NATIONAL QUALITY FORUM

Moderator: Cancer Project
August 23, 2016
2:28 p.m. ET

OPERATOR: This is conference #: 67014766.

Operator: Welcome everyone. The webcast is about to begin. Please note today's call is being recorded. Please standby.

Operator: Good day, everyone, and welcome to the National Quality Forum Cancer Standing Committee Post Draft Report Comment Call.

Please note that all committee member lines will be open for the duration of today's call, so please be sure to use your mute button when you're not speaking or presenting. Please do not place the call on hold at any time. And as you are joining by the phone, please be sure to keep your computer speakers turned completely off or muted.

Public members of the call will have the opportunity for public comment later in the call by pressing star-1. These instructions will be repeated at that time.

For committee members that have not yet dialed in to join the call, please do so, so that you can be part of today's discussion.

We would also like to draw your attention to the Links area to the side of the slides. You'll find resource information relative to today's meeting loaded there. Simply click on the link of your choice, and it will open in a separate web browser window and will not disrupt your viewing of the meeting.

And now I'd like to turn the program over to NQF staff. Let's get started.

Shaconna Gorham: Thank you. My name is Shaconna Gorham, and I am the senior project manager staff in this project. I would like to thank everyone for joining the Cancer Post Draft Report Comment Call.

So in the next two hours we are scheduled to discuss the comments received on the report, discuss the consensus not reached measures, and gaps.

Before calling a roll, I would like to turn it over to Melissa and our co-chairs to introduce themselves. Melissa?

Melissa Mariñelarena: Thank you, Shaconna. Good afternoon, everyone. Thank you for joining us and welcome again for those of you who have not joined us before. We're happy to have you, and we will be moving through the agenda, hopefully, get through these votes. And we'll be giving you more instructions on voting.

We're looking to have quorum on this call so that we don't have to send a survey afterwards to get the votes for the consensus not reached. But we'll talk more about the details of what we're going to do now.

And I'll turn it over to Karen and Dave to welcome everyone.

Karen Fields: Hi, I'm Dr. Karen Fields. I'm a medical oncologist in Tampa, Florida, and it's exciting to have us back together again as a group to look at some of the areas that we need to resolve. So welcome everyone.

Dave Cella: Hi, this is Dave Cella. I work in Northwestern University. I'm an outcomes researcher and cancer clinical trialist. And I want to thank everyone for coming at what for many of us is a very busy time, no more of these lazy dog days of August. We have to get kids back in school. We have to finish vacations and then take a two-hour call like this, so thank you for your time.

Shaconna Gorham: Thank you, David and Karen.

All committee members should have an open line, so I'll start with roll call.

Gregary Bocsi?

Gregary Bocsi: Yes, here.

Shaconna Gorham: Brent Braveman?

Brent Braveman: Here.

Shaconna Gorham: Joanne Buzaglo?

Joanne Buzaglo: Hello.

Shaconna Gorham: Jennifer Carney?

(Off-Mic)

Shaconna Gorham: Stephen Chen?

Crawford Clay?

Crawford Clay: Here.

Shaconna Gorham: Matthew Facktor?

Matthew Facktor: Yes, I'm on the line. Thank you.

Shaconna Gorham: Shelley Fuld Nasso?

Shelley Fuld Nasso: I'm here.

Shaconna Gorham: Martin Fleisher?

Jennifer Harvey?

Bradford Hirsch?

Bradford Hirsch: Here.

Shaconna Gorham: Jette Hogenmiller?

Joseph Laver?

Len Lichtenfeld?

Len Lichtenfeld: Here.

Shaconna Gorham: Jennifer Malin?

Jodi Maranchie?

Ali McBride?

Benjamin Movsas?

Benjamin Movsas: Here.

Shaconna Gorham: Diane Otte?

Beverly Reigle?

Beverly Reigle: Here.

Shaconna Gorham: David Sher?

Danielle Ziernicki?

Danielle Ziernicki: Good afternoon. I'm on the line.

Shaconna Gorham: Perfect. OK. So, we are hoping, as Melissa said, to have quorum, particularly when we vote. If not, we'll have to take voting offline and vote on the consensus not reached measures via SurveyMonkey.

I just want to remind everyone that the developers are on the phone, so if we have questions, the operator can open their line so they can respond. But we will move down the agenda and start with the discussion on the common things.

Melissa?

Melissa Mariñelarena: Thank you.

So I hope in all of your free time you had some time to go through the memo. And like we said, the purpose today is to review and discuss the comments that we received during the post evaluation comment period.

We're going to ask you to provide input on the proposed responses the NQF staff drafted to the post evaluation comments. We're going to revote on the criteria where consensus was not reached, and then we can determine whether reconsideration of any measures or other courses of action is warranted, and we can follow-up with you with the next steps after the call.

So, first thing, we received 15 comments from the public and member organizations, and we categorized them into these themes. And we're asking if you see on page -- they start on page 3 and go into page 4 of the comment memo. The first theme that we -- that we recognize was a preference for outcome measures.

We got several comments for two measures, 20930, the Febrile Neutropenia Risk Assessment Prior to Chemotherapy, and 0378, the Hematology Measure for MDS Documentation of Iron Stores in Patients receiving EPO therapy.

And the developer, we sent the comments to the developer and they provided us with a response, and I don't think we need to resend that. But we just want to ask your thoughts on the proposed committee responses, and we drafted two separate ones -- one for each measure.

And I can read the first one where we say, "Thank you for your comments. The committee agrees that a febrile neutropenia outcome measure would further the goal of high-quality efficient healthcare rather than this process measure. However, the committee also recognizes that certain processes and structure measures are still used for assessing quality especially where outcomes may be difficult to measure.

In addition, the committee suggested incorporating the febrile neutropenia risk assessment into Computerized Physician Order Entry, or CPOE, in standard orders to increase the feasibility of the measure in the future. And this was based on the comments where the commenter talked about it would be difficult to capture the febrile neutropenia risk assessment in an EHR. And I

know the committee had an extensive conversation about this, but recommended the measure.

The other proposed committee response was to 0378. The commenter mentioned that the QOPI data was probably topped out. And during the meeting when there's the measure developers have mentioned the study by Dr. Gregory Abel that found that 56 percent of patients had evidence of pre-ESA iron assessments, so there was a gap based on the literature that was provided to us.

So the response that we drafted up was again verifying that 56 percent of patients still have a gap in care. And based on that, the committee agreed that that data suggested there is still a gap in performance for this measure.

So, our question is, does the committee agree with the proposed responses for these measures? And we could just do, I guess, so if we have a discussion or is there any proposed changes to the responses?

Dave Cella: So I -- this is Dave. I think I was tagged to lead this discussion. Is that right?

Shaconna Gorham: Yes.

Dave Cella: Yes.

Melissa Mariñelarena: OK.

Dave Cella: So, thank you to the NQF staff for preparing the proposed response. Why don't we take them one at a time because there are three, correct?

Melissa Mariñelarena: There was two.

Dave Cella: Oh, OK, I'm sorry.

Shaconna Gorham: No problem.

Dave Cella: So, for 2930, the febrile neutropenia, now if we -- do we have enough members for a quorum or do we take votes from the current members and do the non-attending members by SurveyMonkey?

Melissa Mariñelarena: We don't.

Shaconna Gorham: So we don't have to vote on -- we don't have to have a vote for the deemed comments. We just need to have a discussion and know if you agree -- if the committee agrees with the proposed responses. When we get to the consensus not reached measures, that's when we actually have to think about quorum and voting.

Dave Cella: I'm sorry. Thank you for that clarification.

Well, are there any -- is there any disagreement with this -- with these responses now taking both of them into consideration, the febrile neutropenia and the iron?

Karen Fields: I'll comment first. I thought that the -- this is Karen Fields. I thought that both of those proposed responses were appropriate and reflected the responses that the committee had been looking for during the period of review.

Dave Cella: Any others?

Thanks, Karen.

Shelley Fuld Nasso: This is Shelley Fuld Nasso. I agree with you -- with your comment, Karen.

Dave Cella: Thank you, Shelley.

It's helpful. Even if you just want to say you agree, it's helpful for me to get a sense since we're all on the phone. You know, I just want to make sure that the silence doesn't mean there's somebody that's got a concern that they're not raising.

I happen to agree with Karen. I think these are both, you know, well-targeted responses to the concerns that we're expressing.

