

## **NATIONAL QUALITY FORUM**

**Moderator: Lindsey Tighe**  
**May 9, 2012**  
**12:30 pm CT**

Operator: Welcome to the conference. Please note today's call is being recorded. Please standby.

Angela Franklin: Hello, this is Angela Franklin and I have with me Lindsey Tighe and Adeela Kahn for the Cancer Endorsement Maintenance Project. This is Phase II.

Today's work group will be focusing on Breast Measures and -- excuse me -- and we have also our Steering Committee on the line, as well as our developers for the - for these measures and I'd like to take a quick roll call of our Steering Committee.

Larry Marks?

Dr. Lawrence Marks: Present.

Angela Franklin: Joseph Laver?

Dr. Joseph Laver: Yes.

Angela Franklin: (Patrick Roth)? Nicole Tapay?

Nicole Tapay: Yes.

Angela Franklin: And Dr. (Maylin) and (Jennifer Donovan) were not able to join. Or, I'm sorry, (Heidi Donovan) were not able to join today.

Female: Is there anyone else on the line from the Steering Committee?

Elizabeth Hammond: Yes, Elizabeth Hammond.

Female: Hi.

Angela Franklin: Hi, Elizabeth. All right. Do you want to go through the ((inaudible))?

Female: No.

Angela Franklin: Okay, so today's focus as I said is the Breast Measures, Part I of the Breast Measures, and the process will be that our Steering Committee members who are lead discussants will tee-up the measure for us going through each of the criteria and giving their impressions of the measure. And then we'll throw each measure open for discussion by the larger group.

Are there any questions before we get started?

Female: (Jessica) the ((inaudible)) from ACS on the line, do - will be willing to speak to this measure and have their lines open for discussion please?

(Jessica): I'm sorry, there was some feedback on the line, I was unable to hear that?

Female: Sorry, can you open the lines for anyone from ACS for this discussion, please?

(Jessica): Yes, Ma'am, one moment. And their lines have been opened.

Female: Thank you.

Angela Franklin: Thank you. Just a reminder ((inaudible)), if you're not speaking please place you phone on mute.

So our first measure is 0219 post-breast conservation surgery ((inaudible)) and the measure steward is the American College of Surgeons, and our lead discussant is Larry Marks.

Dr. Lawrence Marks: Okay, thank you. So this is overall I think a reasonable measure we can go through. The things were sent out - I guess the votes from the group were sent out and it was largely consistent I believe all the reviewers who looked at this. Standard therapy for early stage breast cancer is a lumpectomy followed by breast radiation. There have been multiple randomized studies demonstrating very consistently an improvement in ((inaudible)) control and certainly in the overview when you lump up the studies together, an improvement in survival that's fairly meaningful: about 6 or 7 or 8%. Those are overall survival improvement.

So this measure is essentially - essentially looking at that, so the ration - it's not a primary health ((inaudible)). The rationale is certainly reasonable. The impact, again, a 7% improvement in overall survival for post lumpectomy I think is a rational thing.

The one question I had about this was, there should be consistency on the denominator statement includes Stage I, but then the denominator exclusion includes T1A and T1B, that's a sub-set of Stage I. So there's some inconsistency in the language, it needs to be clarified I think.

And then it was only for ER negative tumors. Then maybe the sponsor could explain why it wasn't sort of more general, for all tumors, because the improvements to the role of radiation is generally used in ER negative and ER positive patients.

So I think it's a reasonable impact. Going through the criteria, I think the evidence is pretty high quality, there's multiple randomized studies showing that radiation improves the outcome and fairly consistently. As well, so I think that the threshold to measure and report was met. The reliability seems reasonable as well as this is a relatively straightforward thing to measure, whether or not a patient was given radiation.

The question I also have for the developer is, is the measure intended to be something that a surgeon would use in terms of whether or not the patient was referred for a consultation for radiation therapy, whether it's something that a radiation oncologist might use, you know, percents of patients who they're seeing who are indeed given radiation, et cetera, is a little unclear to me. For example, the logistics of how that would be used.

But I think it's reliable, reasonably valid as well, again, the voting, everybody gave these high usability, high or moderate usability and feasibility as well so preliminary endorsement was I think pretty much agreed upon by the five people who filled out the survey beforehand. I hope that's all clear. And that's what I had to say, I think.

Female: Does anyone from ACS want to respond to those questions?

Dr. Lawrence Marks: Is anybody from ACS on the phone?

Female: Is there anyone there from ACS on the phone?

Dr. Lawrence Marks: Maybe their phone is muted?

Angela Franklin: I have opened up lines.

