NATIONAL QUALITY FORUM

Moderator: Angela Franklin
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12:00 p.m. ET

Angela Franklin: Hi. Welcome to the Cancer Endorsement Maintenance Steering Committee call. This is for phase two of our project. And the purpose of today's call will be to review comments received, measures considered in phase two. Our chair for this committee is Dr. Stephen Lutz.

And before we get started, I'd like to get through a quick roll call. And Adeela, could you do that…

Adeela Khan: Sure.

Stephen Lutz?

Stephen Lutz: I'm here.

Adeela Khan: Joseph Alvarnas?

Joseph Alvarnas: Here.

Adeela Khan: Eduardo Bruera? Elaine Chottiner? (William Dale)? Heidi Donovan? Steven Edge?

Steven Edge: Here.

Adeela Khan: Karen Fields?

Karen Fields: Here.

Adeela Khan: John Gore? Elizabeth Hammond? Joseph Lavor?

Joseph Lavor: Here.

Adeela Khan: (Jared Lowe)? Bryan Loy?

Bryan Loy: Here.

Adeela Khan: Jennifer Malin?

Jennifer Malin: Here.

Adeela Khan: Larry Marks?

Larry Marks: Here.

Adeela Khan: Robert Miller?

Robert Miller: Here.

Adeela Khan: Naomi Naierman?

Naomi Naierman: Yes.

Adeela Khan: David Pfister? Rocco Ricciardi? Patrick Ross? Nicole Tapay? And Wendy Tenzyk?

Wendy Tenzyk: Here.

Nicole Tapay: I'm here.

Angela Franklin: OK. Thanks. So welcome to the call everyone.

And Dr. Lutz, I guess I will turn it over to you for your introduction. And first up on our panel discussion will be discussion of measure 0031.

Steve Edge: This is Dr. Edge. Once again, most of us do not have an agenda nor do we have the link to the Web site. Could you please re-e-mail that as soon as possible?

Adeela Khan: I just send out the link to the Webinar.

Steve Edge: (I'm counting). Thank you.

Stephen Lutz: OK. This is Steve. I think, I'm not sure how much work we actually have to do if it will take two hours. But welcome and I think we're actually closing in on some finish lines, so that is exciting. And I don't know if everyone has everything but I think the first thing listed is to go over the 0031, which was the breast cancer screening.

I'm trying to recall who was the one that presented that to us. I think he gave us like just a (two-second thumbnail) so we kind of catch up with the original (inaudible).

Angela Franklin: Dr. Lutz, this is Angela, sorry to interrupt. We did have just a quick request to go ahead with the two measures that pull them out of order. And those are measures number 391 and 392. This is for discussion of those first and then we'll go to 31. I'm sorry about that.

Stephen Lutz: It's OK. So I don't recall which one of those are so let me…

Angela Franklin: That was – so the first measure 0391 was breast cancer resection pathology reporting. And we had a comment there and I am not sure if we want to read the comment that we received and have the committee weigh in on the response from the developer.

Stephen Lutz: OK. Can we just say – I think 391, is that the one I have just a thumbnail that says reporting pathologic T category pathologic N category with histologic grade? Is that we were discussing?

Female: That's correct.

Stephen Lutz: OK.

Angela Franklin: And the…

Stephen Lutz: Did we pass that or not pass it?

Angela Franklin: Yes. We are supportive of the measure.

Stephen Lutz: OK. And then what was the comment?

Angela Franklin: We have to pull that out.

Female: OK. Comment was submitted by (Carmela Bauccino). It says that this measure only assesses standard practice that should be routinely occurring for all patients in the future, but the measures of patient outcomes will be needed to be developed.

Angela Franklin: And do we also have the measure developer for this measure? I believe that's AMA-PCPI.

Male: Oh, yes. So this is (inaudible), MA-PCI – excuse me – PCPI representative from the College of American Pathologists.

Angela Franklin: OK. I know you – those request to discuss this measure with the committee, did you have comments specifically to respond to the comment?

Male: Basically, we realized that the CS standard of practice or what should be standard of practice and yet our surveys a few years ago indicated only about an 80 percent compliance with the simple measure. And then even some more recent data that we got from, I believe (Mr. Stewart), indicated an 88-87 percent compliance with it. But we realized that it addresses things which really should be standard of care routinely occurring.

What we are able to tell there is a documented gap in this measure. And we do certainly intend to expand and to evolve the measure over time. But for now, we feel that because of the documented care gap in this that it is appropriate for us currently.

Angela Franklin: OK, thanks. And was there any discussion from the committee members?

Stephen Lutz: This is Steve. I think – I think we actually had this discussion if my memory serves and that we sort of did the same thing that, you know, this seems like it would be obvious and everyone should be doing it. But we just don't seem to

find, you know, data that it's closer to 100 percent. So I think – I think we're sort of agreeing – had previously agreed with the comment that we just heard.

Anyone else's memory? Can they help me? But I think we already sort of agreed with that type of comment that…

Female: I think we did about this number of the measures saying that this was sort of low bars and we would hope that the next time around there would be some newer measures that would reflect the current science.