Matthew Facktor: It's Matt Facktor …

(Crosstalk)

Benjamin Movsas: So, this is Ben. I agree.

Dave Cella: Thanks, Ben.

Danielle Ziernicki: This is Danielle Ziernicki. I agree as well.

Matthew Facktor: Matt Facktor agrees, too.

Melissa Mariñelarena: Right. Thank you.

Dave Cella: Hey, that's probably enough of a consensus sense there, so we can move on.

Melissa Mariñelarena: Yes. So the second theme that we identified was we just called it the request for changes. We got a couple of comments about Measure 0559, combination chemotherapy is recommended or administered within four months of diagnosis for women under 70, also around Measure 0220, adjuvant hormonal therapy, and Measure 0459, the risk-adjusted length of stay …

(Off-Mic)

Melissa Mariñelarena: 14 days after elective lobectomy for lung cancer.

Right here, we're just asking to review the changes, and it was most recommendations around clarification in the specs of the title of recommended and administered. The developer did respond, and these measures were all -- also we're going to be talking about them in the consensus not reached because we have to revote on all of them. So we actually don't have to have a specific discussion on these right now because we're going to be voting on them shortly.

Dave Cella: Got it, OK. So should we go on to theme three?

Melissa Mariñelarena: Sure. So the next theme was comments on the two measures that were recommended for reserve status with inactive endorsement. And we got sort of the same theme -- type of comments for these measures where either a

change to the specs, and some of these are the recommended versus administered type of question, and then preferring an outcome measure.

And ASCO provided their responses for each of the individual measures. And then for the committee we drafted a response which aligns with our policy here at NQF around reserve measures that are in reserve status.

So, the proposed committee response that we drafted includes the Standing Committee will periodically review measures in reserve status for any change and evidence of deterioration in performance or unintended consequences or any other concerns related to the measure. The Standing Committee may remove a measure from inactive endorsement status if the measure no longer meets NQF endorsement criteria. Any review, may occur upon the request from the Standing Committee or measure steward to return the measure to active endorsement.

So again, the question is does the committee agree with this proposed response? Would anybody like to add anything to it if these were measures 1857, 1878, HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies and HER2 testing for overexpression or gene amplification in patients with breast cancer?

Dave Cella: So, this is Dave. My sense of this was that this -- these were -- nobody argued with the importance of this practice, but there was no patient variability to justify they're not being retired. So I think what we're saying here is that it will remain retired, but if there -- if there's detected deterioration in practice perhaps due to their being retired, they can be brought back. Is that -- is that correct?

Melissa Mariñelarena: That is correct.

Dave Cella: Does the committee agree with that?

Len Lichtenfeld: Dave, this is Len. I certainly agree with that. The conversation was pretty, pretty straightforward at the committee meeting, I think, in the -- so I certainly agree, and I'd obviously be interested in hearing what others have to say.

Karen Fields: This is Karen.

Danielle Ziernicki: This is Danielle Ziernicki. I agree as well.

Karen Fields: Oh, OK. And this is Karen. It's -- the status isn't retired though, it's reserve, meaning they're still -- they're inactive …

Dave Cella: Right.

Karen Fields: … but reserve just to clarify. And so I agree. I think that the only thing that I saw that stood out was the developer reminding us that the fourth response about QOPI self-selecting practices. But I think that's an ongoing issue with all of these measures. Not everybody uses the measure, so it's hard to know what the national trends are, so I agree.

Len Lichtenfeld: Karen, if I may, this is Len again. We have responses from folks in the room that they heard it elsewhere as well not that it's a necessarily rise (over the low) of evidence that you want, but then on a national level from the payers' point of view, it's almost 100 percent. So …

Karen Fields: I agree with you. We were discussing that.

(Crosstalk)

Len Lichtenfeld: Yes …

Karen Fields: Yes, I …

Len Lichtenfeld: … because it appears to reflect practice.

Karen Fields: Given the cost of those agents, it's hard not to have the …

Len Lichtenfeld: Yes, yes.

Karen Fields: … alignment so.

Len Lichtenfeld: All right.

Gregary Bocsi: This is Greg Bocsi. And again if someone presents evidence that the gap does indeed exist and it could be taken back into active, correct?

Melissa Mariñelarena: That is correct, yes.

Gregary Bocsi: And so I think that's a good response then.

Beverly Reigle: This is Bev Reigle. I agree.

Melissa Mariñelarena: Great. OK. Now we will move into the consensus not reached measure. There were six measures where consensus was not reached on different data -- different criteria. And all of the criteria where consensus was not reached is both passed. So today, as we vote, we have to get a vote greater than 60 percent just like in the meeting, and if we do not get more than 60 percent, then the measure will not pass because just like it happens in person when we are voting on a tough criteria, if we do not pass, we stop the discussion even though we've already gone through all the other criteria during the meeting because we're going back to revisit these criteria here.

In the memo, we did provide a summary of the issues during the meeting and tried to capture again why consensus was not reached. But we will -- Karen and Dave will have to take turns facilitating the discussion, and then we'll provide you with some more instructions. And I'll hand that off to Shaconna.

Shaconna Gorham: So I just want to remind everyone that we are going to vote on consensus not reached today, but we will have to send out a SurveyMonkey to capture those votes for committee members who are not present on the call today.

We will vote. Those who vote on the call today will not have to revote on -- with the SurveyMonkey that will be sent out. This is not a final vote because we will have to collect the vote from the remaining committee members.

With that, Shan, can you give us a quick demonstration on how voting will work?

Shan Evans: Absolutely. At the moment, you're screen-sharing. I don't want to stop you from doing that, but if you could so we could go back to the slide, that will be

wonderful. And right now, we do have 14 committee members logged in and able to vote, so we have achieved that.

And let me just go ahead and move us back. There we go.

Len Lichtenfeld: Can I ask a point of clarification?

Shaconna Gorham: Yes.

Dave Cella: If 14 is a quorum …

Shaconna Gorham: Yes.

Dave Cella: … doesn't that, by definition, mean that this vote will stand as opposed to …

Shaconna Gorham: Yes.

Dave Cella: Yes. So …

Shaconna Gorham: Yes. We had a few more committee members joined, so that is good. So yes, we have achieved quorum with 14 members, and so this is -- this will be a final vote.

Dave Cella: So as long as we all stay on the call -- that's a -- that's a plea to all of you. If we all stay on the call through the voting process, then we should not have to do the SurveyMonkey.

Len Lichtenfeld: Dave, this is Len. I just want to let you know I contacted your staff earlier. I will not be able to be on the call for …

Dave Cella: Oh.

(Crosstalk)

Len Lichtenfeld: … reasons. I can't go through it right now. I apologize for that. I'll …

(Crosstalk)

Benjamin Movsas: Yes, likewise, Dave, that's also true for me, Ben. As I had told the group, I have to sign off for this theme, so I apologize.

Dave Cella: OK. So we'll get through as much as we can without further delay. And we'll limit the number that we need to do a SurveyMonkey for.

Is that correct, Shaconna?

Shaconna Gorham: Yes.

Dave Cella: OK.

Shan Evans: Excellent. So as committee members would look at the screen now, you see a sample just simply reads "Sample: Option 1, Option 2." You'll notice that there are some small boxes to the side of those options in between the letter A and B and the option. You'll simply click those boxes. Committee members only will click to register your vote for those options, and we will see those votes calculate in real-time.

Feel free to test it now if you'd like. If the boxes failed to appear, you can refresh your session at any point by pressing F5 on your keyboard or Command-R from Mac.

And I'm going to go ahead and move us off of this slide and back to a regular slide deck.

And back over to you, Shaconna.

Shaconna Gorham: All right. So I am going to put the memo -- screen-share the memo again. One minute.

OK. So the first measure is 0220. And, David, you are facilitating this measure, Adjuvant Hormonal Therapy.

And just a reminder, Matthew Facktor will not be able to speak or vote on this measure.

Dave Cella: OK, so that -- but can you remind me who are the reviewers? Let's turn straight to the reviewers.

Shan Evans: Karen and Beverly.

Dave Cella: Karen, you want to take it away and then Beverly?

Karen Fields: OK. So, this is to remind everybody briefly number 220 Adjuvant Hormonal Therapy, it's evaluating the percentage of female patients age greater than 18 a diagnosis -- who have their first diagnosis of breast cancer, stage -- AJCC stage T1cN0M0, and IB through -- or stage IB through III whose primary tumors are ER/PR-positive with tamoxifen or third generation aromatase inhibitor within one year of diagnosis.

