

NATIONAL QUALITY FORUM  
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CANCER ENDORSEMENT MAINTENANCE  
STEERING COMMITTEE

+ + + + +  
WEDNESDAY  
MAY 23, 2012

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The Steering Committee met at the  
National Quality Forum, 9th Floor Conference  
Room, 1030 15th Street, N.W., Washington,  
D.C., at 9:00 a.m., Stephen Lutz, MD, Chair,  
presiding.

PRESENT:

STEPHEN LUTZ, MD, Blanchard Valley Regional  
Cancer Center  
JOSEPH ALVARNAS, MD, City of Hope\*  
ELAINE CHOTTINER, MD, University of Michigan  
Medical Center  
HEIDI DONOVAN, University of Pittsburgh

School of Nursing\*  
STEPHEN EDGE, MD, Roswell Park Cancer  
Institute  
KAREN FIELDS, MD, Moffitt Cancer Center  
JOHN GORE, MD, MS, University of Washington  
School of Medicine  
ELIZABETH HAMMOND, MD, Intermountain

Healthcare  
JOSEPH LAVER, MD, MHA, St. Jude Children's  
Research Hospital\*  
BRYAN LOY, MD, MBA, Humana, Inc.  
JENNIFER MALIN, MD, PhD, WellPoint  
LAWRENCE MARKS, MD, FASTRO, University of  
North Carolina School of Medicine\*

ROBERT MILLER, Sidney Kimmel Comprehensive  
Cancer Center at Johns Hopkins

DAVID PFISTER, Memorial Sloan-Kettering  
Cancer Center  
ROCCO RICCIARDI, MD, MPH, Lahey Clinic  
Medical Center\*  
PATRICK ROSS, MD, PhD, The Ohio State  
University Comprehensive Cancer Center -  
James Cancer Hospital  
NICOLE TAPAY, JD, Eli Lilly and Company  
WENDY TENZUK, Colorado PERA

NQF STAFF:

HEIDI BOSSLEY, MSN, MNA Vice President,  
Performance Measures  
EUGENE CUNNINGHAM, Project Manager,  
Performance Measures  
ANGELA J. FRANKLIN, Senior Director,  
Performance Measures  
ADEELA KHAN, Project Analyst, Performance  
Measures  
KAREN PACE, Senior Director, Performance  
Measures  
LINDSEY TIGHE, Project Manager, Performance  
Measures

ALSO PRESENT:

MARK ANTMAN, DDS, MBA, AMA-PCPI Measure  
Development  
MARY BARTON, MD, National Committee for  
Quality Assurance  
SEPHEEN C. BYRON, MHS, National Committee  
for Quality Assurance  
LINDEE CHIN, MD, ActiveHealth Management  
KERI CHRISTENSEN, MS, AMA-PCPI Measure  
Development

MICHAEL HASSETT, MD, MPH, Dana Farber Cancer  
Institute\*  
KRISTEN McNIFF, MPH, American Society of  
Clinical Oncology  
CAROL S. PALACKDHARRY, MD, MS, ActiveHealth  
Management  
FAY SHAMANSKI, PhD, College of American  
Pathologists

V.O. SPEIGHTS, JR, DO, College of American  
Pathologists and Texas A&M Health  
Science Center College of Medicine

ANDREW STEWART, MA, American College of  
Surgeons

SAMANTHA TIERNEY, MPH, Physician Quality  
Reporting Initiative\*

EMILY E. VOLK, MD, College of American  
Pathologists\*

DAVID WITTE, MD, PhD, FCAP, College of  
American Pathologists

\*Present by teleconference

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1 P-R-O-C-E-E-D-I-N-G-S

2 9:05 a.m.

3 MS. FRANKLIN: Hello, and welcome  
4 to the Cancer Endorsement Maintenance Steering  
5 Committee Meeting. We are looking at Phase II  
6 of this project.

7 And in the room I have with me --  
8 my name is Angela Franklin, I'm the Senior  
9 Director for the Project.

10 Dr. Steven Lutz is our Chair. And  
11 in the room with me on the project is Lindsey  
12 Tighe, our Project Manager, as well as Adeela  
13 Khan, our Project Analyst and Eugene  
14 Cunningham, our Project Analyst.

15 So, with that we'll go ahead and  
16 get started with introductions and disclosures  
17 of interest around the room. And then we'll  
18 go to our members that are on the phone.

19 MS. BOSSLEY: About disclosures,  
20 you did that the last time, but we have  
21 several people who are new. So if you have,  
22 again, anything that is relevant to the work

1 before this Committee, a slightly different  
2 set of measures, please disclose anything  
3 related to that. Other than that, you can  
4 just say "no disclosures." But, again, just  
5 covering our bases since a few new people in  
6 the room.

7 MEMBER TAPAY: Nicole Tapay. I've  
8 changed jobs since the last meeting, so I'm  
9 actually now with Eli Lilly. But I'm not aware  
10 with respect to any of these standards any  
11 conflicts.

12 MS. FRANKLIN: Since we started on  
13 that end, do you mind, Dr. Miller, we'll start  
14 with you.

15 MEMBER MILLER: Thank you.

16 Bob Miller with Johns Hopkins.  
17 And I can't remember if this disclosure is  
18 relevant, but I'll just say it: Research  
19 funding from Pfizer.

20 MEMBER EDGE: Stephen Edge. I'm  
21 Chair of the Commission on Cancer.

22 As disclosed originally, I've

1 participated on development of measures six or  
2 seven years ago but have not since.

3 CHAIRMAN LUTZ: I'm Steve Lutz,  
4 radiation oncologist from Findlay, Ohio.

5 No new disclosures.

6 MEMBER CHOTTINER: Elaine  
7 Chottiner, University of Michigan.

8 No disclosures relative to these  
9 measures.

10 MEMBER TENZYK: Wendy Tenzyk,  
11 Colorado Public Employees Retirement  
12 Association.

13 No disclosures.

14 MEMBER GORE: John Gore,  
15 University of Washington.

16 No disclosures.

17 MEMBER FIELDS: Karen Fields,  
18 Moffitt Cancer Center.

19 No new disclosures.

20 MEMBER HAMMOND: Elizabeth  
21 Hammond, University of Utah and Intermountain  
22 Health Care.



1                   No disclosures.

2                   MEMBER LOY:    Bryan Loy, Humana.

3                   I have no new disclosures.

4                   MEMBER PFISTER:    David Pfister,  
5                   Memorial Sloan-Kettering.

6                   No new disclosures.

7                   MEMBER ROSS:    Pat Ross of Ohio  
8                   State.

9                   No disclosures.

10                  MS. BOSSLEY:    So, since our  
11                  general counsel is not here, I'll just ask the  
12                  question that she always asks:  Is there  
13                  anything that your colleagues have disclosed  
14                  that in any way you'd like to discuss or have  
15                  additional questions on, any concerns?

16                  (No response.)

17                  CHAIRMAN LUTZ:  Disclosures on the  
18                  phone?

19                  MS. BOSSLEY:    Oh, yes.  And then  
20                  we have people on the phone.  Sorry.

21                  MS. FRANKLIN:    Could the Steering  
22                  Committee Members on the phone please give

1 their disclosures since last meeting?

2 MEMBER MARKS: Larry Marks,  
3 University of North Carolina at Chapel Hill.

4 No new disclosures since the last  
5 meeting.

6 MEMBER DONOVAN: Heidi Donovan,  
7 University of Pittsburgh.

8 No new disclosures.

9 MEMBER RICCIARDI: This is Rocco  
10 Ricciardi from Lahey Clinic.

11 No disclosures.

12 MS. FRANKLIN: Thank you. All  
13 right.

14 And with that, I think we'll move  
15 into a very quick overview of our evaluation  
16 process. So we'll move on.

17 Again, this is our Steering  
18 Committee Chair, Stephen Lutz, is here in the  
19 room with us as well as NQF staff: Heidi  
20 Bossley, our Vice President for Performance  
21 Measures, myself, Angela Franklin, Senior  
22 Director, Lindsey Tighe, Project Manager and

1 Adeela Khan, our Project Analyst.

2 As you're aware, we completed our  
3 in-person meeting for our Phase 1, at which  
4 time we had 27 measures for review and those  
5 measures primarily addressed hematology,  
6 melanoma, prostate, lung, oncology cancers as  
7 well as palliative care.

8 Today we begin our work on Phase  
9 II. We currently have 18 measures in front of  
10 us for review and we'll be addressing breast  
11 and colorectal cancer at this time.

12 The four major endorsement  
13 criteria are:

14 Importance to measure and report,  
15 intended to measure those aspects with the  
16 greatest potential of driving improvement;

17 If this criterion is not passed,  
18 the other criteria are less meaningful, so  
19 this is your must pass criteria, or one of  
20 them.

21 Next we'll look at scientific  
22 acceptability of the measure properties. And

1 the goal here is to make valid conclusions  
2 about quality. If a measure is not reliable  
3 and valid, the risk of improper interpretation  
4 in the field is great. This is also a must  
5 pass criteria.

6 Then, if the measures pass these  
7 two, we move on to look at the useability of  
8 a measure and the goal is to use it for  
9 decisions related to accountability and  
10 improvement. If a measure is not useful, we  
11 probably do not reach the feasibility  
12 assessment.

13 Feasibility is our last criterion.  
14 Ideally, we want the measure to cause as  
15 little burden as possible in the field. If the  
16 measure is not feasible, we should consider  
17 alternative approaches.

18 If a measure as a whole is  
19 considered suitable for endorsement, we'll  
20 evaluate the measure if it needs to be  
21 harmonized and determine if other measures in  
22 the portfolio need to be evaluated and choose

1 a best in class measure.

2 Looking at new versus endorsed  
3 measures. All measures new and endorsed are  
4 expected to meet current criteria and  
5 guidance. Our endorsed measures are expected  
6 to present data from the implementation of  
7 measure as specified in 1b of our form,  
8 Opportunity for Improvement. There also  
9 potential for reserve status if we feel like  
10 a measure the gap has narrowed, has topped  
11 out, but there's a possibility to put it into  
12 reserve status if we feel like we need to  
13 bring it up and continue to measure on it if  
14 the gap widens once again.

15 Reliability and validity testing.  
16 We're also looking for endorsed measures at  
17 the reliability and validity testing to be  
18 expanded unless it meets the high rating.

19 Useability of the measure. We want  
20 to see actual use in public reporting and  
21 other accountability and improvement programs  
22 or specific plans and a timeline for use.

1                   For feasibility, we want to see if  
2                   there were any problems with implementation or  
3                   unintended consequences as the measure is  
4                   implemented.

5                   So, in front of you, you have our  
6                   generic rating scale that we've been using.  
7                   We're looking at 1a High Impact, 1b the  
8                   Performance Gap as mentioned earlier,  
9                   Usability and Feasibility.

10                   Importance to measure and report,  
11                   I think we walked through that earlier.

12                   High impact indicators as a  
13                   national health goal or priority. There's  
14                   data on numbers of persons affected, high  
15                   resource use, severity of illness or  
16                   consequences of poor quality.

17                   For the gap in 1b we're looking  
18                   for data demonstrating considerable variation  
19                   and performance or overall less than optimal  
20                   performance. And we're also looking for data  
21                   on disparities in care and the potential for  
22                   reserve status where endorsed measures can be

1 assessed at this point.

2 Moving onto 1c Evidence, we're  
3 looking at quality, quantity and consistency  
4 of the body of evidence.

5 Again, individual Committee  
6 Members have rated the measures based on the  
7 evidence submitted. As part of the Steering  
8 Committee process we allow you to let us know  
9 if you are aware of additional evidence that  
10 could be presented. And we would continue to  
11 evaluate the measures on all remaining  
12 criteria.

13 After our work group discussions,  
14 if we're confident of the evidence presented  
15 by the Committee Members and the measure is  
16 likely to meet criteria for high impact and  
17 scientific acceptability, we'll look at that.  
18 And we could also ask the developer to provide  
19 additional evidence for consideration.

20 Here we have our evidence decision  
21 logic. And we've also included in your packets  
22 a quick guide that you can also reference as

1 we go through the meeting. And if we feel  
2 like there's an exception, if the Steering  
3 Committee as a whole feels like there's basis  
4 for an exception to our evidence subcriterion  
5 1c, here's our decision logic.

6 For an outcome measure, there's a  
7 rationale that supports a relationship of the  
8 health outcome to at least one health care  
9 structure process, intervention or service.  
10 And then if it's a process or other type of  
11 measure, we'll look at if there's no empirical  
12 evidence, we'll look at whether expert opinion  
13 is systematically assessed, with agreement  
14 that the benefits to the patients greatly  
15 outweigh potential harms. So we can invoke  
16 the exception in that case.

17 So, here's some additional  
18 considerations for the exception.

19 The impact and opportunity for  
20 improvement; that is a performance gap must be  
21 met. There should be a strong rationale. The  
22 proximity to the desired outcome should be



1 that performance measures for distal  
2 structures and processes may be less likely to  
3 drive significant improvements.

