at least the comments that we offered, and some of the other comments that we have heard about, is that, while we definitely think that sepsis is important, I don't think we should conflate the importance of the topic area with the scientific rigor of the measure, but that most of these professional organizations, including mine, do not endorse the metric as it is.

We think that there's enough concern about the metric that it's not presenting the degree of scientific vigor that we would want to see with the lack of unintended consequences for something to address an important issue like septic shock and sepsis.

So I have had some offline conversations. I think the issue is really the scientific rigor of the evidence that these component aspects of the metric are, in fact, impactful, and that that evidence isn't just going to be simply before and after studies with multiple confounding -- it isn't going to be something as simple as variations in practice. It needs to be a little bit more rigorous.

And the recently published standards of the Surviving Sepsis Campaign went through all of the component elements that are in the SEP-1 metric and found that almost all of them have a very low -- I'm not sure how to say it -- low quality of evidence for those particular component parts. And I think that was one of the things that was brought up in the professional comments as well.

So, again, I mean, I know that this is an important area, topic area, to all of us -- to patients, to the Committee, to the Committee Chair, to the developer, to all of us taking care of patients. I think we need to have the scientific rigor to make sure that this is the best measure that's going to improve outcomes for our patients and not cause unintended harm in the process.

Co-Chair Thraen: Thank you, Geeta.

Other questions or comments from the Committee members?

And this is not a voting issue as much as it is a public comment assessment, I guess, about this sort of debate that's taking place.

Ms. Funk: Curtis Collins has his hand raised.

Member Collins: Yes, I'll jump in.

And I mentioned it as well at our summer call, but throughout our draft report I see reference to antibiotic use. And from the developer responding to, you know, there's just been one UTI study that has shown an increase in antibiotic use.

And the study that I reference was also published in CID around this time where Dr. Townsend provided commentary on some of these comments, which specifically did look at this measure. And they showed SEP-1, their conclusion was that SEP-1 was associated with long-term increases in broad spectrum hospital-onset antibiotics, MDR antibiotics.

So I guess in reading the draft report and the developer's response, I just didn't see that in terms of a comment. So I made a question that we should clarify that statement, because our draft report does state it as fact, and I just don't think that's the case. I don't know why the developer hasn't addressed that, even in their most recent comments. So there have been at least, you know, one study in 111 facilities that showed at least some increase in antibiotic use.

And then I'll piggyback off what Dr. Sood just mentioned. With some of the recommendations that were just published in Surviving Sepsis, one of which is to -- I'll put it up. Kind of in this sepsis population, not septic shock, but they now suggest deferring antimicrobials while continuing to closely monitor the patients.

So is this measure out of step currently as it exists right now in that recommendation for antibiotics in this population? I would argue that it probably is, and that we should really consider that, based on the latest Surviving Sepsis guidelines, which is what this is based on.

Co-Chair Thraen: So, Curtis, before you stop, who did the Surviving Sepsis guidelines? Who's the sponsor of that? Where are they coming from, I guess it the question? What's the organization that has done the review of those guidelines?

Member Sood: So this was published in Critical Care Medicine. My understanding -- and, Curtis, you may have more information about this -- is that this is the gold standard guideline.

Dr. Townsend, I see you're on video. Perhaps you can comment on the gravitas, I guess, of the Surviving Sepsis guidelines.

Co-Chair Thraen: And the reason why I'm asking that is, oftentimes, the guidelines are prepared by specialty organizations, provider organizations. So I

just wanted to know who's the sponsor of this guideline.

Dr. Townsend: Sure. I'd like to comment on a couple of remarks that were made, and then, I'll answer your question directly.

There's a lot of generalities being cast about here without many specifics. And so this statement, for example, that we haven't addressed the fact that the measure doesn't increase antibiotic exposure, or that there has been a decrease, actually, in multi-drug-resistant organisms during the time set when it's been effective, it has not been addressed, but is in our comments. In fact, we directly take this topic on.

As regards the Sepsis Campaign guidelines, I was a member of that Committee in 2008, '12, and '16, and it convenes about 30 international societies to make recommendations on sepsis care. Our current measure is completely consistent, which was the antibiotic recommendations, that those guidelines require, in its current iteration, antibiotics within three for patients with a diagnosis of sepsis, which is precisely what the measure requires as well.

Dr. Rivers: And one thing -- this is Manny Rivers -- is that the body of evidence is based on randomized controlled trials as the gold standard. When you look at the management of sepsis in the early 2000s, there was no standard of care. So when you look at what should we do, what we've been doing, there was nothing. And so when you look at the evolution of this measure, it's, basically, taking into consideration the evolution of the science. Every process, the measure was submitted. So it reflects best practice.

The evidence, even with sepsis care, is still weak. If you look at the indication for the ICU admission for septic shock, it's considered low level of evidence, weak recommendation for a patient to be in an ICU with septic shock because the evidence is not there.

So remember that the wording sometimes can get caught up into some inappropriate interpretations, but that's the level of science that they use in order to evaluate the specific indications.

