National Quality Forum
Appeals Board
Friday, April 29, 2022

The Appeals Board met via Video Teleconference, at 1:00 p.m. EDT, Lawrence Becker and Laurel Pickering, Co-Chairs, presiding

Present:

Lawrence Becker, Co-Chair
Laurel Pickering, MPH, Co-Chair
Ashrith Amarnath, MD, MS-SHCD, Covered California
Thomas Kottke, MD, MSPH, HealthPartners
David Shahian, MD, Harvard Medical School; Massachusetts General Hospital

NQF Staff:

Matthew Pickering, PharmD, Senior Director
Amol Batra, JD, General Counsel
Michael Divecchia, MBA, PMP, Senior Project Manager, Quality Measurement
Tricia Elliot, DHA, MBA, FNAHQ, Senior Managing Director
Elizabeth Flashner, MHA, Manager, Quality Measurement
Gabrielle Kyle-lion, MPH, Analyst
Anuvrat Laxsav, IT Specialist
Mary McCutcheon, MPP, Coordinator
Maura Walsh, Manager, Quality Measurement

Also Present:

John Bulger, DO, CSAC Vice Chair
Sara E. Cosgrove, MD, MS, Johns Hopkins Medicine
Melissa Danforth, CSAC Chair
Robert Dickerson, RRT, MSHSA, Mathematica Policy Research
Helen Dollar-maples, Centers for Medicare and Medicaid Services
Michael Klompas, MD, MPH, Brigham and Women's Hospital
Emanuel Rivers, MD, MPH, Henry Ford Hospital
Aisha T. Terry, MD, MPH, FACEP, American College of Emergency Physicians

Sean Townsend, MD, Sutter Health

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(1:02 p.m.)

Welcome and Review of Meeting Agenda and Objectives

Dr. Pickering: So, welcome, everyone. My name is Matt Pickering. I am a Senior Director here at NQF, working with the NQF Appeals Board team. I do want to thank everyone for their time and participation both today, but also leading up to this meeting.

So, really appreciate the appellant and the organizations that are in attendance today, as well as their representatives. I also want to really appreciate the developers, as well, for being on the call, and those representatives being present today. As well as our Appeals Board, those five members that are present today, and also our co-chairs for the Appeals Board, Larry and Laurel, for their time. And also our CSAC chairs who are present today, to answer any questions related to CSAC proceedings that may arise today.

So, thank you all very much for your time and attention to this issue, as we go through the appeal that has been received through 0500, which is the sepsis measure.

Just a few housekeeping items as you see on the screen here. It's this first slide in the deck.

So, we are using a Zoom platform. So, you have audio capabilities for those Appeals Board members, as well as those relevant stakeholders that I mentioned previously at the opening remarks, and video capabilities.

We kindly ask, if you are not speaking, to keep yourself on mute. And we kindly ask that you do

use the video feature when you are speaking, just so that folks can see you, and we can actually be a little bit more engaging in this virtual environment.

For those members of the public, you do not have video feature, and you are being muted. I will just note up front, and I'll reiterate this, is that when we get to the public comment period, we will then recognize you and unmute you, to be able to share any comments, if we are able to get to that public comment period.

We ask the public to refrain from using any chat. Again, we want to ensure that the proceedings move without any interruption. So, please from members of the public, please refrain from using any of the chat. Again, we will recognize you to speak your comments verbally, if we are able to get to that portion of the meeting.

And as far as the Appeals Board members, there is a chat feature for you. It's the host and panelist. You are welcome to use that chat, recognizing that everyone that is within the speaking roles today, are able to see that chat. But we will be sure to see it. We can recognize you through the chat. You can also use a raised hand as well, if you have any questions you'd like to raise your hand and be recognized. We'll try to do that with our Appeals Board members. But, again, you can easily just take yourself off mute, and ask some questions with the Appeals Board.

All right, so going to the next slide.

So, again, we are here today to review an appeal that's been received for NQF Measure 0500, which is the Sepsis Management Bundle Measure. This work is in support of our endorsement and maintenance contract with CMS. So, this work is under that contract, and we do appreciate all of

their support with these proceedings.

Next slide. So, again, welcome, everyone. I do want to give an opportunity for our Senior Managing Director and our Co-Chairs today to provide some welcoming remarks.

So, first I'll turn it over to Tricia Elliot, who's our Senior Managing Director, and then I'll turn to Laurel and Larry.

So, Tricia?

Ms. Elliot: Great, thanks so much, Matt. I'd like to take this opportunity to welcome everybody to today's Appeals Board meetings, as mentioned by Matt.

NQF's Appeal Board plays a vital role in the measurement development process. The five-member Appeals Board is responsible for adjudicating all submitted appeals regarding our measure development decisions. Any party may request an appeal of a CSAC decision, to endorse a measure, and the Appeals Board reviews all appeals submitted to NQF for consideration. NQF is committed to a fair and transparent process for endorsement, including this appeals process.

As mentioned, the measure being discussed today is Measure 0500, Severe Sepsis and Septic Shock Management Bundle. The measure was submitted as part of the Spring 2021 endorsement cycle.

The purpose of today's meeting, is for the Appeals Board to review and discuss the submitted appeal. The Appeals Board will hear from the appellant, the developer and steward, as well as members of the public, in order to adjudicate the appeal received.

I would like to take a moment to express our sincere appreciation and thanks, to our Appeals

Board members for their service and support of the National Quality Forum.

I'll now hand things over to Laurel for opening comments.

(Pause.)

Dr. Pickering: Oops, sorry, Laurel. It looks like you're on mute.

Co-Chair Pickering: I am. You think I've done enough of these to apologize. Thank you, Tricia. I wanted to talk a little bit about the process that we're going to go through here.

