NATIONAL QUALITY FORUM

Moderator: Infectious Disease
June 1, 2017
1:00 p.m. ET

Operator: This is Conference #92656553.

Welcome, everyone. The webcast is about to begin. Please note today's call is being recorded. Please stand by.

Christy Skipper: Good afternoon, and welcome to the Infectious Disease Post-Comment Call to discuss public and member comments. The purpose of our call today is to review and discuss comments received during the public and member commenting period. And we also want to hear from the committee your input on responses to those comments.

My name is Christy Skipper, Project Manager for the project. And I would like to turn it to my teammates to introduce themselves.

Mauricio Menendez: Hi, everyone. Mauricio Menendez, Project Analyst.

Melissa Mariñelarena: Good afternoon, everyone. This is Melissa Mariñelarena, Senior Director.

Elisa Munthali: And Elisa Munthali, Vice President for Quality Measurement.

Christy Skipper: Thank you. Thank you, all. Before we turn to call roll, I just want to turn it over to our co-chairs to see if they have any opening remarks or comments. If not, we will jump into roll call.

Woody Eisenberg: Hi. This is Woody Eisenberg. I am …

(Off-Mic)

Woody Eisenberg: … by the specificity of some of the comments that have come in, particularly around the bundles for sepsis. So, I will be interested to hear whether committee members have any further comments about those as well as any of the other measures that we will be hearing comments about. So, thank you.

Adam Thompson: It's Adam. I'd just say good afternoon and echo what Woody said and looking forward to the conversations.

Christy Skipper: OK. Thank you. So, now, we will call roll.

Mauricio Menendez: Please say here when you hear your name. Jeffrey Lewis?

Jeffrey Lewis: Here.

Mauricio Menendez: Melinda Neuhauser?

Melinda Neuhauser: Here.

Mauricio Menendez: Rocco Orlando?

Rocco Orlando: Here.

Mauricio Menendez: Jamie Roney?

Jamie Roney: Here.

Mauricio Menendez: Pranavi Sreeramoju?

Pranavi Sreeramoju: Yes.

Mauricio Menendez: Woody?

Woody Eisenberg: Here.

Mauricio Menendez: Emily Aaronson?

Emily Aaronson: Here.

Mauricio Menendez: (Patrick) (Inaudible).

(Patrick): Here. I'm here.

Mauricio Menendez: Esther Babady?

Esther Babady: Here.

Mauricio Menendez: Nanette Benbow? Kathleen Brady?

Kathleen Brady: Here.

Mauricio Menendez: Laura Evans.

Laura Evans: Here.

Mauricio Menendez: Piero Garzaro?

Piero Garzaro: Here.

Mauricio Menendez: Don Goldmann? Jeff Hart?

Jeffrey Hart: Here.

Mauricio Menendez: Michael Lane?

Michael Lane: Here.

Mauricio Menendez: Is anyone on that I didn't call? OK. Thank you.

Christy Skipper: All right. Thank you. And I'd also like to give a chance if there are any developers on the call, if you would like to introduce yourselves.

Sean Townsend: This is Sean Townsend from California Pacific Medical Center.

Christy Skipper: Welcome.

Emanuel Rivers: And this is Emanuel Rivers from Henry Ford.

Christy Skipper: Welcome. Is there anyone else? Any other developers on the call?

OK. Hearing none, I just – before we get started, if you are logged in to your computer, please mute the computer to eliminate any feedback as we move along.

So, as I said, for today's webinar, we are going to be reviewing the comments received during the comment period. And we are going to refer mostly to this document on the screen in front of you, the Post-Comment Call Memo. You may also refer to the Excel comment table. And that table contains every single comment submitted within the project listed by comment number, the organization, the individual who submitted the comment as well as the drafted response to the comment – so, the response that is drafted for the committee and the responses by the developer. So, feel free to refer to that as well throughout the call.

OK. So, just a recap. The committee met in March to evaluate nine measures according to the NQF evaluation criteria. Five measures were undergoing maintenance review and four were newly submitted. All nine of these measures were recommended for endorsement. Following the in-person, your recommendations were drafted into a report and release for a 30-day comment period. And over that comment period, nine comments were submitted.

Earlier this week, we also received a letter from the New York State Department of Health in regard to Measure 0500, Severe Sepsis and Septic Shock, talking about their findings on antibiotic administration and their support of re-endorsement for Measure 0500.

So, we won't necessarily discuss every comment that came in. What we will do is discuss the comments according to the themes. As appropriate, NQF staff has proposed – has written – drafted responses on behalf of the committee. Developers were also given an opportunity to respond to comments.