4 If there's a measure of a more  
5 proximal process or intermediate outcome and  
6 its linkages to our outcome, it's probably not  
7 necessary.

8 And distinguishing between  
9 something important to do in the clinical  
10 process and things that are important to  
11 devote resources to for a national performance  
12 measure.

13 So as reviewed earlier, we're  
14 looking at the scientific acceptability of  
15 measures. We'll be looking at the reliability  
16 and validity. Reliability, looking for  
17 precise specifications on whether testing has  
18 been done at the data element or measure score  
19 a level. For validity we'll be looking at  
20 specifications that are consistent with the  
21 evidence. A validity testing that's showing  
22 at the data elements, a measure score showing

1 results there.

2 We'll look for justification of  
3 the exclusions, a risk adjustment,  
4 identification of differences in performance  
5 and comparability of data source and methods.

6 So, evaluation of the scientific  
7 acceptability is here shown to you in a  
8 graphical context. And again, you'll also have  
9 your quick guides.

10 I think we've run through the  
11 useability piece. Let's see, so I will breeze  
12 through that one.

13 And then feasibility. I think we  
14 talked about this earlier. The extent to  
15 which required data readily available,  
16 retrievable without undue burden and can be  
17 implemented for performance measurement. And  
18 there you have your subcriterion.

19 So when we reach the end of our  
20 review of each measure, where there's a  
21 measure in the portfolio or in front of us  
22 today that is related, we will assess both

1 measures to see if the specifications are  
2 harmonized or, if needed, differences in the  
3 specifications are justified.

4 Then we'll look at measures to see  
5 whether they're superior to competing  
6 measures. That is, they're more valid or  
7 efficient way to measure an issue or if  
8 multiple measures are justified. So we could  
9 reach that conclusion as well.

10 And here's our logic for related  
11 versus competing also in your quick guides.  
12 And we'll go through this logic as we go  
13 through any measures that meet this criteria.  
14 So I will move on, because I think we have a  
15 few of these. And we'll focus on that as we  
16 get to those measures.

17 So with that, didn't want to take  
18 up too much time there, I will turn to Dr.  
19 Lutz, who is our Chair. And we can begin  
20 consideration of our candidate measures.  
21 First measures are best cancer measures.

22 CHAIRMAN LUTZ: Okay. Welcome

1 back, everyone and looking forward through to  
2 getting through these 18.

3 The only thing I say in terms of  
4 procedure, obviously we have Heidi, Larry and  
5 Rocco on the phone, so if they turn up their  
6 name cards on their sides, we're not going to  
7 see them. So in between every few comments  
8 I'll just ask you guys on the phone if you  
9 have anything you want to add, because I hate  
10 to make you have to go last all the time  
11 because we can't see you with your cards up.

12 Going along with that, I guess  
13 Larry, if it's okay with you, I think our  
14 first one is 0219: post-breast cancer surgery  
15 irradiation.

16 MS. TIGHE: He may have had to  
17 jump off just for five minutes, but what we  
18 could do is ask ACS to tee up the measure.

19 CHAIRMAN LUTZ: Okay. If ACS is  
20 willing and able, let's do that.

21 MS. TIGHE: And I guess also we  
22 should explain the process to the developers.

1                   When your measures are being  
2                   discussed, if you want to join us at the side  
3                   tables here, there's a microphone that you can  
4                   speak into.

5                   CHAIRMAN LUTZ:   Larry, are you  
6                   back now?

7                   MEMBER MARKS:   Yes, I'm back.

8                   CHAIRMAN LUTZ: Hi, it's Steve. How  
9                   are you doing?

10                  MEMBER MARKS:   Hi, Steve. I'm  
11                  fine, thank you.   Yourself?

12                  CHAIRMAN LUTZ:   Great.   And you  
13                  know, the only thing that would make the  
14                  morning better is to hear your voice  
15                  describing 219 for us because we are starving  
16                  for it.

17                  MEMBER MARKS:   You're starving for  
18                  219.

19                  CHAIRMAN LUTZ:   I think ACS folks  
20                  maybe are going to give us a little segue in  
21                  and then you'll be up.

22                  MEMBER MARKS:   Okay.   That's good.

1 Thank you.

2 CHAIRMAN LUTZ: Yes.

3 MR. STEWART: Good morning. Being  
4 my first time around here.

5 This is a measure that we  
6 originally submitted to NQF and had reviewed  
7 back in 2006/2007 and received endorsement.  
8 The measure itself has not been respecified or  
9 modified in any form since that original  
10 review process was undertaken.

11 We have taken in to account some  
12 of the comments that were made during the  
13 telephone conference call sessions and  
14 corrected some of the denominator conditions.  
15 So, hopefully, those shouldn't be of concern  
16 at this point.

17 I don't know what else you want us  
18 in the role of developer to comment on at this  
19 point.

20 MEMBER MARKS: Can you specify,  
21 did you change the business about the DL  
22 negative and DL positive?

1 MR. STEWART: We did three things  
2 to this measure. We removed the ER -- the  
3 hormone receptor status condition.

4 We also clarified, I think it was  
5 there was an over-specification in the tumor  
6 stage requirement. Both of these were just  
7 clerical process errors as we moved all of our  
8 documentation into the online forms that NQF  
9 were supporting. It was a click issue on our  
10 part, not a fundamental problem with the  
11 measure specification.

12 MEMBER MARKS: Okay. So there's  
13 no level of inconsistency in the denominator  
14 statement and exclusion; that's what that was,  
15 I think.

16 MR. STEWART: That's correct.  
17 That shouldn't be there anymore.

18 MEMBER MARKS: Okay. Okay. I'm  
19 happy to speak now if that's okay, Steve?

20 MS. FRANKLIN: Yes. This is  
21 Angela.

22 Dr. Marks, if you could just take

1 us through the importance criteria, importance  
2 to measure and report?

3 MEMBER MARKS: Okay. So radiation  
4 therapy post-lumpectomy for breast cancers is  
5 considered standard. Actually, in the  
6 majority of patients, and certainly in the  
7 cohort of patients that are included in the  
8 denominator for this measure, this has been  
9 demonstrated in meta-analyses to improve  
10 overall survival of these patients and most  
11 guidelines recommend this as a standard  
12 treatment for patients post-lumpectomy. And  
13 so this is important. It's not a direct  
14 measure of outcome, but it is an importance  
15 measure of quality of care. So I think it  
16 does meet that criteria for the importance  
17 measure.

18 MS. FRANKLIN: Thank you.

19 Are there any other comments from  
20 the work group members on this?

21 Comments from the larger Steering  
22 Committee? And we're looking at 1a, High



1 Impact.

2 MEMBER PFISTER: So just to  
3 clarify: so as the measure is now with the  
4 modifications, is it receptor status is no  
5 longer specified, and patients with T1a and  
6 T1b disease are all considered to be stage 1  
7 category and they get radiation?

8 MR. STEWART: That's correct.  
9 Yes, on both those counts that's correct.

10 MEMBER MARKS: We have in front of  
11 us on the website that I just pulled up -- let  
12 me see if this is modified from the one we had  
13 a few weeks ago in our phone conference call.

14 MR. STEWART: Yes.

15 MEMBER MARKS: Okay.

16 CHAIRMAN LUTZ: Okay. I think we  
17 can go ahead and vote on that 1a. Okay.

18 So go on. I'm sorry. Go ahead and  
19 take us through to see it. Go ahead.

20 MEMBER MARKS: Well, this is  
21 actually the opportunity to go through 1a and  
22 then go through 1b and go through each of

1       them.

2                   CHAIRMAN LUTZ:  You might as well  
3       just go ahead and go right through, please.

4                   MEMBER MARKS:  Okay.  So there is  
5       some evidence that there is evidence that  
6       there is need for improvement.  There are some  
7       studies demonstrating that radiation is not  
8       routinely delivered to this cohort of  
9       patients, so there is opportunity for  
10      improvement.

11                   I don't know firsthand the data on  
12      disparities by race.  Basically, the  
13      submitters say there is data, I believe there  
14      is data that they may want to speak to that.  
15      But there certainly is data, broadly speaking,  
16      that there is room for improvement.

17                   Going through to reliability and  
18      validity.  It should be relatively  
19      straightforward to measure, since whether  
20      you're getting or not getting radiation I  
21      guess is -- there's evidence from billing  
22      codes and those sorts of things.

1                   The question I have here for the  
2                   developer is it the surgeon who is being  
3                   judged on this, or the medical oncologist,  
4                   whether or not they refer the patients to the  
5                   radiation oncologist, or is it the radiation  
6                   oncologist that could be viewed as being  
7                   judged on this? If that could be clarified  
8                   for me, that wasn't clear.

9                   MR. STEWART: This measure was  
10                  developed and has been implemented to hold --  
11                  to make the accountable unit the hospital or  
12                  the treating facility. So, in a sense, both  
13                  the surgeon and the radiation oncologist are  
14                  being held to account because they presumably  
15                  coordinate that patient's care.

16                  MEMBER MARKS: You're saying it's  
17                  on a facility basis, correct?

18                  MR. STEWART: Correct.

19                  MEMBER MARKS: Interesting. Okay.  
20                  Okay.

21                  CHAIRMAN LUTZ: Bryan?

22                  MEMBER LOY: Thank you.

1                   Could you elaborate a little bit  
2                   or help us understand how you arrived at 365  
3                   days? I'm just wondering where that length of  
4                   time came from, versus a shorter period.

5                   MR. STEWART: So back when we  
6                   originally did the specification work in  
7                   2005/2006, we did a significant amount of data  
8                   evaluation looking at elapsed time between our  
9                   index date being date of diagnosis and the  
10                  date of onset or beginning, start of radiation  
11                  therapy. We looked at that distribution with  
12                  some care.

13                  At that point in time, one of the  
14                  driving considerations was that these measures  
15                  be developed in such a fashion that they could  
16                  be equitably applied across as broad a  
17                  spectrum of institutions as possible. And so  
18                  one of the areas of sensitivity was picking or  
19                  identifying a relevant time in which you would  
20                  expect most patients to start their radiation  
21                  therapy. And in looking at a number of cut  
22                  points, we determined that 365 days or one

1 year from diagnosis was appropriate, because  
2 we had to take into consideration other  
3 intervening treatment modalities that may be  
4 administered post-surgically, and there are  
5 other potential reasons for delays in the  
6 sequencing of therapy for these women. And so  
7 365 was identified at that point as a  
8 reasonable metric for timing of onset of  
9 radiation therapy.

10 MEMBER MARKS: At the time the  
11 clock starts at the time of diagnosis, there  
12 often can be several weeks if not a month or  
13 two until the patient is done with their  
14 lumpectomy, they're having a re-excision, node  
15 dissection and what not.

16 MR. STEWART: And there's also the  
17 possibility that there is a chemo regimen that  
18 could follow that surgical event.

19 MEMBER MARKS: Right.

20 MR. STEWART: And so pushing the  
21 radiation date out made perfect sense at that  
22 time.

1 CHAIRMAN LUTZ: And there any  
2 other questions or thoughts, anyone else on  
3 the phone, either Heidi or Rocco, anyone have  
4 any questions for the developers?

5 MEMBER DONOVAN: I don't have  
6 additional questions, no.

7 CHAIRMAN LUTZ: Okay. We're going  
8 to move on to a vote that quickly? All right.

9 MEMBER MARKS: We're going to be  
10 setting the trend for the day.

11 CHAIRMAN LUTZ: Well, you could be  
12 a hard act to follow, Larry, we don't know.

13 MS. KHAN: Does everyone have a  
14 voting clicker? Okay.

15 Well, when the clock starts, you  
16 can press the button.

17 So we're going to be voting on la  
18 impact. It addresses a specific national  
19 health goal or priority or the data  
20 demonstrated a high impact aspect of health  
21 care. So you're going to vote one for high,  
22 two for moderate, three for low and four for

1 insufficient evidence.

2 MEMBER EDGE: When does the clock  
3 start?

4 MS. KHAN: Right now. You can start  
5 now. We have high impact for this measure.

6 MS. BOSSLEY: We can actually stop  
7 it. The big issue now is the percentages and  
8 we usually do numbers. Is it a quick fix that  
9 you can do? Okay. We'll calculate it later.  
10 Clearly, it's high. And then several moderate.

11 So we're going to vote on  
12 importance to measure, the performance gap.  
13 lb, performance gap, the data demonstrated  
14 considerable variation or overall less than  
15 optimal performance across providers and/or  
16 population groups and disparities in care.

17 So we're going to again vote one  
18 high, two moderate, three low and four  
19 insufficient. You can start voting.

20 So we have 86 percent for  
21 moderate, seven percent for high and seven  
22 percent for low.

1                   And voting on evidence. Again, if  
2                   it's a health outcome with a rationale, you're  
3                   looking at the quantity, quality and  
4                   consistency of the body of evidence. So  
5                   you're going to vote one for yes, two for no  
6                   and three for insufficient evidence.