Each party is going to have up to three representatives, who can speak on their behalf. Each party will be given 7 minutes for their opening statements.

And, afterwards, I am going to ask the Appeals Board members if they have any clarifying questions to either the measure developers, the appellants, or NQF.

And, just as a reminder, those clarifying questions need to focus on two, on the merits of the appeal, which considers two major factors.

One, if procedural errors existed, that are reasonably likely to affect the outcome of the original endorsement decision, such as a failure of NQF to follow processes.

Second being, if there's new information or evidence that was unavailable at the time that CSAC made its endorsement decision, that is reasonably likely to affect the outcome of the original endorsement decision.

And, following the opening statements and the

clarifying questions, the Appeals Board moves to vote on whether the issues presented in the appeal meet one or both, of NQF's eligibility criteria that I just laid out. And that we will vote on each of those criterion separately.

So let me pause there, Matt, to see, see where we go next.

Dr. Pickering: No, thank you so much, Laurel. Exactly, and we will definitely cover this after some of these remarks.

The process that you laid out is correct for the first series of votes, which is, are the, does the appeal satisfy sufficient grounds to move forward for further discussion. And we will open that up in case there is a vote in favor of either one of those criteria as you laid it out.

And thank you so much, Laurel. And I'll also offer Larry, if you want to give some opening statements or remarks, as well?

Co-Chair Becker: Yes, thank you very much, Matt and team. Thanks for all the work. This is important work. We appreciate the appellant. We appreciate the work of the CSAC, and all the people who have spent time on this measure.

I just thought as a little bit of background, let the folks on the phone know, I spent 10 years on the Board, and various committees. Chaired various committees at NQF, and so I have some, some background in these proceedings and these matters. Turn it back to you, Matt.

Dr. Pickering: Thank you so much, Larry. And thank you again to your co-chairs to facilitate the meeting today.

We'll go to the next slide. Okay, thank you, Mary.

And so just the agenda of how this is going to go. First, we're going to do roll call and disclosures of interest with the Appeals Board members on the call. And then we will go over just a brief overview of the process again, and the measure under appeal.

We also then will have the appellant provide their opening statements, as well as the developer. And then, as Laurel had mentioned, there's an initial round of questioning. So, this will be a round robin approach to see if any of the Appeals Board members on the call have any questions.

And after that round robin to collect all those questions, Laurel will triage those questions accordingly, to one of the relevant stakeholders present today.

If the appeal moves forward based on a vote on either one of those grounds for an appeal as Laurel mentioned, we will focus our conversations on whichever, or both of those grounds, need further discussion.

And that is going to be the Appeals Board discussion any of the issues or questions further that they have. And those questions again, would be triaged accordingly to the relevant stakeholders.

We kindly ask that those stakeholders being developers, CSAC chairs, and appellant representatives, remain silent unless being recognized by one of our co-chairs for a question. So, please remain silent unless you are recognized for a question.

After all of that is done, there will be a round of public comments, and then once the public comments conclude, we will then do a final vote, to see if there is an agreement to uphold the CSAC

endorsement decision. From there, there will be just some next steps and then we will adjourn the call.

Again, we will get to public comment in that final vote, if the Appeals Board votes in favor of one or both of the grounds for the appeal.

Okay, next slide. So, I'm just going to do roll call and disclosures of interest here.

So, today we will combine introductions, as well as the disclosures of interest. And for the Appeals Board members on the call, you've received three disclosure of interest forms from us.

One is our annual disclosure of interest, and the other two are specific to the measure, as well as the appeal received today.

So, in those forms we ask you a number of questions about your professional activities. Today we'll ask you to verbally disclosure any information you provided on any of those forms, which you believe is relevant to the Appeals Board, and its charge.

We are especially interested in grants, research, or consulting, related to this Appeals Board work.

So just a few reminders. You sit on this group as an individual. You do not represent the interests of your employer, or anyone who may have nominated you to serve on the Appeals Board.

We are interested in your disclosures of both paid and unpaid activities, that are relevant to the work in front of you.

Finally, just because you disclosed does not mean that you have a conflict of interest. We do verbal disclosures in the spirit of openness and transparency.

Roll Call and Disclosures of Interest

Now we'll go around the virtual table here. I'll start with our co-chairs, and I'll call you by your name. So, please state your name, what organization you are with, and if you have anything to disclose.

If you do not have any disclosures, please just state that I have nothing to disclose, and that will keep us moving along.

If you experience trouble unmuting yourself, please raise your hand so that we can assist you with unmuting your line.

Okay, so I'm going to start at the top. So again, just state your name, organization you're representing, and then if you have anything to disclose.

So, Lawrence Becker?

Co-Chair Becker: Hi, I am Lawrence Becker. I'm actually retired, so I don't represent any organization, and I have no conflicts to disclose.

Dr. Pickering: Thank you. Laurel Pickering?

Co-Chair Pickering: I am Laurel Pickering. I work for Centivo, and I have nothing to disclose.

Dr. Pickering: Thank you. Ashrith Amarnath?

Member Amarnath: Hi. Ash Amarnath, Recovery California. Nothing to disclose.

Dr. Pickering: Thank you. And just calling names as they're on the slide, just for transparency here. William Golden?

(No response.)

Dr. Pickering: William Golden was not able to attend today.

And David Shahian?

Dr. Shahian: Dave Shahian. I am employed by Mass General. In my NQF activities, I have represented Society of Thoracic Surgeons, and I have no disclosures

Dr. Pickering: Great, thank you. And we do have two alternates. These alternates are here to serve if there are any potential conflicts of interest, from the Appeals Board members. But they also are here to step in, in case an Appeals Board member is not able to attend the call today.

So, as we said, William Golden is not able to attend. So, Thomas Kottke?