So, all the – all of the themes that we are talking about today were directed toward, again, Measure 0500. And what I will do is I will give an overview of

all the themes and then turn to our chairs to facilitate the discussion. And your job as the committee is to review each drafted response to the comments and let us know whether or not you agree with that response or if there is something that we have missed or that you would like to add to that response. So …

Woody Eisenberg: Christy, this is Woody. Will we be discussing any of the comments on the HIV measures or were those comments only submitted prior to our initial meeting?

Christy Skipper: The comments for the HIV measures – the comments that we got in were supportive of the committee's recommendation to endorse those measures. So, there was nothing to discuss there.

Woody Eisenberg: Well, the comments from (Bruce Hagan), I assume, were only those submitted prior to our meeting. Is that right?

Christy Skipper: Yes, sir. That is correct.

Woody Eisenberg: Very good. Thank you.

Christy Skipper: And those are also included in that table.

Woody Eisenberg: OK.

Christy Skipper: OK. Are there any other questions?

OK. So, moving on to our major themes, we found a theme of antibiotic administration, level of evidence and scientific acceptability. So, starting with antibiotic administration, four comments addressed – or one comment noted the three-hour time window for antibiotic administration might lead to unintended consequences such as antibiotic overuse. Two other comments questioned whether antibiotic administration rather than early goal-directed therapy had a larger effect on patient survival rate as suggested in work done by Dr. (Kalil). Another comment suggested that the developer reduced the antibiotic administration time window from three hours to two.

So – OK. Now moving on to our second theme, level of evidence. Comments noted the varying level of evidence for the different components and the measure composite including the repeat lactate, fluid reassessment and physical exam. The comment suggested that these components are not equivalent to antibiotic or IV fluid administration and should not be weighted equally in the composite construct. Another comment recommended a simplified three-hour bundle without the repeat lactate and physical exam component.

Moving on to the final theme is scientific acceptability; two comments questioned the patient-level data element percentage agreement rate. The commenters also disagreed with the guidance given to the standing committee on evaluating composite measures. Not that our NQF criteria states that validity and reliability should be empirically demonstrated at the measure score level four composite measures.

And so as we went along, I meant to point out behind each theme or beneath each theme is the developer's response to the comment as well as the committee's proposed response and any committee actions that you all need to take, which I said is to let us know whether you agree with our drafted response.

So, if we can scroll back up to our first theme of administration of antibiotics. I will turn it over to our co-chairs to begin the discussion there as to whether you all have any questions about this theme or agree with the proposed comment or …

(Off-Mic)

Woody Eisenberg: All right. This is Woody. Maybe I will kick it off. There were some comments about antibiotic administration that – leading to an unforeseen consequence of overuse of antibiotics and naturally resultant resistance. Is anyone on the committee interested in pursuing that or are we satisfied with the response that we got from the developers?

Jamie Roney: Woody, this is Jamie Roney. And I agree with the response. Our sepsis team has asked this question amongst ourselves as an interdisciplinary group of infectious disease physicians, ED physicians, doctorally-prepared nurses and pharmacists, and we do not feel as a group that early antibiotics – if you are de-escalating it fast enough, we – (the NDROs) or that there is any empirical evidence to support that. So, I think that citing the Infectious Disease Society's stance and recommendation works for me.

Woody Eisenberg: Very good.

Jamie Roney: I do hear the concern though.

Pranavi Sreeramoju: Woody, this is Pranavi Sreeramoju. I just want to add that I think the consequences of potential overuse of antibiotics; they need to be measured in future studies. We just don't have studies addressing that particular issues. I mean, there is tentative evidence that that may not be a big issue. But it could be. So, it is something that we don't know.

Woody Eisenberg: Very good. Thank you. Are there other comments or questions about that? Are there any comments on the timing? One of the recommendations was that the antibiotics timing should be moved back from three hours to two hours. Does anyone feel strongly about that?

Jamie Roney: This is Dr. Roney again. Sorry. It's Jamie. I am looking at Kumar's work and so many subsequent studies since Kumar's publication. I don't know how we could argue that we should not have a goal of one hour and if we can't get to one hour as soon as possible. So, I as a nurse see three hours as very reasonable. I got antibiotics in within an hour yesterday on a septic shock patient. I just – six hours is a long time when we look at the correlation between morbidity and time to antibiotics. That is just my statement.

Woody Eisenberg: Yes. I think – I think I – we all agree with you, I am sure. The questions is should the performance measure be down at the level of clinical care or is three hours acceptable for a performance measure?

Emily Aaronson: Yes. This is Emily Aaronson.

Female: Go ahead. Go ahead. Sorry.

Emily Aaronson: I was just – this is Emily Aaronson. I would just echo the (attention) that I think that given, you know, the difference between sort of ideal care in an environment in which systems can play a role and what is reasonable for a performance measure, I think three hours, given the evidence, probably is very reasonable. And I would be a little reticent understanding some of the other barriers that folks have to tend with in their organizations about moving it to one hour.