Dr. Lawrence Marks: Is anybody from ACS out there?

Angela Franklin: Andrew Stewart, by chance?

Dr. Lawrence Marks: So I guess maybe it's our queries or our questions could be sent off to them by e-mail or by subsequent phone call would be helpful.

Angela Franklin: Okay, we'll do that. We had - so, we'll check on the lines, too, make sure they're open and in the meantime, are there other comments from the larger work group?

Elizabeth Hammond: This is Elizabeth Hammond. I think the reason they might have left - I'd like to know what their reason is for leaving off ER positive patients, but I think they probably did it because there's that large randomized trial in ER positive patients to - using Oncotype - to stratify them and a lot of people are participating in that. But still those - the standard of care there is still - I think for all the groups including the low-risk for radiation therapy. So it's - I guess that doesn't really clarify the reason. Probably the use of chemo in ER negative patients is much more critical, so that may - I mean the use of radiation in the ER negative patients may be more critical.

Dr. Lawrence Marks: Right. And I can understand the rationale for why they might have done it. They might felt it's less controversial, but it does...

Elizabeth Hammond: Right.

Dr. Lawrence Marks: ...it does sort of perpetuate this myth that...

Elizabeth Hammond: Yes.

Dr. Lawrence Marks: ...that, you know what I mean? That that was - I felt a little uneasy about that.

Elizabeth Hammond: Right. Yes, I think we should ask them the question for sure.

Dr. Lawrence Marks: Right. Okay. Great.

Angela Franklin: All right. We'll move the question for the developer. Any other comments about this measure?

Female: (Jessica)?

(Jessica): Yes, Ma'am?

Female: Andrew Stewart, he said he's trying to dial star 1 on the phone but he can't get through?

Angela Franklin: He actually has an open line.

Female: Oh.

Andrew Stewart: Oh. Can everybody hear me?

Group: Yes, we can.

Andrew Stewart: Very good. I am puzzled because neither the denominator exclusion related to T1M, T1A, T1B tumors should be there and neither should the exclusion around hormone receptor status, should be on this measure, and we will move to correct both of those exclusion criteria.

Dr. Lawrence Marks: Thank you. That would help.

Andrew Stewart: Yes, that's inadvertent and I have to go back and understand my source document from January to understand how that crept into this particular document. I apologize.

Dr. Lawrence Marks: Yes, that same error is actually in one or two of the other proposals from your organization as well.

Andrew Stewart: I think this happened with the way in which we structured our review and assembly of the - of our documentation to submit to ((inaudible)).

Dr. Lawrence Marks: The same thing comes up in 0220 and one of the others, also. Okay.

Andrew Stewart: We'll watch that as the conversation continues. Thank you very much.

Dr. Lawrence Marks: Thank you.

Angela Franklin: Thank you. Okay. Any other comments about 0219?

All right. Hearing none, we'll move on to our next measure, which is 0220. Also an ACS measure, adjuvant hormonal therapy. And Dr. Laver is our lead discussant for that measure.

Dr. Joseph Laver: Thank you. First I would like to use a qualifier that I'm in pediatric oncology and I'm not the subject matter - expert on this, so I had to sort of do my own reading on it.

So with this in mind, I think this is just from looking at the materials and pulling papers and NCCN guidelines, this is a very reasonable measure. It's supported by very good evidence.

(Crosstalk)

Dr. Joseph Laver: ...commercial being played on phone! Means one of the participants put their phone on hold to take another call, and their company's hold ad was playing.))

Female: (Jessica), will you mute that line please?

(Jessica): I'm trying to...

Female: I think it's Dr. Marks's line.

(Jessica): I apologize.

Dr. Joseph Laver: Okay. Hello? Should I repeat it, or...

Angela Franklin: Yes, go ahead.

Dr. Joseph Laver: So, with this that I'm not an expert on the subject, but looking at the evidence I think the measure is very reasonable actually, very good evidence, and published peer-review papers that hormonal therapy is known to decrease the recurrences by 40 to 60% from what I gather. The evidence for it is very solid.

I think it should include - so it should be administered within one year, definitely in strong avenues the denominator, all the - over 18 I couldn't see in the exclusion, it's all for estrogen positive, but I couldn't see pregnancy anywhere or plan to have pregnancy in the denominator exclusion.



Overall it seems a very high evidence, high impact and I thought it was a good measure. I didn't have major comments on it.

Angela Franklin: Thank you, Dr. Laver. Comments from the larger group?

On this measure? With the - a note that there are some typos in the exclusions as noted by ACS earlier.

Any other comments about the measure or the additional exclusions that Dr. Laver suggested?