It's a facility measure, and it's a process measure, and it's for maintenance. It was first approved in 2008.

The committee reviewed the evidence and felt again that the evidence remained strong and therefore, we did not vote on the evidence because there's long-term data to support the use of these drugs in this patient population.

So our problem came when we looked at the importance to measure and we saw that although not required by the NQF for submitting the measure again. There was no new data supplied after 2012 -- or 2012, so we did note previously that there was a disparity gap in 2012. And we -- I -- we discussed the data. I personally had rated the data high, and we had a large discussion around that.

So moving along, I bring up that because when we get down to the questions about validity and reliability, which is where the committee failed to reach consensus, I wanted to make you aware of data that was supplied by the Commission on Cancer ACoS to supplement some of our questions.

So, just so that the committee remembers, we had a couple of issues related to the reliability testing. First of all, the data was not new data, it was a summary of old data. And the only updates to the submission were for -- in

2012 where we saw that there was an 85.5 percent standard deviation, and then they gave us the range of performance measures.

The data was at the data -- analyzed at the data element level with no new data. And the NQF testing requirements require that if the -- that we -- that testing requirements include statistical analysis of the computed measure score or the individual patient-level data for measured entities to determine the proportion of variation due to two differences versus noise or random variation. So the overall performance rates that were supplied to us did not meet these criteria, so data reliability information was rated as insignificant -- insufficient according to the algorithm that the NQF has developed.

So we moved on then to validity, and again the same issues were noted at the time. The developer did provide percentage agreement results for two of the data elements that were included in the numerator. Those were timing of hormonal therapy and therapy recommended but not received.

NQF guidance states that testing should be done for all critical data elements so they only evaluated two data elements. And therefore, it did not meet the NQF for validity testing.

There was a long discussion that ensued, but I draw everybody's attention to the information that was provided by the American College of Surgeons where they gave us updated data concerning performance gaps. So if everyone goes to the end of this packet on page 14 is where we see -- or no, it's the next page, I'm sorry. Page 15 is where we see the performance gaps using our QRS data from 2014 and 2015.

And we can see that gap in performance still exist. And the lowest performance was seen in Hispanics, the highest in whites. There were also some gaps seen in insurance status as well.

So I think that the committee, although they didn't provide us any new data element testing to satisfy some of our concerns and address the NQF standards, they did provide us with evidence that there's an ongoing gap in performance with these measures.

I also wanted to remind the committee that we are allowed to also use our own experience with -- and the committee's experience with both of these -- with this measure. And I will comment that I think that the data elements themselves are validated, elements that are available in the medical record, and reliably reflect the underlying measure. So I would move for us to consider that a performance gap still exists. This is a high -- this is an important measure, and we should consider voting for validity despite some of the gaps using our own experience with the measure as a key indicator.

One more comment and will turn it over to Bev, which is although -- I think we also have to remember that we have reminded the American College of Surgeons that we need to update and modernize this measure for some new kinds of outcomes measures. And maybe this is something we talk about at the end of the day.

The performance gap might be -- we might, for a better measure, ask did the patients really take the drug or other kinds of measures that are more valid for today. So I think we should separate our complaints about the limitations of the measure and recognize that it's a valid and reliable measure of this performance.

That's all I have to say.

Dave Cella: Thanks, Karen.

Beverly? Any comments, Bev?

Beverly Reigle: No, I think she did an excellent job. She -- I have nothing to add to that. It was well done.

Dave Cella: Thank you. Any discussions from anyone on the call? I think we can vote.

I think I'm on an active screen. I don't actually see where the vote is on my screen. Do others?

Female: No.

Len Lichtenfeld: I don't see it on mine either.

(Crosstalk)

Shan Evans: The voting slide should be up momentarily.

Len Lichtenfeld: There it is, OK.

Female: OK.

Dave Cella: Oh, it still wasn't shown on mine. I reboot?

Shaconna Gorham: You may have to refresh, Dave.

Dave Cella: OK.

Shaconna Gorham: So the voting slide should be up. Now we are opening voting for the vote's validity criterion for Measure 0220, Adjuvant Hormonal Therapy, to vote for validity.

We'll also count for reliability.

Shan Evans: And Shaconna, we did pick up an additional committee member, so normally, that would be 15 but you mentioned that Matthew is recusing on this one so that should be 14.

Shaconna Gorham: Yes. Thank you, Shan.

Dave Cella: Shan, where do we place the vote? I do see the scientific properties up -- there we go. Right on our screen we do this?

Shaconna Gorham: Yes.

Shan Evans: Yes, simply click on the screen in the box next to the answer of your choice.

Dave Cella: OK. And then do we hit enter on our computer or just leave it with you?

Shan Evans: Just simply click.

Dave Cella: OK.

Shan Evans: OK, great.

Shaconna Gorham: We have 14 votes in and 86 percent moderate and 14 percent high, the measure passes.

Dave Cella: OK.

Shaconna Gorham: OK, the next …

Dave Cella: We move on to slide 9.

Shaconna Gorham: Yes.

Dave Cella: The 0559 is combination chemotherapy within four months of diagnosis with women with stage IB through III hormone receptor negative breast cancer. I'm sorry, who were the reviewers for that?

Shaconna Gorham: The reviewers for that is Beverly Reigle and Benjamin Movsas.

Dave Cella: And Beverly, how about …

(Crosstalk)

Shaconna Gorham: Again, Matthew Facktor has recused from this measure.

Dave Cella: OK, Beverly, would you …

Beverly Reigle: I think -- I think Benjamin presented this and I'd appreciate it if he doesn't mind doing that. I've got it in front of me but I would really appreciate if he would review it because I think he did that, Dave.

Dave Cella: Is that OK, Ben?

Female: Ben has to hop off so he might already be gone.

Beverly Reigle: Oh, OK.

Female: Yes.

(Crosstalk)

Beverly Reigle: Let me see if I can -- I'm trying to pull up the notes and things. It was combination chemotherapy is recommended or administered within four months or 120 days of diagnosis for women under 70 with- and staging of T1c, no nodes, no metastasis or stage IB through III hormone receptor negative breast cancer.

And I was trying to look at my notes and I apologize. This was based very much on the one that we talked before, so where I have my notes as one of the reasons it wasn't although it's a reliability piece that we felt the overall performance rates did not meet the NQF standards. A calculation algorithm was provided …

(Crosstalk)

Beverly Reigle: Hello?

Male: Hello? Hello?

Beverly Reigle: Yes.

Male: Hello?

Beverly Reigle: Yes?

Male: Hello?

Female: Shan, can you mute that line please.

Dave Cella: That's not …

Female: Yes.

Beverly Reigle: Now, I'm here, I'm here, I'm not sure if -- am I here …

Shaconna Gorham: We hear you, Beverly, you're OK.

Beverly Reigle: All right. So what I was saying is it was very much like what Karen presented in terms of the reason that we did not support it, and it had to do with the reliability, the overall performance rates did not meet the NQF standards. A calculation algorithm was provided but testing was considered insufficient.

I'm trying to look at the -- and I apologize, I did not have an opportunity to read all of the comments on this so I don't know if somebody else has had that opportunity that could speak to the comments.

I don't know if you wanted me to go through the entire report of what we gave at the committee as to the decision, but that was very much the same as the one that Karen just talked in terms of the reasoning for why it was not supported.

Melissa Mariñelarena: Thank you, Beverly. This is Melissa. And yes, I want to remind everyone that we carry the votes over from 0220 which is the one that we just talked about to this one.

That's how they both ended up in consensus not reached because they have the same testing issue. So all -- there were five measures that were submitted by this measure developer. These first two were the ones that we discussed and the testing issues were all the same.

So I want to propose to the committee, if you're willing to carry over the votes that we just took from 0220 and apply it to 0559 like we did during the meeting, the in-person meeting.

Dave Cella: Well, I -- this is Dave, I haven't heard any argument to the contrary since the idea that this is substantially the same issue we just discussed, so are there any objections to carrying over 0220?

Len Lichtenfeld: This is Len, I have none -- no objection.

Beverly Reigle: This is Beverly, I don't either. I'm fine because it was very much the same.