Dr. Townsend: I'd make one more remark to jump on to what Manny just said. The NQF publishes standards for the evidence that's available, and you do require, or permit, I should say, a moderate level of evidence. And a moderate level of evidence requires three to four studies of observational nature that control for confounders. And we definitely meet that standard, and we provided that in the evidence packet.

And since that time, we've provided direct evidence, with the propensity score matching study, demonstrating that the measure also, with specific data at that point, is effective in this population.

So we're really cautious about the generalities and making sure we address the standard that NQF itself sets.

Dr. Rivers: And the question specifically on antibiotics is in your handout on page 4 and 5. We addressed that with two article from The New England Journal of Medicine. So page 4 and 5 of the NQF's summary is where those antibiotic questions were answered.

Co-Chair Thraen: I have two questions to follow up.

One of the recommendations was to remove serial lactate measurements from this measure. One of the overall complaints is that it's a very complicated measure, abstraction burden, trying to capture all the right information. I did not see you address that issue of removing serial lactate measures in your responses.

And then, also -- go ahead.

Dr. Rivers: One of the things we do in the measure

application is an evidence section, which is a very concise review of the literature in regards to each element. And in that section, in a trial from what we call the ARISE trial, which is a randomized controlled trial with severe sepsis and septic shock, they identified lactate and its value in terms of identification and prognostication. It was the single most important variable in that study. And that study was a replication of the original goal-directed therapy study in 2001. That question has been answered in a randomized controlled trial.

Co-Chair Thraen: All right. And then, the second question I had was the request to define the time zero variable. I'm not clear on what that variable is in my mind. And I think your responses were, basically, well, there wasn't that much training or the training has not been very good for the abstracters. You did go through and outline the process of how much time it took, et cetera.

So separate from the idea of implementation for the abstraction process, is there any other reason not to define a time zero approach to that variable?

Dr. Townsend: There is a time zero approach defined in the measure. And it's just that those folks that -- the studies themselves studied that time zero and criticized it. One of them did at least. The other, actually, concludes that the time zero is reliable and achievable. And so I'd point out both of those references are provided.

We are, however, doing something that I believe the Committee, the group of societies that have come together have recommended, which is that we are studying, with many of those members of the societies, which has led to the recusal of some of the members of this panel because they're part of that endeavor, to make sure that we are having the most reliable time zero. And if, in fact, we find that there's one that's more reliable, we would certainly adopt it.

Co-Chair Thraen: Are there other questions from the Committee members?

Member Collins: Yes. I guess I would like a direct answer on why the packet study was not included in the comment regarding antibiotic use and increases in antibiotic use from the developer.

Dr. Townsend: There's zero direct evidence, none, zero, no study that says that SEP-1 directly increases the use of antibiotics, except the one study in one hospital that showed a change in antibiotic usage with regard to urinary tract infections. And that study didn't control for the antibiogram (phonetic) at that facility. It didn't control for the comorbidities of those patients, let alone the site of infection. So I would not put too much stock there.

Member Collins: I will come back. And I'm looking at right here a direct conclusion from a SEP-1 publication that says -- the conclusion was its immediate and long-term increases in broad spectrum MDR organisms. I'm looking at it.

So to go back to just one study, I just don't understand that.

Dr. Townsend: Could I ask you to tell us the study you're talking about?

Member Collins: Yes. It's a study from CID by Amy Packyz in February. The same issue where Ed and IDSA provided commentary on this measure as well, and you provided a comment, Dr. Townsend.

Dr. Townsend: Yes, there were a number of studies that were cited in the Position Paper which claimed that SEP-1 increased --

Member Collins: No, sir. No, I'm talking about the publication since then. So February of this year.

Dr. Townsend: I'm sorry, Curtis, it's so non-specific; it's not clear to me what you're talking about. I'm

sorry. I don't know the nature of the study. I don't know how the methodology was. I don't know the study. I don't believe that -- if it's in the same publication in CID that the Position Paper was in -- and our reputation, and we've directly answered.

Member Sood: So this is Geeta. I just wanted to add -- thank you for sharing your thoughts about this -- it seems to me that there are fundamental discrepancies between the way that some professional organizations and you are interpreting the evidence and fundamental differences in how we weight that evidence.

So I know that this is not really part of the typical NQF process, and you're right, the bar to evidence has been maybe not as high as I would like in terms of using observational studies without the degree of rigor that the Surviving Sepsis Campaign and other organizations would use.

But I wonder if there is an opportunity to have a more collaborative discussion at another point or in some other forum where we can go through all of these papers and talk through the different ways that we are seeing and interpreting this evidence. Because I do think, like Curtis said, there are fundamental differences in how we are seeing this.

Dr. Townsend: There are tremendous debates on sepsis that go on of the enormity that I can't even tell you. In 15 years of doing this work, I've never seen a diagnosis where people disagree less -- more. It's truly remarkable, the variance in opinion that you will see.

To your point, you're right, there are certain societies that don't endorse the measure. There are two critical care societies that do. The Society of Critical Care Medicine has written in favor of this. The American College of Chest Physicians just published our results.