Elizabeth Hammond: No, I think it's a good measure. This is Elizabeth Hammond.

Female: Does anyone from ACS have a comment about the pregnancy exclusion?

Andrew Stewart: If I can be heard, I hopefully can...

Female: Yes.

Andrew Stewart: The way this measure was originally constructed and specified back in 2005-6 before it was initially endorsed by NQF in 2007, the measure was specified using Cancer Registry data and the qualification of child-bearing status, either current or planned, is not a data item that's routinely available through Registry data-sets. So that's why it doesn't appear in this measure as a condition for exclusion.

However, we'll take this under advisement and we'll review secondary diagnosis codes that ICD - secondary diagnosis codes that are reported to us from the Registries to understand whether or not women's pregnancy status - then currently pregnant at the time of diagnosis, is something that we can better understand.

Understanding future reproductive plans of individuals is difficult if not problematic and I'm not sure that one can include or consider an exclusion criteria on that basis.

Angela Franklin: Thank you. Any additional comments from the Committee?

Okay, hearing none, we will move on to Measure 0221 - Fetal Biopsy to Establish Diagnosis of Cancer Precedes Surgical Excision Resection. And the American College of Surgeons is the developer. Dr. Patrick Ross is our lead discussant for this one. Is Dr. Ross on the line? Okay, I don't (hear him).

Female: Would any other workgroup members be willing to give an overview of this measure or we as staff can provide of what you've put into the survey.

Angela Franklin: Let's see. I looked at it very carefully and I could probably do it. I just have to pull it up.

Female: Thank you.

Angela Franklin: Thank you.

Female: What's the number?

Angela Franklin: 0221.

Elizabeth Hammond: Okay, 0221. Yes, okay. This major - I had some significant questions about this measure that I would love the developer to discuss.

First of all, there is a lot of understanding that breast cancer is a serious disease and that it's better for patients if we operate on them less times than more times. And the measure seeks to make it - provides data that it is more likely for a patient to have a single surgical procedure if with the first procedure they have to make the diagnosis as a needle biopsy.

So there is good evidence of - I think strong evidence of (tight) impact of - in breast cancer and also reasonable evidence that needle biopsies do help define that. Unfortunately, the developers have mixed together FNAs and needle biopsies in this measure, which I think causes some confounding of the data and makes the data less strong.

The false negative rate for biopsy and for FNAs, it is much different than each other and so I think that does confound the data, but there is a gap in whether or not such biopsies are performed. Again though, the ideas about the performance gap and the disparities are not well documented in this proposal, although they are stated to be true.

One of the problems is that in rural areas where needle biopsies - the equipment for needle biopsies and the equipment and/or the expertise to do FNAs might not be available. I do not believe there is data that suggests that in those sites it might be prudent to not do an open surgical biopsy on such patients, and I don't think we have any evidence about that.

So I would say that the quality of the evidence here to define - to say that overall this should be done throughout the United States. I think the quality of the evidence is poor.

There is consistency across the studies, but with the proviso that we - it should be stated that there is a difference in the false negative rate of biopsies - needle biopsies versus FNAs and that needs to be taken into account when constructing the measure. So I think the developers - it would be good if the developers would make some inference about that.

The reliability of the data - it measure the way in which the data can be collected. It is very straightforward. The data is readily available, so I think there is no problem with reliability of the data or validity of the data, except that it needs to be the data between FNAs and needle biopsies needs to be stratified in order to make sure that we understand what is happening here.

So the validity of the data is also good because the way in which the sample is collected is fairly standard and available in all of our data sources, and the feasibility of this measure is good.

So I think the measure is usable, but it would - I really think that basically the problem with this measure is whether or not it should be revised sort of overall. It's not a question of the parameters of the measure; it's really a question of whether or not there are going to be - number one, we don't sort out FNAs from needle biopsies.

And number two, that there may be unintended consequences of setting this up as a measure in rural health situations. So it would be useful to get some understanding from the measure developers whether or not this is going to create unintended consequences in rural populations or populations lacking the radiologic equipment to do the needle biopsies.

Female: Thanks. Do we have a response from the developer on Dr. Hammond's comments?

Andrew Stewart: yes, this is Andrew Stewart again. I think those comments are thoughtful and well received. And in fact, we have been worrying about both of those exact same issues as we have looked at how best to implement this measure specifically.

Again, there are some restrictions around the level of specificity of information that comes out of cancer registry data reporting resources.

Female: Right.

Andrew Stewart: Unfortunately, FNAs and needle biopsies are confounded and represented by you know a single code inside a particular data item, and so teasing those apart without a significant reengineering of registry operations is problematic.

