

NATIONAL QUALITY FORUM

Moderator: Lindsey Tighe
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3:00 pm CT

Operator: Welcome today's National Quality Forum conference call. Today's call is being recorded.

Please go ahead.

Female: Thanks all and welcome to the Cancer Endorsement Maintenance Breast Measures Workgroup number 2. We're in phase II of the project and quickly I'd like to take a roll call of the Steering Committee Members on the call.

Steve Edge? David Pfister? Elaine Chottiner?

Dr. Elaine Chottiner: Here.

Female: Karen Fields?

Dr. Karen Fields: Here.

Female: Robert Miller?

Dr. Robert Miller: Here.

Female: Elizabeth Hammond?

Dr. Elizabeth Hammond: Yes.

Female: Okay.

Dr. Elizabeth Hammond: Hi.

Female: All right. So thanks for joining, and we also want to acknowledge that we have developers for each of the Measures on the call. We don't have our lead discussant for the first book - I'm sorry, for the first Measure. And I'm sorry to prevail on you Dr. Miller, I know that you're in a time crunch would you like to start our discussions with a discussion of Measure number 387, Oncology?

Dr. Robert Miller: Yes, I can start with 387. I thought you were asking me to do 1857.

Female: No.

Dr. Robert Miller: Okay.

Female: Sorry about that. No, I didn't mean ((inaudible)).

Dr. Robert Miller: No good deed goes unpunished. I got it, okay. So...

Female: So you know the process for today is that we'll go through each criteria looking at the Measure, and you'll give us your impressions and we'll open the Measure for discussion for the full group after that.

Dr. Robert Miller: Yes. Okay, so let me start with 387. Let me just pull it up since I had the other one open.

Okay, so 387 is an AMA PCPI Measure relating to the use of adjuvant hormonal therapy for women with early stage breast cancer, specifically the population is women age 18 or older with Stage 1C through 3C disease that are either ER or PR-positive, and the interest is what percentage were prescribed a standard adjuvant hormonal therapy either Tamoxifen or aromatase inhibitor during the 12-month reporting period. The denominator is all women with a diagnosis.

And in terms of the denominator exclusions, these seemed fairly appropriate, i.e., disease being metastatic or patients having received a previous oophorectomy, patients who were past the date of diagnosis more than five years, or were within a few months of the completion. Let's see, I guess that was diagnosis date within 3 months of the end of the 12-month reporting period.

And in terms of the -- let me just scroll here -- in terms of the - starting with Criterion 1, the impact, I really didn't have any problem really with any of these, so I'll be very brief. This is a high impact Measure because of the prevalence of breast cancer and because this is a therapy that - for which there is a very large database as to its effectiveness.

In terms of a performance gap, performance gap is not hugely robust, but the COPI Project showed that the performance rate was 93.9% and another study, Patterns of Care Study, was only 80%, so clearly there's some room for improvement there. So I had no concerns about importance to measure and report. Preferable 1B - 1A and 1B, in terms of evidence, I think the evidence is robust. So I'll just leave it at that.

And then, let me just scroll down further here, again some really reliability, this Measure as captured either electronically or in paper records, should produce reliable results. And likewise,

that's why I felt it met all the criteria for reliability, likewise under validity. Sorry, let me scroll back here. That this was - the results were credible.

In terms of usability, no real reservations there since I felt that this was easily recognized the stakeholders, both professional stakeholders and patient groups, and I felt it was highly feasible to do since it's a metric that is captured in other ways.

So bottom line, overall suitability I did not have any reservations. I recommended - my personal vote was for endorsement, and that's my report.

Female: Thanks, Dr. Miller. Do we have comments from the larger workgroup?

Lindsey Tighe: Let me just interrupt really quickly. Operator, if you wouldn't mind opening up the lines for the AMA PCPI staff?

Operator: One moment.

Lindsey Tighe: Thank you.

Operator: And their lines are now open.

Lindsey Tighe: Okay, great. Sorry, (Sintrup), go ahead. Who was trying to speak before?

Female: Comments from the larger workgroup?

Dr. Elizabeth Hammond: I was wondering about whether or not it was - needed to be - there needs - overlap, needs to be addressed with Measure 220?

Lindsey Tighe: We actually noticed that as well, and that it'll be able - once we have the full discussion at the In Person Meeting, we'll be having a side-by-side comparison, assuming both Measures meet the criteria for endorsement where the Steering Committee can evaluate and see where there are opportunities for harmonization if necessary.

Dr. Elizabeth Hammond: Good.

Female: Does someone from PCPI want to weigh in on this before the In Person?

(Pam Charity): This is (Pam Charity) with AMA. I would just comment I guess the main difference I see between Measure 220 and our Measure 387 is that essentially I think they're conceptually the same, you know, measuring hormonal therapy in breast cancer patients. But, I think that the Measure 220 - or I know Measure 220 assesses performance at the facility level, and our Measure is designed to assess performance at the physician level.

Female: Thank you. Any other comments with regard to 387?

Dr. Karen Fields: The thing I would...

Dr. Stephen Edge: Wouldn't the business see that - wouldn't it be better to measure the performance at the patient level? So in other words, we're concerned whether the patient gets it, not whether the facility is responsible or whether the doctor is responsible.

Dr. Elizabeth Hammond: Yeah, that's a good point.

Dr. Stephen Edge: And the facility and the patient and the doctor really haven't shared responsibility.

Female: So (Pam), do you want to speak to that?

Dr. Karen Fields: ((inaudible)) like they measure that they filled their prescription every month, or how would you measure that?

Dr. Stephen Edge: Well, actually that's a very good way to do that, and one can certainly do with claims data very readily. If you have claims data you can know whether they filled it. It's a proxy for taking the medication. So I guess we need to reconcile the facility versus provider, but I would suggest that we err on the side of looking at the patient rather than, you know trying to - the attribution towards one or other.

Lindsey Tighe: This is Lindsey. Just for the purposes of this workgroup call, as far as discussing the Measures, we're really not trying to do a head-to-head comparison of 220 and 387 just yet. So as far as...

Dr. Stephen Edge: Okay.

Lindsey Tighe: Yeah, as far as information for the Measure Developer that's certainly useful, but we don't want to go too far into the comparison of the two.

Dr. Stephen Edge: Okay.

Dr. Karen Fields: This is Karen Fields. I would think that both Measures might be applicable; however, at the physician level at least we're understanding if the provider is prescribing the medication appropriately. The healthcare disparities issue can be addressed about whether the patient had access or - from a facility standpoint a little bit more. But, I think it's hard to address the fact that the real problem is the failing of the system may be for the lower income or lower - other minority economic - or other - or minority groups, as far as accessing and getting appropriate medication.

Female: All right, other comments about this Measure? So we'll get into a deeper discussion about the two Measures as we get to the In Person Meeting.

Okay, moving back to our usual schedule here, our stated schedule, we have Measure number 1857, Trastuzumab. I'm sorry, how do you pronounce that?

(Crosstalk)

Female: Perhaps Dr. Edge could pronounce it for us.