Member Kottke: Thomas Kottke. I'm employed by HealthPartners in Minnesota. I have nothing to disclose.

Dr. Pickering: Thank you, Tom. And Kristine Martin Anderson?

(No response.)

Dr. Pickering: And Kristine told us she was not able to attend today either. So, our Appeals Board today will be Thomas Kottke, Larry Becker, Laurel Pickering, Dave Shahian, and Ashrith Amarnath. And again, thank you all very much for your time today.

I will also mention as well, if those members of the public you may have noticed, my last name is the same as one of our co-chairs. We are not related in any way, so I just wanting to make sure that that is aware for folks, that there's no relation that Laurel and I do have.

Going to the next slide.

Overview of Appeals Board Meeting Process and the Measure Under Appeal Review

So again, the objective for today, is that the Appeals Board will review and discuss the submitted appeal, and to hear from the appellant and developer, and the members of the public, to adjudicate the appeal received, for Measure NQF 0500 Severe Sepsis and Septic Shock, the Management Bundle.

Next slide, please.

Okay, just a quick overview. This was just repeating what we heard in orientation meeting, just so everybody's on the same page.

Going to the next slide. Thank you.

So, the Appeals Board can render the following decisions for today. So, you can dismiss the appeal because it does not meet the sufficient grounds, as Laurel had mentioned previously.

If the Appeals Board does feel that there are sufficient grounds on one or both of those criteria, then the decision becomes to uphold or overturn the CSAC endorsement decision, for this measure.

All votes will require a 51 percent majority, and there's no consensus not reached, and there are no tie breakers.

All decisions made by the Appeals Board are final, and any actions and decisions regarding the appeal, are then made publicly available within the technical reports, and respective project pages on the NQF website.

Next slide.

The meeting procedure will flow as staff, as we are

doing now, opening up the meeting, doing the disclosures of interest, we're providing this overview and then we will allow, we'll turn it over to our co-chairs who will then offer the appellant to give opening statements, as well as the developer.

As Laurel mentioned, each party has three representatives to speak on their behalf today, and each party during their opening statements, will have 7 minutes.

So, I will be monitoring that, and at one minute, I will say you have one minute remaining, just so that you are aware that the time is coming to an end.

And we will kindly as you to refrain from going over that 7 minutes. And, in case you do so, we will just interject.

I'm not trying to be rude, so I do apologize if I interject at one minute right in the middle of your sentence, but I'm just trying to let you know you have one minute remaining.

Following the opening statements, the Appeals Board will have an opportunity to ask any clarifying questions.

So, our co-chair Laurel, will go around the table just to see if you have any questions, and we will document those questions, and then Laurel will triage those accordingly to either NQF, the CSAC chairs, the Appeals Board, excuse me, the developer, or the appellant organization.

Going to the next slide.

After all of the questions have been addressed, the Appeals Board will then move to its first vote, voting on each one of those criteria that you see listed separately.

So, you first will vote to determine if you think that the appeal presented is sufficient grounds that meets procedural errors, or whether there's new evidence that was unavailable at the time of CSAC endorsement decision.

So, if either one of those are in favor, the Appeals Board will continue its discussion on one or both of those issues, depending on which, which one moves forward.

If both of those are no, the Appeals Board feels that the appeal does not meet these criteria, there's not sufficient grounds, then the endorsement decision will be maintained for the measure. There will be no public comment and the meeting will adjourn.

Next slide.

Again, if there are sufficient grounds on one or both of those criteria, the Appeals Board will then open up discussion to focus in on one or both of those criteria.

There may be questions again that are triaged accordingly to the relevant stakeholders here today. And then, once all those questions are done, we will have the opportunity for the public to have any comments.

Each member of the public will have two minutes to give their comments. And, similar as the opening statements, NQF, myself, will let you know when you have 30 seconds remaining.

When you have 30 seconds remaining, and then again we don't mean to interject and be rude, but we just want to make sure that we get everyone in within that, that timeframe.

The appellant and developer, and CSAC chairs, and the Appeals Board, are not to respond to each

individual commenter individually.

Rather that you just hear the comments, and then after all of the comments have been gathered, there will be one last opportunity for round robin to see if there is any discussion or final questions, before we move to a final vote.

And that final vote is whether or not you agree to uphold the CSAC endorsement decision, for this measure.

The only way that the measure will be overturned, is if 51 percent or more of the Appeals Board members vote no to overturn the measure. The measure will be, that way the endorsement decision will be overturned.

Any other option will be maintain endorsement.

Next slide.

So now we want to do a voting test. So, this is for our Appeals Board members. You should have received a Poll Everywhere link in an email communication before this meeting.

It is a Poll Everywhere link only for our Appeals Board members. We just want to make sure everybody's got that up and running.

So, if you could find that Poll Everywhere link, open it up, and we will do a voting test. And I will turn it over to Gabby to run the voting test.

So, if you do not have that link, please let us know and we can send that again to you.

Gabby?

Ms. Kyle-Lion: Okay, can you all see this screen?

Dr. Pickering: Yes.

Ms. Kyle-Lion: Okay, as Matt stated, only Appeals Board members should be voting on this question.

So, voting is now open on our test vote, which is does pineapple belong on pizza? Your options are A for yes, or B for no.

(Pause.)

Dr. Pickering: Missing one vote.

(Pause.)

Dr. Pickering: Is anyone having trouble with the Poll Everywhere?

Dr. Shahian: Yes, could you resend the link to me? I'm not getting that.

Dr. Pickering: Is that Dr. Shahian? Yes.

Dr. Shahian: Yes.

Dr. Pickering: Yes, we can. So, we'll have the staff resend the link to you, Dr. Shahian.

Dr. Shahian: Thanks, sorry.

