NATIONAL QUALITY FORUM

Moderator: Sheila Crawford
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Operator: Welcome to the conference. Please note, today's call is being recorded. Please stand by.

Wunmi Isijola: Hello. Thank you, (Amy). Hello, everyone, and thank you for dialing in to today's call. We will – today is the Surgery Standing Committee Post Comment call. This is NQF staff. My name is Wunmi Isijola. I have here Reva Winkler, Andrew Lyzenga, Amaru Sanchez, and Melinda Murphy.

Today, our objective is really to go over many of the comments that took place during the deliberation from the in-person meeting. Many of the comments came from the actual report. So, as you see on the screen, we have the memo that we've compiled based on the comments that were submitted. Really, what we're going to do is just (I'll go through) this. And if you have any questions or concerns, please feel free to jump in, but we really want to adhere to the memo.

Andrew, Reva, do you want to …

Reva Winkler: (Run around)?

Wunmi Isijola: Yes. And before we get started, I just wanted to see who we have on the line. Well, if you're present, please let us know. Anthony Asher? (Joyce Bonnet)? Robert Cima? Richard Dutton? Elizabeth Erekson? Lee Fleisher? Frederick Grover? Bill Gunnar?

William Gunnar: I'm here.

Wunmi Isijola: Great. Thank you, Bill. Mark Jarrett? Clifford Ko? Barbara Levy? Barry Markman?

Barry Markman: Here.

Wunmi Isijola: Thank you, Barry. Kelsey McCarty?

Kelsey McCarty: Here.

Wunmi Isijola: Thank you, Kelsey. Lawrence Moss.

Lawrence Moss: Hi, I'm here. I don't have computer access but I have phone. Thank you.

Wunmi Isijola: OK, great. Thank you. Amy Moyer?

Amy Moyer: I'm here.

Wunmi Isijola: Thank you. Keith Olsen? Colette Pitzen?

Colette Pitzen: I'm here.

Wunmi Isijola: Thank you, Colette. Lynn Reede?

Lynn Reede: Present.

Wunmi Isijola: Thank you, Lynn. Gary Roth? Christopher Saigal? Robert Sawin? Allen Siperstein? Larissa Temple?

Larissa Temple: Here.

Wunmi Isijola: Thank you, Larissa. And A.J. Yates?

A.J. Yates: Present.

Wunmi Isijola: Thank you. I know our operator informed us that there were individuals calling in. Were there any other committee members that I haven't called or …

Lee Fleisher: Hi, it's Lee Fleisher. I was just was connected.

Wunmi Isijola: Thank you, Lee.

Robert Cima: And Robert Cima. I was just connected.

Wunmi Isijola: Great, thank you. Was there any one else?

OK. Do we have any of our developers on the line?

Colleen Hughes: Yes, hi. This is Colleen Hughes with the American Urogynecological Society.

Wunmi Isijola: Thank you, Colleen.

(Toni Kaye): This is (Toni Kaye) with the AMA-PCPI.

Wunmi Isijola: Great. Thank you, (Toni), for joining.

Jane Han: Jane Han and Stephanie Oliva from STS are on the line.

Wunmi Isijola: Great, thank you.

Jane Han: Thank you.

Matthew Popovich: Matt Popovich from ASA.

Wunmi Isijola: Thank you, Matt.

Maureen Amos: Maureen Amos from ASA.

Wunmi Isijola: Thank you, Maureen. OK. So, we'll go ahead and get started. And based on the memo, one the first themes that were identified during this point and time was Measure 268. During the in-person meeting, consensus was not reached, and that was based on the usability and use criteria. It was determined that the committee had issues with the lower percentage of professionals actually reporting to PQRS. And we wanted the developer to actually comment to that to give kind of their rationale for the committee. And I believe that's PCPI.

(Toni Kaye): Hi, that's correct. This is (Toni). And so, our rationale for the usability and use criteria was that I think during the discussion of the measure, there was some confusion or concern about what seemed like a pretty low reporting rate in the PQRS program of this measure. It was somewhere around 9 percent. And so, when you actually look at the PQRS program as a whole and you look at, you know, they've released an experienced report, as called, where they give the reporting rates for all of the measures, and that's actually one of the higher reporting rates. And we had in our letter, I think it's something like 70 percent had reporting rates below 10 percent, and 30 percent of the measures were below 1 percent.