So the difference in opinion exists. There are

collaborative groups that are meeting. I don't want to speak too freely about it because it's not fair to those who are recused who can't speak about it. But there are ongoing meetings to try to have meetings of them.

(Simultaneous speaking.)

Dr. Rivers: So if I can put this one comment out there, it is that the mortality in our SEP-1 population is 27.5 percent in patients who are non-compliant to the measure. When you are compliant to the measure, your mortality went to 21.81 percent. That mortality is probably one of the highest mortalities of any NQF measure you have. And you have a 6 to 7 percent mortality rate.

We're not perfect. It's not the ideal measure. But we made significant progress. This measure was submitted in 2008, has undergone NQF reviews almost three to four times. So this is not a brand-new measure. It has progressed to improve mortality.

Member Sood: True. I guess my concern is that it was never a smooth measure, as you've pointed out. And I think that's partly where the robustness of the scientific method is so needed. Just like we know this from COVID, right? The ACIP, does J&J vaccine actually increase the clots rate?

Understanding the causal implications and the causality in an observational study is not easy to do, as my mentors have taught me. Just because there's a reduction in mortality, it's very difficult to establish causality. And therefore, I think it would be really important for us to have collaborative discussions. When many professional societies aren't really in line with this metric, I think, that makes it even more important that we have robust scientific discussions where we talk through the evidence a little bit more rigorously.

Co-Chair Thraen: So I want to turn this over to the

NQF staff and ask them, what are our options at this point in time? I'm hearing a recommendation from Geeta that she'd like to have a more in-depth analysis and discussion of the scientific rigor. We've already voted on that scientific standard, and this is post-comment. So where do we go from here?

Dr. Pickering: This is Matt.

So that's correct, Iona, a reminder that the Committee did evaluate this measure and it passed. If the Committee wishes to make recommendations for the measure moving forward for the next evaluation, you could do so. There are also ad hoc reviews that we have in place in which the measure comes back off-cycle. So now, the maintenance cycle is about three to four years, when a measure comes back and everything is evaluated again. There are instances where that could happen off-cycle, and that is when additional evidence of unintended consequences are presented and considered, in which the Standing Committee may be reconvened off-cycle to evaluate the evidence that has been submitted by members of the public, or others, saying that there are unintended consequences related to this measure or there are potential risks that need to be reevaluated with this measure, based on the evidence that has been proposed. So that is another opportunity.

As far as where we are today, this measure has passed. So in order to change that, the Standing Committee does have within its power to reconsider the measure specifically for a criterion, but that would be a re-vote, a vote on reconsideration and re-vote on that criterion.

We wouldn't be able to do any sort of collaboration on the components of the measure or the evidence at this juncture. We would be able to do that off-cycle for an ad hoc review, again, submitting any other evidence that needs to be considered by the Standing Committee due to the risks that this

measure may have or potential harms outweighing the benefits, as an ad hoc review. And that would be considered out of the cycle, right, to bring it back off-cycle.

Or if the Standing Committee feels that or agrees that there needs to be a reconsideration of the measure during this current cycle, you have it in your power to reconsider the measure, but that is a formal vote to reconsider the measure. That would be more than 60 percent in favor to reconsider the measure for the specific criterion you would wish to reconsider, and there must be clear rationale as to why you are reconsidering the measure, if there is new evidence that has been proposed that the Standing Committee did not have available to them during the time of submission.

Co-Chair Thraen: So does that vote to reconsider, is that something that we are doing now today at this point in time?

Dr. Pickering: That is, if the Standing Committee would like to, there is potential to do that, if the Standing Committee feels that the measure needs to be reconsidered, but it has to be for the specific criterion and a clear rationale as to why it's being reconsidered.

And I would just remind the group that, if it evidence, right, so you have to clearly state the rationale as to why you would want to reconsider the measure for evidence, because the measure originally has passed during this evaluation cycle.

And that is any new evidence that the Standing Committee did not have available to them during the time of submission, because you have evaluated that evidence or had it available to you during the time of submission and passed the measure.

Member Sood: So, Matt, this is Geeta. Obviously, I'm one of the people that has a strong opinion about this, as I think a lot of people do in different

ways.

I guess I would somewhat defer to you on what the best approach is. Certainly, there is new evidence. I don't think we can minimize the new Surviving Sepsis Campaign guidelines with their recommendations and recommendation changes. So if we wanted to reconsider, there is definitely rationale to be able to do so.

You've also outlined several options in terms of reevaluation and consideration in the more ongoing process as well. So I guess I would be looking for guidance from other people who are potentially --

Dr. Townsend: So I'd like to speak. We've not established that there is a discordance between the new Surviving Sepsis Campaign guidelines and this measure, as written. It's an assertion. You can't point to a specific where there's a difference.

Member Sood: So I'm sorry to interrupt you, Dr. Townsend --

Dr. Townsend: And I am not finished yet. I need to --

Co-Chair Thraen: All right. All right. Stop. Stop. I don't think we want to get into a counter-defense and back and forth. I think the question is to the Committee members. So it sounds to me like Geeta's recommending a vote to choose whether or not we want to reconsider this measure, based on the public comment.