7                   MEMBER MARKS: I'm sorry. We're  
8                   voting on, is this for health outcome?

9                   MS. KHAN: You're just voting on  
10                  the evidence piece.

11                  So we have 93 percent for yes and  
12                  seven percent for insufficient evidence.

13                  So we can move on to scientific  
14                  acceptability.

15                  MS. FRANKLIN: Okay, Dr. Marks, if  
16                  you could --

17                  MEMBER MARKS: Yes?

18                  MS. FRANKLIN: Okay. Hold on,  
19                  sorry.

20                  CHAIRMAN LUTZ: You went through  
21                  so quickly and efficiently they thought there  
22                  was still more to discuss. We're still voting.



1 MS. KHAN: So looking at  
2 reliability. We're looking at the precise  
3 specifications and the testing. We'll vote  
4 one high, two moderate, three for low and four  
5 for insufficient evidence.

6 Dr. Ricciardi, if you could send  
7 your vote in.

8 So you have 71 percent for high,  
9 29 percent for moderate.

10 MEMBER MARKS: I do have a  
11 question, this is Larry Marks, for the  
12 developer, if I could right here. What is the  
13 threshold for this? Because certainly there  
14 are patients who are 65 with comorbid  
15 conditions where it would be reasonable not to  
16 do the radiation. So is the expectation that  
17 this would be 100 percent, or is there a way  
18 of excluding patients from the denominator who  
19 are deemed not to be medically appropriate for  
20 radiation?

21 MR. STEWART: We have not chosen to  
22 include any comorbid condition consideration

1 in this measure. We have simply followed the  
2 randomized clinical trials evidence that  
3 established an age cutoff at under 70.

4 MEMBER MARKS: Thanks. And what  
5 is the threshold of expectation or is that  
6 sort of dropped? Did you figure it out?

7 MR. STEWART: Well, quite  
8 independently, through other processes, the  
9 Commission has recently established  
10 performance thresholds for this measure across  
11 its 1500 programs where we are anticipating,  
12 we're expecting at least a 90 percent  
13 threshold to be met, understanding fully that  
14 there are a vast majority of institutions that  
15 will easily exceed that expected rate.

16 MEMBER MARKS: Okay.

17 MS. KHAN: And moving on to 2b,  
18 validity. That includes the specifications  
19 are consistent with the evidence, they're  
20 looking at the testing, exclusions, risk  
21 adjustment, meaningful differences and  
22 comparability between data sources.

1                   So again one high, two moderate,  
2 three low and four insufficient evidence.

3                   So you have 53 percent for high,  
4 40 percent for moderate and seven for  
5 insufficient evidence.

6                   And moving on to usability. We're  
7 looking at meaningful and understandable use  
8 for public reporting and accountability and is  
9 it useful for quality improvement.

10                  So, one high, two moderate, three  
11 low and four insufficient information.

12                  We have forty percent for high and  
13 60 percent for moderate.

14                  And moving on to feasibility. The  
15 data generated during care electronic sources,  
16 susceptibility to inaccuracies and unintended  
17 consequences have been identified and data  
18 collection can be implemented.

19                  So again, one high, two moderate,  
20 three low and four insufficient information.

21                  So 53 percent high and 47 percent  
22 for moderate.

1                   And now voting on overall  
2                   suitability for endorsement. Does the measure  
3                   meet NQF criteria for endorsement? You're  
4                   going to vote one for yes and two for no.

5                   And we have 100 percent agreement  
6                   on yes, and the measure will pass.

7                   CHAIRMAN LUTZ: All right. So  
8                   next we move on to 220: adjuvant hormonal  
9                   therapy. I think Joseph Laver on the phone is  
10                  the one who is going to direct us through  
11                  this, give us the synopsis.

12                  I guess I should ask. Joseph  
13                  Laver, are you on the phone?

14                  (No response.)

15                  MS. FRANKLIN: We'll go ahead and  
16                  have -- well, we can move on to the next one  
17                  in the process. I think Dr. Laver did say he  
18                  was going to join us. We're just a tad early.  
19                  So we can go on to the next one.

20                  CHAIRMAN LUTZ: So the next one,  
21                  Pat, I think we're doing needle biopsy to  
22                  establish diagnosis.

1 MS. FRANKLIN: First, could we  
2 have the developer just give us a quick  
3 overview of 0221?

4 MR. STEWART: The brief overview  
5 here is the understanding, at least of the  
6 surgical community, that having a pre-  
7 operative needle biopsy prior to surgical  
8 treatment of women with breast cancer is a  
9 necessary prerequisite to understanding the  
10 disease being managed.

11 I think we discussed some of the  
12 nuances about this measure on the telephone  
13 conference call, and I think the commentator  
14 from the panel will raise some of those  
15 summary findings and we can address those as  
16 we move forward.

17 CHAIRMAN LUTZ: Okay. Pat?

18 MEMBER ROSS: This measure is very  
19 straightforward. It is a process measure  
20 looking at the needle biopsy to establish  
21 diagnosis prior to surgical excision or  
22 resection. As you know, the ACS Commission on

1 Cancer is the steward.

2 I think that there is value here,  
3 because of the data that has shown the needle  
4 biopsy is at least as accurate as surgical  
5 biopsy. And the value, the importance really  
6 goes to what impact it can have on improving  
7 quality of care, on improving quality of the  
8 surgical procedure and there may even be some  
9 cost/benefit, cost/effectiveness components to  
10 it as well.

11 I think the developer does a great  
12 job in elucidating all of the components.  
13 There's one question on the disparities by  
14 population group, which I think they've raised  
15 the issue that age, race/ethnicity, geography  
16 as well as details about the individual  
17 providers all account for the disparities,  
18 which I think are probably significant  
19 regionally.

20 And I think this is -- the  
21 evidence is observational studies. I think  
22 that this is something that is of value and

1 will be easy to measure.

2 One of the limitations is the fact  
3 that this is not a technique which would be  
4 available everywhere. There is a user  
5 component to it in terms of successfulness  
6 accomplishing the task. But I think that it  
7 is something that will be straightforward, it  
8 will be easy to measure and it will in fact  
9 impact the quality of care for the patients  
10 requesting it.

11 CHAIRMAN LUTZ: Was there anyone  
12 else in the subgroup that had the phone  
13 conversation about this that wants to chime  
14 in?

15 Okay. Elizabeth?

16 MEMBER HAMMOND: On the phone I  
17 raised two questions. One was whether or not  
18 this measure is valid in rural areas where  
19 needle biopsies may or may not be appropriate?  
20 And second, should the measure be stratified  
21 by cytologic versus needle biopsies which have  
22 different value in this sort of setting?

1 MR. STEWART: I think I can answer  
2 both of those questions.

3 In response to the first, we  
4 understand the sensitivity around rural  
5 settings. Unfortunately, the Commission on  
6 Cancer has accredited programs where we  
7 essentially have our implementation forum.  
8 About one percent of our programs are placed  
9 in purely rural counties, and about 12 percent  
10 of our programs are in urban non-metro  
11 counties when we look at the distribution and  
12 geographic placement of those. So it's hard  
13 for us to comment explicitly on the question  
14 of rural settings.

15 In contrast, however, we do have  
16 access to services and resource data from  
17 these institutions. Eighty percent of our  
18 programs have diagnostic imaging available to  
19 them, and the other 20 percent provided by  
20 referral.

21 So even in locations where these  
22 sorts of procedures are not readily and



1 immediately available, patients are referred  
2 to institutions or settings where that's  
3 provided to them.

4 The second point you raise about  
5 cytology versus core needles is a very subtle  
6 distinction. Unfortunately, the Cancer  
7 Registry data sets that we work with routinely  
8 confound those two and we don't make them  
9 distinct and separate. And this has been the  
10 primary concern of ours and has delayed our  
11 implementation of the measure into the field.  
12 So we're sensitive to that and that's largely  
13 why we have maintained this measure over the  
14 past four or five years but not implemented  
15 across our settings because of the way the  
16 data are organized that we work with on a  
17 routine basis.

18 CHAIRMAN LUTZ: Karen?

19 MEMBER FIELDS: So, I would like  
20 to comment from the surgeons in the room about  
21 core biopsies because that would still be our  
22 gold standard that we want to move to, so why

1 wouldn't we create a measure that works  
2 towards getting to that end point?

3 CHAIRMAN LUTZ: Stephen?

4 MEMBER EDGE: I would actually  
5 argue that we should not make any effort to  
6 make a distinction between cytologic versus  
7 stereotactic core biopsy. The vast majority  
8 of these procedures are done with stereotactic  
9 core biopsy in 2012 as opposed to, perhaps,  
10 1998. And if a specific center is very  
11 experienced with fine needle aspiration and  
12 uses fine needle aspiration, I would see no  
13 problem with that. I think those of us who  
14 are expert in breast cancer in the field  
15 recognize the potential limitations of fine  
16 needle aspiration with insufficient material  
17 or a lack of cytologic diagnoses. But if the  
18 program is very experienced, I would not  
19 hesitate to endorse that program's use of fine  
20 needle aspiration.

21 I think the benefit of getting  
22 that additional granularity of information is

1       outweighed by the benefit of getting the  
2       information that people are doing needle  
3       biopsy in the first place.  So, I would  
4       actually argue against concerning ourselves  
5       with this nuanced distinction in a quality  
6       measure.

7                   CHAIRMAN LUTZ:  Karen?

8                   MEMBER FIELDS:  One more issue  
9       about all of these measures is the data is  
10      from 2007 and 2008 for all of us to use for  
11      these measures.  And I wondered if we saw any  
12      improvement or increased acceptability,  
13      because I do think that the general knowledge  
14      about needle biopsies before surgery has  
15      increased in that time period.  So, did we  
16      have any data to compare  or any trends,  
17      because I think that helps us to understand if  
18      this is also a valuable measure?

19                  MR. STEWART:  Yes, there was a  
20      paper published last summer following a  
21      presentation at the Surgical -- at SSO the  
22      prior March that described increased patterns

1 in preoperative needle biopsy for this cohort  
2 of women. And I can find that citation and  
3 forward it to the NQF staff.

4 MEMBER EDGE: Is that the --

5 MR. STEWART: It's Dr. Williams'  
6 paper. That paper is looking at the National  
7 Cancer database. It's referenced in your  
8 materials from 2003 to 2008. So it doesn't  
9 really address Dr. Fields' question.

10 MEMBER FIELDS: My question is:  
11 it's so much more a part of the diagnostic  
12 workup than it was even at the time that this  
13 measure was first proposed; do we still have  
14 a problem? That was my question, because  
15 we're endorsing a lot of measures here and I'm  
16 trying to decide if there's a national  
17 problem, do we see any evidence of  
18 improvement? That was my question.

19 MR. STEWART: I think, for better  
20 or for worse, all these data systems suffer  
21 from some degree of lack of currency. So in  
22 2008/2009 -- for me in my world, 2010 is as

1 current as I see things and can assess them.  
2 And I don't have that data at my fingertips  
3 right now.

4 CHAIRMAN LUTZ: Can I ask a  
5 question similar to what Dr. Marks asked in  
6 the last one? Is this meant to be a never  
7 event or is this meant to be something where  
8 someone deviates greatly from, you know the  
9 norm that it's an issue? Because one of the  
10 reasons I ask is the week that I started  
11 looking over our current set of these  
12 measures, I had a patient who had a core  
13 biopsy, it was negative. The surgeon, in their  
14 experience, said, this doesn't add up. They  
15 excised and it was cancer.

16 And so if it was a never event,  
17 this really takes that option of, boy, it  
18 still doesn't add up, I want to know and then  
19 do this.

20 I mean, this isn't an "if you ever  
21 do it, you're in trouble" measure is it?

22 MR. STEWART: No.

1 CHAIRMAN LUTZ: Okay.

2 MEMBER EDGE: Steve, in the case  
3 that you just cited that patient would be  
4 coded as having had a needle biopsy. I believe  
5 that's true.

6 CHAIRMAN LUTZ: Is that true?  
7 Would the patient have been coded --

8 MR. STEWART: If the result of the  
9 biopsy was negative, if the procedure was  
10 actually performed, we would have to recast  
11 that event.

12 CHAIRMAN LUTZ: Oh, good. Okay.

13 MR. STEWART: But not sensitive to  
14 the outcome or assessment of that event.

15 MEMBER EDGE: But you can expect  
16 that between 10 and 20 percent of women who  
17 have biopsy will have to have a surgical  
18 biopsy. There are technical reasons why you  
19 can't do a core biopsy; the lesion is very  
20 peripherally located and cannot be located on  
21 the mammogram, it's very deep within the  
22 breast, or it's a very small breast. So there

1 are technical reasons why a stereotactic  
2 needle biopsy cannot be done, and somewhere  
3 between 10 to 20 percent of women will  
4 probably have surgical biopsies. So this is  
5 not one where you can set up a 100 percent or  
6 even a 90 percent.

7 CHAIRMAN LUTZ: Bryan?

8 MEMBER LOY: I'd direct this back  
9 to I guess the surgical expertise in the room,  
10 and that would be: are we somehow creating a  
11 measure that is promoting the use of a biopsy  
12 when the surgeon believes that those results  
13 are not going to inform the ultimate decision  
14 to excise?