Dr. Stephen Edge: Trastuzumab.

Female: Trastuzumab.

Dr. Stephen Edge: Trastuzumab and we ask our patients to pronounce it and they don't get it, right?

Female: Yes.

Dr. Stephen Edge: No, it's a good tongue-twister, which is why everybody says Herceptin, but they really should be saying Trastuzumab.

Female: Got you. I apologize for that. And our...

Dr. Stephen Edge: That's okay.

Female: ...Measure Developer for this Measure is ASCO, and we had opened the lines for ASCO and Dr. Stephen Edge is our lead discussant for this Measure and you can go ahead.

Dr. Stephen Edge: Great. Well, certainly the Trastuzumab is appropriate for women with HER2-positive breast cancer, as we'll discuss in a few minutes with another Measure, and in general it's used for women with HER2-negative breast cancer is inappropriate. Though, we won't have to put an asterisk next to that as the data from randomized trials suggest that in fact in the adjuvant setting, which is the setting suggested for this Measure that the odds ratio for Disease 3 recurrence is the same for women with HER2-negative, as it is for HER2-positives cancers as there was a subset of women on the original trials that were found on central review to be HER2-negative.

And in fact, as I believe there's an ongoing National Cooperative Clinical Cooperative Group, Clinical Trial examining the role of Trastuzumab in the adjuvant setting in women with HER2-negative breast cancer. So with that asterisk it is generally not appropriate for women with HER2-negative cancer.

The Measure there for a Measure is a significant issue. The developer does not appear to have shown that there is a major issue with this question on their own work with the Quality Oncology Practice Initiative, or COPI Initiative. The mean performance on this Measure was 99%. There's no other data presented showing that there was a further variation. There were the outlier, practices were only 8 - where the Measure was 80%, but they - there was no data provided on the number of cases the median, the number of practices with outliers, or the estimated number of cases in the United States. There was no other data from payors or other sources provided to support that there's an issue in this.

So the - I was concerned in the definitions of the numerator - the denominator regarding this because the absence - the only way you really define this would be the absence of claims for Trastuzumab, rather than relying on a self-report of the physician. So in general, I found that, you know certainly the level of evidence is high that you should not give this drug to women with HER2-negative cancer.

The available data is that the concordance with this Measure is already extremely high, which in many respects limits its value as a quality Measure. They rely on self-reporting of the physicians in the COPI methodology or the random subset of physicians, I don't think, would be adequate for the purposes of CMS reporting. And I'd like to some more comments, I think, from the developer on some of those questions.

Female: Do we have someone from ASCO on the line?

Operator: Their lines are open.

Kristen McNiff: Hi, this is Kristen McNiff. If you hear me I could begin to address some of...

Dr. Stephen Edge: Hi, Kristen.

Female: Yes, we hear you.

Kristen McNiff: So just to address the final concerns, I think, about the high concordance rate within COPI. The COPI participants are a self-selected group, so we do sometimes see a higher performance among the COPI participants, which are a group of practices, albeit a fairly large national group of practices who have self-selected to participate in this Quality Improvement Registry Program.

And - but when we see a variation across the practices then we think that there is room for improvement, regardless of whether there might be a high concordance overall. So we do position this as a Measure that's important to assess more widely as we do believe that there is a gap in performance. There have been some unpublished data from payors, but unfortunately they are not published, so we are not able to include them regarding the use of Trastuzumab in patients for whom there has not been a claim submitted.

And in terms of, we'll come to this later in the Measure, but we do believe that HER2 testing should be documented by the medical oncologist and that should be in the medical oncologist record. I agree that looking at claims is a way to find this information; however, ASCO has taken the position that if the oncologist does not have documentation that the patient is HER2-positive then the treatment should not be given.

So part of the definitional notes within our submission and within our Measure is that absent the documentation is - counts as overuse of Trastuzumab. So we do have the expectation that that - not only is there documentation that the test was administered, but there's documentation that the - of the HER2 status to support the use of Trastuzumab.

And I don't know if - I believe Mike Hassett is on the call as well. He may have comments about some of the clinical questions that you raise too.

Mike Hassett: Hi. Yes, (Kris), this is Mike. I'm here. So I support the - all the stuff that you said. I think one of my concerns, acknowledging that the performance, relative to the Measure within the ASCO Company Program, is relatively high is kind of a valid concern. Although, as (Kris) had alluded to, there are some non-published studies outside of that cohort that suggested some overuse for the drug.

And I think that there's at least some concern that as use of Trastuzumab becomes more widespread the tendency to overuse it may actually increase over time, and then therefore the tendency to see declining performance, relative to this Measure, is a potential in the future. I think that there's also a recognition and a desire to not - to prioritize Measures and to focus on aspects of care that not only address underuse of our (committed) therapies, but the potential overuse of non-recommended and potentially toxic therapies.

With regard to the data in HER2-negative patients and Trastuzumab, I think the best data that are out there are in patients with metastatic disease, which suggests not a - suggests...

Dr. Stephen Edge: Right.

Mike Hassett: ...no response rate to Trastuzumab-based therapy, and...

Dr. Stephen Edge: Right.

Mike Hassett: ...there are a few subsets in the adjuvant trials of HER2-negative patients on central review; although, a lot of those patients were HER2-positive on local review, and I think it's not clear about exactly how to interpret them. And I would say that the standard of care across the spectrum now is still against the use of Trastuzumab for patients who have HER2-negative disease.

Dr. Stephen Edge: Honestly, I was - in reading this Measure I was thinking that the Measure might better be targeted at women with metastatic disease, because if I was asked where I thought we might see more overuse in people pressure to use this, (it would be in) metastatics anywhere, treatment options may begin to be limited.

So I was sort of wishing that you had written this Measure for women with metastatic disease, but that's wishful thinking since you didn't do so.

Mike Hassett: You know, and I think it's a good point in understanding where to take Measures like this in the future, and to expand them to, you know other populations. I think, or at least my hope, speaking personally is to start with an area where - you know to start at one point, and then continue to raise the bar. And I think folks say on patients with metastatic disease may be an interesting direction to continue to grow with this type of Measure.

I think also this question may become a little bit more complicated in breast cancer therapy as the role of HER2 targeted therapy and the use of HER2-targeted therapy becomes more complicated. There are some studies now in patients with metastatic disease who have, you know positive HER2-negative disease and have progressed on hormonal therapy where investigators are exploring the using of HER2-targeted therapies as treatment because of this theory that secondarily they develop overactive ((inaudible)) of the HER2 pathway.

For that reason, and because there's a little more flex in the metastatic cohort, and to some extent to the consequences of being wrong are perhaps a little bit less right now and the population is smaller, this seemed like a good place to start as we sort out some of the questions with metastatic disease.

Dr. Stephen Edge: Is there an exception in here of - for the numerator for women who are on a clinical trial? I didn't see it, but...

Mike Hassett: I don't remember...

Dr. Stephen Edge: I believe this is in - there's an NSABP trial for women with HER2-negative cancer to receive Trastuzumab.