Did I say that correctly, Matt?

Dr. Townsend: May I add a question? May I just ask Matt a question? If the Committee could ask, I think it's fair the developer can ask.

Co-Chair Thraen: The developer generally only responds to questions. They don't argue for or against. They only respond to questions in this process, partly because there are two members of

this Committee, for example, who have to recuse themselves accordingly. So they're not able to argue for or against as well.

So in order to maintain that consistent standard, I think you've presented your evidence. You presented it well. I don't think we want to get into a debate about this right now.

I think we have to make a decision as to whether or not we did a sufficient job when we reviewed the measure early on by going through the science, or if the new evidence that is theoretically available at this point in time, that wasn't included in our considerations, is strong enough that we would want to reconsider revisiting this particular measure. I think that's the question.

Am I correct on that, Matt?

Dr. Pickering: Yes, that's the question. So, again, if there is a Standing Committee member that wishes to reconsider the measure, we need to put that on the record.

Co-Chair Thraen: So, Geeta, that's you.

Dr. Pickering: And then, clearly articulate what the rationale is and the criterion you would wish to reconsider.

Mr. Dickerson: So, Matt, this is Bob Dickerson.

I just have a question. I want to make sure that everybody's clear on what the criteria are for reconsidering. Because I know you kind of walked through that. We've had new guidelines published, updated guidelines published October 4th. We've also had, as Dr. Townsend referred to, and was cited in the responses to public comments, an additional publication that came out since this was discussed.

I guess the question I'm trying to make sure that everyone understands is, when you're looking at

evidence since this was last discussed, what evidence are we looking at? I mean, is this just something that we're focusing on a single thing or what is the scope of the evidence? And is this a Committee decision on which evidence to consider and which evidence not to consider?

Member Sood: Well, we're not considering the evidence in this question or vote, right? We're just saying whether it should be reconsidered, correct?

Mr. Dickerson: But I thought that was one of Matt's points in terms of reconsidering, is there has to be evidence to support reconsidering.

Co-Chair Thraen: That's correct.

Dr. Pickering: Yes, in order to reconsider, you have to, we have to, the Committee has to identify the criterion that they would want to re-vote on, right? And that's part of the reconsideration. So the reconsideration is, yes, we want to reconsider this criterion because of X, Y, Z, because of this. And that this is the rationale or evidence to support that reconsideration.

If you're reconsidering on the evidence criterion, that needs to be clearly stated as to why you want to reconsider the evidence criterion, because there is something that wasn't considered previously that the Standing Committee didn't have available to them.

The reconsideration vote is to have the Committee whether or not they agree or disagree to reconsider the measure, based on that rationale. If the Committee does vote to reconsider, it would go to that criterion that has been drawn into question, and then, discuss that criterion, and then, re-vote on the criterion.

Member Green: Well, can I make a suggestion?

Dr. Townsend: May I ask a question, Matt? In terms

of scientific acceptability, does NQF permit, for a moderate quality of evidence, observational data?

Dr. Pickering: So not scientific acceptability, but for evidence.

Dr. Townsend: For evidence?

Dr. Pickering: Yes, for evidence. In Table 2 of our Measure Evaluation Criteria, it lists out the different grading of evidence from high to low and what aligns with that evidence. And for moderate, you can have two to four studies. They could be non-randomized controlled trials or observational studies, as long as there is adequate control for potential bias, things like confounding. So that is permitted within our current criteria, to have non-randomized controlled trials or observational studies, as long as they have scientific rigor, right? So they're controlling for the adequate amount of bias, controlling for those confounders, and you're looking at two to four studies that can be in support or that could be submitted to support that evidence criterion.

Co-Chair Thraen: There was somebody else that had a question?

Member Green: It was Rob Green.

I would suggest maybe -- we're talking about the new guidelines that came out. If we have Geeta just name the things that are most changed that would be against the current measure, and then, we could vote on whether or not that's of substantial nature to even have a vote.

Because I think we're just talking about something that's new, but many people here -- I think I know what she's talking about, but maybe she could state what it is that has changed. It would be helpful.

Member Sood: I'm assuming that's referring to me, is that right?

Member Green: Yes, it is.

Member Sood: Well, I mean, to be honest, I wasn't prepared to answer that question. I have the Surviving Sepsis Campaign paper here. I think there are significant differences related to antibiotic use and the allowance, I guess, for not including -- not being as aggressive about immediate antibiotic use, as well as a whole bunch of other changes from the 2016 recommendations which have been a part of the SEP-1 guideline, the metric, from my understanding.

So I guess the short answer is that I can read off a few of the high-level changes pretty quickly, but I'm not prepared to answer that question in any significant detail yet.

If the Committee decides that we want to re-vote on this, which I am kind of leaning towards, I think that would be a good time to talk about this. Clearly, there's new publications that have come out since the last time we reviewed the metric that influenced the metric.