Shaconna Gorham: Yes. And Beverly, to clarify, the only comment was administered versus prescribed so …

Beverly Reigle: And that's what I saw and I didn't seem to have …

(Crosstalk)

Dave Cella: But this is staying with prescribed, right?

Beverly Reigle: Yes, it's as is …

Dave Cella: And that's the comment in the push -- that's the comment to push the envelope to actually administering and then following up with those who were not administered for reasons for exclusion. But that really -- that's not what's going to go forward, correct?

Beverly Reigle: Correct.

Dave Cella: OK.

Shaconna Gorham: It will stay with prescribed.

Beverly Reigle: And ACF provided a pretty extensive response to our commenter and did address their issues. Again, we are voting on validity because of the validity testing that we had at the time. But again, if everybody is comfortable with it, we can just bring the votes from 0220 forward.

Dave Cella: Let's do it this way. I'm going to ask if there are any objections to carrying forward the 220 vote, and if there are any objections we'll vote. If there are no objections, we'll just carry forward without a vote, OK?

Female: OK.

Dave Cella: All right. Are there any objections to carrying forward the 220 vote? Going once, twice.

Male: Gone.

Female: OK.

Dave Cella: Right. So now we move on. Thank you.

Female: Thank you.

Len Lichtenfeld: David, this is Len, and again, I apologize to everyone, but I do have to …

(Off-Mic)

Len Lichtenfeld: I will have to leave the call. I appreciate being part of it today. Thank you.

Dave Cella: Thanks for sticking on this long.

Shaconna Gorham: Thanks, Len.

Beverly Reigle: OK, moving on to 2963, this is our legacy e-measure, Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Prostate Cancer Patients. Our discussers were Brad Hirsch, and I don't believe Jodi is on the line, and Ben was the committee member that was conflicted with this measure. I'll hand it over to you, Dave.

Dave Cella: Yes. So we have -- we have no reviewer on the call to discuss this one, right?

Bradford Hirsch: No, this is Brad, I'm here.

Beverly Reigle: Brad is on.

Dave Cella: OK, Brad, go ahead.

Bradford Hirsch: Yes. So I too am not fully up to speed for what it was previously but I remember pretty good context. So this is an e-measure that is really exactly the same as the -- as the standing measure for the avoidance of the (abuse of bone and adjust) any electronic system.

Our key turn at the time I believe was that their aspects of exclusions and such, they were going to be difficult to be able to capture or potentially difficult to capture things like pain, it would be exclusions from the denominator and numerator. And so there were questions about the reliability being able to get it as an e-measure.

It appears that the response from the review -- or from the submitters were -- which is a valid response, is that, you know, this data is being collected into Meaningful Use programs and this is ongoing and so it isn't available today.

But, you know, they said, thankfully NQF allows measure developers and stewards simulated patient data generated within the BONNIE tool in order to evaluate the feasibility and scientific acceptability of measures. An adequate data is not available for analysis.

And so to some degree at the end of the day, the question is going to be as bad as the approach that NQF allows and, you know, they meet the criteria even if we don't have the data to justify whether things like pain can be adequately captured at scale using an e-measure in electronic sense.

You know, I guess I would -- I would ask NQF folks to a degree if it's valid to say that we don't think it could be done, if (stating) that the criteria of the BONNIE tool to it. Did that make sense?

Beverly Reigle: Yes.

Dave Cella: Yes. I mean I -- my recall of the discussion in the face to face meeting was that nobody really argued with the measure itself in terms of clinical practice, but the conversion over the e-measure, there was limited data available. And the response is basically to say, what, cut us a break here or there was any data provided?

Bradford Hirsch: Well, so the response is that the NQF has supplied this BONNIE tool which is their simulation tool which doesn't really answer the question necessarily. I think it was part of our concern at the meeting and remains my concern on whether it can be really aggregated from electronic healthcare data and claims data. But the NQF does put forward the BONNIE tool.

So does the NQF have any comments? I mean, you know, my explanation would be the same as it was prior but, you know, if we truly are allowing for the use of BONNIE tool as a surrogate until real data is available then I think they met the criteria here.

Melissa Mariñelarena: So this is Melissa from NQF. So I think the issue here was the committee was asking for a correlation of the -- of the e-measure with the existing registries/claims measure.

And they can't do it because they don't have -- the developers don't have the performance data from the e-measure because it's not available to them at this time. In their response, they did say, you know, they're hoping for data and then they would perform this type of testing.

What they met the criteria for -e-measure -- or for legacy measures that NQF, they did provide what we require. And again, they don't have the data to be able to perform the type of testing that the committee was asking for.

Dave Cella: Yes, the first one …

Diedra Gray: This is Diedra Gray. Are we able to respond?

Melissa Mariñelarena: Yes, go ahead.

Diedra Gray: Thank you. My name is Diedra Gray, I'm with the PCPI. And just for clarification, we did reach out to CMS because this measure is currently included in the Meaningful Use program as well as PQRS.

The Meaningful Use data is not available at all to anyone unfortunately, and that would be, you know, the best I guess way to obtain data for reliability testing for eCQM that are included in that program or included in a federal reporting program.

We also reached out for PQRS data and we did receive a sample but it was insufficient, it was not a statistically significant sample. And so we did go ahead and submit the e-measure with the BONNIE data in order to meet NQF requirements.

And we did let the committee know at the in-person meeting that once the data does become available from PQRS and they have more -- a more adequate sample for us to analyze that we would provide that updated data analysis.

Melissa Mariñelarena: Thank you, Diedra.

Dave Cella: Very helpful. You know, it seems to me …

Karen Fields: Melissa -- I'm sorry, this is Karen. Melissa, I guess one of our questions before is how -- if we approve this, can we ask for early review of the data or a secondary review of the data or something along that line so that we could feel that we've got to understand that some of our questions and concerns were answered rather than approving measure for a prolonged period of time with no resolution to our concern?

Melissa Mariñelarena: Well, the measure would be due for maintenance in three years. Like Diedra just started, they are not sure when they're going to have the data available. We can ask that as soon as the data is available for them to provide this type of testing to submit it and then we can have the committee review it then.

Female: Annual updates too.

Melissa Mariñelarena: And we also have annual updates. They have an opportunity to submit information on annual updates, but understanding, as she just said, they don't know when they're going to have the data available to be able to do this type of testing.

Karen Fields: And I appreciate that, I'm just thinking that the committee might feel more comfortable if we knew we're going to get some status reports about the data if available.

Diedra Gray: This is …

Dave Cella: Yes.

Diedra Gray: This is Diedra again. We would be happy to reach out to CMS again for updated data once the 2015 PQRS data becomes available, unfortunately, it's not available yet. It's usually available towards the end of the year, so during annual updates, we'd be happy to provide an update to NQF if that would make the committee feel more comfortable.

Female: Thank you.

Dave Cella: This is -- this is Dave Cella. So I think Karen really put her finger on it. At least what's on my mind here, I mean it's a good measure. The issue really is -- I wouldn't say -- it's somewhat of a technical issue as to -- you know, as to whether or not the e-capture is reliable and valid. I think it's a significant concern.

PCPI and the committee and probably NQF were all sort of between a rock and a hard place where from the committee's perspective, you know, I'll speak for myself only, but it does seem like what Karen was saying I agree with is that there is a reluctance to approve something for three years knowing that it might be problematic and yet we can appreciate PCPI can't get the data right now. So what's the harm in either a provisional approval with a revisit in a year or waiting until that data -- those data are available which might put more pressure on CMS to provide it?

Melissa Mariñelarena: So we don't -- this is Melissa, we don't have a provisional approval with either endorsements or not but like Diedra just said, they can -- they can come back to us with the data that they have and we can provide that to the committee to review it as soon as they have that either through their annual updates.

Dave Cella: Can we do it in -- so we can do it in one year instead of three years?

Elisa Munthali: This is Elisa.

Female: So -- OK.

Elisa Munthali: This is Elisa from the NQF. So the measure would still receive full endorsement for three years but what we are going to do and the committee's recommendation is stipulate that PCPI should come back in a year with this additional analysis for the committee to look at. So it will be a requirement for PCPI to do.

Dave Cella: And then what happens in a year when they come back with that data? Let's just save for the sake of understanding that the data looked unreliable, what

happens to the approved measure, does it stay approved for the next two years or does it come up?

Elisa Munthali: No, because that would be a major criteria then. So it would be essentially what it is as an ad hoc review. So we have an annual review process in which developers make changes to their measures all the time. Those are minor. They're not material nature but this would be a material change.