Stephen Lutz: I mean certainly, you know, significant enough about the written comment we'll consider whether we pass it, I mean, unless someone else…

Male: Right. The comment is supportive, right?

Stephen Lutz: Right.

Angela Franklin: Yes.

Male: I'm sorry. Why did we ask for comments?

Angela Franklin: The developer wanted to respond to the comment that was – that was made about the measure.

Male: OK.

Angela Franklin: So…

Male: We did pass it though, correct?

Angela Franklin: Yes. Yes, we did.

Female: Sorry, can we vote for the draft report for public and member comment to give the public a chance to lay in on their recommendations that the Steering Committee made for all of the measures. So was it necessarily about anything other than a process check for us that's not specific to this measure?

Stephen Lutz: I think we'd say unless mistaken that we agree with the developer's comment and appreciate them coming on to help us. But I think, yes, it's what we

already sort of agreed on before the public comment came in. I don't see anything to change.

Angela Franklin: OK. All right.

Adeela Khan: Do you want me to (inaudible) about that?

Angela Franklin: Not yet.

Adeela Khan: OK.

Angela Franklin: So that brings us down to 392, colorectal cancer resection pathology reporting, P.T. category and P.N. category with histologic grade. And it's also – let's see can pull up to that one.

Adeela Khan: Comments are the same, ma'am.

Angela Franklin: Same. It's the same comment, similar comment. So is there's additional discussion from the steering committee about this one? Or – looks like we've covered it.

Male: We've covered it.

Angela Franklin: All right. All right, Dr. Lutz, we can go back on to our agenda and move on to the breast cancer measure.

Stephen Lutz: OK. And I think we had just – I think we had just mentioned that (thumbnail) so I can find it, this was 0031 and percentage of women 40 to 69 years of age who had a mammogram to screen for breast cancer.

I think we had a good healthy discussion about this in terms of some of the disagreements we've seen in other published guidelines and we had, as I recall, chosen to defer trying not to take aside. But I'm not sure that that was well accepted by the folks to check things beyond us. So I think they want is to make a statement if I'm understanding correctly. Is that the judgment?

Do we have a specific – do we have a specific comment from someone asking whether, you know, what they wanted of us or whether they wanted us to discuss this one further?

Angela Franklin: So for this measure, we discussed it at the in-person meeting and there was request that we not vote on the measure at that time, so we have not voted as a steering committee on this measure. And we were waiting comments from the field regarding the changing underlying guidelines.

So the committee still would need to take into account the comments received during the period and then discuss and we'll need to put this out for a vote for the steering committee. So we still have a process to go through for this one.

Heidi Bossley: Right. And this is Heidi. Just to add so you all remember and I know you haven't in front of you. But when you discussed the important criteria that pass on impact and performance gap, but because of the inconsistency or insufficient evidence on the age it did not have that. You had two yes, one no and then eight for insufficient, which was part of the reason I think you wanted to get as many comments from the field on what everyone's current thinking is for these measures and you received it looks like three comments.

So part of the question I think you did a preliminary vote, two yes and nine no, when you did put this out and you want to perhaps change your recommendation. That was really a preliminary (sense of thought) recommendation at that time.

Does that make sense?

Stephen Lutz: It does make sense everything I bring up, because I think someone in the group brought this up when we discussed it. Someone in their comments said there's an alternative the measure could be age stratified with those who are 40 to 49 having either mammography or documentation of a discussion.

And I know we've been, you know, sort of hesitant to vote having measures that involve just discussions of something. But, you know, I'm not sure. Again, we're back toward that age 40 to 49 obviously from the comments so still people think that it could go either way.

(Cecine): Hi Heidi. This is (Cecine). I just want to let you know Bob and I are here and wondering if we can say something…

Heidi Bossley: Sure.

(Cecine): …for NCQA.

Heidi Bossley: Please go ahead.

(Cecine): So we got three comments and two of them support the measure. The third one said, harmonized with the task force screening guidelines. And I think what this does even though at a small number sort of reflect the fact that we do have a measure where we have some major national organizations that are recommending screening from 40 to 49. And the task force itself doesn't recommend against it per se but said that it should be an individual decision to take it into context patient preferences.

So the issue of whether or not we should stratify the measure is actually something that we are looking at right now. I think we noted in the past steering committee that we are currently reevaluating the measure. We are reevaluating a measure in the sake of national guidelines that recommends, you know, slightly different thing.

One of the options that we are looking at is if we do break it up, you know, between 40 to 49, 50 to 74 it's possible we could, you know, have the measure look at this age range that is recommended by many organizations. But if we wanted to we could take the 50 to 74 age that is the one part that is completely aligned with all the different organizations. And may be that's the age stratification that we could use for public reporting or other programs in which the measure resides.

So, you know, we had noted that this is – this is something that we're looking at now. And unfortunately, our processes and timeline still enough aligned with NQF. But we're moving the endorsement we're not sure it's the right way to go.