Mike Hassett: My - I don't remember off the top of my head. My feeling would be that, you know maybe - if you're getting Trastuzumab as part of a clinical trial that shouldn't be...

Dr. Stephen Edge: Right.

Mike Hassett: ...counted against you, and that's...

Dr. Stephen Edge: Right. I think you might want to examine all of your Measures and make sure there is such a clinical trial exception of the numerator.

Kristen McNiff: So there is. Steve if you look on page - top of Page...

Dr. Stephen Edge: Okay.

Kristen McNiff: ...7.

Dr. Stephen Edge: I'm sorry if I missed it.

Kristen McNiff: Yeah, so we - to - if the Trastuzumab was administered according to a clinical trial protocol...

Dr. Stephen Edge: Perfect.

Kristen McNiff: ...then that actually counts as being concordant with the Measure.

Dr. Stephen Edge: Perfect. Perfect. Oh, yes, I see it there. I'm sorry.

Kristen McNiff: Okay.

Dr. Robert Miller: So this is Bob Miller...

Dr. Stephen Edge: So what do other members of the Committee feel about this issue of the very high level of reported concordance and the absence of other data showing that there is practice gap her?

Dr. Robert Miller: So Steve, this is Bob Miller, and I have - do have trouble with this one because it just doesn't ring true to me as a breast oncologist that I really wish we - we would feel a lot better about putting this Measure forth if we could demonstrate a performance gap in another dataset. You know, I remember in my previous location a local payor alleging that oncologists were routinely using Herceptin for HER2-negative patients, but when we tried to analyze those data it really came back to the testing issue and the documentation issue.

And certainly, I mean, I agree with what, I think it was Mike Hassett just said about if - or maybe it was Kristen said about it, it needs to be documented. But, I just don't see this as one of the big problems of our time, and I just have trouble with premise of this Measure. I mean, the evidence that you shouldn't do is very strong, but I just feel like it fails on the performance gap and that's showing me that this is really a problem that needs to be corrected in this fashion.

Dr. Elizabeth Hammond: This is Liz Hammond, I totally agree with that suggestion. I don't think there is a performance gap. The data is strong, but I'm not supportive of this Measure, because I don't think it's an area - a place where we have a problem.

Dr. Karen Fields: This is Karen Fields. I guess I'm the one that wrote wide performance gap because if there's 20% of the patients in some practices getting Herceptin inappropriately I thought that was significant. So can the developer tell us a little bit more about - I mean, I understand 99% mean, but if there's practices giving a toxic drug - a costly toxic drug inappropriately I thought that was a significant issue.

Kristen McNiff: Yeah, this is Kristen. So we - I would have to pull additional numbers. We don't go back to the practices with the poor performance and, you know do any additional data collection from them, so the data that they report are really the data that we have. That said, if - you know we can certainly...

Dr. Karen Fields: Well, I mean Steve's point was, was it a practice of three patients and - or something like that, but I'm sorry, just 20% of the people getting a drug that cost \$100,000 a year, it's inappropriate. So I think it's a performance gap and I would think it was a reasonable Measure to evaluate.

I'd defer to other people's thoughts on that, but I understand that we're very compulsive at academic centers documenting HER2 status making sure that we're not - that we're measuring HER2 correctly, and making sure that we're not giving a drug when it's not indicated. But clearly, there was a performance gap on a group of providers that voluntarily submitted their data to this - to COPI, and it just was striking to me that...

Dr. Stephen Edge: So what I would - I'm going to suggest that before the In Person Meeting that ASCO; A, provide us the exact question that was asked and the exact data elements that were provided from the medical oncologist office; and B, provide us the statistical analysis of this rather than just the mean and the range. I suspect this was very, very few patients, probably one or two practices, and a very outlier practice rather than affecting a lot of patients. But, I think we could see a more definitive statistical analysis of this practice pattern.

Dr. Elizabeth Hammond: (That and just coming) in and looking at the documents.

Dr. Stephen Edge: Pardon me?

Dr. Elaine Chottiner: This is Elaine Chottiner. We're going to have the exact same discussion when we get to the HER2 testing where there was a 98% concordance, whereas the performance gap was 75% to 100% in the practices surveyed. So I think this is a broader issue.

Dr. Stephen Edge: Right.

Lindsey Tighe: Kristen, with the statistical analysis that they're asking for, is that something that we could feasibly have at In Person Meeting?

Kristen McNiff: Yes.

Lindsey Tighe: Okay. Thank you.

Dr. Stephen Edge: Okay, if I'm allowed to, I could even talk with Kristen offline about how we might structure that, but only if I'm allowed to by NQF.

Lindsey Tighe: Yeah, you're allowed to. If you wouldn't mind just looping one of us in on that conversation that would be great.

Dr. Stephen Edge: Okay. Kristen, we can try to do that if it helps for me to be involved.

Female: Okay, any other comments about 1857? So we'll go to the next Measure, which is 1858, and it's Trastuzumab administered to patients, actually as - with early stage cancer. And we did have Dr. Pfister to - as lead discussant for this, but he's not able to join the call. Is there someone from the Steering Committee willing to lead discussion of this one?

Dr. Stephen Edge: Well, I'm happy to generally review it. Certainly, the practice guidelines called for the use of Trastuzumab to be administered with chemotherapy to women with T1c Stage 1 cancers or Stage 2 and 3 breast cancers that over express or have amplified HER2.

Sidebars that I might - you - I mean, we might change - we might recommend that the ASCO consider changing the title to Trastuzumab is administered with chemotherapy to patients with blah, blah, blah, but that's a sidebar.

The Measures apply to women 18 years of age and older who have HER2-positive cancers administered within the - to begin within four months of a diagnosis. And as I recall reading this, it's for one year of treatment as stipulated by the randomized clinical trials. There's very high level evidence. This is one of the most dramatic affects we've seen. Certainly, this is a treatment which has saved - which is going to be saving many, many lives over the time.

I - as I'm not prepared - I wasn't prepared to give this discussion, I don't remember the evidence. Kristen, is ASCO on the line right now?

Kristen McNiff: Yes. Can you hear us?

Dr. Stephen Edge: Yeah. Kristen, what page is the data on in which it was - the data supporting this? I'm sorry, I - because I wasn't prepared to do this.

Kristen McNiff: I'm - the data supporting the use of Trastuzumab...

Dr. Stephen Edge: Showing the practice - no, the data showing the practice variation.

Kristen McNiff: Oh, let me scroll to that.

Dr. Stephen Edge: I'm terribly sorry that I'm not prepared to do this.

Kristen McNiff: All right, if you look - I think it's in two places. It's on the bottom of 13. So it's another with high - a high mean concordance and range across the practice; 97% of a mean, and then 60, 100 max.

Dr. Stephen Edge: Yeah. Again, you might consider doing the same kind of analysis for us for this...

Kristen McNiff: (Yep).

Dr. Stephen Edge: ...given that finding. Of course, this might be more complicated, and Dr. Mike Hassett might want comment, this might be more complicated because there may be other factors, particularly the impact on this question.