Michael Lane: Yes. This is Mike Lane. I agree with that. I think three hours is a reasonable performance measure now. You know, I think there is potential opportunity, you know, going future reviews to lower it out …

(Off-Mic)

Michael Lane: … performance on the measure improves.

Woody Eisenberg: Are there any other comments related specifically to antibiotics? Now, it sounds like …

Male: No.

Woody Eisenberg: … the committee is satisfied with the responses that we have heard and with moving forward to other aspects of the measure.

Christy, let me ask you, what should we address next after antibiotics? What is the next theme that you would like us to discuss?

Christy Skipper: If we can just hear the committee indicates that they are – that they approved of our proposed response. It is there at the bottom of the screen. "The committee agrees that monitoring for unintended consequences is an important part of the measure development and implementation and quality improvement program. The committee recommends the developers continue to modify the measures specification as needed as the evidence in sepsis and septic shock continues to evolve."

Male: Yes. That sounds good to me.

Female: Yes.

Male: Agreed.

Male: Agreed.

Female: Yes.

Female: Agreed.

Male: Agreed.

Female: Agreed.

Woody Eisenberg: Is there anyone who disagrees with that proposed committee response?

Donald Goldmann: Hello.

Woody Eisenberg: Christy, I think, we're good on this one.

Donald Goldmann: Hi. This is Don.

Woody Eisenberg: Sorry.

Donald Goldmann: I have been trying to speak and nobody is responding, so I called back in and I also chatted. I am not ready to move on unless I can be heard.

Woody Eisenberg: Let's hear you, Don.

Male: We can hear you now.

Donald Goldmann: So, can somebody please remind me where the three-hour threshold came from? Is that arbitrary based on what we think is feasible for some organization or is that – was that claimed to be an evidence – I can't follow because you keep scrolling up and down on the comments. So, maybe I missed it.

Christy Skipper: We would ask the developer if they would like to respond to that if they can respond to that question.

Donald Goldmann: Is the developer on the call?

Male: So, this is …

(Crosstalk)

Sean Townsend: Yes. Hey, Don – sorry I …

Male: Yes. Go ahead – go ahead, Sean.

Sean Townsend: It's Sean Townsend. And I apologize. I, too, was on mute. The three-hour standard initially came from a guesstimate of what might be feasible for hospitals to do before the evidence was published in sepsis that every hour counts, Kumar in 2006 at the first publication. We made up a guess of what could be done when someone arrives in the emergency room. They would be seen by a triage nurse, have to get into a gown, get an x-ray, get some IVs placed – that type of thing – and picked the three-hour standard. And of course, the evidence emerged afterwards that every hour makes a difference in terms of mortality for patients with severe sepsis and shock. Yet we still found that many institutions didn't perform to get antibiotics in by three hours, even though we'd all agree, I think, the sooner the better. So, we then just as a performance metric held institutions to at least getting the antibiotics in three hours.

Donald Goldmann: Yes. So, given that background, I always ask is there a patient on the call who has experienced sepsis in a loved one. Because I would not be unable in my organization, Boston Children's Hospital, to defend a three-hour threshold. In fact, what we teach our staff is that if the patient comes in, let's say, with meningococcemia, you get the antibiotic in and ask questions later.

So, you know, if you have a clinical syndrome that is compatible with severe sepsis, waiting or having a standard for three hours seems unconscionable to me. I just don't get it. It can't be defended to a patient advocacy group.

Woody Eisenberg: Don, this is Woody. One of the items we were discussing earlier that you may have been on the call or you may not have been was the difference between a clinical guideline and clinical care on the hand and a performance measurement at the institution level on the other. And what we are trying to do with a performance measure is to reach some compromise that may not be the ideal for clinical care but that may be workable in terms of differentiating high-quality care from other kinds of care for an institution.

Donald Goldmann: Yes. I heard that. I heard that and I get that. And I know we are not drafting clinical practice guidelines. But since the whole idea behind this and the developer's response is about life and death decisions, I think this is a place where performance clinical care come together. And I can't put my name on a – on a – on a performance measure that on its face is not acceptable clinically. It just doesn't make sense to me.

If 60 of the organizations in the country can't meet that criteria, then let's get serious. I mean, we would never have this kind of criteria for a – toward a balloon time or for treatment of stroke. And I just think this is way too permissive and I can't defend it. I can't sign my name to it. So, I can be outvoted, but I don't – I don't like it.

Male: If I could just – I'd like to just help …

(Crosstalk)

Woody Eisenberg: Are there other comments or questions about this?