(Bob): This is (Bob) at NCQA to remind of the timeline. We're taking the reevaluation of our measure. We just had our measurement advisory count for breast cancer screening last month and we're taking it to our committee on performance measurement, which is our version of CSAC if you will, and taking that to them in September –this September. After that we'll go to public comment in February of 2013. And then if approved to public comment and final (feed-in) review then that measure would be updated June or July of 2013.

Stephen Lutz: This is Steve. I think if you, you know, it goes 50 to 74 and that ends up being we vote on and it passes that doesn't say that 40 to 49 shouldn't be or should be. In other words, it's simply not addressed. So it doesn't say it's inappropriate it just doesn't address it and therefore leaves it open for whatever, you know, recommendations come in 2013 or beyond.

Male: (Inaudible). I mean, you know, I think this the interface between implicit with the metric is that the metric is sort of implying that this is the standard. And I think that – you know, I think remembering those comments are made at the discussion at (inaudible) community meeting that I think one of the issues that came up was is this the metric as crafted clearly the standard for the group from age 40 to 49.

You know, certainly a number of highly people that know a lot about breast cancer and a lot about would say yes they think it is. But if, let's say, just to let say if the other side of this if, you know, you're a patient and you're saying, well, you know – you know, there's pretty – seems like a pretty big body the United States task force and seems that a little different idea about this.

And, you know, it's not and say it's sort of implied that it is standard when a pretty major body in our country is saying that it's, you know, we need to look at this carefully. It'd say, you know, there is (inaudible) internal medicine in the last couple of years. You know, it's something which is a – and when I look at the three comments received, the one was – obviously the one from the insurance entity said to harmonize with the guideline. The first one says endorsed as is.

But even the one that quoted the other organizations embed the third paragraph they put in is, you know, the wording was like arsenal turn of strategy would be to have for the 40 to 49-year-old group and sort of risk stratified sort of approach that the metric would reflect that risk stratification. And I think the issue right now is that theirs is no risk stratification in the group. They have a few exclusions if you mastectomy and stuff.

So I would probably say that when you're on the face of looks like two to three comments in the endorsed measure as is, well, I'd say one of them definitely endorsed the measure. The second comment endorses it but says yes but implicit they embed in it that this is an alternative way to look at it.

Stephen Lutz: Well, if I could try – I mean, that's a very good point. If I try and think it is a lay person, you know, if someone says a quality measure one would assume that quality measure at least has to have some sense that everyone does agree on it. So 50 to 74 pretty much everyone agrees on again we're back to just (inaudible). The measure of quality is whether it's done in the people we know it has to be done on them.

And 40 to 49 as suggested from the comment is still in almost in three different places. It's almost impossible to my mind to leave it in if it's going to be passed. And if it has to be left in, I'm not sure if there's an easy way currently to make it OK as a true-quality measure or you're measuring the quality of care in these patients. So I don't know, I mean, from a very strict standpoint it's hard that that's in there for me to come to a conclusion.

Robert Miller: Hey, this is Bob Miller. I just wanted to comment – excuse me – that I don't think anything has changed from our discussion in the in-person meeting that, you know, I'm not comfortable endorsing this measure because of this uncertainty. And I mean, I appreciate the other viewpoints but that's the (cracks) of the argument, right? So that's what everyone has been saying. Everyone has a viewpoint on this.

But I agree with what Steven just said. I think as a quality measure I think we're trending in some dangerous ground if we go on record endorsing this in

this time of uncertainty. So I don't see that these comments have changed my thinking about what our discussion was when we met in person.

Female: (Inaudible)

Female: I totally concur with the statement. I, too, am unmoved at this point.

Male: I agree.

Male: I agree.

Female: I agree.

Male: (Inaudible) I agree, yes.

Wendy Tenzyk: It's Wendy. I agree also.

Stephen Lutz: Would we – would we change, I mean, would we suggest it just changed to 50 to 74 and then that's a non-issue or do we say that it just needs to be settled for 40 to 49 before we go on, you know, before anyone goes on to make any statement? I mean, I can see a 50 to 74, but is that a bad thing or is that, you know?

Female: I think – I mean, I think, you know, any (counter interval) evidence and consensus round 50 to 74, 40 to 49 there's a lot of controversy and the difference between a quality measure a guideline is that quality measure implies that you're providing bad care if you don't provide everyone in that group with a mammogram according to the numerator statement.

Bryan Loy: So if stratification – this is Bryan Loy – if stratification is an option in this discussion and somebody will have to stop if it not, is it the non-debatable quality measure that is in the 40 to 49-year-old that requirement of having the provider have a discussion about the risks and benefits of breast cancer screening and not the imaging?

Male: Yes. But that's hard for us to measure, right?

Female: Right. And that's not, I mean, I think stratification doesn't get around the problem. You're just reporting the results differently for the different group, but I'm concerned. So I think having a different measure for the 40 to 49-year-old, you know, may be a measure that says, you know, if you have family history you should have a mammogram. If you don't have family history, you know, or other risk factors then you should have a discussion.