And that's one of the issues that I had reviewing the Measure is that there is no upper age limit cutoff. There's only the consideration that the physician documented that they weren't going to give the treatment because of comorbidities or - I don't remember the exact wording. But, your statistical analysis might have to include a multi-variable analysis, which might be more difficult to do in the next two weeks, of factors associated with omission of Trastuzumab in this setting.

Dr. Hassett, do you have any thoughts on that question?

Dr. Mike Hassett: So I would say that a very likely agent is going to be associated with the absence of Trastuzumab therapy for HER2-positive breast cancer, as is comorbid disease; although, at least in the studies age wasn't associated with a decrement and benefit from Trastuzumab therapy, which is in contradiction to the story with adjuvant systemic chemotherapy in general.

So you know I think for healthy - people who are generally healthy, regardless sort of age there's actually been a push to use Trastuzumab in these...

Dr. Stephen Edge: Right.

Dr. Mike Hassett: ...folks. And part of that is I think because of the concern that the risk of relapse is relatively early, so you know even in an - you know an 82-year old...

Dr. Stephen Edge: Right.

Dr. Mike Hassett: ...if that 82-year old has a HER2-positive breast cancer that breast cancer could recur in the next one to three years.

Dr. Stephen Edge: Yeah.

Dr. Mike Hassett: And it's not the - it's - to some extent, the risk of recurrence and the distribution and over time isn't the same as what one would expect for a (near) positive cancer.

Dr. Stephen Edge: Right. I had this very discussion with a 79-year old women with a 8-millimeter HER2-positive cancer earlier this week, so you can see we're going to have an interesting time as we get her - all her pathologic data coming forth.

Dr. Mike Hassett: Yeah.

Dr. Stephen Edge: So I think the Committee's going to have to decide, does the exclusion of the doctor saying, "It's not appropriate to give this treatment," is that sufficient for excluding somebody from the numerator, or including somebody in the numerator as being concordant? I think that's something that our Committee needs to discuss.

Dr. Karen Fields: This is Karen Fields, I'm also - I was the one that put the other exclusion. The other exclusion was a cardiac exclusion. They should - that should be listed as an exclusion. That - and one of the other questions I asked, one of my other comments was, it's not always easy in a - to get that four-month window, and so maybe the variation and the performance gap was that there was delays in surgical treatments in the first place, or other delays.

So perhaps the variability was due to measuring for four month - for receiving Herceptin within four months - or Trastuzumab within four months.

Dr. Stephen Edge: We have the same issue when we're measuring on chemotherapy administration along the Measure that's being applied through the commission of cancer. I don't remember the number for the NQF. I believe Andrew Stewart is on the phone; although, he's probably muted at the time, and I - if he can be unmuted I was going to ask him if he could, off the top of his head, give us an estimate of the number of patients who with ER-negative breast, whose therapy begins after four months.

Karen, I think that's a really important point.

Operator: His line is now open.

Dr. Stephen Edge: Sorry to put you on the spot, Mr. Stewart, but...

Andrew Stewart: Thanks, Steve. The number, proportionally it's about - it's less than 5%.

Dr. Stephen Edge: Really? Okay.

Andrew Stewart: I remember doing the sensitivity analyses on that Measure a number of years ago, looking at a portion of women in the measured appropriate denominator who initiated the adjuvant therapy outside the timeline that we were considering, which ended up being 120 days or four months. And it was one of the reasons for selecting that timeframe limit was to make sure that we were, you know giving all institutions that we work with, you know equitable or even opportunity to, you know demonstrate, you know patient concordance with the Measures.

And I think in the end it was less than 5%, but I can double check and bring that information.

Dr. Stephen Edge: Okay.

Dr. Karen Fields: But I have to actually raise a slightly different issue, because you're just talking about beginning adjuvant therapy.

Dr. Stephen Edge: Right.

Dr. Karen Fields: And Herceptin has to follow on the heels of anti-cyclin-based therapies.

Dr. Stephen Edge: Oh...

Dr. Karen Fields: So Herceptin might not...

Dr. Stephen Edge: ...good point.

Dr. Robert Miller: Right. I was going to say the same thing that I...

Dr. Stephen Edge: Good point. Good point.

Dr. Robert Miller: Yes, this is Bob Miller and I actually would be very surprised that it's that low. In an unselected population that it's - that only 5% don't make the fourth-month cutout, because the way the numerator reads, "Administer within four months of diagnosis." So...

Dr. Karen Fields: Yeah, (people)...

Dr. Robert Miller: ...you know was the first diagnosis made on a core needle biopsy? You know, in our institution it could be longer than it should be, but by the time they've had their definitive surgical procedure, they have the tissue expanders in, then they get two months of AC before they start their Taxane and Herceptin.

I mean, I just - I don't know that that's - I think there's a lot of that going on. I mean, you know there's two...

Dr. Karen Fields: But, I don't think it's inappropriate either...

Dr. Robert Miller: Yeah.

Dr. Karen Fields: ...because they'll have started systemic therapy, which was...

Dr. Robert Miller: Right. Right.

Dr. Karen Fields: ...what you were quoting the data on. If ((inaudible))...

Dr. Robert Miller: Exactly.

Dr. Stephen Edge: Right.

Dr. Robert Miller: Yeah.

Dr. Stephen Edge: I'm actually looking at an unpublished study we have from the NCCN that we're working on right now. I have it opened on my computer looking at time to start chemotherapy from date of diagnosis at NCCN centers, and about 85% to 90% of women start chemotherapy by 16 to 17 weeks, or about four months.

So I think ASCO should take a - relook at this Measure to say when the Trastuzumab should actually start, or revise the Measure to say something on the -- and this is just a suggestion -- say something on the order of, "Begin systemic therapy that includes Trastuzumab by four months,"

or whatever timeframe is selected, because the chemotherapy, as Karen said, will start and the -
you know the Trastuzumab actually may well not start for another two or three months.

Dr. Karen Fields: Yeah.

Dr. Stephen Edge: Does ASCO want to make any comments, (Karen) - Kristen or Mike, do you want to
make a comment on that?

Kristen McNiff: Well, we certainly will take that into advisement that this is a useful discussion. The thing I
will say is that ongoing receipt of AC is denominator exclusion.

Dr. Karen Fields: But, that means everybody's going to fail. All the centers are going to fail...

Dr. Stephen Edge: Right.

Dr. Karen Fields: ...because as a best-case scenario - well, as heard 85% of the NCCN centers get it
started within four months, and they're starting the anti-cyclins, that's a two to three month delay
before you start the Herceptin...

Dr. Stephen Edge: Right.

Dr. Karen Fields: ...so that means 85%...

Dr. Stephen Edge: So...

Dr. Karen Fields: ...of the centers are going to fail.

Dr. Stephen Edge: ...Kristen, you just said that ongoing AC is a denominator exclusion and if they - you...

Kristen McNiff: (Well, that)'s...

Dr. Stephen Edge: ...exclude women who get AC, you're excluding the majority of the women who will go on to get Trastuzumab...