15 MEMBER EDGE: The answer is no,  
16 but there are a substantial number of cases  
17 where you do a core biopsy, particularly for  
18 microcalcifications, where the core biopsy  
19 will show a specific benign lesion, but we  
20 know from published literature that the  
21 sampling issue means that there is cancer in  
22 the surrounding tissue in somewhere between

1 five and 20 percent of the cases. So when  
2 atypical ductal hyperplasia is identified,  
3 that's somewhere on the order of five to 20  
4 percent, depending on which paper you read,  
5 those women actually will have either in situ  
6 or in a few cases invasive cancer in the  
7 surrounding tissue. And so the standard is to  
8 proceed with surgical excision even though the  
9 biopsy is technically benign. That's probably  
10 the circumstances of the type of case that Dr.  
11 Lutz was outlining.

12 Dr. Hammond, do you have any  
13 comment on that?

14 MEMBER HAMMOND: No. I think  
15 that's accurate.

16 CHAIRMAN LUTZ: David?

17 MEMBER PFISTER: So just that I am  
18 clear when we go to measure this, let's say  
19 the person has their diagnostic evaluation  
20 elsewhere. And, for whatever reason, they  
21 don't do a needle, but they do get tissue so  
22 they do an incisional biopsy. But then they



1 end up getting their treatment done somewhere  
2 else. And then I'm at that somewhere else  
3 place and now I'm managing the breast cancer.  
4 And there would appear to be little reason to  
5 do anything before I do the surgical procedure  
6 because I clearly have tissue, but while I  
7 might have personally pursued that diagnoses  
8 differently, it is what it is. And then when  
9 they go to evaluate my performance based on  
10 how the numerator and denominator are defined,  
11 how will it be tracked when you have care  
12 divided in two different settings? Do you see  
13 what I'm saying?

14 CHAIRMAN LUTZ: I agree. I mean,  
15 I think for the first one we voted on today  
16 and maybe several others we're going to have  
17 today it's an issue of the system is not as  
18 well defined in some geographic areas as it is  
19 in others.

20 MEMBER PFISTER: Because I think  
21 that it has -- earlier was probably about the  
22 rural factor, but I think when you

1 particularly get to larger rural centers, lots  
2 of times the diagnoses will be made for better  
3 or for worse in terms of the process by which  
4 it was arrived at elsewhere and then where the  
5 recipient of what was kind of done at that  
6 time. And so it's unclear to me how the  
7 numerator and denominators as defined is going  
8 to distinguish cases where you are often the  
9 get-go in terms of how the person is evaluated  
10 versus ones where part of its clearly been  
11 elsewhere, you inherit a certain amount of  
12 information and then you kind of make the best  
13 of the situation even though it may not have  
14 been how you would have proceeded in the first  
15 place and how this measure actually evaluates  
16 that.

17 MEMBER EDGE: Well, this issue of  
18 attribution is quite difficult in many of  
19 these measures. I'm not sure, were the  
20 developers asked to specifically comment on  
21 the issue of attribution in any of these  
22 measures?

1                   CHAIRMAN LUTZ: I'm not sure they  
2 were asked to.

3                   MEMBER EDGE: I don't remember  
4 reading through that there's a specific issue  
5 of attribution. Maybe that's a shortcoming of  
6 the way that we asked the developers to do  
7 this.

8                   CHAIRMAN LUTZ: Right. And I  
9 think one of the things we've learned from  
10 being on the Committee is we end up looking  
11 for any unintended consequences. So this  
12 comes up a lot, because this is one of the  
13 recurring concerns.

14                   Before I forget, anyone on the  
15 phone, anyone have any thoughts to add, anyone  
16 have their card on their side on the phone?

17                   MEMBER MARKS: I think just  
18 because -- I was thinking of this from before  
19 -- the radiation question from the last item  
20 very similar, right? The surgeon went to a  
21 biopsy from a surgery how do we code that to  
22 get to the liability get to the issue? It's

1 a huge problem; I didn't realize that.

2 MEMBER PFISTER: I understand what  
3 you're saying but I see that as a slightly  
4 different permutation in the sense that there,  
5 I think there's little argument that  
6 something's going to get done and that the  
7 measure is evaluating whether radiation is  
8 done within a certain period of time.

9 Here, the person who would  
10 ultimately potentially would be subject to  
11 measurement based on this metric is going to  
12 potentially modify how they might proceed  
13 based on information they inherit. And I  
14 guess, at least in my mind, it seems to be a  
15 slightly different issue of attribution.

16 MEMBER MARKS: I recognize that  
17 this is different, but it's similar as well,  
18 right? But if one queries the database from  
19 that facility, you know not having record of  
20 a prior needle biopsy, so for that case that  
21 facility might be deemed not in compliance  
22 when indeed the patient did have a biopsy.

1                   MEMBER EDGE: But the way the  
2                   Cancer Registry is now structured, however,  
3                   that Registry would say that the patient did  
4                   or did not have a needle biopsy and it would  
5                   say where the original biopsy was done. It  
6                   would say the original biopsy was done at the  
7                   reporting institution or was done at another  
8                   institution and would have a date when the  
9                   biopsy was done.

10                  MEMBER MARKS: Oh, okay. Is that  
11                  captured in these registries?

12                  MEMBER EDGE: Can Mr. Stewart  
13                  comment on that question?

14                  MR. STEWART: I'm sorry. The  
15                  person on the phone, the question was what  
16                  again?

17                  MEMBER MARKS: I was asking  
18                  whether registries do indeed capture that  
19                  information about a prior biopsy.

20                  MR. STEWART: Yes. Yes. So there  
21                  are a couple of considerations here.

22                  One is that Cancer Registries by a

1 whole set of other rules and regulations are  
2 obligated to have tracked down that  
3 information if that's available.

4           They also have the ability to  
5 distinguish the combination of where certain  
6 events took place. And this is something I  
7 have not looked at for this particular  
8 measure. But we can distinguish between  
9 patients who were diagnosed elsewhere and  
10 treated at the reporting institution or  
11 diagnosed and treated at the reporting  
12 institution to understand what the relative  
13 balance or dynamic of that data look like to  
14 understand if the denominator needs to be fine  
15 tuned around those sorts of considerations, if  
16 that begins to address the concern on the  
17 table.

18           CHAIRMAN LUTZ: Well and Heidi  
19 points out, I think that the denominator  
20 statement says diagnosis and all or part of  
21 first course of treatment performed at the  
22 reporting facility. And so maybe that would

1 leave --

2 MR. STEWART: I think that does  
3 address the question from the other side of  
4 the room where --

5 CHAIRMAN LUTZ: Right.

6 MR. STEWART: -- we're only  
7 looking at patients whose entire encounter for  
8 the diagnoses and management of their disease  
9 happened inside the walls of the reporting  
10 institution and we don't have a problem with  
11 patients moving between hospitals here.

12 CHAIRMAN LUTZ: Karen?

13 MEMBER FIELDS: I was just going  
14 to comment earlier but it's an extension of  
15 that. Perhaps the wording in all of these  
16 needs to be, you're reporting your analytic  
17 cases where you have all of the responsibility  
18 for tracking down, and then you're attributing  
19 it to that -- you're not attributing it to any  
20 one person but you're tracking down the  
21 analytic cases for which that institution  
22 takes responsibility. Because even if you're

1 going to say part or all of their initial  
2 therapy, patients move around and it would be  
3 very difficult to get this data if you didn't  
4 say something in all of these like analytic  
5 cases.

6 MR. STEWART: I think you'll find  
7 in the measures that we'll talk about today,  
8 this one and then one tomorrow around colon  
9 disease where we know that it's either  
10 basically a single-modality intervention that  
11 we're trying to capture and evaluate, we close  
12 those parameters to make sure that it's all  
13 happening within the reporting institution and  
14 that's our accountable organization or agency.

15 When you move into the multi-  
16 module therapies such as the conservation  
17 surgery and radiation measure that we just  
18 discussed, we're not sensitive to the fact  
19 that we want to look at only analytic cases  
20 within a reporting institution. We're  
21 concerned about the continuity of care for a  
22 patient, and so we're patient-centric in that



1 sense. And we're very ecumenical about making  
2 sure that if surgery is done in institution A  
3 and radiation is done elsewhere, both  
4 institutions are being watched to be  
5 accountable for the continuity of that care  
6 for that patient.

7 CHAIRMAN LUTZ: I was just going  
8 to add one aside. It might be too far astray,  
9 but one thing this doesn't help control, and  
10 I've seen this in three geographic areas and  
11 heard about it in others, are places where  
12 surgeons overdo their diagnosis.

13 So I actually have worked with --  
14 there are surgeons who do an FNA, it's  
15 positive. Then they do a core. Then they do  
16 an incisional. Then they do an excisional.  
17 Then they do a re-excision. Then they do a  
18 sentinel lymph node biopsy. Then you do an  
19 external lymph node dissection. And so I  
20 think one of the things you have to keep in  
21 mind is that surgeon is doing great with this.  
22 They are doing 100 percent. They will always

1 have some -- you know, it sounds funny, but  
2 actually you know a busy practice in Memphis,  
3 small rural area in Ohio I've seen this and  
4 I've heard about it from friends around the  
5 country. It's not -- again, we practice  
6 usually in bigger centers where we see good  
7 care. There's a lot of things -- first in  
8 reading through this, I thought well there's  
9 a lot of folks that may look good when they're  
10 not.

11 Dave?

12 MEMBER PFISTER: I am a little  
13 confused by that discussion prior to your  
14 comment. The way that the numerator and  
15 denominator is currently specified, any  
16 further descriptions, say, that, let's say  
17 it's limited to people that were -- you know,  
18 had everything done at one institution. That  
19 is not the case. It's as specified as it is,  
20 which would mean that people that were  
21 diagnosed at one place but then managed  
22 elsewhere are all part of this denominator.

1 Like there's no further descriptor analytic  
2 cases, only the institution cases, et cetera.

3 MR. STEWART: No. If you read the  
4 denominator statement it says diagnosis and  
5 all treatment at the reporting facility.  
6 There's a linguistical trick here. In my  
7 world, an analytic case is more than just  
8 that, it may lead to other characteristics.  
9 This is actually the subset of what I consider  
10 to be an analytical case.

11 MEMBER PFISTER: So you're saying  
12 that the diagnosis -- so what you're saying is  
13 that the diagnosis --

14 MR. STEWART: Both the diagnosis  
15 and the treatment have to have occurred at the  
16 reporting institution.

17 MEMBER PFISTER: Okay.

18 MEMBER FIELDS: It says first  
19 course of treatment. So that means just the  
20 surgical treatment?

21 MR. STEWART: No. First course  
22 treatments means everything to manage that

1 diagnosis until the time of recurrence or  
2 disease progression.

3 MEMBER PFISTER: But in most  
4 circumstances, Steve, that would be surgeon,  
5 right, in terms of first course of treatment?

6 MEMBER EDGE: Yes.

7 MEMBER PFISTER: Like, I would say  
8 95 plus percent of the time surgery is going  
9 to be the first thing.

10 CHAIRMAN LUTZ: Anybody else on  
11 the phone have a comment?

12 (No response.)

13 Any other discussion or we moving  
14 on to vote? Looks like we're voting.

15 MS. KHAN: So voting on 1a,  
16 impact. Again, addresses a specific national  
17 health goal or priority or the data  
18 demonstrated a high-impact aspect of health  
19 care. So one high, two moderate, three low  
20 and four insufficient.

21 So we have two high, 13 moderate  
22 and one insufficient evidence.

1                   And moving on to performance gap,  
2                   the data demonstrated considerable variation  
3                   or overall less than optimal performance  
4                   across providers and/or population groups.  
5                   One high, two moderate, three low and four  
6                   insufficient.

7                   So you have three high, 12  
8                   moderate, one low and zero for insufficient.

9                   And going on to evidence. It's  
10                  one for yes, two for no and three for  
11                  insufficient evidence.

12                  And that's 14 yes, one no and one  
13                  insufficient evidence.

14                  So going to reliability. We're  
15                  looking at precise specifications and the  
16                  testing. Again, one high, two moderate, three  
17                  low and four insufficient evidence.

18                  And four high, ten moderate, two  
19                  low and zero for insufficient evidence.

20                  Looking at 2b, validity. Again,  
21                  looking at specifications are consistent with  
22                  the evidence, testing, exclusions, risk

1 adjustment, meaningful differences and  
2 comparability in data sources.

3 So one high, two moderate, three  
4 low and four insufficient evidence.

5 Can we have everyone press their  
6 button one more time?

7 So we have three high, ten  
8 moderate and three low and zero for  
9 insufficient evidence.

10 And we moving on to usability.  
11 We're looking at usability for public  
12 reporting and accountability and for quality  
13 improvement.

14 So, one high, two moderate, three  
15 low and four insufficient information.

16 Can we have everyone do it one  
17 more time?

18 Four high, 10 moderate, two low  
19 and zero insufficient information.

20 Going on to feasibility. We're  
21 looking at the data generated during care  
22 electronic sources, susceptibility to

1       inaccuracies and unintended consequences are  
2       identified and data collection can be  
3       implemented.