To the second point about basically unequal expectations or inappropriately trying to set a level playing field where institutions have variable levels of resources and expertise available I think is a valid one. And that for better or for worse is the nature of the way you know health care resources are organized and distributed in the country and we realize that.

So for actually both of those exact reasons, while the college developed and has maintained the specifications for this measure, the college has not chosen to implement it as - through its reporting and auditing tools to its 1500 hospitals that have cancer COC or Commission on Cancer accredited programs because we understand that there is - there will be an inevitable confounding because of the lack of specificity that exists in - on the data side.

And we also know that - we are also sensitive to the fact that rolling out and implementing a measure through a report card mechanism where not all institutions have an equitable opportunity to respond and demonstrate concordance is problematic.

So while we recognize both of those limitations, we have chosen to hold onto the measure and keep it in front of the NQF review process because at the very least, we do have the opportunity to influence the data question while we may not be able to influence the institutional resource question.

Elizabeth Hammond: So other than - it might - I wonder if there is a possibility through resources that you have or individuals that you could identify to try to get some data from individual institutions about availability of those resources and also you know I guess mostly the availability.

So for example, I work in Intermountain Healthcare, which is a large integrated delivery system. We have urban hospitals and we have rural hospitals, and we could perhaps get some data for you that would speak to the availability of that resource. And I would think that many other hospitals that are accredited through your cancer network might also be able to find the information out about that.

Andrew Stewart: That's actually a very good point and the administrative wing of the accreditation program here at the college actually does routinely collect resource and service information that's available at each individual center.

So it's quite possible actually for us to identify institutions that self-report the availability of the appropriate radiologic - radiology resources to be able to identify hospitals where this measure would be appropriate to be applied and to potentially you know consider you know removing hospitals from the reporting mechanism or the feedback mechanism where those resources didn't exist.

Now, whether or not that causes a secondary level of disservice by not informing hospitals where they lack that level of radiologic service and about how to best approach the breast cancer patient, is a secondary question.

So I think the reviewers had suggested quite nicely you know ways to consider you know feasibility and implementation, we take those under advisement, and I think they are well put.

Female: Thanks, Andrew. I just wanted to clarify that the measure currently is - it says that the intended use will be public reporting, but it's currently not in use.

Andrew Stewart: That's correct for the reasons that the reviewers suggested.

Female: Okay.

Andrew Stewart: We've not implemented in our reporting feedback mechanism - the routine metric to our programs.

Female: Okay, any other questions from the Steering Committee. All right and I just wanted to check.

Andrew, this is not one where there is a switch in the denominators. Is that true?

Andrew Stewart: No, of the three that we've talked about so far, the only one in which there is a glitch in the denominator specifications is 0219.

Female: 0219. Got you. Okay, any other comments about this measure - 0221. Okay, then that brings us to our next measure, which is 0559, Combination Chemotherapy Considered or Administered within Four Months of Diagnosis for Women Under 70 with AJCC T1c or Stage 2 or 3 Hormone with Receptor-Negative Breast Cancer. And this is also an American College of Surgeons measure.

Dr. (Maylin) is our lead discussant for that one, but she is not able to join. We wanted to throw it open to the workgroup to see if anyone else would like to tee up the measure for us.

Elizabeth Hammond: I think I can do it. This is Dr. Hammond again.

Female: Thank you.

Elizabeth Hammond: Slide 9, right.

Female: That's correct.

Elizabeth Hammond: Okay, let's see. Okay, I'm just trying to open it so I can look at the data again, which hopefully will remind me of what I said and thought. I think this measure speaks to - I think it is covering a very important point that is for patients who are - who have estrogen receptor negative breast cancer should be considered for multi-agent chemotherapy within four months of diagnosis.

There is good evidence that chemotherapy is helpful to this patient group. There are a lot of patients involved in the problem, so I think there is evidence of high impact. The data has pointed out there is limited data in patients over 70 and there are reasons to have those patients opt out, so I think it's prudent that they are excluded from the measure and there are abundant citations about this, including randomized control trials. There is evidence of variations in care and unfortunately, those variations in care mostly relate to socioeconomic status, race and ethnicity and the location of the services, which are something that - it would be nice if our measuring this would help to fix.

So the evidence is - there are multiple randomized control trials, so the quantity of the evidence is great, the quality of the evidence is great and the consistency of the evidence is great.

There is no problem with any of those things. This measure has - again, it's being captured through the Cancer Registry -- it's in the data. It is available there and routinely collected, so that should be something that could be well done without any kind of difficulty.

So the data is - there reliability and validity of this study should be - are - should be excellent. And in fact, I think it's been under - it's been done before, right?