Kristen McNiff: People who are...

Dr. Stephen Edge: ...if I just heard you right.

Kristen McNiff: ...still receiving their AC.

Dr. Karen Fields: Right, but...

Dr. Stephen Edge: But, then how do you then - how does the timeline work for this Measure?

Kristen McNiff: Because you capture people in our sample who were completed - who had completed their AC.

Dr. Stephen Edge: But then they have started Trastuzumab more than four months after diagnosis.

Dr. Karen Fields: Yeah.

Dr. Stephen Edge: I think the time - I think what you're hearing is the timeline probably needs to be worked, and I think you and Mike and others probably might want to rethink it. And again, if you want Karen or me or someone to help think - help you think it through that would - that could be done.

Dr. Elizabeth Hammond: This is Liz Hammond, I also have a concern about the, not - and not a concern about the timeline, but I have a concern about whether or not we're really adequately measuring the right thing here. I mean, the - Herceptin - there are positive incentives for people to give Herceptin to patients, but they might be giving it to patients, as we've discussed, too late, but more likely they're giving it to people who shouldn't be getting it because they have cardiac problems or they should be evaluating them for cardiac problems.

I mean, I think there should be something in this Measure that helps us know that the patients are being carefully evaluated, especially those that have been on AC for cardiac problems or risk factors that would make it likely for them to have a problem with Herceptin, because I say if you're looking to make a Measure that's going to have importance that would be the way to do it.

Kristen McNiff: So I think that's a very useful feedback. We do have a specific clinical inclusion that - the details of which are not provided and we could certainly add them that cardiac tox - or cardiac disease is one of the specific issues noted. And I agree that's a very important measure. I think it's a little bit of a different measure, and what I hear from you is maybe that, you know you're feeling is that that is the more important quality issue.

But, these are all - this is all helpful feedback. I don't know, Mike, if you've got any comments? We can definitely, I mean you know (bring) - think about this more after the call.

Dr. Mike Hassett: Yeah, I would agree that these comments have been excellent. With regard to the cardiac issue the incidence of people who start AC, the incidences of cardiac toxicity between the initiation of AC and the initiation of Trastuzumab does - is relatively low.

There aren't a lot of population-based analyses of adequacy of cardiac function testing during that period of time although, and I think and part of group that's trying to drill down that question actually presently and we're trying to put some data together around that particular issue. And

just anecdotally have not seen a lot of risky behavior with Trastuzumab therapy in patients who have cardiac toxicity that develops after the initiation of AC.

But, it sounds like kind of drilling down a bit more on some of the denominated exclusion from the timeline, we can talk about those.

Dr. Elizabeth Hammond: Yeah, patients who have been on AC ought to be reevaluated for their cardiac status, because of that.

Dr. Mike Hassett: Yeah. (That's a good)...

Dr. Elizabeth Hammond: And that's the point is that if you're trying to think about measures that are going to actually help patients, then the best measure would be for any doctor who is thinking of using Trastuzumab to make sure that the patient doesn't have any cardiac toxicity prior to the initiation of that drug, and especially patients who have been on AC. Not before they got the AC, but after.

Dr. Stephen Edge: Is that true, in terms of standard practice for giving standard ACT Trastuzumab that reevaluation for cardiac status is done at the completion of AC? We have a number of medical oncologists on the phone.

Dr. Karen Fields: I personally would say that's not standard practice. That was how the first clinical trials were done. But, if you're giving AC in the standard dosage you're getting below - and you did a baseline cardiac function and you gave less than 300 - you gave 300 milligrams per meter squared, or less is the usual adjuvant regimen, people don't always get that second MUGA to - you know to decide about getting Herceptin because you're - you stayed within safe limits in - on a healthy person, and we showed that we didn't. Like less than, what is it, 4% to 10% of the

patients get cardiac toxicity, but cardiac - a history of a cardiac toxicity or a decrease injection fraction should be an exclusion criteria.

And the, some practices may do MUGAs, but I don't know that every practice does a MUGA during - prior to Herceptin if just ((inaudible))...

Dr. Elizabeth Hammond: Right. But, if you think about the - if you think about this from the patients perspective, even 4% to 10% of cardiac toxicity is a pretty bad outcome.

Dr. Karen Fields: And it was always pretty much reversible with discontinuation of the drug. I understand that this - that's a separate practice question that's a little - I think it's an important - very important issue, which is we understand that the patients - the appropriate patients are getting the drug appropriately, and they're being monitored adequately for toxicities, it's just taking an injection fraction right after anti-cyclin may not - if - in a patient that had a previously normal MUGA may not answer that question, because, you know ((inaudible))...

Dr. Elizabeth Hammond: Well, it's at least worthwhile to do some general questions of the patient to find out, and physical examination to find out whether or not there are any signs of cardiac toxicity, because the - I'm well aware - I'm a heart transplant pathologist, in addition to being a cancer pathologist, and I see patients who have had very poor outcomes. In fact, require transplantation from Adriamycin, some of whom have been on low doses.

And so, I have a healthy disrespect for Adriamycin, in terms of cardiac toxicity. It's not a benign drug and I think it would be smart to - I mean, it seems like the - having a measure just to make sure that everybody who's got a positive HER2 test gets Herceptin is something that is already something every medical oncologist would want to do is to look at (these). There are already incentives to do it, what we want to do is incentivize doctors to do things that they might not do that are important for patients.

Dr. Karen Fields: And I don't disagree that Adriamycin is not a benign drug.

Female: Okay. So hearing the comments on this Measure, Kristen, it sounds like there's this Measure and then a Measure that the Committee would like to see. We might have to get with you offline to see what, if anything, can be done with this Measure to make sure that - you know to see if there's any changes that we could make based on the suggestion received today.

Kristen McNiff: Right, we will do that.

Female: It'll make the Measure - because I mean, the only concern is how the Measure was tested and whether it would still hold up if certain things were added or modified in certain ways.

Kristen McNiff: Okay. We'd be happy to have that conversation with you.

Female: Thanks. Are there any other comments about 1858? Okay. All right, moving on our next Measure is 1878, HER2 testing in breast cancer. ASCO is also the Measure Developer for this Measure, and Dr. Karen Fields is our lead discussant. Oh, I'm sorry, Dr. Elaine Chottiner is our lead discussant for this Measure.

Elaine?

Dr. Elaine Chottiner: All right, this Measure, I think, is very straightforward. There's a large body of evidence supporting doing HER2 testing, it's high impacting a number of patients that are involved, it's feasible, the data reliable and valid. The same issue comes up though again, which is we'll see concordance, and this again is based on COPI data. And I've lost the section, but it was about 7000 patients and 210 practices with 98% concordance, and 75% to 100% in practices.

So I think that it's easy to endorse it for the question about whether there really is a gap (in her).

Female: Thank you. Are there any other comments about the Measure from the larger workgroup?