That's a different measure. Just stratify and the current measure just means you're reporting different risks, you know, you're reporting the results differently for the different age groups. I don't think that gets around the issue, because basically, you know, what do you make of the result for the 40 to 49-year-old, I mean, you know, so at least it doesn't penalize I guess in terms of including that, you know, what the issue is for providers who have a different age distribution.

But I think it actually could end up being harmful because people could somehow point to it and say that gee, we need guidelines to say that they should get mammograms because the results are so terrible or something. I mean I think there are also sort of unintended consequences of reporting a measure that isn't based on good science and consensus.

Bryan Loy: Yes. Maybe I'm not making my point very well. I was just – I am at a belief that if the 40 to 49-year-old quality measure was documentation of an informed consent-type discussion around breast cancer screening, it seems to me there be far less debate.

Female: Yes, that makes sense.

Stephen Lutz: I think it was a separate measure. I think…

Female: Yes.

Male: (Inaudible)

Stephen Lutz: I mean, it's a separate measure. It could be considered separately and I have to think it went awhile because there's more complexity. But, yes, as a

separate measure maybe is part of the same measure that's just reported differently that kind of makes me…

Bryan Loy: Right.

Stephen Lutz: …feel funny.

Bryan Loy: And I feel funny about having a measure for a stratification that embeds both imaging as well as the discussion or informed consent process. I don't know what you'd do with that information. I don't know what you'd do with the results. You know, I'm not sure how it impacts anything, outcomes or…

(Cecine): Hi. This is (Cecine). I just wanted to make clear that hand in hand with reporting out the measure differently would be stratifying the measure I think gives the people the opportunity to use the measure differently as well.

And so if we accept the fact the, you know, quality measure is only as good as the preventive used in stratifying the measure and, you know, tracking 40 to 49 because it's still important for some people given that breast cancer is a heterogeneous disease, I think we would all agree with that. And then having 50 to 74-age stratification allows people who are implementing the measure to be able to use that age stratification for public reporting, for accountability and accreditation program and that sort of thing.

So that would be the ultimate end result of stratifying it. So I agree that just stratifying in and out of itself is not necessarily our end goal. It's really changing the measure in a way that allows us to use the measure in the appropriate program appropriately. I think there are so many people who would be interested to understand the screening rate in the 40 to 49-year-old. And so this whole plan measure would allow plans to be able to do that knowing that they are not having that stratification necessarily publicly reported out or use an accreditation or anything like that.

And in that way, you do not have a measure that just discards an age group for which we do have American Cancer Society, ACOG and other organizations recommending mammogram. So I just wanted to just make that part clear, too.

Karen Fields: This is Karen. How do we – are we allowed to change the measure. So I thought that that was one of the difficulties with all of these.

Male: Right.

Heidi Bossley: So this is Heidi. Maybe I could kind of give you sense of or I think perhaps where (inaudible) might be, because you're correct. This is a measure that is maintained by NCQA. And as you've heard, they are in the process of updating it. But unfortunately, the finalized measure won't be ready until 2013.

So in some instances when we know there's something that within a few months it will be changed, we have a different scenario. But in this instance, you're really voting on the measure as it stands right now or you're making the final decision. Because there's really no other alternative in front of you I think at this point, because NCQA is not ready to say that they know what that is.

Male: So we have to – so we have to not endorse this present.

Heidi Bossley: That is – I think that is the question before the committee on whether or not you want to make a final decision to (endorse) or not.

Male: If we can amend it, we're all not comfortable with 40 to 49, we can endorse it.

Heidi Bossley: I have to say though I actually happen to say that all the big cancer programs that we respect, American College of Surgeons, NCCN, American Cancer Society, all endorsed mammograms in that setting. So I think that I would vote differently than the rest of the discussions going.

Male: Yes. A practitioner can with a straight face say that they're not screening people who's in 40 and 49, they'd be very valid in their opinion and they shouldn't be deemed for it.

Heidi Bossley: Agree. I'm just saying that if we're talking about there's a transition and the standard right now from all of our medical society is that that we should be

screening. I don't see what where we have a discussion about whether we are concerned about what quality is there isn't…

Female: But it's not true, I mean, basically the organization that has the highest level of evidence supporting it and there's the one that's turned to the most is the U.S. Preventive Services Task Force. And I don't think they cover the American Cancer Society to have the same weight as the USPSTF.

Steve Edge: I think – this is Steve Edge. I think there's a big difference between pulling something forward as the quality measure but which were going to hold people accountable and endorsing a practice. I strongly support mammography screening for women age 40 to 49. I think to the wording the way the preventive services task force did this was someone unfortunate though, though when you get everybody in the same room we're actually all in the same team and all understanding the same data. But the quality measure for accountability is different from endorsing a practice.

Stephen Lutz: I would say it's even different in tracking. If you say this has changed where you're simply tracking, I know several people who will look at the NQF measures simply far enough to say what did they do, which way do they fall.