Dr. Pickering: No worries.

(Pause.)

Dr. Pickering: So, I think, for the interest of time, let's go ahead and we'll have the staff resend you that link, Dr. Shahian.

Dr. Shahian: Right.

Dr. Pickering: We'll go ahead and keep moving forward, just to make sure we kind of get to what we want to talk about today.

So, go ahead, Gabby, let's close it and see where we stand here.

Ms. Kyle-Lion: All right, voting is now closed on our test vote. Four, everyone said yes, so very interesting.

All right, I'll pass it back to you.

Dr. Pickering: Oh, wow. Okay, that's probably the most exciting question we have during the meeting.

Thanks, Gabby, very much. And Mary, would you mind re-sharing? Thank you.

And we'll go to the next slide. Okay, so now I'm just going to tee up the measure, and some of the history leading up to the day, before we turn it over to our co-chair Laurel, and the opening statements.

Okay, so our measure here today again is NQF 0500 the Severe Sepsis and Septic Shock Management Bundle Measure. The measure steward and developer, is Henry Ford Hospital.

This is a maintenance measure, so again, maintenance measures are those measures that have received endorsement from NQF, that are coming back through for reevaluation of that endorsement.

The brief description of this measure, it focuses on adult 18 years and older, who with a diagnosis of severe, severe sepsis or septic shock.

It assesses measurement of lactate, obtaining blood cultures, administering broad spectrum antibiotics, blood -- fluid resuscitation, vasopressor administrative, reassessment of volume status, and tissue perfusion, and repeat lactate measurements.

So, those are the components of this measure. So, this measure is a bundle. It's a composite measure, with those various varied components as you see listed there.

Now as reflected in the data elements and their definitions, the first re-intervention should occur within three hours of presentation of severe sepsis, while the remaining interventions are expected to occur within six hours of presentation of septic shock.

Next slide, please. Okay, so a little bit of a history of this measure. It was originally endorsed in 2008. It did come back through maintenance endorsement in 2013, in which it was, it did receive an endorsement decision.

However, an appeal was also received in 2013 based on the CSAC decision. That CSAC decision was upheld by the Appeals Board at that time, or excuse me, the NQF Board at that time.

And the appellant concerns for that appeal, was that the resuscitation must be guided by a central venous catheter, and that patients are identified retrospectively by ICD-9, discharge diagnoses, and the time identified as time zero for patients that developed sepsis while in the emergency department, or hospital.

So, the endorsement decision was upheld, and the NQF Board of Directors added that with the, that the hospital transfers are excluded.

To look at the hospital transfers and see if they're excluded based on recommended, and recommended an ad hoc review, when the evidence came to light around these issues.

So, an ad hoc review did take place in 2015 by the Patient Safety Standing Committee. And the Patient Safety Standing Committee expressed concerns about the requirements for invasive monitoring of the central venous pressure, and oxygen levels through the central lines.

And after discussion and negotiations with the measure developer, and also some process trial investigators, and also specialty societies, there was a compromise reached on the evidence, and replacement of one of those elements for the measure. And the endorsement was upheld with the revised measure.

The measure did come back for maintenance endorsement in 2017, and an endorsement decision was upheld by the CSAC.

And then of late, of recently back in 2021, there was a maintenance endorsement for the Patient Safety Standing Committee.

And the CSAC did uphold the Patient Safety Standing Committee recommendation for endorsement, and the appeal was, and thus, we have the appeal received today, and which we are convening to discuss on our proceedings today.

Next slide. Okay, I'll turn it over to Laurel, who will then facilitate our opening statements, and our first round of questions with the Appeals Board.

So Laurel, I'll turn it over to you.

Co-Chair Pickering: Great, thanks, Matt. I think I jumped the gun a little bit earlier with a review of the process. But just to remind everyone, each party can have three representatives speak on their behalf.

Each get 7 minutes and after the opening statements, I'm going to go around and ask the Appeals Board members if they have clarifying questions.

So, why don't we jump in to the beginning statement, the appellant's statement, and I think Dr. Klompas, you're going to be, you're going to

start?

Appellant and Developer Opening Statements

Dr. Michael Klompas

Dr. Klompas: Yes, that's correct. Thank you very much. My name is Dr. Michael Klompas, and I'm joined here today by Dr. Sara Cosgrove, and Dr. Aisha Terry.

So, I'm an infectious disease physician at Brigham and Women's Hospital, in Boston. I'm also the head of the Infection Control Department Group over there, and a co-author on the most recent version of the Surviving Sepsis Campaign guidelines.

I'm here speaking on behalf of six professional organizations, the Infectious Disease Society of America, Society for Healthcare Epidemiology of America, the Society of Infectious Disease Pharmacists, the Society of Hospital Medicine, the American College of Emergency Physicians, and the Pediatric Infectious Disease Society.

And the reason we are here is because we all care deeply about sepsis. Our shared deeply held mission is to improve sepsis care, and sepsis outcomes.

And, as front-line physicians and pharmacists, we have all personally cared for many, many patients with sepsis, being witness to the devastating toll it can exert on patients and their families. And have repeatedly seen how excellent care can, and does, save lives.

However, we have significant concerns with the current SEP-1 measure, including number one, the process by which it was re-endorsed; and, number two, important new data that has emerged regarding its performance under real world conditions, that cast doubt about the measure's

capacity to improve patient outcomes, our shared goal.

Our concerns with regard to the re-endorsement process. So, two key members of the NQF panel with deep content expertise in sepsis, were recused from the meeting due to perceived conflict of interest.

The current conflicts of interest, however, were nothing more than a deep interest in sepsis, and having a record of having published technical critiques of SEP-1, including recommendations for possible modifications.