Dr. Robert Miller: Yeah, this is Bob Miller. Just wondering people's thoughts about whether there should be a denominator exclusion based on size? I mean, we routinely check HER2 for any invasive cancer, but I think that most clinicians are unlikely to prescribe Trastuzumab as a therapy for HER2-positive cancers that are T1a, so 5 millimeters or smaller, although I'm (sic) know there's some people that do that.

But, there might be a small subset of patients that have very tiny invasive tumors where HER2 testing is not possible. I'm not sure I think that that lets them off the hook for getting a test did, but I just, you know trying to look at all sides on this and make sure that we're not penalizing some small percentage of situations where the results of the test may have no clinical implications.

Dr. Elaine Chottiner: This is Elaine. I concur that we do not usually test tumors less than 5 millimeters.

Dr. Karen Fields: And I just was going through the protocol and it does quote the NCCN guideline that says, ".6 to 1 centimeters in known negative patients should be the only group considered for Trastuzumab." So that would suggest that most people aren't looking at it below . - or at .5 or less.

Dr. Robert Miller: I mean, I'm playing devil's advocate because at my institution, I'm sure many, you know we still have the discussion with patients when we know it's HER2-positive and it's a 4 millimeter tumor, because there might be circum - we don't have data. You know, I think that's pretty clear, but in the absence of data practice patterns are such that it's not at all unheard of that

Trastuzumab is used in the adjuvant setting. So - but I - you know I'm just trying to think this through about whether size should enter into this at all or not.

Dr. Elaine Chottiner: I've tested...

(Crosstalk)

Dr. Elaine Chottiner: ...some - I'm sorry in smaller tumors that were high grade or estrogen-(linked) negative, so I think that you would like to leave that flexibility and not (ding) people for not checking it in small low-grade tumors.

Dr. Stephen Edge: Actually - I mean, perhaps Dr. Hammond has a comment here, but I think in general most people generally do these biomarker tests on an invasive cancer, with the exception of when there's too little tumor on which to perform the test.

Dr. Elizabeth Hammond: That's correct. That's absolutely correct. The - we always do it - we do it routinely on anything that's invasive cancer, so the test is done. Whether or not the patient receives the treatment is not, you know...

Dr. Stephen Edge: Right.

Dr. Elizabeth Hammond: ...is different.

Dr. Stephen Edge: But, the place you will find, if you review the path report where there is no report of a HER2 test is where there was only 2 millimeters of cancer. And when you cut the block again to make another slide to do the HER2 test...

Dr. Elizabeth Hammond: Yeah.

Dr. Stephen Edge: ...there isn't any tumor. There just isn't any tumor. So...

Dr. Elizabeth Hammond: Right.

Dr. Stephen Edge: ...that's...

(Crosstalk)

Dr. Stephen Edge: ...why you might have size cutoff. The problem is if you put a size cutoff into the Measure you may be giving the subtle message that you don't need to do this, and then you'll find the practice changing because of the Measure, which would be unfortunate.

Dr. Elizabeth Hammond: Right. Right, I think that, you know we don't - I've - we are just in the process of revising the HER2 guideline again, actually this year, and there's strong sentiment on the part of the medical oncologists around that team to, you know give patients what they call the benefit of the doubt since Herceptin is a very effective drug. They are pushing on us to make sure that the guideline doesn't ever allow patients who don't have HER - don't express HER2, by some means or another, from keeping them from getting Trastuzumab.

So I support the idea of removing the size inclusion just because of all the things that have been said. I think the guideline, it actually conflicts with the guideline as it's currently exists, and will in the future, and that is saying that we do not - we advocate that in the guideline that every patient who has any invasive cancer gets the testing formed.

Dr. Robert Miller: Ultimately, this is Bob again, I'm fine with that. I just wanted to raise the point, I want to make sure we weren't making this too narrowly defined, but I'm - clinically I kind of agree with you.

Kristen McNiff: And I would just like to point - this is Kristen, can you hear me?

Dr. Robert Miller: Yes.

Dr. Stephen Edge: Yes.

Kristen McNiff: Okay, I'd just like to point out that insufficient sample for results is included as a...

Dr. Elizabeth Hammond: Good.

Kristen McNiff: ...data element within the numerator.

Dr. Elizabeth Hammond: Good.

Dr. Robert Miller: Okay.

Female: Other comments about this Measure? Okay. All right, hearing them we'll move on to 1855, Quantitative HER2 evaluation by AIHG uses the system recommended by the ASCO/CAP guidelines, and this is a Measure jointly developed by ASCO and the College of American Pathologists.

Our lead discussant for this Measure is Karen Fields, and if you would like to tee up the Measure for us, Dr. Fields?

Dr. Karen Fields: Sure. This Measure proposes that we - I understand the percentage of patients that get quantitative breast HER2/neuropathy immunohistive chemistry evaluation using the existing ASCO/CAP guidelines, either manually or with a computer-based assist program using the

optimized algorithms before testing. The numerator is all patients receiving quantitative breast HER2 immunohistive chemistry, and the denominator is all patients that are HER2-positive and there were no exclusions.

It's a high - breast cancer is high impact and we've already discussed that it's a useful and important piece of information when making therapeutic decisions about patients with breast cancer, because of whether or not we should give Trastuzumab, and I won't (reissue) any of those things.

The guidelines were developed several years ago and basically explaining when we should use FISH assays to further quantify the immunohistochemistry staining. And the reason that the developers, and I'd love to hear a little bit more from the developers, and I love the fact that I had a colleague that was a pathologist helping me to this assay, but initially anything greater than 10% staining was called positive.

Now we have ranges of positive, which is greater than 30% of the invasive tumors intensely pick up the stain around the entire membrane, versus equivocal, which is 10% to 30% versus negative, which is less than that. So - and then, it - then if we're equivocal we think about utilizing FISH testing to further quantitate the positivity - or - of the HER2 test.

What I didn't understand about this guideline is - or what I understood, and I hope I'm explaining it correctly is that it's a Measure that's based on clinical guidelines, but there's not a lot of - there's a presumption that because the manufacturing guidelines are different than the clinical guidelines that there's a performance gap. But, there was no data presented that there was a performance gap, rather than the suggestion that there's probably a performance gap because of the difference between the guidelines and this - and the manufacturing - manufacturer suggestions for using the guidelines.

And so, their validity testing and reliability testing was to be determined as part of the development of this Measure. I thought that the - all the data is indirect data; although, there was a suggestion in the data initially that when they - when CAP did a survey of 757 labs, only 84% of the labs surveyed were reporting criteria correctly. So that was the evidence to support the use of this. There's no randomized trials or anything to look at this particular aspect; although, randomized trials are related to why we want to use the data once we have it, rather than how we're developing the data.

So I think it's a valid Measure if we think that there's a disparity that's as high as 84%, and that gets back to some of the comments earlier about when we did central reviews we changed the patients from positive to negative and from negative to positive. So I thought that was a valuable Measure and I recommended it for consideration.

Dr. Elizabeth Hammond: All right. This is - can I make a comment at this point? This is Liz Hammond.