This is a measure that is ongoing...

Female: Yes.



Elizabeth Hammond: ...or is this a new measure?

Female: This is a maintenance measure.

Elizabeth Hammond: A maintenance. So it is - it - that's where we get all the data from...

Female: Yes.

Elizabeth Hammond: ...that there is - there is - because there are nice testing results showing that still it's not 100% of patients are in this category, the - there are 6.4% of patients that still have low outlier performance rates.

And the standard error of that measurement is 22%-23%, so there's still room for us to work on this measure. The - I think that the validity of the measure is good. I don't think there are any significant risks to the validity of the measure. It is currently being collected, so it's definitely feasible.

I - one of my questions about all these measures like this -- are we routinely collecting the information about socioeconomic status, race and so on? It says that we - it says in here that it - that it is being collected.

But since that's not - the measure isn't being stratified for that, how do we - I guess I would like to ask the measure developer how we are going to get good information about that, or are you going to stratify the reporting based upon these factors so that it will encourage people who are using this measure to try to improve those areas where they have worst performance?

Elizabeth Hammond: Could ACS respond to that?

Male: Yes, thank you. Those are good questions.

The Cancer registries routinely collect race and ethnicity information and we're able to validate the - we're able to validate that data by executing comparisons with data we see in publicly-released Federal registry files -- for example, the (SIR) data sets and the NPCR data sets that are available.

So we're comfortable what the race ethnicity information that we're receiving from these institutions. The institutions also report to us the insurance status of individual patients at the time of diagnosis and...

Elizabeth Hammond: Oh, great.

Male: ...and that information's actually been validated through a CDC-funded re-abstraction on study in at least three or four states.

I can't remember which ones exactly, but the conclusions that were reported at a national meeting last June indicated that those data were reliable and the CDC panelists actually, you know, recommended that they could be used for a variety of analytic purposes.

And we've seen these data used at least reasonably recently through the Kentucky Cancer Registry, looking at using insurance status as a proxy for socioeconomic status and examining differential patterns in lung cancer presentation and outcomes -- not that that bears directly on breast cancer, but I think it can be easily extended.

And then finally, what we do here at the college is that we actually link our case records to census bureau data, so we also append our data sets with area-based metrics of income and educational status.

So while these data may not be at the patient level, we know that we can describe hospital case mix characteristics by the geographic area based on zip code, not census-level - census tract or county by the zip code of median family income and educational attainment.

And we actually use those to stratify reporting back to hospitals around these metrics - these measures themselves.

Elizabeth Hammond: So you do provide that information back to the hospital at...

Male: Yes we do.

Elizabeth Hammond: Oh, that's - so that's - that is - I think that's exactly the kind of thing that I was searching for.

I think, you know, now that we can actually measure whether or not they gave chemotherapy, the next question is, are some patients getting it more than others?

And could you -- by reporting the data back to the providers and the hospitals -- get them to do a better job with the disadvantaged groups? So that's great information.

And so I strongly support this measure and I think it should be approved.

Female: Thank you. Other comments from the Work group? No? Okay. Quiet group today.

That moves us to our next measure -- History of Breast Cancer -- and that's number 0623 --  
Cancer Surveillance. The developer is ActiveHealth Management.

And at this time, I want to make sure the lines are open for anyone from ActiveHealth  
Management and...

Elizabeth Hammond: ((inaudible)) (Jessica)?

Operator: I am working on getting those right now.

Elizabeth Hammond: Okay.

Female: Thank you.

Elizabeth Hammond: Good.

Operator: Just a second. You're welcome.

Female: We did not have ((inaudible)).

Female: Hello?

Female: Hello.

Operator: And the lines are now open.

Female: Great. Thank you. We have as a lead discussant Heidi Donovan. She's not able to make it today. We can, again, throw it open for the Work group members to discuss and there's also - we also have comments from the Work group written on the surveys.

Female: ((inaudible)).

Female: Sure. I'll just go ahead and go through some of the concerns raised by the Work group members and then we'll have you all open it up for discussion.

As far as the importance to measure and report, there were concerns on the 1 C criteria -- the evidence. The concern stems from the quantity and quality of the evidence being low.

There are some comments that performing this measure on a 12-month interval is unusual or at least - or - excuse me - on a 12-month interval is the usual but it is not clear that it should be and that insurance companies will not often pay if the interval is less than a year, so often screening tests are done at slightly greater than a year to avoid an argument with the insurance company.

Another comment that there's no good data that the patients who are screened are doing better than those who are not screened after a diagnosis of cancer. It might be logical that this is weaker than the - or the (RTR) hormones or chemo metrics, where there is data that those interventions improve outcomes.