Dr. Rivers: I must comment that the Surviving Sepsis Campaign are guidelines. There was a guideline, unilateral guideline, done two years ago that said antibiotics should be given within one hour, including fluids, et cetera. And that was unilaterally put out by the Surviving Sepsis Campaign.

Member Sood: So, again, I mean, I appreciate the developer's participation in this. My understanding is that right now this is more of a process, NQF issue, and not an evaluation of the evidence between the developer and the Committee. If I'm wrong about that, Matt, or others, please let me know.

Co-Chair Thraen: So I think, Geeta, you have to make a decision. Are you asking for a re-vote, or a reconsideration vote?

Ms. Funk: Can I just jump in, too?

John James has his hand up.

Member James: Can I add something to the discussion? This is John.

Co-Chair Thraen: Yes, you had your hand up. Go ahead.

Member James: It seems like we're trying to take a snapshot of something that's moving fast. I'm not a follower of sepsis research, but my sense is that the research in that area really has ramped in the past few years. And you've got all these guidelines and things changing quickly.

And if the time constant for reevaluation of these measures is three years, it doesn't seem like that's frequently enough. And we're always going to be caught in this trap of, what's the new data; what's the new guideline? And do we apply it sort of retrospectively to the measure as submitted? I mean, are we trapping ourselves here? That's my question.

Dr. Rivers: But also I want to let people know that the nature of sepsis research since the year 2002 --

Member Collins: We've discussed the developers talking. Can we mute the developers? I think this is an important discussion.

Dr. Townsend: I formally object. This is inappropriate. We are advocates. We were invited to this meeting. If you needed to have a meeting without us, you could not invite us.

And it is the case that this is a public meeting and we should be able to address public comments. That's why this was held as a meeting. And so I don't think you actually have the standard right that the developers aren't allowed to comment. And I do not appreciate being asked to be muted. I think that's insulting and unfair.

Co-Chair Thraen: I think the point -- I want to go back to Geeta.

Geeta, are you asking the Committee to have a reconsideration vote?

Member Sood: Thank you for that, and thank you for other people asking questions, so that I had time to think.

I would suggest, yes, it may be that people don't -- opt to not to that, and if so, there's clearly other formats to re-review. But it sounds like it would be easy enough, and there's enough discourse in this very important, very controversial metric for years to warrant at least asking the question, should we reevaluate?

Co-Chair Thraen: Okay. So then --

Ms. Duseja: This is Reena Duseja from CMS. You know, I think you need to take this back to NQF in terms of process. Because I'm observing this whole meeting and we're not following the process here. So I just want to point that out, as an observer from CMS watching the discourse during this time.

Co-Chair Thraen: All right. Thank you for that. So, NQF?

Dr. Pickering: Right. So the Committee is able to reconsider a measure based on what they have been discussing if they have clear rationale as to what they're wanting to reconsider. That is in the power of the Committee to do so. But, again, clear rationale as to what it is that they're wanting to reconsider.

And then, if the Committee does vote to do so, then they're able to go back to the criteria and discuss further, and then, vote on that criteria.

Co-Chair Thraen: So what I heard is Geeta's requested a re-vote to reconsider this measure on the evidence. The rationale behind that are the

updated guidelines, as of October 4th, and additional publications to be considered.

Is there anything else?

Mr. Dickerson: This is Bob Dickerson again.

I just have a point of clarification for Matt or a question of clarification. So I mean, from what you're describing, yes, it does sound like having a vote to reconsider evidence is within the realm of the Committee. My question, though, as we're looking at that -- what I'm hearing from Committee members is many Committee members are not familiar with the new guidelines that have been published.

Co-Chair Thraen: That is correct, yes.

Mr. Dickerson: So even if there's a vote to reconsider evidence, it seems like it would be premature for the Committee to really have a clear, robust, informed discussion, and then, re-vote on the evidence, since so many Committee members aren't familiar with this new evidence.

Co-Chair Thraen: Well, then, I don't think we would do that now. I think there would have to be a process by which that evidence would be re-reviewed by the Committee members.

Mr. Dickerson: Okay.

Co-Chair Thraen: So we're not voting on -- all we're voting on is the request to reconsider.

Mr. Dickerson: Okay.

Co-Chair Thraen: And the request to reconsider may not pass. It has to pass.

Mr. Dickerson: Okay. Thank you for that clarification because I thought that I did hear that there would be a request to reconsider. Then, the Committee would discuss the evidence and could re-vote on the

evidence criteria.

Co-Chair Thraen: I don't think anybody's prepared to vote on the evidence.

Mr. Dickerson: Thank you.

Member Green: I think that was meant at a different time, shortly in the future, about a very specific issue that Geeta brought up about the new guidelines that we have not yet reviewed.

Co-Chair Thraen: Correct.

Member Green: I would second that vote.

Co-Chair Thraen: Okay.

Mr. Dickerson: Thank you for the clarification.

Co-Chair Thraen: So if there are no other concerns, could we put that into the voting block of yes or no?

Dr. Pickering: Yes, so can we just restate what the rationale is for reconsidering the measure and aligning that to a specific criterion that the Committee would want to reconsider?