So, these low reporting rates really are just kind of a function of the PQRS program and nuances with how you participate in that program. And so, we don't feel that that's really the reflection of the usability of our particular measure but rather that just is the way that it's currently – the program that it uses in and that that program includes, you know, lots of other NQF endorsed measures as well.

Wunmi Isijola: Thank you, (Toni). I wanted to turn it over to the actual lead discussant for this measure. Do we have Dr. Siperstein and Dr. Sawin, if you wanted to make any comment?

Allan Siperstein: Yes. Allan Siperstein, I'm here.

Wunmi Isijola: Thank you.

Allan Siperstein: Can you hear me?

Wunmi Isijola: Yes.

Allan Siperstein: Oh good.

Female: Yes.

Allan Siperstein: No. I agree entirely with the developer's response and it's kind of a relative number that would be considered to be enough people to make it a reasonable measure. Some of the other questions that came up during the discussion also

had to do with the fact that antibiotic administration is really, you know, a team sport and which it may be ordered by the surgeon or somebody else doing the preemptive evaluation often administered by anesthesia. And so, part of the question is how to properly ascribe, you know, credit for the order and delivery.

Wunmi Isijola: And does the developer have a response to that?

(Toni Kaye): I think that we can certainly appreciate the notion around it being a team sport. And I guess the thought is that, you know, whoever happens to be on those procedures, whether it's who ordered the drug or who administers, either one would meet the measure. So, that's how we've tried to account for that. So, that is certainly a concern that we've considered.

Wunmi Isijola: Thoughts from any other committee members?

(Crosstalk)

Wunmi Isijola: Oh sorry.

Male: Basically, we have said that we were going to not retire or what – I don't remember the word we used to elevate these that we don't really – it wasn't trying to skip ones but we said …

Wunmi Isijola: I think you are thinking about the reserve status that we did put a lot of measures in. Actually, your original votes on this measure for opportunities for improvement didn't qualify it for reserve status. You actually approved it 14 to 9 that it did meet the criteria for opportunity for improvement. So, that wouldn't be necessary for this particular measure. It did pass that criteria.

Male: But it's the same measure basically as appropriate administration of the antibiotics. So, we're saying – I mean there was some inconsistency in the committee then because we're saying (inaudible) consider a useful measure across patient but PQRI, you can't.

Male: Well, would you think that that warrants a reconsideration then for the sake of consistency across the measures? I don't know if we want to raise that

possibility at this point, but right now, we haven't reached consensus on the measure. The other ones did actually pass through with reserve status. So, at this point, the sort of decision in front of us is to – is whether – is to vote the measure up or down to take another vote on the measure and then send that recommendation on to the NQF membership for their vote.

I think as Reva mentioned, it did pass the important criterion in the first place, so reserve status is probably off the table. So, we're really just considering whether a yes or no question here, should the measure be recommended or not.

Kelsey McCarty: This Kelsey McCarty. For some reason – and I could be remembering this incorrectly, but I found the ones that we've put in to reserve status were around the timing not around the selection.

Wunmi Isijola: Actually, there were eight measures you put in the reserve status around all of the different aspects of prophylactic antibiotics.

A.J. Yates: Hello. This is Yates. I was under the impression that we've put them on reserve status because they had topped out as process measures. And I could see that logic being applied to this particular measure. And I think the sticking point here, that didn't let this become a continued reserve status measure was below utilization of this, but realizing that this is the PQRS utilization being reported and not the reporting within those places trying to use it. I could make the argument that it's OK to reopen it as being appropriate for bumped up to reserve status on that basis.

Wunmi Isijola: We will need – we're going to ask the committee to revote because consensus wasn't reached the first time around. We're giving you the opportunity to consider the comments that were submitted both by the developer as well as comments from two surgical specialty societies indicating their support of the measure and one commenter who was concerned around some of the specifications which I think the memo described as well as the developer's response. So, all these could be factored in.

It sounds like there's an interest in having the committee reconsider the potential for reserve status even though your initial votes would really not have indicated that. Am I hearing that correctly?