With respect to scientific acceptability of the measure properties, again there is some inconsistency from the raters here. There are some comments that it is vague and it's not clear if patients with mastectomies are to be included in the measure.

There are concerns that there isn't information presented other than general characteristics of the size and nature of the database. And another comment there is, 'Insufficient evidence on the reliability and validity of identifying the recurrence or Metastatic disease.'

Usability -- there is some inconsistencies there. It was pretty spread amongst the group as to the usability of this measure. Feasibility -- again, it was widely variable too, with some comments that there are often clinical and insurance reasons for this to not be done every 12 months.

And there is difficulty to identify recurrence of the Metastatic or other illnesses or malignancies that would make surveillance no longer appropriate.

Those would be comments from the Work group on the survey. Is there anyone else who would like to speak to the measure from the Steering committee?

Elizabeth Hammond: I think you -- this is Liz Hammond again.

I think you've summarized the concerns well. I think for the measure developer, the - there is work that needs to be done on this application to make it more specific and consistent and with information that is easier for us to evaluate, because it's too vague the way it is for us to really make a good decision based on the data that we have and I think the measure developer needs to know that.

Also, I think there is a real concern about the 12-month interval. There are, you know, there are recommendations now that that interval may be too close and it would be good for the measure developer to provide some good rationale for the evaluation of this measure at that - at that interval.

Female: Do we have a comment from the developer?

Female: Yes. I think what we'll - I guess we could start with one concern at a time. Which one do you want to address first?

Female: Would you like to address the 12-month one first? This is Carol Palackdharry.

Female: Yes, that would be fine.

Dr. Carol Palackdharry: Yes. I, you know, we have actually only gone back to the 12-month time because that's what we believed that NQF has always wanted in the past for consistency of reporting.

However, I personally do believe that -- and since I'm a breast cancer survivor -- I'm the Oncologist on here, too -- and that I happen to know that even when I get my own surveillance studies, that often insurance companies won't pay for it if it's not exactly over 365 days -- I would feel comfortable increasing that time to 15 months.

But the reason we brought it back to 12 - and usually within our own measures, we have it as longer exactly for that reason. So we wouldn't have a problem ((inaudible)) with that.

We thought that you wanted it 12 months exactly, so that's why we went back to 12 months.

Angela Franklin: So this is Angela. I just - is - what the science shows or what the evidence supports is what we're looking for.

Dr. Carol Palackdharry: Well, you know, the - what the evidence actually all supports and what the evidence has said is annually.

How you want - how you define annually has been up in the air. As we have - as we also have looked at our database and have looked at how the insurance reimbursement goes, we usually accept 15 months.

Female: Okay.

Operator: That's great. Anyone from the Steering committee, are you in agreement with that proposed change?

Male: ((inaudible)).

Operator: Anyone from ((inaudible))...

Female: Nope. Go ahead...

Operator: Sorry.

Female: Go ahead for comments. Go ahead.

(Bonnie Dear): Okay, quick question. This is (Bonnie Dear) from ActiveHealth. If you're interested in us changing the measure as (Carol) pointed out, we are more than willing to do that. And will we be allowed to make that change? Will the measure be opened for us?

Female: Yes. We'll be happy to reopen the measure.

(Bonnie Dear): Okay. Thank you.

Female: Any other comments from the committee regarding the time window?



Okay. All right. Any other comments regarding the measure from the Steering committee? All right, I'd - I had thought I'd heard someone. But hearing none, I guess we'll move on to our next measure.

Female: ((inaudible)).

Female: Actually, can we - can we address the other questions that...

Operator: Oh, certainly.

Female: Certainly. Sorry -- we were - we were waiting for you guys to list out the questions ((inaudible)) so that we could - we could address them appropriately.

Operator: Oh, certainly.

I'm pulling from what's displayed on the Webinar right now, as there were questions with the 12-month interval, which you've addressed. There was a question that there is no good data that the patients who are screened are doing better than those who are not screened after a diagnosis of cancer.

Female: I'll leave that to Dr. Palackdharry to address from her literature review and as a subject matter expert in this field.

Dr. Carol Palackdharry: I'm sorry. Are you talking about screened or are you talking about surveillance because this measure pertains to women who have already had a breast cancer?

And what we're looking for, for instance - we're not talking about detection of metastatic disease. We're talking about detection of local recurrence that could still possibly be curable. So I'm not sure. Do you mean screening or surveillance there?

Female: They use the language screening. I'm honestly not sure which workgroup member this comment comes from. Is there...