4                Again, that's one high, two  
5       moderate, three low and four insufficient  
6       information.

7                One more time. Again, the receiver  
8       is actually over here, so if you want to point  
9       your clicker over here. I think it's fine. I  
10      got them all.

11              So we have three high, ten  
12      moderate, three low and zero insufficient  
13      information.

14              And overall suitability for  
15      endorsement. Does the measure meet NQF  
16      criteria for endorsement? One yes, two no.

17              Dr. Laver, are you on the line  
18      now?

19              (No response.)

20              So we have 12 yes and four no. The  
21      measure will pass.

22              CHAIRMAN LUTZ: All right. So just

1 double checking, Dr. Laver is not on yet,  
2 right? Okay. Then we will skip forward to  
3 559. We'll have the developer frame things  
4 for us and then Jennifer just came on in  
5 because she had a desperate need to tell us  
6 more.

7 MR. STEWART: So is this the  
8 combination? 559?

9 This is a measure looking at  
10 multi-modal management of appropriately staged  
11 hormone receptor negative breast cancers for  
12 women under the age of 70 with the expectation  
13 that using diagnosis date as the index  
14 reference point that combination chemotherapy  
15 be started or initiated within four months or  
16 120 days of diagnosis.

17 I don't know that there was much  
18 commentary or requests for clarification  
19 during the telephone conference calls. I  
20 would like to have the commentator pick it up  
21 from here, and I'll be happy to answer  
22 questions as they arise.



1                   MEMBER MARKS: I'm sorry, are we on  
2                   559 or 220?

3                   CHAIRMAN LUTZ: We're on 559. The  
4                   person who is going to present 220 is not on  
5                   the line yet, so we skipped forward to 559.

6                   MEMBER MARKS: Thank you.

7                   MEMBER MALIN: So I think this  
8                   measure, you know, is probably one of those  
9                   measures that has reams if not the most data  
10                  behind it. It's one of the ones with the most  
11                  data behind it in terms of evidence that it  
12                  improves patient outcomes.

13                  I think clearly it's important,  
14                  this is high-impact. I would say it's been in  
15                  use for a long time. There's ample data on  
16                  its reliability and validity, feasibility and  
17                  usability.

18                  I would say probably these are  
19                  more kind of general concerns, the necessary  
20                  concern specifically about the measure is that  
21                  at this point it's pretty dated. It's not  
22                  necessarily -- you know, we should probably

1       strive to have measures that keep up with the  
2       current nuance in breast cancer treatment and  
3       providing good breast cancer care is more than  
4       just providing chemotherapy generally.  And  
5       so, you know, I would encourage the developers  
6       to think about ways to maybe improve upon this  
7       going forward.

8                   And then the corollary of that is,  
9       I think, because this is such a generic mom  
10      and apple pie measure, most of the data out  
11      there suggests at this point that there's not  
12      a lot of gaps in care related to this measure.

13                   Any questions?

14                   CHAIRMAN LUTZ:  Bob, you had your  
15      card up early on this one.

16                   MEMBER MILLER:  So, my question is  
17      the verb "considered."  How is considered  
18      tracked in the medical record?

19                   MR. STEWART:  So the registry  
20      coding systems allow and provide opportunity  
21      for the capture of information describing the  
22      fact that physicians or attending physicians

1 responsible for the patient's care did one or  
2 a number of things. Either documented it in  
3 the medical record that the treatment or the  
4 chemotherapy in this case was appropriate but  
5 there were other extenuating circumstances,  
6 patient's overall other health condition. what  
7 not, that recommended care was simply not--  
8 you know, the standard of care was simply not  
9 recommended for those reasons.

10 Also, they do capture indications  
11 that that consultation occurred and the  
12 patient or their guardian declined the therapy  
13 that the physicians recommended to them and so  
14 forth.

15 So, there are probably about three  
16 or four different ways that a generic umbrella  
17 of considered is captured and reported through  
18 these systems.

19 MEMBER MILLER: So are those  
20 elements coded in some standard fashion?

21 MR. STEWART: They are. They are.

22 MEMBER MILLER: Okay. Because I

1       guess that would be my concern, is: how do you  
2       really know if something was considered? If  
3       wasn't documented, it wasn't done. You know,  
4       I'm just thinking of my own practice, you know  
5       I don't code this way, but I can see easily  
6       how a decision was made not to give  
7       chemotherapy after an extended discussion. If  
8       it's not abstracted properly from the written  
9       or the electronic medical record, you're not  
10      going to see that. So I wondered about just  
11      about the consistency of application. But I  
12      understand your explanation. I wasn't on the  
13      small work group on this one, but do you  
14      present data that shows that the consideration  
15      you said has tested, that it's reliable?

16                   MR. STEWART: We do that in two  
17      ways. One is that we actually indicate in our  
18      report-back mechanisms to the hospital what  
19      their quote/unquote "considered rate" happened  
20      to be so that they can identify themselves as  
21      whether they were either low or high outliers  
22      in that regard.

1                   Secondly, during the accreditation  
2 site visit we actually have peer reviewers  
3 examine selected medical charts and we  
4 actually target nonconcordant and charts where  
5 it's indicated that considered therapy was not  
6 actually given so that we can verify that that  
7 was actually documented in the medical record.  
8 So we do external objective validation checks  
9 of that reporting information.

10                   CHAIRMAN LUTZ: Karen?

11                   MEMBER FIELDS: So would an  
12 appropriate exclusion criteria be patient  
13 declined? Because that's not one of the  
14 exclusion criteria.

15                   MR. STEWART: No. If the patients  
16 are advised that chemotherapy is recommended  
17 for their condition and they decline it, that  
18 case appears in both the numerator and the  
19 denominator. We're interested in making sure  
20 that clinicians and medical systems are  
21 cognizant of this particular standard of care  
22 and are documenting the fact that even if the

1 patient doesn't actually receive or have the  
2 chemotherapy administered, that they had made  
3 the choice not to do so. We want to make sure  
4 that the physicians who are responsible for  
5 that patient's care are quote/unquote "doing  
6 the right thing at the right time" even if the  
7 patient subsequently declines.

8 MEMBER FIELDS: And do you also  
9 capture lost to follow up, I assume, then too?

10 MR. STEWART: Lost to follow up in  
11 the sense of?

12 MEMBER FIELDS: Well, declining in  
13 some of these populations is lost to follow up  
14 because the women that would be likely to  
15 decline might seek alternative therapies, you  
16 might not have that --

17 MR. STEWART: I don't think it's  
18 that nuanced. The data that are reported  
19 through the registries simply signal  
20 administration or lack thereof. And if it's  
21 not administered and there's evidence in the  
22 medical record for why that wasn't done, and

1 it fits the appropriate considered criteria,  
2 that's how it appears.

3 The fact that the patient may go  
4 elsewhere for alternative therapy or  
5 intervention isn't something that we would  
6 pick up as a matter of course.

7 MEMBER PFISTER: As Larry was  
8 saying, this has been sort of a heavily vetted  
9 measure. So there's like, you get vetting  
10 fatigue after a while. So at the risk of  
11 saying that, how do you know that they didn't  
12 get crazy combination chemotherapy?

13 MR. STEWART: We don't. We  
14 distinguish between single agent and  
15 multiagent. But what that combination  
16 happened to have been is not something that's  
17 been standardized to this data collection  
18 mechanism.

19 MEMBER PFISTER: Because, you  
20 know, clearly there are things which would be  
21 viewed as kind of fairly mainstream and  
22 acceptable combination chemotherapy to give

1 here. I know when I was involved in a  
2 practice guideline in lung cancer several  
3 years ago that there is in fact wrong  
4 combination chemotherapy to give. In fact,  
5 people seemed like they did worse with the  
6 wrong combination chemotherapy and it seems --  
7 you know, again, you might say well, gee, 95  
8 percent of the time they're getting a  
9 reasonable thing so it's going to come out in  
10 the wash. But it seems that at least what  
11 drugs they get that that should be -- you  
12 know, that should be accessible information  
13 electronically. And I'm just thinking about  
14 like raising the bar in a measure like this  
15 that's been heavily endorsed. You know, I  
16 think raising the bar a little bit would be a  
17 reasonable expectation.

18 CHAIRMAN LUTZ: We'll do Elaine and  
19 then Karen and then check on the phone.

20 MEMBER CHOTTINER: Okay. Going  
21 back to this process of looking at exclusions.  
22 I think that what you're describing is very



1       cumbersome and to rely upon people going back  
2       to the chart and pulling out reasons why  
3       patients didn't get chemotherapy is very  
4       difficult, especially if this is going to be  
5       incorporated into one of the PQRS measures it  
6       would be difficult to report the coding. And  
7       I think it would be much better if you do have  
8       a category for patient refusal or  
9       comorbidities or something that would give us  
10      an easier way to pull that information out.

11                 CHAIRMAN LUTZ: Karen?

12                 MEMBER FIELDS: How do you capture  
13      neoadjuvant therapy and staging then?

14                 MR. STEWART: We capture dates of  
15      service so we know whether or not the  
16      chemotherapy is being provided neoadjuvantly.  
17      And we also capture both clinical and  
18      pathologic staging information. So I think we  
19      have those considerations accounted for.

20                 MEMBER FIELDS: That's fine.  
21      Because staging is no longer pathologic  
22      staging.

1 MR. STEWART: No. This is no  
2 longer pathologic staging.

3 CHAIRMAN LUTZ: Okay. Heidi,  
4 Larry, Rocco, anyone on the phone?

5 MEMBER MARKS: Yes. I'm sorry. I  
6 stepped away for a few minutes, and maybe this  
7 was addressed. Is the goal again 100 percent,  
8 because the same issue applies about the  
9 comorbidities and what not?

10 MR. STEWART: Again, consistent  
11 with my earlier comment, the Commission is  
12 setting a bar of 90, knowing that there will  
13 be some flexibility in the way that we look at  
14 these data, but we will expect institutions to  
15 be able to demonstrate at least a 90 percent  
16 concordance knowing that 100 percent is likely  
17 but not always going to be observed.

18 MEMBER MARKS: Do we know 90 is a  
19 national number for this one? Also the  
20 radiation one, for that matter. What percent  
21 of patients have comorbidities that would  
22 prevent the delivery of radiation or chemo?

1 I don't know the answer, but maybe someone  
2 does.

3 MEMBER MALIN: Also, I would think  
4 90 would be kind of a low bar. This isn't  
5 receipt of chemotherapy, it's consideration of  
6 it. So it should be close to 100 percent.

7 MEMBER MARKS: Yes, that's true.

8 MEMBER MALIN: It means you didn't  
9 do your job if you didn't consider it, at  
10 least.

11 MEMBER MARKS: This is less  
12 stringent than the radiation one where it was  
13 actually delivery of radiation.

14 MEMBER EDGE: I think there is a  
15 couple of differences here. A couple of  
16 points here.

17 First of all, Larry, this measure,  
18 unlike the radiation measure, the patients  
19 with comorbidity, as Mr. Stewart outlined, are  
20 included in the numerator as having received  
21 concordant care. If the doctor said, "I  
22 understand that this person would generally

1 receive chemotherapy but because of these  
2 comorbidities they should not," and they are  
3 considered concordant and would be in those  
4 patients who would be positively considered  
5 for this measure.

6 MEMBER MARKS: Okay.

7 MEMBER EDGE: The second issue is  
8 that, again, I believe the developers were not  
9 asked to set a threshold measure for us to  
10 consider, nor were we looking at attribution.

11 As Mr. Stewart said earlier, the  
12 Commission on Cancer has separately, for the  
13 purposes of its accreditation program for  
14 cancer programs, has set a standard of 90  
15 percent and if centers fall below that, they  
16 have to develop a written action plan and  
17 demonstrate to us on our site visit surveys  
18 that they have acted on it. But those have no  
19 bearing on our deliberations here, is my  
20 understanding.

21 And I would agree with Dr. Malin  
22 it's a relatively low bar, but again it is

1 completely separate from our discussions here.  
2 The Commission set that as a place to start to  
3 say we need to meet this standard, and there  
4 was a lot of discussion of whether it should  
5 be 85 or 90 or 95 or 100. But since it's  
6 never been done before to set this kind of  
7 standard on a national level, we started at  
8 90.

9 But that really has I think --  
10 that level of expected concordance has no  
11 bearing on NQF discussions because I think the  
12 developers were not asked to present that kind  
13 of information.

14 MEMBER MARKS: All right. Thank  
15 you.

16 MS. BOSSLEY: This is Heidi. Maybe  
17 I should add a little clarification as to  
18 exactly -- you're right. We don't  
19 specifically ask for benchmarks. And it's  
20 been something that the committees have tried  
21 to determine should there be.

22 I do think it's interesting when

1 you look at the reliability results here, you  
2 do provide some data from '07 and '08, and  
3 that may help to answer some of the questions.  
4 And it looks like cancer programs back then in  
5 the 75th percentile had performance of 100  
6 percent. So it at least gives you a sense of  
7 where everyone is.