Allan Siperstein: Allan Siperstein here. Yes, I'd give that a yes and then I remember we also had discussion in terms of how this particular measure is mentioned different from the 0528 antibiotic, prophylactic antibiotic selection for surgical patients. And the question is what different groups or areas for improvement these two measures were targeted at. That former 10528 is one of the ones that were recommended for reserve status. (Inaudible) hearing from the developer how – you know, what population or opportunities that the measure that we're discussing, you know, differs from 0528.

(Toni Kaye): Hi, this is (Toni) with the AMA. So, the way – the main way in which this measure differs from 0528 which is the SCIP measure is that our measure was developed with the intent to include as many procedures as possible in its scope. So, to do that, we limited it to first and second generation (cyclosporine) which have – are the broadly applicable across procedures. Whereas that this higher level, 0528, they chose to – they've instead limited the number of procedures. And I don't know off of the top of my head, you know, which procedures those include. But then they've chose to include any antibiotics that would be appropriate for those procedures. So, they have a broader scope of antibiotics that meet the numerator, where we have narrow numerator, so that we can have a broader group of patients included in the denominator. So, that's the primary difference behind the scenes in these two measures.

Wunmi Isijola: Any other comments from the committee?

Lee Fleisher: Yes, it's Lee Fleisher. Just, you know, is there any evidence – a lot of things we've heard about was unintended consequences of not continuing some of the SCIP measures as part of PQRS. Do they have any evidence that is a true concern?

Reva Winkler: Lee, this is Reva. I'm not really sure what your question is.

Lee Fleisher: Basically, not the SCIP measure themselves but the analogous PQRS measures. One of the things we've heard in the committee is comments regarding why they shouldn't go on reserve…

Reva Winkler: Right.

Lee Fleisher: … is because people begin to utilize non-approved measures, that this was the thing that kept people focused on this particularly issue because, as we've discussed, there is no fact – not that the evidence has changed, it's that it's topped down.

Reva Winkler: Right. A couple of comments I would make is you're going to find that we received several comments around that question, so that's going to be the next topic on our agenda to discuss. So, we will be talking about that in more detail. But I really would caution everybody to not look at reserve status as not approved. That is not the case. Those measures remain endorsed. All right? It's just that reserve is a special status of endorsement, but it remains endorsed with the explicit purpose of keeping them available for potential use as needed, but at the same time, signaling that they seemed to be topped out in their current use.

Frederick Grover: So, Reva, I came on – this is Fred. I came on a little late. Was this one on reserve or not on anything…

Reva Winkler: No, you did not vote for it to go for reserve. You voted that it still had opportunity for improvement and you passed it for – the importance criteria, you passed it and the scientific acceptability criteria. It wasn't until you got down into usability that there was some discussion but it was your final recommendation where the measure did not reach consensus.

Frederick Grover: OK.

Male: So, I guess the question is, should we vote at this point?

Reva Winkler: Right. I mean – and what we're going to do is because you didn't reach consensus, we will ask you to revote and because we're going to need to get

everybody's input, we're going to ask you to revote. And Wunmi will tell you how we're going to do that.

Wunmi Isijola: Yes. And we'll send you a survey monkey post-call so that you can revote and obviously incorporate any of your comments that support your voting.

Male: OK.

Reva Winkler: OK?

John Handy: John Handy here. I just want to clarify Lee's question a little bit, or an answer to Lee's question. So, once you're on the reserve status, there's no more monitoring, there's no more resources, so we really don't know if once you're placed on reserve, if it therefore starts to lose its clinical penetrance.

Reva Winkler: Yes. I want to confound what NQF does which is strictly the endorsement of measures with what potential end users may or may not do with those measures.

All right, so, in terms of how measures are being used out there is unpredictable perhaps for us. And certainly, the maintaining of endorsement in reserved status is really meant to assist folks who may want to, you know, come back and use the measure again in a couple of years to monitor the situation. Exactly how measure implementers will do that in their various programs is sort of beyond NQF sphere of influence.

(Crosstalk)

Frederick Grover: … you the user, couldn't they?

Male: Yes.

Reva Winkler: Absolutely.

Frederick Grover: Yes, like business as usual.

A.J. Yates: Yes. And in this particularly case, as the PQRS, it may be something that CMS selects to keep in their armamentarium.