Member Charbonneau: Can I ask a question before we do that? I'm so sorry.

Co-Chair Thraen: Hmm?

Member Charbonneau: Can I ask a question, please?

Co-Chair Thraen: Yes. Yes, yes.

Member Charbonneau: I would like to ask a question of the measure developer. Does the new guideline -- would the new guideline make you lean towards changing your measure in any way or not?

Co-Chair Thraen: Is the developer still on the line?

Dr. Townsend: Yes. I do believe that we would meet

the new evidence. If we're talking new evidence, it's a review of the existing evidence in the guideline. I haven't heard where we don't. And, in fact, if there is a re-review, we're going to meet it.

Dr. Rivers: And you have to understand that, over the last 10 years, there's been no randomized trial to change the landscape of sepsis there. So if you want to go by the guidelines, and you want to look at the evidence, then, you look at the original research. There is nothing.

Member Charbonneau: Thank you.

Co-Chair Thraen: Yes. Any other questions before we call a vote?

Dr. Pickering: I'll just state this again. Before we go to a vote, there needs to be a clear rationale as to why you're reconsidering the measure. And if the Committee does vote to reconsider, that discussion will happen on this public (audio interference) around reconsidering whatever specific criterion you would wish to reconsider. Because if there's any new information that's been submitted the Committee needs to reconsider, that needs to be clearly stated.

I will also remind the Committee that this measure can still move forward as is, and then, an ad hoc review, if there's additional evidence that needs to be presented to the Committee can be submitted for potential ad hoc review off-cycle.

There is also the option of this measure moving forward and recommendations made to the developer to address the concerns that this Committee does have related to the measure, which will be considered in the next round of evaluation, which would be the maintenance review cycle in three or four years.

So those are other options --

Co-Chair Thraen: So, Matt, you just outlined three possible options, is that correct, in my understanding? One is the vote to reconsider the measure; a vote to pass it and do an ad hoc review, or the vote to -- there was a third one that I block on now.

Dr. Pickering: No, so the only vote that would happen would be reconsideration --

Co-Chair Thraen: Okay.

Dr. Pickering: -- since it's already passed.

Co-Chair Thraen: Okay. And then, the evidence for reconsideration is the updated guidelines that no one's familiar with, as of October 4th, and any additional publications in which there seems to be differences of opinion between the developer and some of the members of the Committee.

Member Sood: Well stated.

Dr. Rivers: There's an article by Dr. Sean Townsend that was published in CHEST that wasn't included in this that's supportive of the measure.

Co-Chair Thraen: And there's additional evidence to support as well.

Dr. Rivers: Yes.

Member Sood: That was the developer. So it sounds like the developer is also talking about new evidence, but -- yes, I guess that would --

Co-Chair Thraen: So any new evidence to date pro or --

Ms. Duseja: I'm happy to submit that from CMS as well, that there is new evidence.

Co-Chair Thraen: Yes, CMS and from the developer and from other sources that are out there. Does that capture it, Matt?

Dr. Pickering: So the rationale would be that you want to reconsider the measure because there's additional evidence that the Committee would like to consider?

Co-Chair Thraen: Yes, and that there seems to be enough differences of opinion, that a member of the Committee has requested that it be reconsidered.

Dr. Pickering: Okay.

Member Sood: Well said.

Ms. Duseja: Hey, Matt, this is Reena Duseja from CMS. I have a question on this.

How do you define actual rationale for evidence here? It looks like there's opinions, based the guidelines, that has been addressed on this call, but where does it qualify to having an ad hoc review with emerging evidence versus like putting this into a re-vote? Could you clarify that, please?

Dr. Pickering: So the ad hoc review would be also submission of additional evidence that NQF, as well as working with the Co-Chairs, would consider to determine whether or not an ad hoc review of the measure would be needed, based on the evidence that's submitted.

In this case, reconsideration during this meeting is similar to where, if the Committee members feel that there is strong enough evidence that they should reconsider the measure in some way, they're able to do so, but they must vote from this and they must vote about this during -- sorry, there's someone at the door, dogs barking. They must vote to reconsider that measure.

And that rationale is that there is strong evidence to indicate that there is a need to reconsider the measure with specific criterion, and that could be unintended consequences or thinking of additional evidence that is not supporting the measure in

some way.

Member Sood: So it seems like there are a lot of people, with the kinds of questions that are being asked, that either have opinions that it should be reconsidered or should not be reconsidered. Perhaps it would be easier to just put it to a vote, and then, we can address that.

Dr. Pickering: Yes, so if you want, if people are ready to go, then we can go to the vote for reconsideration.

Are there any additional comments, any hands raised, or anyone in the chat box we need to reconsider here or consider?

Ms. Funk: There are no hands raised. And I'm just checking the chat box. There is a comment from a Committee member in support of ad hoc review. I don't know if he wants to speak up on that point.

Member Falvey: No, I think we've heard quite enough.

Ms. Funk: Okay.