8 It appears to be, again, that's  
9 four years ago, but fairly high. So I'm not  
10 sure that a benchmark in this instance  
11 actually would be needed because it looks like  
12 it's actually high. But I think you all need  
13 to talk that part through. Based on the data  
14 you're seeing, it is rather high. There is  
15 some variation, but again I think that's the  
16 question in my mind that probably should be  
17 answered.

18 CHAIRMAN LUTZ: Anyone else have  
19 comments or thoughts?

20 MEMBER DONOVAN: I do have some  
21 questions about the reliability data that was  
22 presented. So performance ratings that are

1 so high and reliability testing that, to me,  
2 it doesn't look like it really addresses the  
3 extent to which people are able to accurately  
4 extract information on this consideration  
5 variable. It seems impossible that we can  
6 weigh performing services more than issuers'  
7 reliability than their performance. So, that's  
8 one question.

9           And then the other question is: is  
10 there a precedent for how to handle sort of  
11 longstanding measures that seem to need to be  
12 upgraded or made more current, you know, when  
13 the previous measure was viewed as sort of a,  
14 as everybody said, mom and apple pie sort of  
15 measure that now seems to be sort of a measure  
16 that may start achieving and not really  
17 capturing current practice? That's a strong  
18 statement, I don't mean not capturing current  
19 practice, but not nuanced enough to catch  
20 whether the chemotherapy administered was  
21 appropriate.

22           MR. STEWART: And so in order of

1 the two questions, the response to the first  
2 question is that, from all of our work and  
3 evidence, the institutions with low-lying  
4 performance rates tends to be a reflection of  
5 completeness of information in their registry  
6 systems. And so what we've discovered is that  
7 as we put these measures into play,  
8 institutional completeness and accuracy of  
9 data have increased as institutions have paid  
10 attention to the fact that they're being  
11 watched. It's the classic Hawthorne effect.  
12 So I think I'll stop my answer at that point.

13           And then secondary, I think you're  
14 quite right. We suspected this at the outset  
15 that a number of the measures that the  
16 Commission and the College put forward to NQF  
17 that are being discussed again here were  
18 pretty straightforward. And in some cases,  
19 they remain that way. I think some of the  
20 suggestions for how to push the edge of the  
21 envelope and raise the bar and add additional  
22 levels of possible specificity to these



1 measures are probably well worded, but they'll  
2 take some time to fully assess and understand  
3 how best to do that.

4 CHAIRMAN LUTZ: Okay.

5 MEMBER DONOVAN: Has there been a  
6 precedent where there has been a formal  
7 request that the bar is raised prior to the  
8 next review or the sense that it's, you know  
9 trying to close the measure and sort of  
10 request formally that, you know, this measure  
11 be stopped and then a new one be proposed?

12 MR. STEWART: Is that a question  
13 for the developer or a question for NQF?

14 MEMBER DONOVAN: It was a question  
15 for NQF.

16 MS. BOSSLEY: So this is Heidi.

17 It's a very good question and you  
18 actually have both options on the table. So  
19 I think we should vote once you're done  
20 discussing it, see if the measure passes as it  
21 is against all the criteria.

22 You can put forward

1 recommendations on what you think you would  
2 like to see the next time around if this  
3 measure does pass the criteria. Or, it is  
4 your choice if this measure doesn't pass,  
5 endorsements removed and then there will be an  
6 opportunity hopefully in the near future that  
7 they can bring forward another measure that  
8 addresses some of the concerns in the areas  
9 that you would like. So, you have both  
10 options.

11 MEMBER LAVER: Can you update us,  
12 which measure are we talking about?

13 CHAIRMAN LUTZ: We're on 559.

14 MEMBER LAVER: Okay.

15 CHAIRMAN LUTZ: All right. Any  
16 other suggestions or thoughts? It looks like  
17 we're going onto voting.

18 MS. KHAN: So voting on 1a,  
19 impact.

20 MEMBER LAVER: So I'm not in front  
21 of a computer, so I have to have a computer to  
22 vote or --

1 MS. KHAN: You can just say your  
2 votes over the phone and we'll put them in for  
3 you.

4 MEMBER LAVER: Okay.

5 MS. KHAN: Do you have a vote on  
6 1a, impact?

7 MEMBER LAVER: So are we doing it  
8 by phone call or --

9 CHAIRMAN LUTZ: No, for you. It's  
10 high, moderate, low or insufficient for impact  
11 on 559.

12 MS. KHAN: So we have eight high,  
13 seven moderate and one insufficient evidence.

14 MEMBER LAVER: I vote by pushing  
15 the buttons or how?

16 MS. KHAN: Dr. Laver, you can just  
17 say high, moderate, low or insufficient over  
18 the phone and then we'll capture that for you.

19 MEMBER LAVER: Okay. Moderate.

20 MS. KHAN: Okay. So it's tied  
21 eight high, eight moderate and one  
22 insufficient.

1                   Voting on performance gap. Again,  
2                   it's high, moderate and low or insufficient  
3                   evidence.

4                   And Dr. Laver, did you give us  
5                   your vote?

6                   MEMBER LAVER: I'm looking through  
7                   the pages. And this is the same measure,  
8                   right?

9                   MS. KHAN: Yes, it's performance  
10                  gap. Same measure.

11                  MEMBER LAVER: Okay. I vote two.

12                  MS. KHAN: Okay. Thank you. So we  
13                  have one high, 12 moderate, three low and one  
14                  insufficient evidence.

15                  And moving onto the evidence,  
16                  we're going to vote one yes, two no and  
17                  insufficient evidence.

18                  And Dr. Laver, you can just say  
19                  your vote whenever you're ready.

20                  MEMBER LAVER: Three.

21                  MS. KHAN: So we have 12 yes,  
22                  three no and two insufficient evidence.

1                   And going on to reliability,  
2                   you're going to vote one high, two moderate,  
3                   three low and four insufficient evidence.

4                   MEMBER LAVER: I'll vote two.

5                   MS. KHAN: Can we have everyone  
6                   press their number again?

7                   So we have seven high, eight  
8                   moderate, two low and zero insufficient.

9                   Voting on 2b, validity. It's one  
10                  high, two moderate, three low, four  
11                  insufficient evidence.

12                  Dr. Laver?

13                  MEMBER LAVER: Two.

14                  Can I ask you a question while  
15                  everybody's voting? Did you discuss already  
16                  the 220?

17                  CHAIRMAN LUTZ: No, we waited just  
18                  for you. We're actually going to do that  
19                  next.

20                  MEMBER LAVER: Okay.

21                  MS. KHAN: So we have seven high,  
22                  eight moderate and two low.

1                   Gong on to usability. We're going  
2 to vote one high, two moderate, three low or  
3 four insufficient information.

4                   And, Dr. Laver?

5                   MEMBER LAVER: On which one now?

6                   MS. KHAN: This is usability.

7                   MEMBER LAVER: Three.

8                   MS. KHAN: We have six high, six  
9 moderate and five low.

10                  And going on to feasibility, one  
11 high, two moderate, three low or four  
12 insufficient information.

13                  And Dr. Laver?

14                  MEMBER LAVER: I vote three.

15                  MS. KHAN: So we have three high,  
16 nine moderate and five low.

17                  And overall suitability for  
18 endorsement, does the measure meet NQF  
19 criteria for endorsement? Yes or no.

20                  And, Dr. Laver?

21                  MEMBER LAVER: I'm debating here.  
22 So give me a second.

1 MS. KHAN: Sure. Whenever you're  
2 ready. So we have ten seconds left on the  
3 clock. Did you want to put a vote in?

4 MEMBER LAVER: Okay. I would say  
5 yes, one.

6 MS. KHAN: Okay. So we have 14  
7 yes and three no. So the measure will pass.

8 CHAIRMAN LUTZ: All right. So  
9 we're onto 220. So we will have our  
10 developer present first and then move on to  
11 you, Dr. Laver.

12 MEMBER LAVER: Thank you.

13 CHAIRMAN LUTZ: So if the  
14 developer is ready?

15 MR. STEWART: So analogous to the  
16 measure we've just discussed, there are many  
17 of the same sorts of components and  
18 considerations at hand.

19 This is a measure that examines  
20 adult female breast cancer patients with  
21 hormone receptor positive disease and  
22 appropriate midstage diagnosis for whom we

1 would expect hormone therapy to be either  
2 recommended or administered --

3 MEMBER LAVER: Could you speak up?

4 MR. STEWART: -- within a 365-day  
5 time frame. I'm sorry.

6 Similar to the measure we just  
7 reviewed with respect to adjuvant  
8 chemotherapy, this measure examines adult  
9 women with appropriately midstaged breast  
10 cancer who are hormone receptor positive with  
11 the expectation that tamoxifen or third  
12 generation aromatase inhibitor be administered  
13 or considered within 365 days of the index  
14 date of diagnosis.

15 I don't think I have anything more  
16 to comment on with respect to the numerator  
17 and the denominator criteria. There were some  
18 comments raised during the phone conference  
19 call. I'll be happy to address those during  
20 the discussion as they arise.

21 MS. FRANKLIN: All right. Dr.  
22 Laver, if you could lead us through your



1 discussion of the measure.

2 MEMBER LAVER: Okay. Again, as I  
3 said previously, I am a pediatric oncologist  
4 so it was a stiff learning curve for me to  
5 look into breast cancer.

6 I reviewed the literature and  
7 there's a tremendous body of literature with  
8 high evidence and quality data that treating  
9 within 365 days is beneficial and improves  
10 survival and improves quality of life. So I  
11 for one supported the measure. I think it's  
12 a well-thought one. I think it's feasible to  
13 do. I think measuring quality of care, this  
14 is a parameter that should be measured.

15 I'll stop here.

16 CHAIRMAN LUTZ: All right. Is  
17 there anyone on the conference call about this  
18 that had anything to add?

19 MEMBER MARKS: Just a question  
20 about the stage, the same business about the  
21 Stage I versus II, were there some  
22 inconsistencies similar to one of the other

1 metrics because T1 -- I guess not. I'm not  
2 seeing that.

3 MS. FRANKLIN: We have a response  
4 from the developer.

5 MR. STEWART: I think in the  
6 denominator statement we are clear that it's  
7 a AJCC T1c for Stage II or Stage III --

8 MEMBER MARKS: Okay. Yes. I'm  
9 sorry, a different one I'm thinking of. Thank  
10 you.

11 CHAIRMAN LUTZ: Any other  
12 questions that come to mind? I think the  
13 developer has more to add.

14 MR. STEWART: So just to bring  
15 closure on the commentary from the telephone  
16 conference call, a question was raised whether  
17 or not we had considered the exclusion of  
18 pregnancy or planned pregnancy from the  
19 denominator of the measure.

20 MEMBER LAVER: Yes, I remember  
21 that.

22 MR. STEWART: So I promised to

1 look into that. First let me just caveat.  
2 There's no way we can anticipate planned  
3 pregnancies in our data sets, so that's  
4 neither here nor there.

5 We did look at a diagnosis of the  
6 cohort of patients in the denominator of this  
7 measure constituted just over 110,000 women,  
8 of which we identified 63 who had a secondary  
9 diagnosis code in some way related to  
10 pregnancy or pregnancy care, which constitutes  
11 one half of one percent of the denominator.  
12 Whether or not that constitutes sufficient  
13 specificity concern to exclude those women or  
14 not, I would invite comment on.

15 I would only go on to observe that  
16 half of those women actually did eventually  
17 show up in our data set as having received  
18 hormonal therapy for their breast cancer. So  
19 it's not clear to us at what stage in their  
20 pregnancy they were when the original  
21 diagnosis occurred, but it's plausible that  
22 post-delivery hormonal therapy was

1 administered to those women as would be  
2 appropriate, I presume.

3 MEMBER LAVER: Well, do people  
4 have to report pregnancies in the same  
5 database so you can have an idea of how many  
6 were on tamoxifen and got pregnant or you can  
7 capture this in data if you target it?

8 MR. STEWART: These data are  
9 reported to us as secondary diagnoses or  
10 conditions that exist at the time of the index  
11 disease diagnosis, which was prior to the  
12 breast cancer.

13 MEMBER LAVER: I see. But not  
14 somebody being two years on tamoxifen and then  
15 reported, right?

16 MR. STEWART: No.

17 MEMBER LAVER: So this would be  
18 tactical measure.

19 CHAIRMAN LUTZ: Karen?

20 MEMBER FIELDS: The measure is  
21 just that they started and were given  
22 tamoxifen or aromatase inhibitors. So

1 obviously our suggestions for improvement  
2 would be how do we measure that they got the  
3 prescribed course and they got the right  
4 duration of course, and they got the right  
5 kind of anti-estrogen therapy based on their  
6 menopausal status. So those are, I think, the  
7 shortcomings of the measure, but obviously  
8 there was a huge disparity already, we have a  
9 disparity issue, so we aren't there yet, but  
10 I guess at the end we should also make  
11 recommendations about improving the quality of  
12 the measure.