Reva Winkler: OK. So, any other comments from the committee? We will be sending out the questions for you to revote on it. And hopefully we can do that in a couple of days and get that wrapped up for you.

Any other questions or comments before we move on to the next agenda item?

You know, one thing Wunmi didn't mention as we've started talking about is we did get a goodly number of comments that really said nothing than we agree with the committee or we support the committee. So, I just wanted to be sure that you were aware that a lot of those comments were really, "Yes, you guys are doing great." So, the things we were able to pull out for discussion were actually quite few.

But as I mentioned, the next thing that got several comments was the whole issue around reserve status. There was a general comment about NQF use of reserve status as well as specific comments on specific measures that you placed on a reserve status and the potential implication for measure use. I think from NQF perspective in terms of response, we want to clarify and make it really clear what reserve status is and what it's intended to do and what its purpose is.

So, our response, in addition to anything the committee may want to say, is really to be sure that people have an accurate understanding so that – reserve status measures are endorsed by NQF. They are just designated somewhat differently to signal that they have been used and seem to be topped out at this point. And I will let Lee Fleisher kind of tell you a little bit more.

But actually in July after your committee meeting, we went to out consensus standards approval committee and discussed the fact that we were seeing a lot more reserve status measures and the implications of that for NQF. And the committee basically felt that this was a good thing. They felt that the reserve status was an important thing because otherwise without reserve status, these measures would lose endorsement. And they felt that that was not serving the measurement world well and that rather than lose endorsement to just designate them that these measures, you know, are otherwise really good, credible, valid, reliable, and valid but that, you know, they seem to be topped

out at this point in time. Keeping them on reserve status is a way of also maintaining their availability for the people to use if they do want to go back and recheck and monitor performance. So from NQF's perspective the CSAC didn't have any problem with the fact that this committee recommended so many measures for reserve status.

Lee, I don't know if you wanted to say anything more about that.

Lee Fleisher: Just that we wanted to signal that not approved was different from still valid but topped out. But that was – I think, Reva, you said it well, but one of the concerns that many of us expressed and the committee agreed was, if something gets turned down, that may signal that it's wrong to do and that was not what we wanted. That's why we thought what the committee did was thoughtful and may serve as the approach that other committees take.

Allan Siperstein: Allan Siperstein here. I thought that the text that you provided in the document that it really clearly defined reserve status, made a lot of sense. So I think a lot of the comments that came in, came from an incomplete understanding of exactly what you stated the reserve status is. And that the number of those measures were process measures that have been supplanted by outcomes measures, which I think the direction we need to move in.

Reva Winkler: OK. Any other thoughts or does the committee feel they want to respond to those comments in any additional way?

Lee, do you think we've covered the comments in terms of the reserve status?

Lee Fleisher: Yes, I think you did and, you know, CMS – I think the good thing is if they're – of course there are groups who would like to keep them fully endorsed and as we go through the individual measures, that can be the decision of the committee. But CMS as you state still has a right to use them, these measures, because they remain as you stated endorsed.

Reva Winkler: Right. I wasn't planning on going through the – one by one. If anybody in the committee wants to pull out any of them specifically, we encourage you to do so.

Barbara Levy: This is Barbara. I would just make it crystal clear in our responses that this in no way means that they're not available for you. So I mean, over and over again, that seems to be the misinterpretation that people have.

Reva Winkler: Right. OK. We can do that. All right. Anything further on the reserve status comments? Is there any action that the committee wants to take in that regard? It certainly didn't sound like it.

OK, then really we have two major specific comments. I wanted the committee to be aware of, there isn't – and one of them was on the measure 0114, the risk adjusted post-operative renal failure measure which I believe is for CABG surgeries. And they're suggesting adding some other specifications and bedside modalities. And the developer has provided a thoughtful response. I don't know if the developer wanted to take the opportunity to just elaborate on you're written response.

Jane Han: This is Jane from STS. We actually don't have any surgeon representatives on the call today but …

Reva Winkler: Right, OK.

Jane Han: … we think it's a pretty comprehensive response to the question or to address the question and/or the comments, sorry. And if you have any follow-up questions we can certainly take them back to our leadership for discussion to …

Reva Winkler: Sure.

Jane Han… follow up accordingly.