Emanuel Rivers: Yes. This is Manny Rivers. We submitted this measure in 2008. And at that point in time, there was no guidance as far as antibiotic administration timing. We originally had six hours because there was "emergency department measure" and there was a hospital measure. Over the course of time, there was – this measure has been up in front of the committee at least three times. And this was a graduated time element based on available data as well as the practicality of ED care. And so, that is why it was a separate one hour for inpatient, three hours for ED patients because the time of diagnosis and the time of ED arrival, there turned out to be a lot of mitigating issues that made

that timing a little bit difficult for emergency medicine. And so, there is a combination of factors including the science of how that came about.

Donald Goldmann: Yes. And I get all that, you know. But I also hear in the (Hinterlands) a growing sense that NQF can be a little inflexible and ossified in its approach when lives are at stake in patient care. And the country has moved beyond that. And here is an example where the evidence has matured.

I think everybody on the call agrees two hours makes – at the least, makes more sense than three hours that is often used as a – in studies as a threshold time. So, I just – I don't understand why we are letting internal process trump, you know, clinical and evidence-based logic. I don't get it. But I am new to the process. So but, I won't – I won't be able to go out and give a lecture defending it.

Helen Burstin: Yes. No. This is – this is – no – this is – this is Helen Burstin. And thanks …

Emanuel Rivers: I remember the NQF began …

Helen Burstin: Yes. I'm sorry.

Emanuel Rivers: The NQF began with a six-hour timeframe and this is actually, over time, in less than eight years, has been compressed to three hours and one hour. So, there has been, I think, some adaptation over time.

Donald Goldmann: Yes. It used to be acceptable to get six days of antibiotic prophylaxis for surgery. So, I mean – now it is one dose. So, stuff moves. And can't we be agile on this or – I'm just happy to be outvoted, but that is my opinion.

Helen Burstin: Don, this is – this is Helen Burstin. I think that is a fair question and it is certainly the issue that was raised in the comment from Hopkins. Again, I think it is not an issue of us being ossified. I think it is an issue of, you know, does the committee agree this is where the evidence currently reside? So, I think that was the key question raised at the beginning of this call. Most people agree that that was where the field was moving.

But I guess, the question would be for the sake of the performance measure, could it truly be different than the guideline? I mean the ability to capture something in the right time may not necessarily say that you are giving it later. So, I'd be curious to hear from, you know, some folks like (Ed) and others who have been really engaged in this, you know, the implementation of the measure to help us think that through.

Sean Townsend: The only remark I could make – and this is Sean Townsend again. I'd defer to (Ed) if he has remarks to make. But just to clarify, part of it is what Don said. You know, he mentioned stroke and AMI. It is very easy when you have a point in time where you say, "This is ST elevation MI," "This is a positive troponin," "This is a right-sided hemiplegia" to announce start time and time during which you have to get something done. Diagnostics are tricky. And especially around sepsis care, you are not sure if you are simply treating a cellulitis or a severe sepsis until you have labs done, for example, oftentimes to detect organ dysfunction.

So, while my sentiments are with Don – and I do try to hold my own institutions to a one-hour standard – the practical demands of care have made this challenging to progress it at a performance measure level.

Emily Aaronson: This is Emily Aaronson. I would echo that comment. I think the biggest issue is exactly that around time zero and around the incredible complexity. And what we saw in a lot of those supporting documents initially when we reviewed this measure was the huge variability as different groups try to look at time zero. And understanding that that is such a problem, I think that, you know, narrowing that to one hour could be really problematic just for the integrity of the measure.

Marietta Angelotti: This is Marietta Angelotti from the New York State Department of Health. I just – could I just interject one thing about that we have been doing?

Woody Eisenberg: Please.

Marietta Angelotti: Thanks. I just wanted to mention – and I don't have the data in front me – that we have been measuring the one-hour antibiotic measure separately from

the bundle and that is something that we are debating right now about whether to keep that in or not since it is not in the NQF bundle. And I am pretty sure that we did not put the one-hour data that we got in our – the report that we just issued from the 2015 data. But again, it is something that is still up in the air for us.

Woody Eisenberg: This is Woody. Are there any other comments or questions regarding this particular theme? If not, Melissa, maybe we should make a vote again on whether we are happy with the proposed responses.

Melissa Mariñelarena: What we can do is add Don's concerns into the draft report because that would be redlines before it goes out to comments.

Woody Eisenberg: Yes.

Melissa Mariñelarena: The draft response, I think, is pretty general that it captures that where we – you know, you encourage the developer to continue to modify the measure. And as Sean and Manny stated, they have done that, it has evolved over time. And, you know, you do want to encourage them – for the measure to continue to evolve, but we can add some language around some more – specific language around the concern about antibiotics and we can redline that before it goes out to vote.