13 MR. STEWART: So the question of  
14 menopausal status was extensively discussed  
15 when the NQF originally reviewed this measure  
16 five years ago. The conclusion was that the  
17 feasibility of determining menopausal status  
18 was very low, and so there was a decision made  
19 to basically include all comers in this  
20 measure and not distinguish around that fact.  
21 It's just a shortcoming of not just our data  
22 set, but probably many others that could be

1 used to assess this.

2 The second question about care  
3 compliance, if you will, is not one that we  
4 measure directly. But even in associated work  
5 where we've had a chance to look at claims  
6 data sets and what not, you know we can tell  
7 the fact of prescriptions being written and  
8 filled. It's also clear that there's some  
9 elasticity, if you will, in patients  
10 continuing to fill those scrips over time.  
11 And those sorts of data enterprises to look at  
12 concordance or patient compliance over time  
13 were very difficult to think about from a  
14 feasibility perspective. You know, where we  
15 had simply chosen to focus on the fact of, you  
16 know, at least initiation or the prescription  
17 being written for the patient to fill. And  
18 using that as our indicator for compliance  
19 with the standard of care.

20 MEMBER FIELDS: And we will  
21 discuss this and make recommendations, but  
22 there's also another measure this afternoon

1 that's the same endpoint. So how do we deal  
2 with that? Because it actually has some  
3 different exclusion criteria.

4 MR. STEWART: If I can comment  
5 quickly.

6 So I've had brief conversations  
7 with the other developer of that complementary  
8 measure and we'll see if we can address your  
9 concerns this afternoon when the conversation  
10 comes up.

11 MS. BOSSLEY: Right. So this one  
12 is a facility, the other one that you'll look  
13 at is clinician. So those would be viewed as,  
14 I would think, related. They're not  
15 competing, because they do have different  
16 levels of analysis. The question will be: are  
17 they harmonized. And it sounds like there's  
18 discussions already.

19 So part of what I think the  
20 feedback you should provide is exactly where  
21 you think the harmonization should occur and  
22 we'll walk through that once -- we'll do a

1 table of the two, and I think that will be  
2 helpful. And then, again, go back to the  
3 developers and see what they can do. But it's  
4 a very good question.

5 MEMBER LAVER: Race can be  
6 extracted from the electronic medical record,  
7 right?

8 MR. STEWART: Yes.

9 CHAIRMAN LUTZ: Anybody else on  
10 the phones have anything to add? All right.  
11 Are we moving on to vote?

12 MS. KHAN: So voting on 1a,  
13 impact. Again, it's high, moderate and low or  
14 insufficient evidence.

15 MEMBER LAVER: Laver, I vote one.

16 MS. KHAN: So we have 14 high,  
17 three moderate, zero for low and zero for  
18 insufficient.

19 Moving on to 2b, performance gap.  
20 High, moderate, low or insufficient evidence.

21 MEMBER LAVER: So basically if you  
22 vote low, there is no performance gap?



1 MS. KHAN: Yes, that's correct.

2 MEMBER LAVER: Did I get it  
3 correct that the data show 3.5 outlier, 3.5  
4 percent?

5 MS. KHAN: Andrew?

6 MR. STEWART: I'm sorry, I don't  
7 have that full set of documentation in front  
8 of me. So the 3.5 percent that you cite are  
9 hospitals -- are the proportions of hospitals  
10 that we have applied this measure to where  
11 they lie at a significantly low performance  
12 rate. You know, beyond a standard deviation  
13 or some such from the mean.

14 MS. KHAN: Did you want to put  
15 your vote in?

16 MEMBER LAVER: Yes. Three.

17 MS. KHAN: Okay. Thank you.

18 So we have five high, two moderate  
19 and one low and one insufficient evidence.

20 And looking at 1c the evidence,  
21 you're going to vote yes, no or insufficient  
22 evidence.

1 MEMBER LAVER: Laver, I vote yes.

2 MS. KHAN: So you have 16 yes and  
3 one no.

4 Moving on to reliability. High,  
5 moderate, low or insufficient evidence.

6 MEMBER LAVER: It's Laver. I vote  
7 high.

8 MS. KHAN: Can we have everyone  
9 press their clicker again? One more time. No.  
10 All right.

11 We have 11 high and six moderate.

12 Moving on to validity. High,  
13 moderate, low or insufficient evidence.

14 MEMBER LAVER: This is Laver.  
15 High.

16 I will have to step out for a few  
17 minutes.

18 MS. KHAN: All right. Thank you.

19 MEMBER LAVER: So I can tell you I  
20 vote high and yes on all of the coming ones.

21 MS. KHAN: Okay. Thank you very  
22 much.

1                   Can we have everyone press theirs  
2 one more time, please? There we go.

3                   So eight for high and nine for  
4 moderate.

5                   Moving on to usability. So we  
6 have ten for high, six moderate and one low.

7                   And looking at feasibility, again  
8 high, moderate, low or insufficient  
9 information.

10                  We have seven high, ten moderate,  
11 zero low, zero insufficient information.

12                  And overall suitability for the  
13 endorsement, does the measure meet NQF  
14 criteria for endorsement, yes or no.

15                  We have 17 yes, zero no so the  
16 measure will pass.

17                  CHAIRMAN LUTZ: I think that based  
18 upon the strong start that Member Marks gave  
19 us, we made it to the break a little bit  
20 early.

21                  MEMBER MARKS: Thank you.

22                  (Whereupon, at 11:03 a.m. off the

1 record until 11:25 a.m.)

2 CHAIRMAN LUTZ: And a request was  
3 made if we could find who is still on the line  
4 from the Committee that's going to be voting.  
5 I know, Larry, you said you're free in about  
6 five minutes.

7 Rocco, you still on?

8 MEMBER RICCIARDI: I'm still on.

9 CHAIRMAN LUTZ: Okay. And Heidi?  
10 All right.

11 So, I guess Rocco will be our lone  
12 holdout after Larry steps aside and unless  
13 Heidi comes back on. All right.

14 So the next one we have is 1857.  
15 I think it's the HER2/neu. I think ASCO is  
16 going to be the one that's giving us the  
17 framework and then Stephen Edge is going to  
18 give us the perspective from this Subcommittee  
19 that looked at it. So, I think ASCO is  
20 presenters first.

21 MS. McNIFF: Thank you.

22 So the first measure you'll be

1 reviewing 1857 is of course the three related:  
2 HER2 testing and appropriate use of these  
3 measures that ASCO has submitted for breast  
4 cancer.

5 We did submit a few updates in  
6 response to the work group calls. And Dr.  
7 Edge pointed out to me that one of his  
8 recommendations he did not give me, which is  
9 to change the title to make it clear that  
10 we're talking about the adjuvant setting. And  
11 so if that's all right with NQF staff, we can  
12 certainly make that change.

13 MS. FRANKLIN: Sure. We will open  
14 the measure for you.

15 MS. McNIFF: Thank you. Happy to  
16 do that to clarify.

17 I did want to make one general  
18 statement that is relevant to all of the three  
19 measures we'll be reviewing this morning and  
20 also right after lunch, and that is that we  
21 recognize and understand the comments that we  
22 heard about the high performance demonstrated

1 by QOPI data. Did look further at the data as  
2 requested by the folks on the work group, and  
3 you know confirmed that the QOPI data do show  
4 a little bit of variation, but both the mean  
5 and the median are high and practices are  
6 clustered to the extreme cortile. And this is  
7 similar to some of the other measures that  
8 have been reviewed this morning.

9 We want to reenforce that QOPI is  
10 a selected group and they're participating  
11 voluntarily in a quality improvement program.  
12 So this group is likely not reflective of care  
13 overall nationwide.

14 We would ask that you consider  
15 these measures in the same way you thought  
16 about some measures brought initially for  
17 consideration for accountability use in the  
18 past, and that is to see what happens when  
19 they are used outside of the QOPI system in an  
20 accountability way and we can see whether  
21 there is variation within the wider  
22 communities with wider use.

1           At the point of reconsideration of  
2           the measure, of the maintenance review, within  
3           a few years we show that there is not  
4           variation, then we would absolutely agree that  
5           the measure should be retired from  
6           accountability use. But at this point we're  
7           suggesting that the approach be taken, we see  
8           what happens when these are implemented  
9           nationwide.

10           CHAIRMAN LUTZ: Okay. So, Stephen  
11           is this your --

12           MEMBER EDGE: So as people recall,  
13           this is to measure the appropriate nonuse of  
14           trastuzumab in receiving adjuvant therapy for  
15           stage I T1c and zero or stage II or III breast  
16           cancer. And the concerns that we raised were  
17           related to what Ms. McNiff just discussed with  
18           the very high performance on QOPI and really  
19           the absence of data from other practice  
20           settings besides those volunteers who choose  
21           to participate in QOPI. And whether those are  
22           or are not high performers, I don't think ASCO

1 has demonstrated, although I could be wrong on  
2 that.

3           And beyond that, I think the  
4 importance is certainly clear that women  
5 should not receive an extensive and toxic  
6 therapy when there really is no indication.  
7 There is a clinical trial now looking at the  
8 use in HER2 negative breast cancer, but the  
9 clinical trial's exclusion is included in the  
10 measure.

11           The measure properties are  
12 certainly acceptable.

13           The useability will require  
14 probably chart abstraction at the hospitals,  
15 cancer registries, collect immunotherapy. And  
16 Mr. Stewart and I'd have to comment as to  
17 whether trastuzumab is considered chemotherapy  
18 or immunotherapy in the cancer registry  
19 system.

20           Is trastuzumab considered  
21 chemotherapy or immunotherapy in the cancer  
22 register system? I don't recall the answer.



1 But the registry still does not code the exact  
2 name of the drug, so it will require  
3 significant chart abstraction unless there's  
4 ability to get electronic health record data  
5 abstracted automatically, which is probably  
6 quite some years away on a national basis, or  
7 if there's an ability to obtain administrative  
8 claims from payers. Certainly Medicare could  
9 do that if this was implied in the medical  
10 population.

11 It's certainly a useable measure.  
12 It's feasible, though it would require some of  
13 the things we just talked about, and I don't  
14 think there's any measures here. So I think  
15 they're largely addressed the concerns that we  
16 had regarding the claim.

17 CHAIRMAN LUTZ: Okay. Thank you.

18 Bryan?

19 MEMBER LOY: I just wanted to go  
20 back to the comment you made about  
21 demonstrating performance gap that was back on  
22 this page just a moment ago. I'd like to

1 understand a little bit better what your  
2 finding in your data. Is that largely the  
3 variance and the opportunity for improvement  
4 largely a lack of documentation or is it in  
5 fact those folks receiving trastuzumab that re  
6 HER2 negative?

7 MS. McNIFF: So while we don't  
8 know necessarily. But the position is that  
9 there needs to be documentation in the record  
10 about HER2 status. I mean, actually it would  
11 be better if the three measures were flipped  
12 in order. And if the documentation is not  
13 there, then the treatment decision should not  
14 be made.

15 So, there is the possibility in  
16 Dr. Hammond's office during the work group  
17 call as well, certainly that the HER2 testing  
18 was done. But ASCO's position is it needs to  
19 actually be documented in the medical  
20 oncologist's record before the decision to  
21 give or not give trastuzumab is made.

22 MEMBER LOY: To the earlier

1 comment made if you've got folks receiving  
2 therapy in the face of HER2 negative result,  
3 that's a different problem versus  
4 documentation problem. So, I don't know if  
5 that needs to get resolved or not, but it just  
6 feels like two different levels of severity.

7 I appreciate your reaction to  
8 that.

9 CHAIRMAN LUTZ: Robert?

10 MEMBER MILLER: So without being  
11 repetitive here, I just want to speak to the  
12 values of parsimony with these measures. And,  
13 you know, I guess this one just strikes me as  
14 one that doesn't make sense. That as a  
15 practitioner I just can't see this happening  
16 very often. And it's not a very data-driven  
17 answer, I understand, but you know if I as a  
18 breast oncologist ever did this knowingly, I  
19 mean I can't imagine anything more egregious--  
20 a few things, I suppose. But second, I can't  
21 imagine that I'm going to slide this by too  
22 many payers. And second, and again I know

1 that's not what the measure is all about, but  
2 again just speaking to parsimony, I can think  
3 of a lot of interventions in oncology that  
4 should be never events, but I would just  
5 submit my judgment. I'm not sure this makes  
6 it if we have to pick and choose, we can't put  
7 every measure. It's more opinion than data.

8 CHAIRMAN LUTZ: Karen?

9 MEMBER FIELDS: I have two  
10 questions, one for the sponsor or the steward,  
11 which is again I know you started out and  
12 explained this to us. But of that range, 80  
13 to 100 percent with a 99 percent mean do we  
14 have numbers, we have ideas about what the 80  
15 percent means? Is it five patients or is it  
16 thousands of patients? Because certainly we  
17 should not give a drug -- I mean, I thought  
18 that that gap was very wide and we shouldn't  
19 give a drug to patients that shouldn't be  
20 receiving it, so making it important to  
21 measure. But I agree with Dr. Miller, the  
22 payers are going to capture this so does it

1       need to be a quality measure? Because the  
2       payers, it's such an expensive drug, it's such  
3       a well known indication at the moment that the  
4       payers will do the quality monitoring for us  
5       in a different way. Because nobody's going to  
6       dispense that drug without evidence that  
7       you're HER2 positive.