Reva Winkler: So, any questions or comments from the committee? Does the comment in response from STS prompt the committee to want to do anything different about your recommendation on this measure or need for further information or clarification?

Allan Siperstein: This is Allan Siperstein. I was actually the primary discussant on this measure. And I think it simply clarifies the question and was well answered

by the developer. They just want to make sure that doing continual hemodialysis was properly credited within the measure and I think it was t – the response was perfect.

So I don't think it changes anything with the measure.

Reva Winkler: OK, great. Any other comments from anybody else on measure 0114?

William Gunnar: Yes, this is Bill Gunnar, I concur.

Reva Winkler: OK, great. Thanks, Bill.

Male: Yes, I concur as well.

Reva Winkler: OK, good deal. OK, the only other measure specific comments we had was on measure 0178 and this is the measure of improvement in status of surgical wounds, which is a home health measure. And they ask for a clarification in the episodes of care, in which the patient was eligible to improve, so I'm think it's a clarification of definition. The developer has stated the response pretty straight forward. Is this an adequate response to? Does the committee feel that they're clean what the measures intended to do and how the data is captured?

Barbara Levy: This is Barbara. It clarified it for me. I remember we had an issue with this at the committee meeting where we weren't clear. So I think this is helpful.

Reva Winkler: OK, great.

(Crosstalk)

A.J. Yates: I would agree with that. It's certainly it establishes the fact that it starts at a level not healed which is I think what a lot of us were concerned about is something healed already. So, I'm on agreement.

Reva Winkler: OK.

Male: Yes.

Reva Winkler: All right. It sounds like – yes.

Frederick Grover When they say not healed, is it – I mean is it a closed wound or is it an open wound? I was the presenter (on this today). I mean if it's not healed but is it a closed wound or an open wound …

Reva Winkler: OK. So is it a closed …

A.J. Yates: As a developer…

Male: I mean …

A.J. Yates: … I think that if you – if he is categorized using a four-item scale, I believe, indicating stages of healing, I'm not quite familiar with what those – each of those stages represents. Maybe if the developer is on, they could clarify that or we could go back to them and get a bit more clarification. Is anybody on from STS?

Frederick Grover: Well, I mean, if the other committee members are OK with it, I'm OK with it. But then the question is, you know, you have a fresh post-operative wound, you have a closed wound – I mean I think there's a difference between when you have a nurse visit, whether they're going out to look at a closed, you know, clean surgical wound or are they doing therapeutic measures on an open wound to help it heal? I mean that's my opinion but if the other surgical – I mean if the other committee members don't feel it's relevant then I don't thing you have to provide.

Allan Siperstein: Oh, no, I agree with you. I mean I never understood this measure from the beginning.

Reva Winkler: OK.

Frederick Grover: Yes, I assume – this is Fred, that these were all open wounds. But just think of the…

Allan Siperstein: … and they said no, it was, any – and that's what they said. The patient has a surgical wound that's observable. I think that means – I mean – and then what they said was, any wound that they assess, now they may assess it and say,

"It's healed or healing and move on." But, I mean, I'm still trying to figure out the value of this measure for them but, you know, I'm OK.

(Crosstalk)

Allan Siperstein: Open wound that we're monitoring and we're doing a therapeutic intervention, that's what the measure should be on. It should not be on all surgical wounds.

Reva Winkler: OK.

Frederick Grover: Right, right, right, because you have to count the fact, too, that, you know, that in conjunction – I mean nurse visits are very valuable. You know, when you have an open wound and it's difficult for the patient to return to the doctor for follow-up. And my initial question is, you know, if it's a closed wound and they're following up with a member, you know, and these are home visits, correct?

Reva Winkler: Yes.

Male: These are home – yes, these are home visits. So then the question is, I just wanted a clarification, the skilled nurse goes out, there's a closed wound, how many times they stay in and what is their endpoint for healing if it's a fresh, clean, surgical closed wound.

Reva Winkler: OK. We can certainly follow up…

(Debra Beach): Hello? Hello, it's (Debra Beach).

Reva Winkler: Hi, (Debra). You're here. Excellent.