Donald Goldmann: You know, I just – in case anybody misinterprets what I said, especially Helen, who is – I don't mean that NQF is ossified. But what I keep hearing is that a performance measure is not like a clinical measure and things evolve over time and there are certain criteria for graduating a measure forward that has been approved for many years. And I think that is all great as long as we as committee members can say we kept this at three hours because we didn't think that your hospital could do what is required within two hours. So, we made it three hours to give them some leeway because it is complicated. That is a hard – it is a very hard argument to make to a patient advocacy group.

Helen Burstin: I think it is a fair point. But I think the core of our process – and this is Helen again – is that we are, in fact, very responsive to updated evidence, and I think that is why we have this group of experts to help us make that determination. So, certainly, I think the other side of it is, I think, as you heard, there's a lot

of concern about when the timing of this begins that makes the actual calculation of the number of hours pretty complex. Even if it is administered clinically at the right time from a measurement perspective, it can be pretty difficult.

Michael Lane: In the – this is Mike Lane again. Sorry. In the revised comments, could you be a little more specific about the other concern stated? Because I agree the evidence probably supports earlier antibiotic (is better) and three hours is a – maybe a pragmatic approach since we have difficulty applying – identifying when it starts so that when we re-review this measure in the future, we can make sure that we have – the committee remember all these concerns that we have brought up?

Melissa Mariñelarena: Yes. We will be sure to include the full discussion and highlight that in the report.

Michael Lane: Thank you.

Pranavi Sreeramoju: This is Pranavi Sreeramoju. I just have a question. Is there a place to state the intent of the measure? What I am hearing – and this is something I have felt globally about all NQF measures – that the intent for the measure is not – sometimes not clear or it doesn't come across. So, for example, the three-hour antibiotic – I think what Don is saying is three hours doesn't suggest a sense of urgency for treatment of sepsis, which is absolutely true.

At the same time, we chose three hours because of the practicality because we don't have a good way to measure time zero, although, as a clinician, when I see a patient and I know that is sepsis, the antibiotic goes in. So, can we convey that in the measure itself so that people don't get confused or we don't convey around – convey the intent properly?

Woody Eisenberg: Pranavi, I am not sure what your point is exactly. Is there some wording you would like to add to the post-comment?

Pranavi Sreeramoju: Not so much a comment but the measure itself. You know, when the measure information sheet comes out, is there a place in there where NQF as a committee states the intent of that measure like, for example, the three-hour

antibiotic – somewhere a footnote or comment, something that says we do not intent the three-hour time as a – as not – as not conveying appropriate sense of urgency, you know. Am I making sense? Like we want to make sure that the three-hour window does not reflect a lack of urgency.

Christy Skipper: Pranavi, this is Christy. That is definitely a recommendation that you as a committee can make to the developer, and we can also include that in the report.

Pranavi Sreeramoju: If that is – if that is an option, I would like to make a recommendation to include such a comment. I mean, we can spend time to get proper verbiage. But I think I can (wave) my intent. I think Christy you got my intent.

Donald Goldmann: Yes. That would be very helpful, it's Don. Anything that signals to the – anything that tends to bridge what I see as a yawning (gulf) between the people who worry about measures in a hospital and the people who provide live-saving care would be a blessing. And including language that shows the concern for the patient and the urgency as opposed to the technical specifications of a measure would be helpful.

Female: So, if I could just ...

(Crosstalk)

Jamie Roney: This is Jamie.

Female: Sorry. I'm sorry. I just …

Jamie Roney: I was just wondering if we could add the words "with the goal of one hour." You could say "within three hours with a goal of one hour" when I relooked at how this is worded.

Melissa Mariñelarena: Hi. This is Melissa. I think, at that point, we might – that would be a little – that would be considered more of a change to the measure. What I would ask Sean and Manny is if it would be OK if we added some language in the rationale in your measure submission form that the intent is to administer the antibiotic within an hour or, you know, the sooner the better. And I think,

Sean, you had some of that language in your response, you know, and we can follow up with you after this that we could put that in your rationale when you submit your measure.

Sean Townsend: I am happy to have that there. And you know, I just want to echo I am one of the big advocates for sooner the better. And if we can make the measure appear that way and that we are trying to evaluate it over that framework, that is great. I will also commit to testing, getting a sufficient amount of data to test what we can do with the one-hour standard for future evaluations of the measure.

Melissa Mariñelarena: Great. Is that OK with – sorry – is that OK with the committee?

Woody Eisenberg: Is there anyone on the committee that – this is Woody. Is there anyone on the committee that would object the modifications that Melissa is suggesting? Melissa, I think we are good on that.

Melissa Mariñelarena: Great. Thank you.