And so it would really trigger an ad hoc review. And so the committee would be determining whether they've met the standards for that, and if not then the measure would no longer be endorsed.

Dave Cella: Within that three-year period, so at the time …

Elisa Munthali: It would be after one year point from now, yes.

Dave Cella: So I think then what you're saying is it meets the concern that Karen raised that I'm sort of amplifying which is that there is a chance in one year to have a look at this -- or within a year, maybe at most a year to have a look at the actual data and re-evaluate.

Elisa Munthali: Yes. And you'd only be looking at this criterion and this data, yes.

Dave Cella: OK, OK. Well that would be fine, I think. So do others have a comment? I've been talking the mic.

Shelley Fuld Nasso: This is Shelley. I think this argues for why we need to meet more regularly than every three years. And I know you're talking about an ad hoc review but maybe it's an annual review and not everything is up for annual review but it just -- I think that would add to the comfort levels.

You know, some of these measures that are -- that have data or questions outstanding but especially in the field like cancer where, you know, the gaps are so broad. It's just -- that was how I felt after the end of our in-person meeting where we weren't able to approve the measures that in theory or in concept were very good, but with this three-year cycle, it's -- that's a long time not to be able to review them.

I know you -- I know there's the mechanism with the ad hoc review but it seems like there needs to be something a little bit more formal for questions like these.

Elisa Munthali: Yes, Shelley, that's a great point. One of the things that we added to our process in the last year is what we're calling an off-cycle period for standing committees. And this is where we don't have an active project in which committees are evaluating measures but it will give you an opportunity to look at the portfolio, the cancer portfolio in this case to talk about those issues.

Of course, the endorsement decisions are tied to particular measures and -- unless there are some sort of recommendation that comes out at the point of endorsement, we can't be revisiting until there's a change that's material in nature and it triggers an ad hoc review.

But with that said, we did recognize that committees cannot wait every three years I mean especially if we're saying that you have oversight over this portfolio, you need to meet more frequently so that you can understand all the issues and, you know, help us to advance their portfolios, the different topical (A.O.) portfolios.

Dave Cella: Any other comments? So do we have a quorum still?

Shaconna Gorham: We don't.

Dave Cella: OK. So this vote will be for a three-year approval with the understanding that there'll be an ad hoc review in a year, correct?

Female: Yes. If they bring back the data, yes.

Dave Cella: OK. Oops.

Karen Fields: And I guess one more question, sorry to be out of, so what happens if -- so we heard what happens if they bring back the data, it's not reliable, what happens if they don't bring back the data, they just fail to follow through?

Elisa Munthali: So any third person, NQF could bring an ad hoc review, anyone can bring an ad hoc review on the measure. This was an issue, a significant issue that was

raised during this evaluation process. So you can bring it up and ask PCPI that time for the data. And if the data are not adequate or they don't have it then we'll follow the same process.

Dave Cella: So that means it's up -- it will be up to us to request it?

Elisa Munthali: It sounds like PCPI has agreed. And Diedra, you're on the call, Diedra?

Diedra Gray: Yes, Diedra, I'm here.

Elisa Munthali: Yes. So it sounds like Diedra has agreed for when the 2015 data would be released, I think at the end of this year, so by the time this measure is due for its first annual update, it sounds like the data may be available, correct? Then you'd be able to present that to the committee.

Diedra Gray: Yes. I also have a process question if that's OK.

Elisa Munthali: Sure.

Diedra Gray: So at the time that we present the data later in the year or whenever it becomes available, if it -- assuming that the data shows that the measure is reliable, would that still trigger an ad hoc review or would it only be triggered in the -- in the event that the reliability data was not great?

Elisa Munthali: So it's the -- it's actually the type of data, so it is -- the ad hoc review would be triggered because it's a major criterion and it's major information regardless of what it talks -- what it says about the data. Does that make sense?

Diedra Gray: It does.

Elisa Munthali: OK.

Dave Cella: Are we ready to vote?

Shaconna Gorham: Yes. This vote again, we do not have a quorum, so this vote will require additional votes in order to be final. So the members on the call today will

vote and then we will send out a SurveyMonkey onto the remaining committee members.

We are voting now on Measure 2963 Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Prostate Cancer Patients. This is the legacy e-measure and the committee will be re-voting on the reliability criterion.

Female: And everybody …

(Crosstalk)

Shaconna Gorham: Yes.

Female: OK.

Shaconna Gorham: So again, this is not a final vote. We have 92 percent moderate and 8 percent voted low, and we will get the remaining votes via SurveyMonkey.

Now, we can move on to Measure 0459 Risk-Adjusted Length of Stay Greater Than 14 Days After Elective Lobectomy for Lung Cancer. And Karen, you will be facilitating this measure. There are no committee conflicts and your discussers are Gregary Bocsi and Matthew Facktor.

Karen Fields: So Greg, are you going to present again?

Gregary Bocsi: Yes, I'm happy to do that. So 0459 I remember is Risk-Adjusted Length of Stay Greater Than 14 Days after Elective Lobectomy for Lung Cancer. And it's basically just as it says in the description, there are some risk-adjustments and then there's a calculation of the length of stay.

And so where we failed to reach consensus previously was on the importance to measuring report. And then in addition, and there was a comment about this and part of our discussion also was whether, you know, 14 days was a useful, you know, timeframe, useful means of measuring performance to begin with.

So I guess briefly to address that aspect of things, you know, we had asked whether they could provide performance data on 10 days versus 14 days, and that data is at least present and available.

However, they -- I guess Oncology Nursing Society also questioned about whether the, you know, 14 days versus a more pure outcome measure would be preferable and the developer drew our attention to another measure, 1790, which is Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer, which in some ways I guess would overlap in terms of the applicable patient population. So I don't want to say it's a competing measure but it's an alternative measure for trying to get at the same thing.

And so what they pointed out though was that as compared to that measure, this measure would be more geared towards assessing healthcare resource utilization more so than just morbidity or mortality with the assumption that longer lengths of stay would be more costly.

To the more, you know, I guess critical point, I think that where people had questions where -- whether or not there were -- was a persistent performance gap. And so if you look across the different regions where this was measured and across different periods of time, basically, you know, any way you cut it, it tended to be somewhere between like 4 percent and 5 percent of patients had a prolonged length of stay, you know, they were north, east, south, west, you know, 2009, 2014, 2015.

So there was additional data provided by the developer sort of the trend in the, you know, measure of central tendency over time and it seemed to be, you know, sort of fairly stable over time.

And so again, we didn't reach consensus on whether there was a performance gap. That's sort of like the additional information we have is that the mean and median levels of performance have been largely consistent since 2009 through 2015. And so I guess the question remains, do people feel that that indicates that there is a performance gap and people have just not made any measurable improvement or that there really isn't a performance gap and people sort of max out.

Shaconna Gorham: Thank you, Greg. That was a nice summary because it was a long conversation and there were a lot of issues related to it. Matt, you do have anything to add?

Matthew Facktor: No, I think that was -- that was well-summarized. Thank you.

Shaconna Gorham: My other question that I remember, Greg and Matthew, that the committee wrestled with was the smaller volume centers had -- compared to the larger volume centers sort of skewed some of the data in the first place just because of volume made them more reliable and valid procedure and we also might see variation gaps that might not be as easy to quantify because of that.

So I think we were assured by the (FTS) and the developers that volume was -- that the measure wouldn't be impeded by volume but I know that we spent time worrying about that. Any other comments on that?

So Melissa then I -- we need to then as a group then vote on the importance to measure withy -- as our next step and is that correct?

Melissa Mariñelarena: Yes, you're going to be voting on performance gap.

Shaconna Gorham: Oh, performance gap.

Melissa Mariñelarena: And this is -- yes, and this is a must-have criteria for importance to measure. So performance gap is a must-have criteria and that's what you'll be voting on.

Karen Fields: OK. Any other discussion from the group and any other comments from our reviewers, recommendations or thoughts? So it sounds like we're ready to vote and so why don't we go ahead and proceed.

Shaconna Gorham: OK. Voting is open for 0459, importance to measure a report performance gap and you can begin to do now.

Melissa Marinelarena: Is that everybody?

Shaconna Gorham: Thirteen votes. One more.

Melissa Marinelarena: Did we lose somebody?

Karen Fields: Looks like we might have.