Now, these are not conflicts in our opinion, but rather bona fides that demonstrate these members' high level interest and expertise, in sepsis and SEP-1.

The exclusion of these key members for these reasons was particularly disturbing, because the measure stewards who arguably have identical conflicts by virtue of their investment in the measure, were allowed to participate. And, by all accounts, it's so vigorously, including repeatedly interrupting and contradicting speakers, restraining the realm of conversation.

Our second issue, is regarding important new data that has emerged, since SEP-1 was last evaluated by the Patient Safety Committee. In the particular, what we now have based upon publications over the past year, is real world experience with SEP-1 implementation.

These are important because we no longer have to speculate about the potential impact of SEP-1 based on incongruent bundles, or observational studies which are at very high risk of bias. And that we can now directly evaluate what has the impact of SEP-1

been in real world practice, on patient outcomes.

And there are three key studies, all published in high profile journals. They're published in Clinical Infectious Diseases, the Annals of Internal Medicine, and JAMA Network Open. These are all rigorous time series analyses, of the impact of SEP-1 on processes of care and outcome.

The first was set in 11 hospitals associated with the University of Pittsburgh Medical Center.

The second was an analysis of 114 hospitals distributed countrywide, using a common electronic medical records system.

The third was 26 hospitals spread across seven states, in a study coordinated by Duke University.

Now, all these studies looked at monthly or quarterly rates of SEP-1 process measures and outcomes, and assessed for significant changes coincident with the deployment of SEP-1. Did the release of SEP-1 lead to a meaningful change in these processes, or in patient outcomes?

And these studies were remarkably congruent in their findings. All three studies documented that in real world practice, SEP-1 was associated with significant increases in one or more of lactate checking, and broad spectrum antibody utilization, but no change in meaningful patient outcomes.

Depending on the study, there was either no change in hospital mortality, that was the University of Pittsburgh study. No change in the combined outcome of hospital death or discharge to hospice. That was the national study.

Or in fact, in the study coordinated by Duke University, there was an increase in the relative mortality trend following the implementation of SEP-

1.

The studies that showed no change at all were not subtle. This was not a matter of there was a trend in a positive direction that denotes this. There was no change whatsoever. And, again, in the third study, a suggestion even that mortality rates start to increase after release of the study.

Now, the measure stewards will no doubt point to a study they published in CHEST, comparing outcomes with SEP-1 bundle-compliant versus non-compliant patients. We believe, however, this analysis was deeply flawed for the following reasons. There was an inherent bias in any kind of observational study like this, in favor of less sick patients. Patients without shock.

And the reason is because the SEP-1 requires less work, less process of care, for a patient without shock.

That means it's easier for a patient without shock, to pass the measure. However, patients without shock also have lower mortality rates.

In addition, there are other factors that affect whether or not patients pass SEP-1. Clinical care is not random, but is highly influenced by patients presenting syndromes, they come in with these severe illness, et cetera.

The investigators tried to control for these factors by propensity matching patients across the bundle, to those who's not.

But despite their best attempts to do so, and they did try hard, there was still considerable differences between those who passed versus fail SEP-1.

Those who failed were more likely to have persistent hypertension, 7 percent versus 4 percent;

high lactates 17 percent versus 9 percent; and septic shock, 25 percent versus 15 percent.

The investigators did include inside of their study, one --

(Simultaneous speaking.)

Dr. Pickering: Sorry, Dr. Klompas, just one minute. Sorry, Dr. Klompas, go ahead. One minute.

Dr. Klompas: Thank you. They did include a hierarchical analysis looking at compliance just among those with septic shock. In other words, a more apples-to-apples comparison. And in that analysis, there was no difference in mortality rates for SEP-1 compliance versus non-compliant care. In fact, mortality rates were numerically higher among those who passed the measure.

So, in sum, the process that led to SEP-1's re-endorsement was marked by procedural irregularities that excluded input from panel members with deep contact expertise.

In addition, critical new data has emerged in the past year that were not considered at the time of re-endorsement.

These include three high quality time series analyses, including data from over 150 hospitals, that all found that this very labor intensive measure has increased antibody utilization and lactate checking, but has not saved lives.

We have a shared goal of improving sepsis care and outcomes, and the consensus of six professional societies is that SEP-1 has not achieved this goal.

It is therefore, imperative for us to modify this measure, if we are to realize our shared goal of saving more lives.

Thank you.

Co-Chair Pickering: Thank you, Dr. Klompas.

We are now going to have the opportunity to hear from the developer, an opening statement, and Dr. Townsend, I'd like to turn it over to you now.

Dr. Sean Townsend

Dr. Townsend: Thank you very much for the opportunity to address the Appeals Board today.

I'd like to thank the NQF staff for preparing us to present. And I'd also wish to express my gratitude to the Appeals Board members for generously donating their time today, to this matter.

It's our understanding that the Appeals Board has a narrow focus, considering just two questions.

The first is, did procedural errors occur, such as failure to follow NQF's consensus development process.

And the second is, is there new evidence that was unavailable at the time CSAC made its decision for endorsement, that is now available?

I would like to say that as regards the remarks that Dr. Klompas just made, the three studies that he just mentioned, did not appear in the appeal letter.

They are therefore, probably not appropriately discussed in this forum, because the contents of the appeal letter should be the topic of this discussion.

I'll move on to the first question regarding procedural errors. The appellants have brought up two concerns.

First, the appellants are concerned that the recusal of two Patient Safety Committee members, may

have itself, been a procedural error.

The committee members were recused for two reasons. First, both published articles critical of the sufficiency of the evidence supporting NQF 0500.

One of the measure evaluation criteria is the sufficiency of the evidence. These opinions conflicted then, with their duties to serve as impartial judges. And they could not render an impartial decision.