Member Falvey: I mean, there seems to be some concerns of unintended consequences, and I think it might be helpful to digest that evidence and consider it in context with some of the other things that have come up. And we can submit that as a formal process.

Co-Chair Thraen: So the vote went away; the option went away. So I did not vote. There it is. Okay.

So should we go ahead, Committee Members, and vote? This is about reconsidering this measure.

Dr. Pickering: And just a reminder, more than 60 percent of those voting for this measure need to vote yes in order for it to be reconsidered. If that is not met, then it will not be reconsidered.

Co-Chair Thraen: And our denominator is 16, is that correct?

Ms. Funk: That's correct.

(Vote.)

Co-Chair Thraen: We have two more votes.

Ms. Funk: And 14 is quorum on this measure. So if we don't get those two more, we do have enough to move forward.

Dr. Pickering: Has anybody on the Standing Committee not voted or is having issues?

Co-Chair Thraen: There's 16.

Dr. Pickering: So, again, the team is just confirming the results for consistency in scoring.

(Pause.)

Co-Chair Thraen: That's correct. Those who have had to recuse themselves are not voting.

Dr. Pickering: Just confirming with the team. I appreciate everyone's patience.

And just for a reminder, the team could just read off the question, and then, responses, and we can go through the results.

Hannah, are you there?

Sorry, we're having some -- sorry, Hannah, we can't hear you. So maybe another team member could read off the question and the results?

Ms. Funk: Sure. So the question was does the Standing Committee wish to reconsider Measure 0500?

And there were 6 votes for yes; 10 votes for no. And so this measure will not be reconsidered.

Co-Chair Thraen: All right. Thank you for that discussion. Thank you, Committee Members. We appreciate your input, and this was a challenge to all of us, and we will move forward.

Member Sood: And I just wanted to say thank you for everybody's consideration and reviewing these comments and thoughts. So thank you, everybody.

#3389, Concurrent Use of Opioids and Benzodiazepines

Ms. Funk: Okay. So we can move to the next portion of our discussion.

So there were three other measures as part of this cycle that were reviewed. These also passed.

Measure 3389, Concurrent Use of Opioids and Benzodiazepines received five comments. All were in support of the measure. And so there is no Standing Committee action needed at this time. You can review those comments as part of the meeting materials, if you wish.

Next slide, John. Thank you. Okay.

Co-Chair Septimus: Can I say hallelujah?

(Laughter.)

#0674, Percent of Residents Experiencing One or More Falls with Major Injury, Long Stay

Ms. Funk: Absolutely.

Measure 0674, Percent of Residents Experiencing One or More Falls with Major Injury, Long Stay, also passed and received no public comments. So no action is needed at this time.

#0679, Percent of High-Risk Residents with Pressure Ulcers, Long Stay

And next slide. And Measure 0679, Percent of High-Risk Residents with Pressure Ulcers, Long Stay. Also

passed and received no public comments. So there is no action needed by the Standing Committee at this time.

Related and Competing Measures Discussion

Okay. Next slide, please. So now we'll move on to our related and competing measure discussion for 3501e, since it did pass earlier in the meeting.

As a reminder, we already had the related and competing discussions back in June for the other five measures that had previously passed. The table on the screen is a reminder of what this discussion will entail.

So a competing measure is considered to have the same concept and the same target population. So in these instances, the Standing Committee would need to have a best-in-class discussion.

There are also related measures, which is what we have for 3501e. So related measures have either a different target population and a different concept, and if both of those items are different, there's no competition between the measures, and no harmonization is needed. If there are some similarities, then the developers are asked to appropriately harmonize their measure with other related measures.

So if there are similarities, the point of this next conversation is to see if the Committee has any questions or concerns with what the developer has listed in their measure submission with regards to the related measures or if the Committee has any recommendations that they'd like to offer to the developer to be included in the final report.

So the overall goal of this is to try to mitigate any potential burden to the system in the number of measures and the differences across related measures.

Next slide, please. Oh, and that's more of what I just said. Great.

So the related measures for 3501e are Measure 3316, Safe Use of Opioids, Concurrent Prescribing, and Measure 3389, Concurrent Use of Opioids and Benzodiazepines, which was actually part of this cycle.

So in the developer's submission, they mentioned that all of these measures do have the same general target population, which is adults greater than 18 years of age who receive opioids. However, the focus of each measure is very different.

So the Hospital Harm measure, 3501e, it focuses on patients who receive excessive doses of opioids during their hospitalization and subsequently require naloxone to prevent further harm.

Measure 3316 focuses on patients who receive concurrent opioid or opioid and benzodiazepine prescriptions at discharge, putting them at risk of adverse drug events after hospital discharge.

And Measure 3389 tracks concurrent opioid and benzodiazepines outpatient prescriptions.

So in the submission the developer states that as a result of these varying measure focuses, the hospital harm, opioid-related adverse events measure has a broad denominator of all inpatient adults who received a hospital-administered opioid, while 3316 as a more narrow denominator of adults greater than or equal to 18 years who are prescribed an opioid or benzodiazepine at discharge from the hospital-based encounter, and also excludes patients with an active cancer diagnosis, palliative care order, or length of stay greater than 120 days.