And the first 40 to 74 included they're not going to look at it and say, "Oh, well, you know, the 40 to 50 was just for tracking, but there isn't really a quality measure here because were still deciding," they're not going to do that. And so even when it's just a tracking, even if we could switch to that, I still think, I mean, I've talk to several of my colleagues who are not at least have been involved and still a very good oncologist. That's how they look at NQF.

Which way did they fall? Give me a one-sentence answer. They're not going to understand that we just like to track. They're just not.

Male: Yes. And then I would further that you say it's a value and it's a measure then folks will (inaudible) underscores the need to take some sort of action. I'm not sure we declared that, you know, we don't in that strata when we value the screening or versus the actual discussion one way or the other. I think it can pretentious in a very confusing message.

Angela Franklin: But I do agree that since there's controversy and I agree that the physician has with a well documented discussion with the patient makes that individual patient decision. So I don't know that – but I don't how we can – how that will be measured outside of this guideline. Because the women are going to be there, they got the mammogram or they didn't, I don think anybody is going back to review the notes to find out that there was a discussion about that.

So I don't know what to do with this measure, because I don't think we can modify it and I agree that there's a lot of way to interpret that data.

Naomi Naierman: May I ask – this is Naomi. May I ask the NQF staff when is it that you expect a more definitive statement about when measure might be going out to your review – further review?

Angela Franklin: Are you asking about the steering committee is going to do next?

Naomi Naierman: No, no, no, no.

Angela Franklin: OK.

Male: Is to when?

Naomi Naierman: Yes. When will we have a chance to look at this again or how much time will it pass before this measure is revised or not?

Angela Franklin: So NCQA, could you just again say when the final measure would be ready?

(Bob): Sure. So I'm going just try to be as frank and transparent as I possibly can about this.

Literally, you know, we have – not only do we have the clinical questions that you've all raised and raised quite well. You know, you also have the public policy decision that is kind of the background music to this – to this measure and background music toward 40 to 49 it's still there. And as you know that's because it was included in the Affordable Care Act legislation, which is something that none of us get to vote on. It just happens and there we have it.

So I think the term – I think that many people have said that, you know, we're kind of in this transition place and we've been in this transition place since USPSTF came out with it's recommendations and in the public policy agenda went in a slightly different direction. And it has to try to navigate that as a measure developer and also as a measure implementer, because this measure is, as you well know, across the country for health plan evaluation.

And I think that – I think that while we may be going forward with the stratification recommendation, the CPM is a mindful body and it has it's own opinions. And we have been not terribly great always predicting what direction they will go. I can say historically that CPM holds the USPSTF recommendations at high value and many of CPM members have served or are serving on the USPSTF. Our current chief, I mean, our current vice president for Performance Measurement was a scientific director for the USPSTF during the breast cancer screening evaluation.

So we really understand the (dawn) quite well. I think that in terms of timing, you know, directionally we will know at the end of September what the CPM is thinking and that will inform our public comment in February. I think we'll know a lot – I think we can anticipate what the public comment would be except our pubic comment we usually get 100 to 200 responses. And so when you take that process quite seriously it's quite effective.

And then we'll know in May, because that's our meeting where there will be a final vote. We have a board of director vote, which takes place after that just like the NQF process. So I think directionally we'll know a lot in September, not the entirety but we'll know quite a lot. So I mean that's fairly...

Naomi Naierman: That's next month.

(Bob): Yes, that's just in a month. Correct.

You know, this measure has been used as longstanding and it's in the middle of a lot of things. If NQF chooses not to endorse the measure currently, you know, then, you know, the measure will continue to be as (inaudible) and then it will go it's process and then later change, stay the same or change dramatically.

Whatever the case maybe, I'm not going to predict that. But it's still going to be used and then, you know, it will change when we go through this process. And then I guess what we'll have to do is come back to NQF and ask, "Gee, it's just changed. If you do endorse it September, can you please put us on a…" I don't know what you can do, an expedited review or something this measure doesn't follow up the NQF portfolio. It would seem shame to do that for such a short period of time.

Heidi Bossley: (Bob), this is Heidi. Can I ask you, because I want to make sure that I have it clear as well. When could you hand a revised specification (inaudible) what happen to NQF? When is the earliest?

(Bob): Because of our process, we have to have public comment. We cannot have that.

Heidi Bossley: That's why I want to make sure, because again I know the recommendation will come out in a month, but you wouldn't be handing it to us correct until May of next year? Is that correct? Do I have that right assuming you have reviewed it?

(Bob): Yes. As long as the process allowed the board votes, so as soon as CPM voted then in May we could…

Heidi Bossley: OK.

(Bob): …resubmit the measures assuming there's a process you would need to take place that would carry over until a month or so and we would be comfortable to submit it. And then if there was – the board made some interesting move and didn't support it, we simply withdraw the measure.

Heidi Bossley: Right. We can take care of that. But so – this is Heidi now answer the second part of I think Naomi's question, which was what would NQF then do. So the question is before you today based on what you have whether the measure to meet evaluation criteria, assuming that you do not recommend this measure and an endorsement is removed, we would then work with NCQA to find the next project where we could submit it.