Secondly, both committee members engaged in work with the measure developers. The NQF policy requires that if committee members have done so, that they must be recused.

I would simply mention that these were, recusal occurred on behalf of the members themselves and NQF. The measure developers had nothing to do with instituting the recusals.

The recusals followed procedure. They were not violations of procedure. There is a policy that governs this.

I'd like to turn now to the appellant's second procedural concern, that the developer's zealous defense of the measure somehow interrupted the work of the committee.

First of all, there are no published rules of orders outlining parliamentary procedures at NQF meetings. I wish there were.

If there were no published rules, all the lapses that may have occurred, are subjective. For example, if there's no means to signal you'd like to be heard, what should you do?

Is interjecting to counter misinformation a lapse of decorum? These types of questions and dilemmas,

faced the developers as they were listening to the information bandied about at committee.

Second, NQF rules state that to be successful, an appeal predicated upon a procedural error, must have harmed a formal NQF process. So, for example, failure to follow the consensus development process must have occurred.

While passions were on display at these meetings, there is no allegation that NQF core processes were derailed.

In fact, all NQF consensus development processes were observed despite any tensions. This conclusion is consistent with the remarks of the Patient Safety Committee chair, and the CSAC leaders in the CSAC meeting summary.

For these reasons, the appellant's request for consideration of an appeal on procedural grounds, should be dismissed.

I'd like to turn our attention to the appellant's second ground for appeal. That new evidence has emerged that was unavailable at the time the CSAC made its decision.

The reported new evidence that concerns the appellants, is the publication of the 2021 Sepsis Campaign guidelines. The three studies that were mentioned, did not appear in their letter.

These guidelines were electronically published the first week in October of 2021. They were available at the time of the Patient Safety Committee meeting on October 13, 2021. And when CSAC met on December 1, 2021.

That timing in and of itself, satisfies the NQF criteria to dismiss this appeal. The standard is whether the evidence was available. It need not actually have

been considered.

As such, we move for a dismissal because the evidence is not new, and was available at the specified time.

Although we must demonstrate only that the evidence was available, the meeting minutes reflect that there, in fact, was a vigorous discussion of the guidelines, and the sufficiency of the evidence.

The committee even voted on the topic, deciding not to reopen the evidence criterion after this discussion was held.

Let's pause for an intellectual exercise for a moment. Let's suppose the Appeals Board chose to remove the endorsement, due to failure to consider the '21 Sepsis Campaign guidelines.

The decision to remove the endorsement after the experts on the Patient Safety Committee were given the option to revisit the sufficiency of the evidence, in light of the new guidelines, and voted that option down, would suggest that the Appeals Board lacked confidence in the Patient Safety Committee's experts.

For all we know, the voting majority was familiar with the guidelines. Experts should be lauded for their content expertise. We should not assume that they did not know what they were doing when they voted.

I wish to raise two more points from our appeal reply. First, NQF 500 meets NQF evidence criteria for endorsement on antibiotic administration.

That is, NQF defines moderate quality evidence and two to four observational trials, with control for confounders. This NQF standard is unique from grade standard.

Second, NQF 0500 meets grade criteria for endorsement of a performance measure. Grade relies on the strength of the recommendation, not the quality of the evidence, when it comes to endorsing performance measures.

The strength of the recommendation was strong. We proved this in our appeal reply. This is a critical point, and we do so with citation. These are all independent reasons the appeal on the new evidence criterion should be dismissed.

Finally, I will briefly say that with regard to the three studies Dr. Klompas represented, they did not assess compliance with the measure.

Your before and after designs that looked at what happened after the measure was introduced on a national scale in 2015. However, the performance gap that occurs, is a key part of the consensus development process.

If there was full compliance with the measure, then we would not need to absolutely assess the performance gap. By looking at compliance as the criterion to whether the --

(Simultaneous speaking.)

Dr. Pickering: Sorry, Dr. Townsend, sorry, just one minute. Sorry, go ahead.

Dr. Townsend: By looking at compliance, we are able to assess whether or not there is a mortality reduction in when you comply with the measure. These studies did not assess compliance, and they are defective in that sense.

I wish I could conclude my remarks at this point. Unfortunately, I have concerning news to share with the Appeals Board. I do not share this news lightly, or with any particular satisfaction.

In the course of doing this work, I came across a concern that it was surprising that somehow or another, the evidence was downgraded to low quality, from moderate quality, in the 2021 guidelines.

This surprised me because in the previous three iterations of the guidelines, it had always been graded as moderate quality.

I, therefore, requested the evidence tables from the infection summary, to understand how the evidence was ranked.

It turns out that three major studies that occurred after 2016, were not included in the evidence tables.

The evidence tables in the '21 --

Dr. Pickering: Sorry, Dr. Townsend --

Dr. Townsend: -- infectious guidelines are therefore, deficient.

Dr. Pickering: We are at 7 minutes, Dr. Townsend, I apologize. We'll have to cut it there. I do apologize.

Dr. Townsend: That's fine.

Dr. Pickering: There may be some other opportunities to provide more of those responses with the Q&A sessions from the Appeals Board. I do apologize with that.

Dr. Townsend: That's quite all right; thank you very much.

Dr. Pickering: Thank you very much, and thank you, Dr. Klompas, as well.

Laurel, I'll turn it back to you and see if we can go around the table for any, any questions from the

Appeals Board.

Questions

Co-Chair Pickering: Yes, so as now's an opportunity for the Board to ask specific questions, based on the opening statements. And I'm going to call you each out individually, to ask if you have questions.

David, Dr. Shahian, I'm going to start with you. Do you have any clarifying questions --

Dr. Shahian: Yes, I do.

Co-Chair Pickering: For the appellant or the -- yes.