Shaconna Gorham: No. We had 13 committee members on the line so we need one more vote.

Female: And it does appear we do still have all 13.

Shaconna Gorham: Has everyone voted? We need one more vote.

Melissa Marinelarena: There we go.

Shaconna Gorham: That's OK. We have 13 votes. Again, we will have to get the remaining of the committee to vote. Right now, we have 69 percent moderate and 31 percent low.

Now we will move to discussion on 0460, Risk-Adjusted Morbidity and Mortality for Esophageal …

Melissa Marinelarena: Esophagectomy.

Shaconna Gorham: Esophagectomy for cancer. Karen, again this is you.

Karen Fields: OK. Yes. And so I know that Steven wasn't able to join us on the call at all. So, Greg, do you feel comfortable presenting this again?

Gregory Bocsi: Yes. Sure. No problem. So this is very similar to the risk-adjusted length of stay except here is actually risk-adjusted morbidity and mortality and instead of lobectomy for lung cancer, we're looking at esophagectomy for cancer which I gathered is actually very similar to that other measures 1790 which we didn't review but which they pointed out in the previous comments.

So here, naturally, there wasn't a concern about it being an outcome measure but there was some discussion that morbidity and mortality were effectively treated similarly and that perhaps those two outcomes were qualitatively different and should be weigh differently in some fashion.

But the gist -- the gist of the concern was that this for many providers is a very low volume procedure and looking at the reliability and validity information that was provided, it seemed that unless you did, you know, greater than or equal to five procedures a year, it was debatable, you know, how well this actually characterize your performance.

And so that I believe was the gist, the reason why consensus wasn't reached. Some people felt that it potentially should be re-specified to maybe require that you perform more than five procedures before being able to report and/or they should be re-specified to differently treat morbidity and mortality.

In any case, those are the concerns that I think were captured in the draft report and then we didn't receive any comments from the public related to this particular measure.

Karen Fields: Thank you, Greg. Again, that was an excellent summary of a long previous discussion. The only other questions were I think there was some no new additional comments from STS concerning our concerns for the measure. So is there any discussion by the group concerning validity?

The developer did note that they were developing a new measure that ultimately weighed mortality differently than morbidity although I guess the answer is an event that triggers the outcome is either morbidity or mortality. So I have -- it's an adverse outcome either way that you look at and I don't -- I personally don't have as much problem with combining those for trying to understand the reliability and validity of the measure.

Any other discussions? So I'm going to move that we go ahead and vote.

Melissa Marinelarena: Just to remind everybody, you're going to be voting on reliability and then validity.

Shaconna Gorham: OK. So voting is open for 0460, reliability, you can begin voting now. All right. We need one more vote. Can you please place your vote for reliability?

Female: It's not up on my screen. I only see reliability

Shaconna Gorham: We have it.

Melissa Marinelarena: OK.

Shaconna Gorham: Yes. So we have 15 percent high, 31 percent moderate and 54 percent low. OK. Now we will vote on validity for measure 0460.

Melissa Marinelarena: OK. That's everybody, right?

Shaconna Gorham: We need one more.

Melissa Marinelarena: All right, 13. We need one more vote.

Shaconna Gorham: Please place your vote for validity. We need one more vote. Perfect. OK. We have 38 percent moderate and 62 percent for low.

Melissa Marinelarena: OK.

Shaconna Gorham: Yes. So last measure is 0509, Diagnostic Imaging: Reminder System for Screening Mammograms, I'm sorry, and Karen, I'll hand it back over to you.

Karen Fields: Thank you. So the discussants today are Jennifer Harvey and Shelley Fuld Nasso and I've heard Shelly on the line but have we heard Jennifer.

Shaconna Gorham: Jennifer is not on the call.

Jennifer Harvey: Yes, I'm here.

Karen Fields: OK. So, Jennifer, could you present for us.

Karen Fields: That's Shelley.

Jennifer Harvey: So just have to -- this measure basically evaluates sending of reminder letters to patients that is time to schedule their next mammogram. The interval is based on their recommended mammograms so if it's -- if they are doing recommending every other year mammography then that would be every two years, a reminder is sent, if it's one year ,then one year.

The main concern about this measure was the validity testing. When we discussed this back in March, the validity is implied basically that this measure was assessed by two different expert groups.

You know, basically the idea is does this improve outcomes or not. Well, I mean, it's hard to know but based on expert opinion, the National Mammography Database Committee and members of the Commission on Breast Cancer for the American College of Radiology, the opinion was yes.

I think there's concerns that were raised in march where that what about exceptions that as patients were older or had mastectomies or had other health issues that those obviously should not be included. However, those were very small number of patients. It was like four. So it's a very small number that were excluded and already is an exclusion.

So that's sort of my summary for the validity.

Karen Fields: Thank you, Jennifer. That was an excellent summary and, Shelley, do you have anything to add?

Shelley Fuld Nasso: No. I was just a little unclear on, you know, with some of these others we had, you know, more kind of data to inform our discussion from the meeting but it doesn't seem like there were any comments here or anything provided that would change our discussion that we had in -- at our in-person meeting.

Karen Fields: Yes. That is the case and there was an additional comments and I don't think we got any feedback from the American College of Radiology, correct, Melissa or …

Melissa Marinelarena: That's correct or at least that was noted.

Judy Burleson: Hello, this is Judy Burleson of the American College of Radiology. Is it possible for me to make a few comments?

Karen Fields: Yes, please.

Judy Burleson: On doing data analysis on the low level of exceptions, unfortunately, we were not able to get additional data at this time on the exceptions since the first year

that was available for reporting the measure for the PQRS program was 2014 and that was limit of the data that was available from CMS.

We can get the data for 2015 PQRS and look at the level of exceptions reported to see if it has increased and do some analysis on that but we're just limited by what was available. And I would also like to point out, I don't we think discussed this, I don't think this was mentioned at the in-person meeting and this may speak to why the exception reported was low.

But the measure is designed with some flexibility so that it -- what it is requiring is for patient who's come in for screen mammography -- mammogram for that patient information to be entered into our reminder system with demographics and contact information so that the patient could receive a reminder letter as appropriate for that case.

So potentially if a site has patient who may not need to return based on medical conditions or history suggests mastectomy then it's not a requirement to send out the letter. The measure is looking at that there is a system available for sending out letters as appropriate. So there is flexibility there for patients in that case.

So that does bring about a question on the need for the exception. That is something that we added to the measure and discussion with CMS based on input they had received from participants in the PQRS but -- and looking at the 2015 data, we may see that again there's low level of use of the exception and may consider removing the exception for that reason.

So that is just something I wanted to offer to the Committee.

Karen Fields: Thank you for those comments. To the reviewers, does that clarify any of your comments or questions? And anyone from the rest of the Committee have any other comments?

So just to clarify, ACR is suggesting that they're going to assess the addition of that exclusion as -- to see if it added any value to the measure ultimately after you get your data. Am I interpreting that correctly?

Judy Burleson: Yes.

Karen Fields: OK.

Shelley Fuld Nasso: You know, I think that's fairly reasonable.

Karen Fields: OK. Well, without any other questions or comments from the rest of the Committee, I think it's OK to move ahead to vote.

Shaconna Gorham: OK. OK. So we can vote on 0509 and we will vote on the validity criteria. You can begin to vote now. OK. So that is 62 percent moderate and 38 percent low and that concludes our voting for our consensus-not-reached measures.

We again will send a survey monthly to those committee members who did not participate in the call today for measures 2963, 0459, 0460 and 0509. With that, we will move into our discussion on gaps. Melissa?

Melissa Marinelarena: Hi, this is Melissa again. So the document that you received of the NQF cancer portfolio and related measures, this was -- we started to talk about gaps during this committee meeting and we used the patient episode of care framework.

So this part here that we're looking at on the screen was or you will be looking out on the screen was taken from the report and it just describes the patient episode of care which I think we went over during the meeting that haven't looked at different phases of care for the patients and this helps sort of refine this -- the framework that we're using.

The next pages are similar to the way I identified gaps during the meeting, but this time I tried to separate early disease or treatment of early disease and advanced disease as to separate so that we can look at the gaps between the two different treatments.

Some of them overlaps. Based on the framework here, early disease is most often defined as stage 1 or stage 2 and then the advanced disease is stage 3 and stage 4. Some of these measures sort of overlaps and that's what you're

seeing here with, like, 1858, 0387 where they go from stage 1 to 3. So I just counted it for both categories.