I know that for sure we will have a project in 20 – what year would that be – 2014 that would look at cancer. Now whether there would be something before that it's always a possibility. We can always find ways that if there's a project that perhaps we have the right expertise on where it would fit. We could work it in even earlier. But that is kind of a timeframe at the moment as I know it now when we would have the next project.

So Naomi, I want to make sure I answered your question on that.

Naomi Naierman: I think, I mean, it seems given what a high lead charged area this is for us to endorse a measure that then gets changed in a couple of months even if it's going to a public comment period, just seems kind of, you know, crazy in adding, you know, more confusion rather than helping to clear things up.

May I suggest that we just make a final decision not to endorse this or at least call the question?

Male: I so second that.

Male: Yes, please.

Heidi Bossley: So this is Heidi. I think what we would like to do and what we typically do because you don't have the whole committee on is to have a SurveyMonkey go out…

Female: OK.

Heidi Bossley: …and have you do that online. Because again, we want the input from the full committee on this, because I think this is one of a great interest to everyone.

Male: (Inaudible)

Male: …We'll just send that out what your summary of that discussion so for the committee members who want to hear.

Female: Yes.

Male: Yes.

Female: We'll send the summary of the discussion with the SurveyMonkey link.

Female: And we'll send it this afternoon. I will just tell you now we're going to have a pretty quick turnaround with your votes and any rational explanation that you can fill in on the text. File closes on Wednesday so we'll get that out to you today and we'll be asking for it back Wednesday evening.

Female: OK.

Stephen Lutz: All right. Is there anything else we're supposed to discuss? I was going to ask some quick questions, I mean, before we get to that. So we had that sort of e-mail flurry e-mail about 0212 and 0214. Does that we've already moved on from those just based on that e-mail flurry or are we on those?

Angela Franklin: I think we have to vote that, Steven.

Female: Our take from your e-mail exchange on 212 and 214 was that unless there is a substantive change to the measure that was not going to be universal of the committee's decision to not recommend those measures for endorsement. When we had some communication with the measure developer and given that these measures use Medicare claims then he would be able to make the kind of change that will allow for distinction of a palliative care unit decision versus any other hospitalization.

So given your quick and uniform response and given the measure developers inability to make the changes that you all recommended, we thought that there wasn't a need for discussion of those measures any longer.

Stephen Lutz: I was only bringing it up because I was – I was quick…

Female: If that is not the case, please quit now.

Stephen Lutz: I was quick and vocal. I say I was quick and vocal and I just want to make sure that I didn't cut anyone else socks. I'm not sure everyone had a comment or idea.

Does everyone remember 0212 and 0214? Oh, what's the specific wording – it was the…

Female: It's the hospitalization and the E exhibit.

Male: Oh, yes.

Stephen Lutz: Great. And so they were to come up again and I get sort of vocal that these were discussed previously in palliative care and failed and in cancer and failed. I just want to make sure that I wasn't jumping or began too much. But, yeah, I mean it seems like we've already decided that, but I don't want to unilaterally speak so loudly that no one else got the say anything else.

Male: So what do we decide on those remind me?

Stephen Lutz: We decided that it was very difficult to hold to hold people accountable for I think hospital visits and ICU visits in the last certain over days of life without being able to subcategorize between, you know, hematologic malignancies versus palliative care admission versus other types of hospital admissions. And then I think someone and one of the NQF review boards asked to look at it again, which sort of set me off a touch since I've already been to it twice.

Male: I see. So we really have to look at it the third time.

Stephen Lutz: Essentially. Essentially, so I was just making sure, you know, I don't want to just kind of type real loud have no else have an idea. But as long as no one else does then it would be nice to move on from just say, yes, we're settled.

Angela Franklin: So Steve, I was there for that discussion. And some of the – some of the committee felt very strongly that all the measures needed to be looked at in (math) and quite honestly I thought they thought they would want us to vote on it again. But I agree with you completely and I specifically told the committee that I didn't think that our committee would have any other discussions about it for multiple reasons, including accessibility and different diagnosis and everything.

So if the, you know, the administrators want to assume that we had an adequate discussion I think no one is going to change their mind and I think we had an adequate discussion.

Stephen Lutz: OK. Yes, I just want to make sure. Good.

Female: The only remaining thing is that in the comment table about we sent to you guys, there were a few comments that we highlighted where the common tested made comments that weren't necessarily explicitly addressed by the steering committee during the in-person meeting.

So we highlighted those and we wanted to point out for your discussion on them. And once we've focused in their three comments to that effect, once we focused in on those, if you all have any comments that we didn't highlight that you want to discuss, we'll those at that point. So that's our agenda for the remainder of the call.

Male: All right.

Female: And the third comment that we highlighted is comment number 2640. It's referred measure 1857, which is an ASCO measure. Is there anyone from ASCO on the line?

Male: So what measure number is it? Because the comments numbers are not in order.

Female: That's measure number 1857.

Mike Hassett: This is Mike Hassett from ASCO.

Female: OK, thanks. Mike, if you wouldn't mind just taking a quick moment to may be explain ASCO's response to the comments that would be pretty helpful I think.