Dr. Carol Palackdharry: Well I just - certainly breast cancer screening yearly has had its - has had many discussions in the literature. But this measure is really pertaining only to women who have had - and I should also say it's pertaining only to women who have had an invasive breast cancer.

I do see that there's a comment up there about DCIS. But we have excluded non-invasive cancers from this measure.

Female: Okay.

Dr. Carol Palackdharry: Okay. There were questions raised about the reliability and validity testing noting that the general characteristics of the - ((inaudible)) nature of the database is the only information given.

Female: Right. So this was actually just brought to our attention by the NQF - by NQF members. We had a call with them two days ago. And we received some new guidelines on - as to how the wording of this should be done, of the reliability and validity section should be done.

But this is a new change for us. And we were not alerted to these requirements for any of our other measures either in prior years or this year. So we're - while we're happy to take a look at the new requirements and complete them to the best of our ability we will need some time to address these concerns because they are brand new to us.

And I think a lot of it just has to do with - it's more semantics where we may not have answered the question in the way that you all were hoping for and maybe with a misunderstanding in both the way the question was asked and the way that we responded.

Dr. Carol Palackdharry: Yes, certainly. And this is - we will be opening up that measure form for you all to make some edits into.

Female: We'll send an email when we do that so you'll know.

Female: ((inaudible)) for you.

Female: And then I think the last question raised was under feasibility, that there's difficulty in identifying the recurrences or metastatic disease or other illnesses or malignancies that would make surveillance no longer appropriate.

Dr. Carol Palackdharry: This is Carol Palackdharry. Maybe we just need to be clearer about that. But we specifically exclude in our measures and we have rules written that people who are - have terminal diseases, who are be - are excluded.

Female: Also I'd like to go back to question - the item, number 2. That's the scientific accessibility and the question about whether mastectomies are supposed to be included. I know we have clear wording about that in the measures but if Dr. Palackdharry doesn't mind expanding a little bit just to clarify.

Dr. Carol Palackdharry: Yeah. We've been - as I'm sure the steering committee knows there - this whole issue of how to address surveillance in women who have had reconstructions has been discussed in the literature.

What we have done in this measure is we have followed what the literature is currently supporting, which is that women who have - which is that if you have a chest wall recurrence that requires imaging to detect these are women who should probably still undergo surveillance with imaging. If it doesn't, if it can be detected by physical exam, yearly surveillances may not be appropriate for them although some of course will still have it. But that's not what we're looking for in this measure.

So women who have had bilateral mastectomy are excluded from this measure. And women who have had bilateral mastectomy with implants are also excluded from this measure. And the reason for that is the literature would say that implants are almost always placed underneath the pectoralis muscles for those women to be able to have local recurrence detected by physical exams.

However there is an increase in women having live tissue implants and immediate reconstruction - with immediate reconstruction. Those implants are placed on top of the pectoralis. And the literature would currently support that those women have surveillance.

So did that make sense to the committee? So bilateral mastectomy is excluded, bilateral mastectomy with artificial implants is excluded but tissue reconstruction is in the measure.

Female: Hello?

Dr. Carol Palackdharry: Do you have...

Female: Hello.

Dr. Carol Palackdharry: Questions on that? Are you still there, guys?

Female: We're still here.

Dr. Carol Palackdharry: Okay.

Female: Any committee members have a comment?

Male: I'm thinking about it. Can you...

Dr. Carol Palackdharry: Yeah. It is kind of a tough one. It's - you have to kind of think through exactly the surgical reconstruction. There is some evidence in the literature. I have - if you want to take a look at it I have it in - I have referenced the articles in there.

Male: Can you send it via email or distribute it so we sort of...

Dr. Carol Palackdharry: Yeah. And I can actually tell you probably the one best article is that one that - I actually have it up on my screen right now. Jennifer Zakhireh, Z-A-K-H-I-R-E-H, that was the one that was in JCO in late 2010 talking about application of surveillance principles to the reconstructed breast. I can give you a DOI number here.

And it's also - I think I've documented that. Oh okay. I'm being told to just - I'll send it to your email.

Female: Great. Thank you.

Female: Do you have a central email address or - I don't - I'm not sure who was asking the question...

(Crosstalk)

Female: Actually you can send it to Lindsey or myself and we'll distribute it to the steering committee.

Dr. Carol Palackdharry: Yeah. It's a good article to have anyway, guys.

Female: Are there any other comments from the steering committee? Okay. With that I guess we will move on to Measure 0031, breast cancer screening. Nicole Tapay, are you on the line?

Nicole Tapay: I sure am. Yeah. I've been a bit quiet. But I've - I think hopefully I'll be able to do this one and then other people please pipe in.