Dr. Shahian: I do. I'd like to ask Dr. Klompas about the statement by the developer just now, that the three new studies A, were not cited when they were, in fact, available. Is that accurate?

And, B, were they, in fact, before after studies, but not studies which address the issue of whether compliance is associated with better outcomes.

Dr. Klompas: Okay, good, thank you.

Dr. Pickering: Sorry, sorry, Dr. Klompas. We, if we could just kind of finish some of the going around the table, and then we'll come back with those questions to, to the relevant stakeholders. I apologize about that, Dr. Klompas.

So, Dr. Shahian, did you have any other questions?

Dr. Shahian: No. I think that'll do it.

Dr. Pickering: Sorry, Laurel, go right ahead.

Co-Chair Pickering: Okay, so why don't we go to Ashrith. Do you have any clarifying questions?

Member Amarnath: Thanks, Laurel. No, I think just

adding to Dr. Shahian's question on the three studies mentioned by Dr. Klompas, if they were published and available before the CSAC meeting.

Co-Chair Pickering: Larry, any from you?

Co-Chair Becker: I have the same question that Ashrith had. I wanted the dates of those three studies that Dr. Klompas mentioned.

Co-Chair Pickering: Great. Tom? Do you have any questions?

Member Kottke: Yes, Dr. Shahian's other question covered my questions. That is, about whether compliance with the measurements reported.

Co-Chair Pickering: Okay. So, I think we've gotten all the Appeals Board members' clarifying questions.

Matt, should I turn it to Dr. Klompas to answer about the --

Dr. Pickering: Yes.

Co-Chair Pickering: -- studies, which is also I think the main issue here, and my question as well.

Dr. Pickering: Okay, great. I was going to say Laurel, do you have a question but it seems like that's the question, okay.

So, yes, Dr. Klompas?

Dr. Klompas: Okay, the, so the three studies, there's the UPMC study from Annals of Internal Medicine. There's the Re-study from JAMA Network Open, and there's the Anderson study from Clinical Infectious Diseases.

My recollection is that the letter did include reference to the UPMC study, the one that was published in Annals of Internal Medicine.

In terms of the exact dates of the studies, I don't want to misrepresent anything so if you tell me the exact date of the meeting, I will look at the dates in which those papers were published, and we'll go here.

I have it open in front of me so I can do that right now. Do you have the date of the CSAC meeting?

Dr. Pickering: Sorry, I'm also just pulling that up. That is, that meeting which took place in December, my apologies, and can you all hear me?

Co-Chair Pickering: Yes.

Dr. Pickering: Okay, great.

Right, so that was a two-day meeting, so the meeting occurred on November 30 and December 1, 2021.

Dr. Klompas: Okay.

Dr. Pickering: So, that was the CSAC, which is the Consensus Standards Approval Committee.

Dr. Klompas: Okay. So, the Barbash study was published in April of 2021, that certainly was available.

The Anderson study, which is the one from Duke, was published online on 5 November 2021. So, that was available.

The Re-study was published, find the date, December the 20th, 2021. That one was not available.

So, the first two were, the third was not.

Dr. Shahian: Matt, I wonder if I could ask a clarifying question, before you move on to the second point. Would that be acceptable?

Dr. Pickering: Yes, yes. If you have a clarifying question, Dr. Shahian, go right ahead.

Dr. Shahian: Clarifying question has to do with the definition of available.

By available, do you we mean somewhere this information was published, or publicly available?

Or, do we mean that it was actually available to the people that were considering the measure endorsement at that time?

It's really, it's an important distinction, I think.

Dr. Pickering: So in this case, available would be for the purposes of an endorsement decision. So, being available for consideration.

Dr. Shahian: So, if a, an article was published in a journal but nobody had found it, or nobody had mentioned it, and it was not available to the people that were considering endorsement, then that would be considered not available, or available?

Dr. Pickering: So, it would be, if the article was available and it was not considered by the endorsement decision body, then it would be unavailable.

Dr. Shahian: Thank you.

Dr. Klompas: Okay, and then I have before me a copy of the ACEP letter, which does directly refer to the UPMC paper. So, that's confirmed.

And then, with regard to these papers, did these papers come in a crisis of care? So most probably the UPMC paper, the one that was available, did. Reported, in particular, on changes on lactate checking over time, antimicrobial utilization, and use of fluids.

So, again, the report was substantial increase in lactate checking and broad spectrum antibody utilization, but no change in hospital deaths.

Co-Chair Pickering: Larry, do you have a?

Co-Chair Becker: Yes.

Co-Chair Pickering: Okay.

Co-Chair Becker: I just wondered if the developer, you know, focusing on that last paper, UPMC, whether the developer had any comments about its content and impact?

Dr. Townsend: Thank you very much.

The UPMC paper is of interest, but there's a confusion here. The Appeals Board, the letter of appeal has to state the grounds for the appeal.

And the letter of appeal doesn't include reference to any of these three studies. It referenced only the 2021 Surviving Sepsis Campaign guidelines, as being the new evidence.

So, we've now entered a space where we're talking about three papers that weren't in the letter of appeal.

So, I would believe it's not proper that we're discussing these. However, I'll answer your question directly.

The UPMC paper, which was available and discussed, in the course of the Patient Safety Committee Meeting, had a mortality rate of 4.7 percent per sepsis patients. That's extraordinarily low.

And the mortality rate for a sepsis patients is always, for your sepsis and beyond, is greater than

20 percent, typically speaking. For most patients; for most studies.

So, there's something unusual about this paper and the way they selected the patients. And they didn't represent actual SEP-1 patients, they were generated and selected by computer algorithm.

And so and my remark is that this paper studied some patients, but not your average sepsis patient.

And it certainly didn't assess compliance. Instead, it assessed what happened before SEP-1 was launched, compared to afterwards on a national scale.