One of the - well, there's - there is a kind of a difficult circumstance that's arising now. As I mentioned just a minute ago, the guideline is under review for re - it's being reassessed and will -- we hope -- get republished with revisions as a - you know an update to the previous guideline was published in 2007. We're planning to publish this update of it in 2012. We hope we'll make it by the end of 2012.

But, one of the issues that has been - has come up is the - is using this difference in the interpretation criteria for immunohistochemistry. That criterion was put in at the time, and there have been two published papers that have documented that it is valid to do that because most - virtually all well-handled specimens will fall above the 30% cutoff. But, there - so there is a little bit of data that ((inaudible)) that does exist.

But, there are complaints about using that difference to 30% that may cause a completion revision of the way in which we define the interpretation guidelines in the new guideline. It would

be a shame to put out a Measure with all the work that's required for validity testing, and so on, if the guideline is going to be revised.

So maybe one of the ways to deal with that would be to other than - instead of making the Measure specific to this particular aspect of the guidelines, it would be useful to know - to try to develop a Measure that asks the question of how many laboratories are compliant with the guideline, because we believe that the guidelines on the subject are helping laboratories do a better job of testing and getting rid of the variation and the errors, but we don't know that for sure.

And the Measure that required evaluation of whether laboratories were following it would be a useful way to do it. Otherwise I think, you know there may be some issues with putting this Measure forward now; although, I totally support it as well if it stands. But, if it doesn't stand then we will be creating a Measure that - where the guideline has changed, and I can't cite - I can't tell you what's going to happen until after the deliberations are over.

Lindsey Tighe: And sorry, just to interrupt for a second, if we could Fay Shamanski's line open, please?

Fay Shamanski: Hello, this is Fay. Can you hear me?

Lindsey Tighe: Yes.

Fay Shamanski: Well, one of the things I was thinking, because this guideline is just making sure that you're using the ASCO/CAP scoring system, if the scoring system changes we can change the footnote, but the Measure is still accurate, right? I mean, the Measure would still stand if...

Dr. Elizabeth Hammond: Absolutely.

Fay Shamanski: ...you just use the system.

Dr. Elizabeth Hammond: Yeah. Yeah, that would be a good way to do it. That would be a good way to do it, just so the Measure Developers understand that there is...

Fay Shamanski: Yeah.

Dr. Elizabeth Hammond: ...a strong chance that something will change.

(Angela): And Dr. Hammond, this is (Angela). This would - change would be reflected, the change in the underlying guideline would be reflected at the annual update that the developers would provide. So that would be addressed.

Dr. Elizabeth Hammond: Good.

Female: Also, because this measure is presented for a time limited endorsement it will undergo another review in 12 months when the testing is provided.

Dr. Elizabeth Hammond: Okay, that sounds great. So then my comments were related to my lack of understanding about how this process really works but I guess I'll get...

Female: Apologies, we didn't introduce it properly, sorry.

Female: Yes, and this is all good information to know as part of the process. So we'll be looking for that update when it comes out. Other comments from the developer or the steering committee about this measure?

Karen Fields: No, I defer completely to the group's opinion on that one. This is Karen Fields.

Male: And nothing else from me.

Female: Okay, so as Lindsey said, this is a time - this measure would be evaluated as suitable for time limited endorsement. So we'll carry that forward to the ((inaudible)) person.

Our next measure on the list is Measure - we skipped - for those of you who weren't maybe on the call we skipped - sorry, went early with 0387 and our last measure on the docket is 0391, breast cancer resection pathology reporting. (CT) category, primary tumor category and (PN) category, regional left nodes with histology grade. And this is an AMA PCPI measure.

And our lead discussant is Dr. Elizabeth Hammond.

Dr. Elizabeth Hammond: All right. So which one - I'm confused, which one is it we're doing first?

Female: Three-ninety-one.

Dr. Elizabeth Hammond: Three-ninety-one, okay, great.

Female: We already had a discussion of 387.

Dr. Elizabeth Hammond: All right, that's right. I was on the call when that happened. I was just confused, okay. So this measure is a measure that seeks to evaluate how likely it is that pathology reports contain the requisite information that is critical for patient care, including the stage - the extent of disease, the PT category, the nodal status, and the histologic grade; all elements that have been found repeatedly to relate to the outcome of patients, their prognosis, and also all important in the way in which the patient is treated.

The disease definitely has high impact and the - and this has been cited, there is a nice discussion about the value of the - of this kind of measure, data related to the performance gap shows that there is a gap of 35.87% of patients who have not received - not had the appropriate information provided if I'm reading that correctly.

So it appears that there is a significant performance gap there and the quality of the data here is data that's been cited numerous times. There's information on the cancer protocol of the College of American Pathologists is one of the cited things as well as the ((inaudible)), breast cancer guidelines. All of which cite specific information.

There is no - there were no specific studies dealing with consistency of information but there's an implicit idea that this - that these things are important, not only in breast cancer but consistency is across all cancers have been shown that there's smart for writing - for reporting the stage of the disease as well as the grade of the cancer and various types of cancers across the body.

So the consistency information is also very good. The way in which the data - the quality of the data is all from these guidelines. As we have found in dealing with other performance measures where we were looking at pathology reporting it's basically similar to the other ones in terms of the quality and consistency of the data. So it would be determined to be moderate.

The reliability of the data should be excellent because the information is required to be reported in many institutions - or all institutions and final path reports usually have to have this information.

The elements that it can be - it's information that should be easily obtainable and reliably obtainable for electronic medical records. The ((inaudible)) all breast cancer resection reports would be included. They are excluding biopsies and biopsies are sometimes considered excision specimens.

So I think part of the problem might be the way in which the biopsies are evaluated. The measure developer might describe for us whether or not - how they're going to be able to tell an excisional biopsy from an incisional biopsy because excisional biopsies can in fact be breast resection specimens.

The - so the data is reliable, it's valid. The way in which it's being obtained and the ((inaudible)) that are put there are - should be excellent. There should be - there have been studies of the reliability and those reliability estimates were excellent. They were 100% so that would seem to be not any kind of an issue.

The utility of the measure is good because it's - the data's available in an electronic means. So in summary, I believe that this is a very important measure and should be approved and carried forward.

Female: Thank you, Dr. Hammond.

Female: Can I ask a question maybe of the developers or maybe of Dr. Hammond?

Female: Yes.

Female: I'm assuming that when they're talking about this they're talking about the - that it's in the final report, which might include multiple biopsies or multi resection reports rather than - you know, because patients get returned to surgery for margins and so sometimes there'll be these summary reports.

It wasn't as clear to ((inaudible)) to me in that and in the measure because the numerator statement says that reports that include T category, N category, and histologic grade. And then

numerator's each final report but I don't know if it's that final summary, final diagnosis report. And I want to...

Dr. Elizabeth Hammond: That's an excellent question and it causes dramatic problems for patients and physicians as well as pathologists because there are usually multiple reports that have this information and how does anyone know which is the most important report.

So I think this is a serious issue. The - and some information about it should be addressed by the measure developer and it also by the way in which we're handling breast cancer reports.