So this is a measure that's been in the news somewhat in recent years. It's the percentage of women ages 40 to 69 who've had a mammogram, screened for breast cancer and the numerator is one or more mammograms in a year. And again the denominator is ages.

Is that correct, 42 to 69 cause other way - other places it says 40 to 69? That was just one question I had.

But it's potentially a high-impact measurement. Breast cancer is obviously a leading cause of cancer deaths.

There's also some disparity particularly in the public plan for lower-income Medicaid plans have a somewhat significantly lower rate at 52% compared to Medicare and commercial plans. And even the commercial plans are only at 71%.

Interestingly African-Americans and white women are at around the same rate. But there's definitely room for improvement for some of the other ethnic minorities including Native Americans and Hispanics.

The screening, the goal would be to lead to earlier detection. There is some conflicting opinion out there ever since the United States Preventive Screening (sic) Taskforce came out with a guideline that raised the starting age for this recommendation from 40 to 50 whereas ACOG recommends it earlier. And NCQA which is the recommender developer for this standard is actually engaged in a reevaluation of this as - I think as we speak cause it said in spring of 2012.

There is some shown risk for false positives in the age bracket that was - the 40 to 49 age bracket. And I don't - I'm not clear if that may have been one of the reasons for the U.S. Preventive Taskforce report.

I think in terms of feasibility it all seems to be fairly strong. It's actually a HEDIS measure so it's captured electronically fairly easily.

And I don't know if I'm missing any important factor. But that's pretty much what I had to note on this one.

I think in terms of the group's recommendations -- let me just pull it up -- but there was, you know, a fair amount of, you know, three to two measurement both on the importance as well as in terms of the assessment and suitability for endorsement. So it only was recommended with a vote of one, you know, three to two. So there's, you know, some concern I think on the group's part as to whether it was well-explained why they had changed the target age range.

Female: And Jessica, can you open the lines for anyone from NCQA please?

Operator: Yes ma'am and...

Sepheen Byron: Hi.

Operator: There's only one on the line.

Female: Great.

Sepheen Byron: Hi. It's Sepheen Byron from NCQA. And I'm here with Bob Rehm and Mary Barton.

Just to respond to the issue of the ages it is 40 to 69. The reason it says 42 to 69 in some places is because of the way the denominator statement is written which is that you turned 40 to 69 at the end of the measurement year. And in this way we capture the 40-year-olds because the measure's looking at biennial screening but just to clarify that.

Female: You might also need to clarify the biennial because I think it might have been misstated earlier that it's looking for a one or more screenings in a two-year period.

Sepheen Byron: Biennial. Sorry if it sounded like biannual. No. It says biennial which is...

Female: ((inaudible)).

Sepheen Byron: One every two years, right?

Female: The measure description piece actually said annual.

Sepheen Byron: Oh, yeah. The form shouldn't say that. But it's not annual.

Female: Do you need us to reopen that for you?



Sepheen Byron: I don't think so. Let me - I can look. Yeah. Our form is correct. It's one mammogram every two years.

Female: I think the last question is with respect to the new guidelines that were issued saying that this should start at Age 50 for women.

Sepheen Byron: So we are currently reevaluating this measure. And, you know, the issue here is that NCQA is really caught between different guidelines here.

The U.S. Preventive Services Taskforce does recommend starting at Age 50 as - but for 40 to 49 it's an individual decision. And then there are other guidelines that recommend starting at 40. So we're reevaluating the issue to see where - if we should change it or not.

Female: Okay. Are there comments or questions from the larger workgroup about this? Did we answer all the questions?

Elizabeth Hammond: I don't have any. This is Liz Hammond. No questions.

Female: Okay.

Dr. Joseph Laver: No questions from me, Laver.

Female: Okay. Okay. Well then let's see. That leads us to public comment.

Jessica, if you could open all the lines. And at this point we'll take comments from the public who are on the line or any comments from anyone on the line.

Operator: And all the lines are open.

Female: Okay. Any comments from anyone? Okay, great. Well thank you very much.

For steering committee members, we will be compiling the information from this workgroup call and we'll distribute it to you all next week in advance of the in-person meeting which is May 23 and 24. I sent an email yesterday. If you did not get the logistics email from our meetings department let me know and we'll resend it.

If you have any questions feel free to contact me. And if you want to join the last workgroup call this week it's tomorrow. We'll be sending out more information about that shortly.

And thank you to all of the developers who are on the line also. And we're done. Thank you.

Female: Thanks.

Male: Thank you.

Female: Thank you, Doctor.

Dr. Carol Palackdharry: You're welcome. Have a good day.

Female: Thank you.

END