But it doesn't tell you how the patients who fared well with the compliant, rather were compliant with the measure, fared.

It only tells you that if compliance was low, that you can't detect a change in the national scale.

I hope that's helpful.

Co-Chair Becker: Thank you very much.

Dr. Pickering: And I'll just interject as well. I will mention that we, the Appeals Board should focus their review and consideration of what has been submitted, in the appeal letter.

So, any additional new information that was not submitted in the appeal letter, should, should not be considered just because it's not been, what has been stated up front in the appeal letter.

So, the appeal letter is what should be focused on for the purposes of the meeting today.

Co-Chair Pickering: Are there any other clarifying questions for the developer, or the appellant?

Dr. Shahian: I think question more for the chairs and for Matt. Matt, regarding your last statement, I just want to be crystal clear.

You're saying if something was not in the appeal letter, then we should not be considering that, is that correct?

Dr. Pickering: That's correct.

So, the appeal letter, what is in question is the appeal itself. And so whatever the appellant organization has proffered within the appeal letter, is what the Appeals Board is to consider, and determine whether or not there's sufficient grounds for an appeal.

Any new information that's not been provided outside of that, should not be considered as part of that decisionmaking.

The decision is really based on the appeal received, as that is following our process. And what is argued as either errors or new evidence that has been presented.

And that should be reflected in the appeal letter. That is what is in question for the meeting today.

Initial Appeals Board Discussion and Vote

Co-Chair Pickering: If there are no other clarifying questions, I'm going to move for the vote.

And, hearing none, okay, I think, Laurel, we'll move to our first vote, and I'll turn it over to Gabby.

Ms. Kyle-Lion: Give me one moment while I pull up my screen.

Can everyone see this?

Co-Chair Becker: No.

Co-Chair Pickering: Yes, I can see it.

Dr. Pickering: I can see the, Larry, was that you? Okay.

Co-Chair Becker: Yes, all right now I came up. I, you know, I refreshed.

Ms. Kyle-Lion: Okay, perfect.

So voting is now open on the first eligibility criterion, which asks, based on the appeal, were there procedural errors reasonably likely to affect the outcome of the original endorsement decision?

Your options are A for yes; or, B for no. And I believe we're looking for five votes here.

Dr. Pickering: And before we close it, I just want to confirm. Dr. Shahian, you've received the link and you're able to vote?

Dr. Shahian: Yes.

Dr. Pickering: Great. It looks like we have five. Sorry, Gabby, go ahead.

Ms. Kyle-Lion: Yes, no problem.

Okay, I see five votes, so voting is now closed on the first eligibility criterion.

There were zero votes for yes, and five votes for no. Therefore, the Appeals Board does not agree that there were procedural errors, that were reasonably likely to affect the outcome of the original endorsement decision.

Dr. Pickering: Okay, thanks, Gabby.

And we'll go to the next vote.

Ms. Kyle-Lion: One moment while I get that pulled

up, everyone.

(Pause.)

Appeals Board Final Discussions and Vote

Ms. Kyle-Lion: Okay. Voting is now open on the second eligibility criterion, which asks based on the appeal, is there new information or evidence, which was unavailable at the time the CSAC made its endorsement decision, that is reasonably likely to affect the outcome of the original endorsement decision?

Your options are A for yes; or, B for no. And again, we're looking for five votes here.

(Pause.)

Ms. Kyle-Lion: Okay, I'm seeing five. Voting is now closed on the second eligibility criterion.

There were zero votes for yes, and five votes for no. Therefore, the Appeals Board does not agree that there is new information or evidence, that was unavailable at the time the CSAC made its endorsement decision, is reasonably likely to affect the outcome of its original endorsement decision.

I'll pass it back to you, Matt.

Next Steps

Dr. Pickering: Okay.

Thank you, Gabby, so much.

If I can ask Mary, if you could pull up the next steps slides, Mary, we'll just talk through that.

So, for all of those on the call, just a reminder that as the Appeals Board has voted that neither one of the grounds meet, or the criteria for an appeal,

there will not be any further discussion of the appeal. The endorsement decision will stand.

And we will not have any public comment, and we will adjourn the call today. But I did want to just touch on some next steps briefly, just so everyone is aware.

Going to the next slide. Thanks, Mary.

So, as a result, we will reflect the decisions and also the discussions today, within the Patient Safety Spring 2021 report, which will be posted online after the meeting in a few weeks, as we go through the review process for that.

I will also be posting a meeting summary of the Appeals Board meeting today, that will also be posted on the Appeals Board page, along with the final decision and votes.

And if you have any questions, you can please contact us at the NQF's Appeals team, as you can see the email, appeals@qualityforum.org.

Going to the next slide. Okay, I do want to again, thank everyone for all of their time leading up to the meeting today.

So, thank you very much to the appellant and the appellant organizations, as well as the developer.

Thank you very much to our CSAC chairs, for being in attendance today in case there was any questions for the CSAC. And again, to our Appeals Board. Thank you very much for your time and careful consideration of the appeal, that has been submitted today.

Thank you very much to Laurel and Larry, for your leadership and guidance, as we worked for the proceedings.

And I also want to very much thank members of the public. I know there was a lot in attendance today to see the outcome of this measure. Thank you for your preparation, as you were probably ready to get some comments depending on what happened with the first tiers of votes. But thank you all very much.

And thank you very much to the NQF team for all of their work today.

Adjourn

With that, we'll adjourn the call. Again, if you have any question, please feel free to reach out to the Appeals Board page. An appeals summary will be posted in a few weeks, and the final decision votes will also be reflected online in the next couple days.

Thank you all very much and have a great weekend.

(Whereupon, the above-entitled matter went off the record at 1:58 p.m.)