Donald Goldmann: And thanks, everybody, for letting me do my – as some of you know, my venting and ranting. I appreciate it. But sometimes, I find if I don't make a point in a really vigorous way, it just becomes part of the minutes. So, I – but – and I apologize if I have offended anybody with my vigor.

Male: I think it is helpful for such a process.

Christy Skipper: OK. Thank you, all. We can move along to our next theme, level of evidence. So, Woody or Adam?

Woody Eisenberg: The level of evidence discussion was a little bit hard for me to follow, frankly. This was – you know, these were the comments that had to do with the instructions that the committee received in terms of what kinds of reliability and validity we should be looking for. Is that – is that the right conversation we are having here?

Christy Skipper: No. The first part of the conversation for level of evidence is whether repeat lactate fluid reassessment and physical exam …

Woody Eisenberg: I'm sorry.

Christy Skipper: … should be weighted equally with antibiotics or IV fluid administration. So, a commenter felt like those three components should not be weighted equally. And then, the second part of that comment was to simplify the measure to a three-hour bundle without repeating lactate or the physical exam.

Woody Eisenberg: Very good. Thank you. Any comments about that?

Jamie Roney: This is Jamie Roney again. I just don't understand why re-evaluation clinically of a patient that is diagnosed with severe sepsis or septic shock would be in question. I think the repeat lactic acid allows us to evaluate our treatment efficacy and effectiveness. And I just – and I feel like it is important to reassess these patients. So, I am kind of confused as to why they find that nor worthy of measurement.

Christy Skipper: OK. That comment – if the commenter, the individual who submitted that comment is on the line, would you like to speak to that?

OK. Are there any other thoughts from the committee about anything that Jamie has said or about this overall theme?

Woody Eisenberg: Well, this is Woody. I agree with what Jamie said. And I don't think the measure developers intended for these individual items to be viewed separately but rather that they should be taken together because together they are – they are what makes sense.

Donald Goldmann: This is Don. So I am a little – I am trying to reconcile two themes here. One is the weighting of each element in a combined three- and six-hour bundle measure and whether or not the six-hour measure ought to be part of the bundle and that it is not really at the same level of either in time or, in some respects, in objectivity and it is a measurement burden. So, I don't know where we got at all that. I know that the people in Northwell, for example, have published and believe that a three-hour bundle (elements) are the critical ones and that the level of evidence for the six-hour bundle, the way it is phrased, is at a different – in a different level.

And I have heard that lot and heard it at the Washington Hospital Association in a talk I just gave out there on the same theme. So, there seems to be a conflation here of how good is the evidence for things that are done beyond three hours and whether or not the addition of six-hour elements just complicates record abstraction and adds to the reporting burden, which is something we will discuss, I think, in another part of this discussion. But they are hard to disentangle.

Woody Eisenberg: Other comments ...

(Crosstalk)

Jamie Roney: Yes. This is Jamie again. I would say – and, honestly, from a clinician standpoint – that we don't always have that follow up of somebody coming to reassess that patient as the nurse at the bedside in the critical care area. And I think the intent is to tell our physicians that this is important enough to come reassess this patient for where they are at. And I know a lot of times they stress this as critical care nurses. But still, they put a lot of burden on us even if we have these orders to bolus for fluid for whatever variable or whatever metric.

But to let us know – I mean I don't know how to put this into words. But it is a lot of times they don't come back to the bedside even if that (sickest) patient bedside. And I think that this measure drives collaborative care together – physician, nurses, pharmacists and whoever else is involved respiratory therapists – at the point of care, which is the bedside. And so, I don't know that it is the measure. But it is really meant to draw them back to the bedside to reassess that patient.

Emily Aaronson: This is Emily Aaronson. Just responding to that, you know, I completely agree that the reassessment piece and, you know, the repeat lactate and a lot of that certainly, as you said, seems very reasonable and it is what I think everybody on this call would consider best care. I am sort of with Don and is trying to reconcile this issue around, you know, just how evidence-based these things need to be for us to really be pushing them to a place where they are a performance measure that physicians are going to be held accountable for.

I think that there is no question that the pieces that the commenter or whoever left that comment, I think, were concerned about that those are the ones that has the least evidence to support them and the ones that I can just say anecdotally at our institution we have the biggest standing up in front of clinicians when they are really looking at us for the evidence for those. And so, I think that that is probably – you know, a little bit of the underlying issue is just how strong the evidence base has to be for each of these individual pieces for us to endorse them.

Woody Eisenberg: So this is Woody. So, is there a feeling amongst the committee members that our response should include some of this thinking?