(Debra Beach): I'm so sorry, I had to call back in. I wasn't in an open line and I was trying to respond to you. So, I might have missed a minute or two of comments while I was trying to get back in, but let me tell you what the definition of the wounds that are not covered is that wounds that are considered to be newly epithelialized so that when the wound bed has completely covered with new epithelium, no exudate, no avascular tissue, no signs or symptoms of infection, that is considered a wound that is not eligible for this measure. All the other wounds are eligible for the measure.

Frederick Grover: So, any surgical wound where the scan is supposed, is together with sutures as you would expect, either cutaneous sutures or subcuticular, you wouldn't be looking at those. You're talking about only a part of that incision broke down and what that be or if it's a wide open wound, is that it?

(Debra Beach): Yes.

The other options are a wound that – a surgical wound that has a wound that's stilled with granulation tissue that's fully – that's considered fully granulating or early partial granulation when there's more than 25 percent of wound that cover with granulation. There – and the – or the not healing which is more than 25 percent avascular tissue or signs and symptoms of infection. So, that we have very clear definitions of the different stages and what should be selected when responding to this item.

A.J. Yates: Would that include various stages of serous drainage?

(Debra Beach): Yes.

A.J. Yates: Yes, I mean, it's not a small portion of elected surgeries that go home now at days two or three, and four with relatively large wounds that may have spotting under dressing or serous drainage. And we've certainly wouldn't call those completely healed yet. And I think that even if the intervention is no more than making sure the patient understands, they need to keep it dry clean and keep a sterile dressing on there, and that's all the more intervention that's given. It's still nursing – it's still providing care. And I think it's reasonable to give them a pass on this.

Frederick Grover: Yes, I agree, too. I agree, too. I just wanted a clarification on this. You know, some of these patients can't get back in, and they have – and they do a great service going out just working at the wound, so.

A.J. Yates: Yes.

Reva Winkler: OK. Any other comments there?

As I've said, most of the comments we received were very supportive of your recommendations, and those were the ones that we pulled out. Did the committee identify any other comment on the comment table that they wanted to discuss?

OK. I don't want to close you out too quickly, but it doesn't really sound like it, right? So, the one last thing we need to do is to go to public comments.

Operator, are all of our lines open?

Operator: No, ma'am. Did you want me to go ahead and prompt for public comments?

Reva Winkler: Please.

Operator: At this time, if you'd like to make a public comment, please press star one on your telephone keypad.

There are no public comments at this time.

Reva Winkler: Great, thank you very much, operator. Lee and Bill, do you have anything you'd like to say before we finish up?

Lee Fleisher: Other than a thank you for all the work done by the committee, I thought it was very thoughtful indeed, as you suggest, to help inform the thought process with CSAC with respect to how to look at reserve status.

Reva Winkler: OK.

(Crosstalk)

Frederick Grover: I think it's encouraging too that we – that the public comment period was pretty supportive of our decisions overall.

Reva Winkler: Great.

Frederick Grover: When is the next round of reviews that we should anticipate?

Reva Winkler: So, currently, we are in negotiations pending future work, but as we mentioned before, you are standing committee. So, you will oversee our

surgery portfolio, if in fact, we have any questions from developers or anything of that sort, we'll definitely pull you in to get your feedback. We are anticipating beginning of next year or so, but once we get more definitive information, we'll definitely inform the committee.

The next steps in terms of these particular measures is they will go out to – for NQF member voting and then to our CSAC and Board of Directors in October. So, we'll be finishing up quite shortly.

So that's really what's happening from here. Are there any last minute questions that we can – comments, concerns?

William Gunnar: No, this is Bill Gunnar. I just, you know, as a first staff of this committee, it was a tremendous amount of information exchange thoughts and minds, and hands and appreciate how definitely that occurred. It's really looks – I found it amazing and remarkably painless.

Wunmi Isijola: And on behalf of NQF, we really want to thank everyone for your participation in this process. I know it's been long and tedious, but we really appreciate your efforts. As mentioned before, the immediate next step is we will send out the survey for your responses with regard to the measure that had reached new consensus. But, as always, please reach out to us if you have any questions or any additional comment.

And with that, I guess we'll give you about an hour plus of your time back.

Female: Thank you.

Wunmi Isijola: So, thank you all.

Male: What a deal.

Female: Thank you.

Male: Thanks, everyone.

Male: Thank you.

Female: Thanks, everybody. Bye.

Female: Bye.

Female: Bye.

END