So I think we want to talk about here we can see where our gaps are and it's all of the blue boxes. We do not have any measures in these areas and then if you look at the type of cancer that we cover, we have sort of a bone cancer, its metastasis or bone metastasis, breast.

I also included -- if you look at the measures that are italicized, those are measures from other projects. So I looked at everything in our database, it found -- there is a cervical cancer screening measure. We also have a colorectal cancer screening. So I was able to slap these into our gaps for screening measures for these types of cancer.

You keep going through it. I placed the hematology and the long and thoracic measures as well.

Under other, we have about five measures that we do not review during this phase that are -- wasn't really sure where to include them. They're not necessarily diagnosis or treatment, so I just labeled them as other and then you see the italicized measures are also related to cancer but in other portfolios. They come from either palliative care portfolio, they help in wellbeing portfolio, and there was another one. But there is some pain assessment. These are still almost process measures.

And then at the end of the document, I just included, again, the long list of gaps that have been identified in various projects from 2008 into 2012 which was our most recent review of the cancer measures.

So I think I will turn it over to Karen and Dave to lead the discussion on gaps and identify where we want to go with this.

Karen Fields: Thank you. I really appreciated your table showing the blue areas and I also really appreciated your categorizing them based on the different phases of therapy.

I think what we'd really want to do is get to discussion with the group today. We've got quite a while left on our agenda here so that we could really spend some more time thinking about where you think some gaps are and where we can go make back and make some stronger recommendations.

So I'm going to -- Dave, do you want to add some comments before we try to solicit some comments from the group?

Dave Cella: Sure. Thanks, Karen.

I also want to thank the NQF staff for putting together this document. Karen and I and the staff added the conversation a week or two ago and this -- excuse me -- sorry about my cough. This came out of that conversation. It's really nicely organized and I think -- unfortunately, it might -- it might show that there are as many gaps as there are covered areas and maybe more gaps than covered areas.

And one big one that the group came up with at the end of the meeting, just to remind everyone, in the face-to-face meeting was a notable gap in outcome measures in general as opposed to process measures which is really the case from most of what we reviewed and I guess for all of the NQF measures.

And just, finally, to note that -- I'm struck by how even risk adjusted morbidity and mortality is really restricted to just thoracic oncology and wondering if this might not be an opportunity to partner with -- in some way with ASCO, you know, who are developing, you know, a sense of common measures.

So I just wonder about that. That seems like if we've got the risk adjustments figured out, there ought to be -- there ought to be outcome measures on risk adjusted morbidity and mortality coming through.

Karen Fields: So I think -- I guess one other comment, I think the hardest part about getting the outcomes data or evaluating outcomes because we obviously still were critical of the two outcomes measures that we had today to evaluate the lung cancer and the esophagectomy measure is the -- how to interpret the data and

how to -- because we're going to have a lower volume of data sometimes or a different kind of data to look at than just the process measure.

So the -- I wanted to ask the committee their thoughts about that. Does that inhibit us from being able to evaluate outcomes measures or how does the committee feel about that?

I'm taking no comments as an ascent or a descent but …

Dave Cella: Well, Karen, I was being -- this is Dave. I was being silent to hope to hear from others but I will say, I think, again, you've really put your finger right on something here which I hadn't thought about until you mentioned it which is, you know, we -- if we apply the same criteria in the same way for outcome measures as we do to process measures, we may be dooming the outcome measures to sail along the way and that's really not our intention, although it may be an unintended consequence of the way we go about the review.

And I -- I don't -- that's not exactly what you said but it's -- it's where I went in my head with what you said. And so I don't know if and how we can address that to be able to both encourage the -- the developing and approving of more outcome measures and at the same time, you know, be a part of that process in terms of identifying what it takes to be, you know, to make it, if you will, as an outcome measure because it sounds like you're, to me at least, I heard you implying that process measures are easier to get approved.

Karen Fields: That's what I'm implying. So who was going to comment? I'm sorry.

Melissa Mariñelarena: This is Melissa and I was just going to clarify as far as the criteria, that NQF criteria, it's exactly the same for an outcome measure versus a process measure except for evidence. That's a little bit different.

But as far as the testing, you know, performance gap, all of that is still the same. We don't have different criteria for that.

And again, to remind the committee, we did have a new outcome measure that was reviewed. It was the ED (business) admissions measure and …

Dave Cella: Right.

Melissa Mariñelarena: And, you know, there was questions about evidence but it was, I think, volume is a big part of it because of the reliability scores and ultimately, I think it did not pass on reliability or validity. But …

Dave Cella: Well, that's a -- that's a really good example. The ED inpatient hospitalization for adverse events, that's the one you're talking about which didn't get brought back to us and I think some of us, I would speak for myself, were disappointed that it wasn't brought back because I would want to see that kind of thing pushed forward but maybe it was perceived to be too big a ball to roll up the hill.

Jette Hogenmiller: But I think it's a good point, excuse me.

(Crosstalk)

Karen Fields: Yes. Go ahead. Go ahead.

Jette Hogenmiller: Jette Hogenmiller. No, I think -- you know, you properly indicate that, you know, how are we going to get in the outcome measures and so many of them really requires some adjustment multifactorial and so how do you get a good measure that's really plain in that regard without some, you know, multivariables, really, being included in there and what we can do. It weren't, I think, a bigger discussion to promote more outcome measures.

Dave Cella: Yes.

Karen Fields: Yes. I mean, I think that's a good example of our -- we had to combine ED visits and hospital stays as just a reflection of an adverse outcome and that felt uncomfortable to the groups because you're -- but I think that was an appropriate blending of a trigger for an adverse outcome.

But so I think that's what I'm trying to get at. But someone else was going to say something and I interrupted. So, please, comments?

Gregary Bocsi: Well, this is Greg. I was just going to inquire. Do the NQF staff see like some trend towards more submission of outcome measures? And if so -- it just strikes me that the outcome measures are potentially something that is very appealing from the perspective of someone who is paying for healthcare or receiving healthcare.

And the process measures are perhaps more natural to think of from the people who are providing healthcare. But in the extent that the organizations submitting measures for approval or weighted towards either group, you may get, you know, disproportionately more outcome versus process measures.

And I just say that from the perspective of pathologist, it's -- it's hard for us to understand exactly how we demonstrably affect, you know, traditional concepts of outcomes when, you know, the services we provide are significantly upstream of any number of various factors that could significantly modify that outcome.

(Alyssa): Hi, this is Alyssa. It's a -- it's a great question. We do have a preference for outcome measures where it all possible but I think you are -- you articulated what some of the challenges are. It's really the data that is linking this outcome to a process and the proximity of that. It's really difficult for measure developers. Those organizations that are bringing measures to us to be able to get the adequate or appropriate data.

But we definitely do have a preference for outcomes particularly patient person, family centered outcomes and we're seeing a slow trend towards that but there's some data challenges as well.

Gregary Bocsi: Yes. And I think that, you know, from the process measure, you know, the measure developer can see how they could potentially intervene in a certain way to achieve a change in their, you know, performance of a particular process.

But in order to come up with an outcome and then to do all the statistical risk adjustment and everything requires the level of sophistication that may not be immediately available to even well intended measure developers, both the data as well as the statistical expertise.

Karen Fields: Yes. I mean, I was just going to -- I mean, this is a related but slightly tangential comment.

I mean, one of the things that I've been struck by, you know, say for example, the, you know, the ER utilization and hospitalization measure, I think part of the reason that failed was the reliability was poor because they've restricted the measure developers, restricted the diagnoses associated with the admissions so that decreased the volume.

You know, similarly, I think some of the concerns about the morbidity and mortality measure was in kind of lumping those together. I mean, I want -- you know, it kind of pained me to see people put so much effort into developing measures and then, you know, to have them shutdown and there's sort of no fallback and, you know, we kind of keep going round and round, wringing our hands that we don't have any good measures and yet some of the, you know, few new ones that have been presented done make it.

So I mean, I just throw this out there for NQF's consideration. Is there -- is there any possible way especially with this, you know, with this standing committee approach to have some more, maybe, interim discussions where developers would be encouraged to present, kind of their in-process work and, you know, share some of the ways that they're thinking about developing measures so that we could provide feedback on what we, you know, think, you know.