We - the College of American Pathologist currently have a breast cancer - or a reporting - cancer reporting initiative going on to try to address the problem and create what's called - would be called a summary or an integrated report.

And - but probably it should have a separate code so that it could be specifically targeted and that doesn't exist at this point in time. So it's not a problem of the measure developer. It's a problem of the way in which we're reporting these malignancies.

Female: Did anyone from the developer side want to chime in on that one? Do we have the lines open for AMA PCPI and CAT?

Operator: One moment, I do have AMA PCPI open. I will open CAT for you.

Female: Thank you.

Operator: Their line is now open.

Molly Siegel: This is Molly Siegel from the AMA PCPI. I think that's a great question. As was stated, it wasn't the issue of the measure developers but what is available to pathologists currently.

And I think that if that were to change that's something that we could then provide the measure to accordingly, which is something that we do sometimes. So I just wanted to add that. I'm not sure if somebody from ((inaudible)) would like to also comment.

Fay Shamanski: This is Fay. Is David Witte's line open as well?

Dr. David Witte: I'm here.

Fay Shamanski: Okay, I think the way the denominator is specified, it would be any report that the pathologist signs off on. And I just wanted to ask Dr. Witte if he agrees with that.

Dr. David Witte: Well, it would strike me as that would be true, Fay. I don't - I remember we had many discussions about specimens other than the first removal of breast cancer. But I don't remember us discussing multiple - whether the multiple reports would all have that information.

I think it's an excellent question but I think the way that denominator is chosen as you point out it would affect every report, would it not?

Fay Shamanski: I believe it...

Dr. Elizabeth Hammond: Yes, it would. And, you know, this is Liz Hammond again. There have been reviews - I've done reviews in Intermountain Healthcare for example, there commonly - at least maybe two reports that have data like this. All the reports may provide a grade designation. Many of them may provide a PT designation, especially if they're resection specimens of some kind.

So it does - it is a confounding factor and I think the fact that College of American Pathologist is planning to try to address this through its - has an informatics committee called the (DIE HIT) committee which is actually taken on as a major initiative.

So I think as it goes through week - month - yearly updates there will be a time where the confounding of this particular issue will be addressed.

Male: This is the right approach.

Male: This is ((inaudible)), also with the College of American Pathologists. I mean I think what we're talking about here is a very good measure with really an inescapable question because the fact is that all we can do is report on what we have.

It's certainly possible that we may have a specimen of breast or other things which has a T category and an N category. And then there's a scan that shows a metastasis somewhere else or possibly even a different procedure by needle aspiration maybe done somewhere else that we don't have immediate access to.

So best we can do is give the T and the N according to what we have at the time with the idea that there can always be more information, more specimens that come up either through our laboratory or even through someone else's that shows something more advanced.

Female: I guess my point of bringing this up was because breast cancer sometimes gets done in stages.

Like, there's the excisional biopsy sometimes or the margins are positive. And then there may be the lymph node - there may be the sentinel node biopsy and then later an axillary node biopsy.

What tends to happen at our institution is there's a lot - there's a series of pathology reports that are combined but at the end the pathologist does the T and N and all the other prognostic indicators and summarizes all of those things.

And I think that's really the goal of reporting is that somebody puts all that together - and I'm not necessarily talking about and later they did the liver biopsy. I don't think that would be the pathologist's responsibility to do that. But the summary path of the primary therapy for the breast cancer comes out sometimes in ribs and drabs, and not all centers, I don't think, put them together in one way.

And that's - but the goal would be to get - to hold people accountable for that final task for that primary therapy. Am I...

Dr. Elizabeth Hammond: That is exactly - that is what we need and the College is working on that through an initiative of its - of one of its committees. And the head of that initiative is a Dr. (George Birdsong), who I think is at Emory. And that is - it's a - breast cancer is one of the major things that they addressed that was a problem here.

So I think that that will be - that this will get handled but in the meantime we have to use the measure. It is a valid measure and it is a good measure. We have to go forward the way it is but I think it will spur the College on if we make the comment that it is good for us to head towards summary reports.

Female: What happens is unfortunately the treating clinician is the one who has to try to ((inaudible)) together. So we're adding up tumor sizes and trying to add up ((inaudible)). We're not always very accurate at that.

Male: And ((inaudible)) again, one of the problems you have when you have, say, an initial biopsy that has some but not all of the tumor and then you have a further resection that has more tumor, then it's sometimes hard to put the jigsaw pieces together and to know what the actual tumor was.

But again, that's a - really an inescapable problem.

Dr. Elizabeth Hammond: But the - no one is better qualified than the pathologist to help us figure that out, to summarize that data.

Male: Right and it behooves us to have access to all the appropriate reports so that we could put that data together.

Dr. Elizabeth Hammond: Absolutely.

Male: Yes.

Female: Any other comments on 387?

Female: Three-ninety-one.

Female: Sorry, 391, not a good day.

Female: I want to make it clear, I did think it was an important thing to endorse. I just wanted to make sure I understood what the measure was.

Male: So will there be some feedback formally from NQF regarding this development of a summary report? And that would be something that a revised measure could - would include. Is that kind of where we end up with this?

Female: Well, we haven't talked about the measure - we would discuss this measure more at the in-person meeting and formalize those comments about the measure at that time because we have to look at the measure as it is before us.

Fay Shamanski: Not disagreeing with anything that's been said but as Dr. Hammond had earlier said, at the moment there aren't - there isn't any way to code that.

Dr. Elizabeth Hammond: No, there isn't. We have to wait - I mean we can make the comment - I don't think we could approve the measure as it is with the comment and strong recommendation that we go forward developing a summary report on breast cancer patients.

Actually, it should happen on all cancer patients, not just breast cancer patients, because it puts the clinician who's treating the patient in a difficult situation trying to assess which of these pieces of paper is the one that they should pay attention to.

So I think all we do at this point - Fay is right, we can't - we don't have a code for that. We don't have a way to collect the data yet but that's what the College is working on. And if we say that that's strongly endorsed that they continue to work on that I think they'll push it forward faster and that will help us all.

Female: And certainly in the report for this project we can note that that is a gap area for future measure development in addition to the recommendation you've just provided.

Dr. Elizabeth Hammond: Great.

Female: Good. So additional comments about this one? All right.

Female: Could we get all lines open at this point to see if there is any member or public comment?

Operator: All lines are now open.

Female: Any member or public comment? Okay, hearing none. As far as ((inaudible)) steering committee members, the in-person meeting is two weeks again, May 23 and 24 in D.C. If you haven't booked travel or RSVP please do so. Our meetings department has sent you an email.

We will be providing a compilation of the summaries of the workgroup calls and we'll be sending them out to you midweek next week for your review prior to the in-person meeting.

Other than that thank you so much for your time, both to committee members and developers, and please feel free to contact us with any questions in the interim.

And you are free to go, ((inaudible)) minutes early.

Male: Thank you all very much.

Female: Thank you all for joining.

Female: Operator, we're all done.

Operator: All right, thank you. Have a great day now.

Female: Thanks, you too.

Female: Thank you.

END