Mike Hassett: OK. It's stuck to me again if I remember.

Male: They want to change trastuzumab to HER2 therapy. That makes, yeah, HER2 directive therapies instead of lifting trastuzumab as being the specific drug.

Kristen McNiff: This is Kristen McNiff from ASCO as well. I'm on, can you hear me?

Female: Yes. So the comment I was saying to was submitted by Genentech and they recommended again endorsement of measure 1857 due limited utility and improvement quality. So if anyone from ASCO wants to may be offer your take on it and then we'll open it up for steering committee discussion.

Kristen McNiff: Yes. I'd be happy to start. I might give you one then you can…

Mike Hassett: That is great.

Kristen McNiff: OK. Yes. This issue I think was discussed in some detail by the steering group about the gap in care and the Genentech folks cite one instance, one study. And so our response, you know, I think (inaudible) has a lot of discussion that we had in the committee.

First is that we do believe in developing measures of under use as well as overused so we do think that that's an important area to focus. There is – we discussed a gap that needs to be addressed and in the future, you know, if that gap goes away then it will be time to remove the measure from accountability. But the gap does exist and that was discussed by steering group already.

There was indication here that it might be that the oncologists do not know what the HER2 status is, but the testing has been done and as a physician that the oncologist needs to know what the HER2 status testing results are and they need to be documented in the record. So the fact that the test was done with the oncologist may not have those at hand when here she is making treatment decisions or document it in the record, which counts as, you know, a mess.

And I think that's pretty much of summary. Do you have other comments, Mike?

Mike Hassett: No. That's great.

Angela Franklin: I for one have some concerns that the manufacturer of the drug didn't (inaudible) to make sure that we were utilizing the drug not over utilizing the

drug by adequate documentation of HER2 testing. So I thought that I took the response with a grain of salt from that aspect.

Stephen Lutz: I agree. It's a little unusual to have them commenting both. No, you don't really need to look at overused. It just kind of struck me the wrong way.

Female: OK. (Inaudible) better discussion. We'll point to two other comments. One of them is comment number 2635. It (adjusted) measure 1859 and 1860. This was discussed at the steering committee (inaudible) combining measures 1859 and 1860.

ASCO has responded to that as well and we just really wanted to cite that just to make sure that the steering committee is still in agreement with these measures being separate. I don't know if anyone from ASCO wants to speak to that also.

Kristen McNiff: This is Kristen again. I'm happy to speak to that as well. Again, I think that this was discussed at the meeting. We saw the point about capturing patient preference. Again, there's not a recommendation in either of these measures that testing be routinely done in these patients.

So, you know, we had a bit of a hard time understanding the patient preferring exclusion recommendation there. It's just for people who are getting the treatment that they should have received with the testing before they – before the treatment decision was made. And in the future report having this be combined is certainly could be considered. But these are fairly new guideline recommendations and we really think there's value in reporting this stuff relates that there's an area that's the mess we're able to, you know, drill down to the appropriate level (inaudible) where the mess occurred.

Female: In the steering, any comments?

Stephen Lutz: Neither makes sense.

Female: And the last comment that we've wanted to (inaudible) is comment number 2637 and it recommends development of HER2 composite measure comprised

of measure 1857, 1855, 1858, and 1878 in order to openly capture the use of HER2 treatment in breast cancer.

There's measure there (inaudible) by ASCO and CAP. And the developers provided their response to that. If they want to speak to it again we just want to make sure the steering committee's position on this.

Kristen McNiff: I'll start some time on a roll here.

Female: Thank you.

Kristen McNiff: CAP and ASCO discussed this and confirmed that we do not think that it would be feasible or meaningful ultimately to combine the CAP measure with the ASCO measures, because they are looking at different use of accountability and they're measuring different levels. So combining those does not seem to have an ultimately clinically meaningful output.

The measures from ASCO specifically, so if we remove the CAP measure from the equation and just look at the measures which are all focused on the medical oncologist and/or the medical oncology practice and are looking at the testing and use of trastuzumab or measures that again, you know, could be reported together and we do think that would be at the, you know, choice of the implementing organization or program, certainly there could be some utility and reporting together.

But again, for the purposes of identifying opportunities for quality improvement, these are each very kind of discrete steps along the way. And just because you over use it doesn't mean you under use. So we do think there's value in continuing to report these independently and thus getting them approved independently.

Fay Shamanski: This is Fay Shamanski with CAP. We didn't think the – well the denominators are different.

So our measures are designed purpose at individual physician level whereas ASCO are at different practice setting. So it wasn't really feasible at the moment to combine them, but we'll certainly think about it as we continue our

measure development efforts in the future where you said that might work. But for the moment, it's not feasible.

Neo Spates: This is Neo Spates also from CAP. And I agree 1855 measures the accuracy of testing done by pathologist. The other measures measure what the positions who get the results do with them. So would certainly agree that 1855 is would be – should not be combined with the other measures.

Emily Volk: Yes. This is Emily Volk, Dr. Volk from CAP and I concur.