Emanuel Rivers: This is Manny Rivers. Is there a question about repeat lactate and evidence behind repeat lactate? There was a study done in JAMA showing that lactate clearance could therapeutically be used to group outcomes. I mean, there is an abundance of data in particular to repeat lactate. So, I don't know if we are going back and revisiting existing evidence. But the marriage of the invasive part of the bundle was taken out because of wording as well as not getting into the weeds, so to speak, in terms of delineating the exact things that a clinician can do.

So, the lack of – the presence of many of these variables came from a compromise to make it much simpler for extraction as well as the clinician's documentation. So, I think I am not sure we are revisiting some prior issues. But I think that some of these things in particular are very well solidly evidenced. And lactate clearance is one of them.

Woody Eisenberg: And any response to that from the committee?

Melissa Mariñelarena: Woody, this is Melissa. And like you see in the response – so, I just wanted to remind everybody that – and I know it has been a while. But in the preliminary analysis, each of the components actually align with the latest guidelines for sepsis and septic shock. So, the very level of evidence comes from the guidelines that groups together – that is where the recommendation has come from.

Woody Eisenberg: Thank you, Melissa.

Amesh Adalja: This is – this is Amesh Adalja. I also agree with Dr. Rivers that I think lactate clearance is an important concept and I think there is a lot of evidence supporting its use in the optimal management of sepsis.

Sean Townsend: This is Sean Townsend. If I could ask just a request. You know, it is very helpful, actually, the approach we took with the antibiotic question above I found helpful because one of the measure developer's dilemma's is that – and I have tried to write this in our response here – is you end up only being able to submit evidence to NQF on the basis of the data you have gathered. And so, we have gathered data about doing this process and that the measure has relationship to mortality associated with the way we have been doing things.

What you don't have is data to submit about the things you haven't been doing. And so, if the committee finds it, in certain instances, useful to instruct us or recommend that we test certain things for future evaluation of the measure, it actually helps us to be able to present the evidence we don't have.

So, if you are asking, for example, "What if you did weight these differently?" and I tested a few schemes so I could present that back, in the present moment, I have no data – no capacity to show you what that would look like. So, it is just an idea that I found the first approach to antibiotics helpful because it gives me an instruction to test.

Woody Eisenberg: So, Sean, it sounds like you would be in favor of having the committee be a little bit more specific about some of its reservations regarding the weighting of the various elements. Is that so?

Sean Townsend: Yes. I think so because I – it would give me in the next several rounds of data gathering a mission to go out and see what some alternative situations would look like so we could present it back, you know, in re-endorsement just in three years.

Woody Eisenberg: Right. Committee members' thoughts on adding that kind of wording?

Female: I think that is a great idea.

Jeffrey Hart: This is Jeff Hart. I would agree.

Female: Absolutely.

Jeffrey Lewis: That is fine as well. This is Jeff Lewis.

Pranavi Sreeramoju: I agree.

Woody Eisenberg: Is there anyone that is uncomfortable with the addition of that kind of wording? No?

And Christy and Melissa, it sounds like we are comfortable adding some working that talk about the further testing of the – or further testing of weighting of the individual elements. We could do the wordsmithing another time.

Christy Skipper: OK. Great. And it sounds like the committee – the committee is also comfortable with the proposed response written there on the screen. That is what I gather. If so, we will move on.

Woody Eisenberg: You mean the proposed committee response as it – as it is here?

Christy Skipper: Yes.

Woody Eisenberg: I think we would be – we would be in favor of adding some wording encouraging the measure developers to test different weightings of the measure's elements. We would like to add that to the response.

Christy Skipper: Got it. Yes. We will revise that.

Woody Eisenberg: Thank you.

Christy Skipper: Thank you. OK. So, our next theme was scientific acceptability. So, this was where the commenter questioned reliability and validity testing, specifically the patient-level data element or the patient-level data percentage agreement rate.

Woody Eisenberg: Right. So, this is the area that I was referring to previously. Sorry for the confusion. And for me, it would be helpful, Melissa, if you could give us NQF's view on the standards for assessing validity for a composite measure because it looked like there was certainly some confusion, at least on the part of the commenters and, then, there was a response that rebutted some of those comments.

Melissa Mariñelarena: Sure. So, the developer, if you all remember, did submit both the patient-level data element testing. And that is where the concerns were because of the low percentage agreement rate. But for a composite measure, patient-level data element testing does not meet the requirements. For composite measures, we require measure-level score testing, both reliability and validity, which the developer did provide.

You know, in the response – in the comments that we got, it says that NQF staff, I think, directed you to not consider it. You know, there was a discussion over it and there were concerns that kind of played out into other discussions around feasibility and usability. But it was a part of the criteria. So, I think there was a lot of discussion around the testing. But again, for composite measures, we look at score-level testing, not patient-level data element testing.