You know, if the developer had heard that morbidity and mortality combined together was not going to really pass the validity test, then maybe they would have picked another pass. I don't know. Something to think about.

Male: You're kind of describing a process that's a little bit more like the way the FDA works with pharma. You know, there could be a little bit more even though it's sort of a highly scripted choreographed exercise, there are multiple points at which a pharmaceutical sponsor can submit materials and get feedback from -- from the FDA.

Shelley Fuld Nasso: This is Shelley. I think that's kind of along the lines of what I was saying before where when, you know, it's -- I think not just having, you know, ad hoc reviews is enough but if there was more interaction in the process, so that it's not just all these -- as Jen said, all these huge amount of effort going into it and then it shutdown, I think your analogy to how the FDA works is good because it's a sort of an interactive process throughout, not just, you know, submit and then you get the no and you've wasted all these time and effort.

Or maybe that isn't some cases but I know that with breakthrough, they're doing that differently. And I think that would be great if we, as the committee, could play that kind of role where we're giving more feedback and maybe that's something as part of the incubator, you know, there could be more feedback on the measures as they're developed so that measures have a better chance of making it through the process.

(Alyssa): Hi, this is Alyssa again from NQF. Those are great points and part of the role of the committee during the off cycle is to talk about issues like that, not just ad hoc with you. I can give you an example of our care coordination standing committee. They haven't had any measure review in the last few years. We're hoping that we'll have an endorsement and maintenance project very soon.

But they did have an off-cycle period in which they talked with developers about perspective measures and development and concept. So it depends on what the direction of specific standing committees have, what's on their plate. An ad hoc with you is one that we may do on an off cycle but talking about these issues, perhaps giving some guidance, to developers on direction for measure development is another.

And then we're also hoping that this will give us an opportunity for committees to talk not just amongst themselves but with between. So we could see an opportunity for the cancer committee speaking with the care coordination committee on some relevant topics. And those are -- that's definitely within the scope of the off-cycle review.

Karen Fields: So I think that's great. I think, you know, I guess, kind of two follow up comments. One would be how to -- how do we effectively market that to the -

- to the developer community so they think about that sort of in their development process and timeline. Is it possible to do it more frequently than annually just, you know, having then a measure developer and sort of knowing different timelines with things. It would seem like, you know, having quarter auctions or something like that would -- would maybe help to prime the pump more.

And then the other thing, just, again, and this is a little bit off-topic again but a kind of another shift, but, you know, the -- specially in a field as dynamic as oncology, the percent of new measures that we're seeing relative to, you know, decades old measures now coming off for recertification, you know, I think is something that we've all been very, you know, disappointed maybe even distressed about.

And so I wonder if there isn't some sort of way to incentivize people who present measures that, you know, that if you're going to present old measures, you have to, you know, submit an equal number of new measures as well or something along those lines so that we don't keep seeing the same tired measures back again.

(Alyssa): So, I can -- this is (Alyssa) again. So with regards to your first point, you know, there is -- we have scope but we have budget as well but we do have, I think, within an off-cycle period quarter webinars. So, you know, there are opportunities depending on what, you know, topics you want to bring forward for us to take advantage of those.

Karen Fields: Yes. No, I mean, I don't think those needs to be done in person. I would think webinars would be more than adequate for, you know, encouraging discussion and getting developers to share their ideas and get feedback, have a feedback opportunity.

Gregary Bocsi: This is Greg. I do have two comments. One, I agree with what I think people have already recommended and that is that it would certainly seem reasonable to me that people, like a developer could submit a clearly incomplete measure for review and if all they had was the reliability component, it would require voting but we could certainly discuss it and provide thoughts or concerns

about how they were, you know, proceeding such that they would have an opportunity to modify what was being done before submitting the whole kit and caboodle for, you know, sort of an up or down vote.

I mean, the -- I think that's what I was hearing and then it sounded like a good idea to me.

The second thought was, you know, with the, you know, document you sent out, the portfolio and everything, it does also get sent to the measure developers, like, you know, here's list of things that, you know, we noticed are missing, how about, you know, stepping up?

(Alyssa): Yes. We are -- reports are posted publicly. The developers know when they're posted but we can maybe take a more proactive role and sharing that. We also -- that the incubator was mentioned earlier. What we also do is with our colleagues working on the incubator, we share the gaps across all of the topic areas when the process of prioritizing those gaps and prioritizing measures and so we're hoping that we can generate or cultivate some relationships through the incubator to help us to fulfill those gaps.

So, yes, those are shared with developers in a number of different ways but maybe we can be a little more proactive with that.

To the other points about, you know, just readiness with the committee, what we do offer throughout, not just a part of the committee or a standing committee or topic area is ongoing technical assistance. So any measure developer can contact us at anytime at any period in their development process if they need any technical advice on their measures, not just related to the process but maybe other technical issues with their measures.

So that's ongoing. Developers do take advantage of it. We wish more did but, you know, it's an ongoing process that we have.

Dave Cella: I'm just getting a little mindful of the time and wondering if we need to move to a public comment. I hate to cut off conversation but we're 10 minutes to a close.

Karen Fields: Yes. Thank you, David.

Shaconna, can you open the line for member on public comment, please?

Shaconna Gorham: Absolutely. Our operator will go ahead and give the instructions now.

Operator: At this time, in order to make a public comment, please press star one on your telephone keypad. Currently, there are no public comments.

Dave Cella: Well, that was easy. We can return to the discussion. The only other item is the next steps and the timeline. But, Shaconna, maybe you can fold that in as you see fit?

Karen Fields: Yes, that would be rather brief.

Shaconna Gorham: Sure.

Karen Fields: To Melissa -- Melissa and Shaconna that we didn't really answer your question about gaps although we gave some other kinds of comments is that what you were seeking, because we didn't say we'd love to see a measure in whatever area. I think your table identifies the areas and then outcomes is, obviously, the goal and better ways to communicate with developers is the strategy. Does that sound enough for you?

Melissa Mariñelarena: Yes. We can include that in the report now and then we can continue working on gaps during the off cycle work that (Alyssa) just mentioned. And further refine our framework and, you know, that gives the committee more time to think about where do you want this to go but we can definitely do that in the off cycle. So you're not going to be done just yet. So for now we're fine.

Karen Fields: We thought -- we thought we would get away with a non-answer answer there.

Melissa Mariñelarena: No, we're going to put you to work all-year round.

Dave Cella: So I just wonder if -- it looks -- it looks like relative to breast and colon that are kind of -- that do sort of cover the, you know, coast to coast from

screening to advanced disease. Thoracic and prostate do not. I mean, maybe we should also make note of that and those are the big, you know, the big four, so to speak.

Shaconna Gorham: And one other area I brought up with David and the rest -- the group behind the scenes last week was shifting to the way oncology shifting and more focus on oral oncolytics and strategies to understand compliance are improved or measure compliance since we're moving more and more to that kind of chemotherapy. We don't really have any measures at all to look at that.

Melissa Mariñelarena: Yes. Thank you.

OK. So we will continue working on our gaps and our portfolio in the off cycle. I guess then you're not off the hook. We're going to put you to work year round.

But for now, the next steps include -- we will follow up with the committee members that were not on the webinar today to vote so that we could get quorum on the rest of the measures. I believe we only got quorum on the first one. So that's the -- for two? OK.

So that's the immediate next steps. We are going to go to membership vote. It looks like we will do it September the 6th. Our membership vote is open for 15 days. So that will go through the 20th. And then we are scheduled to go before CSAC on October 11th.

Shaconna Gorham: And just a reminder, Karen and Dave will represent the committee at CSAC. Your attendance is not required. We definitely welcome your attendance, however.

Melissa Mariñelarena: And then when CSAC reviews the measures, then they go to our board of directors for ratification. And then there's a 30-day appeals period after that. So that will take us into, I think, the first few days of the -- of next year.

So, right now, we will follow up -- so Shaconna and I will follow up via e-mail with the immediate next steps, the SurveyMonkey links and then we will update everybody with the results of the -- of the voting for the criteria.

And I think that's it, right?

Shaconna Gorham: Yes.

Melissa Mariñelarena: Does anybody have any last questions, comments?

Dave Cella: Thank you again everyone for your time.

Female: Thank you also.

Melissa Mariñelarena: Thank you. It's great talking to all of you and we will be in touch shortly. Thank you.

Shaconna Gorham: Thank you. Have a great day.

END