And finally, 3389 addresses outpatient prescription claims and excludes patients in hospice or with a cancer or sickle cell disease diagnosis.

So does the Standing Committee having any questions regarding the harmonization rationale that the developer has provided or any recommendations that you would like to make to the developer? Remember that recommendations do not change the endorsement vote in any way, but they'll be noted in the final report for future evaluations.

Member Sood: So just to clarify, this doesn't require a vote of any kind? It's just do we agree with the --

Ms. Funk: Exactly, yes.

Member Sood: Got it.

Ms. Funk: Do you have any concerns with the harmonization rationale or any recommendations, exactly.

Member Sood: Thank you.

Member Charbonneau: I'll just throw in that I think these are three very different measures.

Member Yealy: Yes, I agree, too. I think they're overlapping, but different and important in different ways.

Co-Chair Thraen: All right. Thank you, guys. Any other comments?

All right. Shall we move forward?

Ms. Funk: Okay. So that concludes our related and competing measures discussion.

And I'll hand it to Erin for public comment.

NQF Members and Public Comment

Ms. Buchanan: Thanks, Tammy. The line is now open for public comment. Please use the Raise Hand feature to join the queue. Feel free to drop your comment in the comment box or just unmute yourself, and please state your name and

organization.

And I'll pause there.

(Pause.)

Co-Chair Thraen: We exhausted everybody from the last conversation.

Ms. Buchanan: Yes.

Co-Chair Thraen: Thanks, Don. And I think Ed also has to get off.

Ms. Buchanan: I guess hearing no comments, Tammy, do you think we should move forward or give everyone a few more minutes?

Ms. Funk: No, there's nothing in the chat and I don't see hands raised. So we can move forward. Thanks, Erin.

Ms. Buchanan: Mm-hmm. Hannah, you're up.

Co-Chair Thraen: Hannah, we can't hear you. We can't hear you -- I'm so sorry -- at all, by the way.

Maybe somebody else can help Hannah with the activities and timelines?

Activities and Timelines

Ms. Buchanan: Yes, I can cover that. Sorry, Hannah.

So in terms of next steps, the CSAC review will take place on November 30th and December 1st. Our team will be sending out information when that comes around.

Following that, the appeals period will be open for 30 days, from December 7th to January 5th.

And the final report will be posted.

Next slide.

Co-Chair Thraen: Thanks, Theresa, for -- she had to leave.

Ms. Buchanan: So as always, if you have any questions, you can email the team at patientsafety@qualityforum.org or call us at 202-783-1300. Information can also be found on the project page, and, as a Committee, you have access to the SharePoint site.

Next slide, please. And now I will pass it back to Tammy for some closing remarks.

Closing Remarks

Ms. Funk: Thanks. Thanks, Erin, and thanks to everyone on the Committee and Iona and Ed for leading us through quite an afternoon. And thank you to all the developers also for joining this call and working hard on these measures.

I'm actually going to hand it to Matt quickly for an extra special goodbye.

Dr. Pickering: Extra special. So thank you, team.

I just wanted to remind the Standing Committee -- and thanks for kind of being on for a few more minutes -- that Ed and Iona have been serving as Co-Chairs of the Standing Committee for several years, and have seen various different measures and various different challenges, and working with various experts in this area to conduct this work. They have done so very steadfast and with diligence, and just have been very accommodating and flexible to all the changes that have been happening with NQF, whether it be our policies in endorsing criteria to staff, to different Standing Committee members, et cetera.

I tremendously, in my time here since January of 2020, have learned a tremendous amount from Ed and Iona. And I know Ed has probably popped off. But I personally, and as well as on behalf of the NQF

team, would like to thank them for their service. This is going to be their last measure evaluation meeting as Co-Chairs.

Co-Chair Thraen: Yay. I'm sorry.

(Laughter.)

Did I break your ear? I apologize.

Dr. Pickering: I wanted to thank them for their service. It's been just a tremendous partnership with them. And thank you.

And I would welcome anyone else in the chat or just to thank them as well.

They will be remaining on as Standing Committee members going into next year for just an additional few six months, through fall 2021, as our new Co-Chairs, Don and John, will be stepping in to take their seats.

But thank you so much, on behalf of myself and NQF to Ed and Iona for all of their hard work and their diligence and service to this great work that we do.

Co-Chair Thraen: Thanks, Matt. And as always, Matt and the NQF staff, they provide the content, expertise, the structure, the technology, the facilitation. We just show up. So thank you for that, and thank you, guys.

Member Sood: And I think Iona gets a special thank you for shepherding the 0500 measure twice now in the last two-three months.

(Laughter.)

So thank you, everybody.

Co-Chair Thraen: Thanks for that. I think that's a meeting, you guys, and I think we are actually ahead of schedule. So that's a new one as well.

Dr. Pickering: That's right.

Co-Chair Thraen: All right. Everybody have good time period until the next time we get to see each other.

Thank you very much.

(Whereupon, the above-entitled matter went off the record at 4:09 p.m.)