Female: Thank you. Is there any steering for the response?

Male: Sounds reasonable.

Female: I would agree.

Female: OK. And last but not the least, comment number 2654. There was a comment made to measure 1857 and 1858. And the recommendation is that instead of saying specific therapy trastuzumab and then instead FDA approved HER2 therapy, ASCO noted that they review measures and update them every six months. And if an alternate therapy is approved then consider it appropriate and the measure will be updated.

Our question to the steering committee is, is that acceptable to you or if you would recommend a name change for that measure?

Female: I would recommend leaving it as is, because FDA approval may be for, you know, different settings and I would think it could end up causing confusion.

Male: Yes. This is one you don't want to change. I mean, GSK happens to make lapatinib. Oh, no, I mean I think, you know, obviously that's what they're talking about. But right now we don't have data that lapatinib in the regimen setting is the appropriate treatment.

If anything the data is suggesting that it may not be the right drug, so there's should be no confusion at all. It's clear and clinical trial data is very clear what works right now. And if it changes I think the comment that, you know,

we can update this as need be. So I don't see any reason to make a change to what our vote was.

Male: And we totally agree.

Female: (Inaudible) question then. So updating in this context doesn't require bring the measure back to a committee. They just simply give (inaudible).

Female: In this context, ASCO would be updating it independently and if it was a substantive change such as the change in the type of recommended therapy at that point NQF would have to convene in ad hoc review of the measure. So it wouldn't be an immediate change but it would be a pretty quick change especially if there are significant changes and evidence pointing to a need to change the measure.

Female: But the standard of care, the prior standard of care would still be being measured and evaluated. So I don't have a problem with that. It's a process question more than anything, because as indirectly referenced we just understand the manufacturer's concern about opportunities for new drugs being evaluated appropriately. However, as long as the process isn't tedious or difficult, I don't have a problem with this not changing the measure at all.

Bryan Loy: This is Bryan Loy. I'm just listening to this dialogue and I'm wondering, you know, as we evaluate this is there a kind of a guiding principle that says that we are more descriptive of therapies versus naming them by name that we would look to? Or is this pretty difficult that we, because let's pretend lapatinib did become the data was there. Do we need to go back and, you know, add drug name by drug name? Or do we begin talking about, you know, general classes of drugs that interfere with the HER2 pathway?

Male: I think we changed it to something that's class specific when this evidence and other drugs in the same have class have the same response.

Bryan Loy: But in that point I would say, you know, is there a way for us to describe the mechanism of action of trastuzumab about naming it by name?

Male: But we don't know for sure that another drug with a similar mechanism of action is going to have the same result.

Female: Yes. I mean, I think, you know, I mean it's still an open question on oncology. But I think right now, you know, not all that (draft) inhibitors work, you know, work for all cancers or multi-kinase inhibitors. I don't know that, you know, you can…

Stephen Lutz: You can't have to both place.

Female: …use that general.

Stephen Lutz: Yes. And I respect that, thanks.

Female: OK. Those were the only comments that we wanted to focus the steering committee on and your review of the comments. Was there anything that we missed that you think needs further steering committee input?

Generally, the comments are supportive or seemed to be in line with the steering committee discussions, which is why we haven't (flagged) down.

Stephen Lutz: All right. Are we supposed to go on to member and public comment now? Is that where we are?

Female: That is where we are. (Nathalie), if you wouldn't mind opening the lines and we take public comment at this point?

Operator: If you would like to ask a question or make a comment, please press star-one.

And there are no questions or comments.

Female: Great, thank you. I guess the next step for the steering committee, we interest (inaudible) make some revision to the report based on the comments received and we will also be sending you, as we mentioned earlier, the SurveyMonkey link and the summary of the discussion on measure 0031.

We'll be asking for your final vote on the measure by close of business on Wednesday. And we do strongly urge you to provide any comments that you

feel necessary in the appropriate space on the SurveyMonkey, because we'll be meeting that, too, for the rational, for the recommendation on the measure.

Just look for it as scheduled to go out for NQF member vote in about two weeks and at that point it will move to the NQF process. Once we get the member vote, it will go to the consensus standards approval committee for review and ultimately to the NQF board for endorsement. We're expecting the set of phase two of measures to be endorsed in October of this year and then just update you on the phase 1 measures.

Those are currently being reviewed by the NQF board right now with the recommendations that you made intact solve the measures with the one caveat that the five ASCO measures that were recommended the 0210, 211, 213, 215, and 216. Will be bundled and recommended to be reported as the set of measures that are being used individually. Those measures assuming no actions taken by the board will likely be endorsed within the next week or two.

Largely, the committee done at this point for you all, Dr. Lutz will be involved in a consensus standard of the approval committee called. But we're very appreciative of all the time and effort that you guys have put into this and thank you for products well done.

Male: Thank you.

Female: Thank you.

Male: Appreciate it.

Female: Thank you.

Male: Thank you.

Female: Thanks.

Operator: Ladies and gentlemen, that does conclude today's conference call. You may now disconnect.

END