Woody Eisenberg: Right. So, you are confirming that the developers did appreciate the appropriate way to do this testing.

Melissa Mariñelarena: Yes. And like they had suggested – like they come in during the meeting, that patient-level data element testing, those validation tests – that had been done by CMS when the measure had it initially rolled out and they had said this during the meeting and they might have said it again. Several – the measure has been updated several times since then and they have worked with abstractors. And I don't know if CMS is on the phone now – when they plan to do some more validation studies. But that was at the patient level versus what the developers provided to us later was at the hospital level. And that was what we were interested in for composite measure.

Woody Eisenberg: Right. So, would it be helpful to get further data element validation testing?

Melissa Mariñelarena: Well, I think CMS will do that. And you know, I'd be nice to see how – from an implementation side to see that that is getting better. Yes.

Woody Eisenberg: OK. Yes. The reason I am asking is because that is part of the proposed committee response, that suggestion.

Melissa Mariñelarena: Yes.

Woody Eisenberg: Very good. OK. Let me – let me open it up. Are there other comments or questions about this? Is there anyone that is not satisfied with either the NQF response or the proposed committee response? No?

All right. Christy and Melissa, it sounds like we are satisfied.

Christy Skipper: All right. Well, thank you. Right now, I will turn it to the operator to hear any member of public comment.

Operator: At this time, if you would like to make a comment, please press star, then the number one on your telephone keypad. We will pause for just a moment.

And there are no public comments at this time.

Christy Skipper: Is (Karin Rubin) on the phone? I know she had trouble getting in but did want to make a public comment.

Female: OK.

(Karin Rubin): Yes. This is (Karin Rubin) from the AMA. Most of my comments that I was going to raise were addressed more thoroughly during the discussion. But I will highlight that we recognize that the developer – and there was some discussion around the differing opinions around interpretation of the evidence that there is research that we provided around new information around ongoing concerns with the measure. And the comment – the developer also highlighted that the measure preserves the physician's ability to tailor care based on the individual patient's needs.

Unfortunately, the measure is placed in an accountability program where there is no room for physician judgment and incentives are based on the highest possible score and the hospital is dinged when the physician uses his or her own judgment when providing care to patient. It, in fact, places the physician in an awkward position with hospital administration and can interfere with the patient and physician relationship.

Physicians frequently tell us that if they deviate from the specifications even when in the best interest of their patient, they are subject to disciplinary action. And so, I just want to recognize the place that it puts physicians in given the measure is in an accountability program but does not allow for deviating from specifications. Thank you.

(Lameno Tesaro): Hello. This is (Lameno Tesaro) from CMS.

Christy Skipper: Yes. Go ahead.

Woody Eisenberg: Go ahead, please.

(Lameno Tesaro): Just a clarification. The SEP-1 measure is in the Inpatient Quality Reporting program. It is a – it is a …

(Karin Rubin): We recognize that. But if physicians, you know, have …

(Lameno Tesaro): I'd just to finish the …

(Crosstalk)

(Karin Rubin): ... hospital, you know.

(Lameno Tesaro): I'd just like to finish the statement, which is that it is a reporting program. There is not a burden regarding performance and that has always been the case with the IQR program. And the reporting is at the hospital level and not at an individual clinician level. So, I just want to clarify that as far as how the program operates.

(Karin Rubin): The AMA recognize how the program is constructed and that it is at the hospital level. But care – physicians administer care as long as – as well as nurses and, you know, others that are part of the care team. And so, there are, you know, rules and protocols put in place based on the measure as specified since it is part of the hospital IQR program.

Woody Eisenberg: So, this is Woody Eisenberg on the committee. So, does that mean that each individual hospital might have specifications that could go to a deeper level than the measure itself? Is that – is that the problem?

(Karin Rubin): Not that I am aware – not that I am aware of. What, you know, has been – as we stated in our comment, when there are instances that they – it is in the best interest of the patient that the physician needs to deviate from the measure as specified, that protocol within institutions does not allow that given the way that measure is specified and the very detailed level of data elements. There are certain levels of exclusions to allow for deviation.

Woody Eisenberg: All right. I see. Thank you.

Christy Skipper: OK. If there are no other member and public comments, we will turn to Mauricio for next steps.

Mauricio Menendez: Hi, everyone. So, just a few next steps. After this call, we will include the committee discussion and recommendations in the draft report, which will then be sent to a 14-day NQF member voting period from June 14 through June 28. Following voting, the committee's recommendations will be sent to the CSAC for approval on July 11 through 12. And that is all I have for next steps if Christy (have) anything else to add.

Christy Skipper: No, I think that's it. Unless there are any questions from the committee, this concludes our post-comment call.

Woody Eisenberg: Very good. Thank you all.

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