8                   MS. McNIFF: So the payers in the  
9       room may want to comment, but we certainly  
10      heard different things. That is not what we  
11      heard from payers. We have not heard that  
12      same story, you know that this would never  
13      happen and that the payers would prevent this  
14      from happening. So others may want to comment  
15      on it, because it's not certainly my area.

16                   In terms of what do the bottom  
17      practices who are scoring look like? They do  
18      tend to have small numbers. So I don't have  
19      in front of me what the end for each one of  
20      those sites are, but yes we do start to get  
21      down to the size records or a small number in  
22      some of those cases.

1                   CHAIRMAN LUTZ:   Okay.   Jennifer  
2                   and then Stephen.

3                   MEMBER MALIN:   I think from the  
4                   payer perspective and whether or not, you know  
5                   all payers review this post-hoc or not, which  
6                   I don't think is routinely done because it's  
7                   very expensive to do that kind of review, I  
8                   still think it's a different issue.   I don't  
9                   think we should mix what's sufficient for  
10                  reimbursement with what we consider good  
11                  quality care.  And in this case there may be a  
12                  lot of overlap, but it's not always going to  
13                  be the case.  So I think if we think it's good  
14                  quality care, we should focus on that.

15                  I have to say, you know I'm of two  
16                  minds with this measure.  I share the thoughts  
17                  that Dr. Miller expressed about -- you know,  
18                  I mean basically I mean at least in -- you  
19                  know places I've practiced over the last ten  
20                  years it's routinely obtained in every  
21                  specimen I have.  I don't think I've seen a  
22                  case where it hasn't been there.  So, you know

1 it would be hard to imagine it not being done.

2 On the other hand, you know I  
3 think a number of the measures that we've  
4 looked at so far today also have gaps that are  
5 negligible, if at all and we endorse them.  
6 And I think that this is at least moving with  
7 the science and focusing on more targeted  
8 therapy. And so we'll hopefully encourage,  
9 you know thoughtful consideration of  
10 submitting new measures.

11 MS. McNIFF: And can I just make a  
12 comment in response to Dr. Malin's comment?

13 From the measure developer  
14 perspective another related comment to Dr.  
15 Malin's statement is that we often -- you  
16 know, if you look at the three of these  
17 measures together as a measure of testing and  
18 then appropriate use, the measure developers  
19 are often criticized for only looking at under  
20 use and not providing the complete picture of  
21 whether the overuse of the drug is also -- not  
22 representing the fact that overuse of the drug

1 is also a quality problem.

2 So, you know again if looking at  
3 from the quality perspective you're able to  
4 identify whether the testing was done, and in  
5 this case more importantly documented in the  
6 medical record and then look at the treatment  
7 decision whether under use or overuse is an  
8 issue.

9 CHAIRMAN LUTZ: Stephen, do you  
10 have anything?

11 MEMBER EDGE: Just to Karen's  
12 comment. I think that most payers at the  
13 current time do not collect information on the  
14 result of HER2 testing and therefore would not  
15 be able to actually apply this measure  
16 directly or audit this. They would have to do  
17 a special audit.

18 I know that very early on in the  
19 use of trastuzumab one large payer did audit  
20 200 cases and found that trastuzumab was  
21 administered to something on the order of 12  
22 percent of people to whom it was administered



1 had not had a HER2 test done. Now this was  
2 2005, '06, '07.

3 I actually was working with a  
4 medical director at one of Jennifer's  
5 companies, Wellpoint Ohio Blue Cross/Blue  
6 Shield and relayed that information to him.  
7 Again, this was very early in this time frame.

8 I understand that they implemented  
9 sort of you had to provide certification that  
10 they had a test that was positive or they  
11 wouldn't cover trastuzumab, and that had to be  
12 submitted within a few weeks of starting the  
13 trastuzumab. But I believe they stopped doing  
14 that because they found that comportance was  
15 so very high and it was not worthwhile. But  
16 that result is hearsay.

17 I don't know if you have any  
18 comments about that?

19 MEMBER FIELDS: I've heard of  
20 that.

21 MEMBER EDGE: Yes. But that would  
22 have been four years ago that it was stopped.

1 Because the comportance was so high.

2 CHAIRMAN LUTZ: Can I ask two  
3 questions, both of which might be nitpicky and  
4 you can tell me to move on. But related to  
5 that one, from a pathology perspective I mean  
6 there are sometimes when the initial biopsy  
7 will come back with the pathology, you know 2  
8 plus, recommend FISH. Then you send it for  
9 FISH. And I notice on here I mean when you  
10 say, Robert, you can't imagine anyone would do  
11 this, I actually know about an oncologist who  
12 if you had a 2 plus there was equivocal  
13 literature go ahead and give that medication  
14 unless someone said you'd better send it off  
15 to get the FISH. And so I'm asking, I mean  
16 that's not on here. So where does positive in  
17 the circumstances --

18 MEMBER HAMMOND: Well, there are  
19 clear guidelines that have been published  
20 between ASCO and the College of American  
21 Pathologists saying that exactly under what  
22 circumstances the test is positive, equivocal

1 and so on and what extra tests have to be  
2 done, when FISH has to be done, what the  
3 thresholds are and so on. But there is  
4 considerable confusion about that still in the  
5 literature.

6 I mean the HER2 Panel is  
7 readdressing that issue right now, in fact.

8 CHAIRMAN LUTZ: And the reason I'm  
9 asking unless I'm reading this wrong, this is  
10 just negative --

11 MEMBER HAMMOND: Negative.

12 CHAIRMAN LUTZ: -- negative.

13 MEMBER HAMMOND: Right. Right.

14 Bob can comment but I think the default if  
15 people think the patient really is the  
16 remaining equivocal, clinicians will use their  
17 clinical judgment to define whether or not the  
18 patient should get trastuzumab or not. And  
19 they are not an absolute exclusion from  
20 treatment at all.

21 MEMBER EDGE: That's correct.

22 CHAIRMAN LUTZ: Karen?

1                   Go ahead.

2                   MS. McNIFF:   I'm sorry, can I  
3                   comment?

4                   CHAIRMAN LUTZ:   Yes, please.

5                   MS. McNIFF:   If you look at the  
6                   definitions in the measures, and this follows  
7                   all the measures, we have the exact  
8                   definitions from the ASCO/CAP Guideline to  
9                   provide the users of the measurers to identify  
10                  what is positive, what is negative and what's  
11                  equivocal.  So the instructions here  
12                  specifically lay out positive and negativity  
13                  and equivocal.  We know that that is an issue  
14                  interpreting correctly, so that's provided as  
15                  part of the measure sets.

16                  MEMBER EDGE:   That helps.  Thanks  
17                  you.

18                  MEMBER FIELDS:   Well, I was going  
19                  to say that's the measure that we're going to  
20                  do this afternoon, too.

21                  MEMBER EDGE:   Okay.

22                  MEMBER FIELDS:   So we should have

1 done it in the right order: Did you measure  
2 it, did you measure it correctly, did you give  
3 it when you were supposed to, did you not?

4 But I would say that I would think  
5 that the payers and the way they scrutinize  
6 this varies in different parts of the country.  
7 Because out West where there's a much more  
8 heavily managed care market, you need to send  
9 in data in order to prescribe to the patients  
10 in the managed care setting a lot more than  
11 out here. So there's probably much more  
12 regional variation than we understand about  
13 this the way that payers are approaching the  
14 meds. And I think, yes, it's going to change.  
15 So that's why having just been out in a place  
16 where it was very scrutinized and if we change  
17 more in the country over the next couple of  
18 years, it's going to become a non-important  
19 measure.

20 So, it may be we'll always measure  
21 it and have some data, but it just seems that  
22 -- I just wanted to comment.

1 I also think that no woman that's  
2 HER2 positive or negative should get Herceptin  
3 outside the clinical trials. So the 80, that  
4 range is very disturbing that there's some  
5 places that are giving it to inappropriate  
6 patients.

7 CHAIRMAN LUTZ: Bryan?

8 MEMBER LOY: Just to round out the  
9 payer comments. So from a payer perspective  
10 I would just say I agree with Karen there's a  
11 lot of variation, but I'd also be quick to add  
12 there's a lot of change on the horizon for us  
13 as well. So if I'm thinking about the broad  
14 spectrum of payers, whether they be regional  
15 plans, small plans, larger commercial plans or  
16 some of the government payers, many of those  
17 folks really don't look at preauth at all and  
18 others when they're looking at claims data,  
19 they have no idea what the result is. And  
20 when you start to look at some of the preauth  
21 processes that are out there today, it's more  
22 of an attestation rather than a, you know,

1 show me what your FISH result was.

2           So I think we're in a changing  
3 environment. I think folks are now looking  
4 for mechanisms in a nonintrusive way to get  
5 lab results as part of a record to be able to  
6 have a longitudinal view of the patient.  
7 Because the other thing that we haven't really  
8 talked about is there's a gap, and I think  
9 someone alluded to it earlier, but you know  
10 sometimes these tests are ordered routinely  
11 and then other times when they can't find the  
12 result, they're asking them at a point in  
13 time, retesting perhaps in some instances, and  
14 you may not have had that member on the plan  
15 during that time. So, I think there's a lot  
16 of noise in the system that we need to at  
17 least be thinking about when we contemplate  
18 reliability.

19           MEMBER FIELDS: Right. Right.

20           CHAIRMAN LUTZ: Can I ask a second  
21 potentially nitpicky question and it'll come  
22 up in a couple of the other submissions? If

1 we picture someone who is not in the streaming  
2 or doesn't read this whole thing, just reading  
3 the measure title, I've been taught when I go  
4 to examinations you don't really get as much  
5 play from something not administered because  
6 you're already sunk, you're going to punish  
7 someone for not -- in my head I keep thinking  
8 of the word "appropriately." That medicine is  
9 appropriately not administered because you  
10 have not within -- I don't know, just for  
11 someone who is not sophisticated and doesn't  
12 know exactly what's right or wrong if they're  
13 coding something and not administered, oh they  
14 didn't administrated, it should be  
15 appropriately not administered or the patient  
16 -- or something where it's more of a positive  
17 statement. Because the measure should be  
18 positive and then you can fall under it versus  
19 something where you are correctly not doing  
20 something. I don't know. I'm sorry, it may  
21 be nitpicky, but it reads confusing to me.

22 MS. McNIFF: But we are happy to



1 change the title to be more clear. And the  
2 not is -- because we report it both ways --

3 CHAIRMAN LUTZ: Right.

4 MS. McNIFF: -- with the different  
5 directionality, so one says one thing, another  
6 one says not. But to stand alone absolutely--

7 CHAIRMAN LUTZ: I don't know if  
8 anyone else agrees, but I read it back and  
9 also see where somebody will look at it and go  
10 "Well, they didn't do it. They didn't know.  
11 It's inappropriate or something." I don't  
12 know what the word is, but--

13 MEMBER PFISTER: Steve mentioned  
14 that they're actually doing clinical trials  
15 now where they're giving Herceptin to this  
16 population. And I thought you said that  
17 there's a clinical trial exclusion, but I  
18 didn't clearly see it in this document. So is  
19 there a clinical trial exclusion?

20 MS. McNIFF: It's in the  
21 numerator. So if you look at the numerator  
22 details if trastuzumab is administrated

1 according to a clinical trial--

2 MEMBER PFISTER: Okay. All right.  
3 Understand. Understood.

4 And then the other thing is that  
5 with regard to the performance gap, and I hear  
6 what you're saying about QOPI being sort of  
7 self-selecting and so forth, but you know  
8 what's the actual -- if you have a mean of 99  
9 percent, the range is 80, you basically have  
10 one practice that was 80 percent. And so I  
11 would suspect that probably the distribution  
12 of practices is, I would guess, virtually a  
13 100 percent all of them. You have one  
14 practice, too, that was an outlier. So I  
15 guess if you could give us some granularity on  
16 that in terms of like how many practices  
17 weren't already totally compliant with this  
18 measure?

19 MS. McNIFF: I mean, I'm not able  
20 to give that to you right now. Again, when we  
21 went back and looked at the numbers, again if  
22 you look at the scatter plot they're mostly

1       toward the top, there are a few practices that  
2       are down more towards the 88 percent. You  
3       know, we acknowledge that the concordance  
4       within the QOPI practices is high.

5                   MEMBER PFISTER: If you compare  
6       and contrast like the appropriate nonuse  
7       versus the appropriate use? Like there's a  
8       bit more described for the appropriate use  
9       measure than there was for the appropriate  
10      nonuse measure. Is that accurate?

11                   MS. McNIFF: I had to catch up  
12      with you, but yes, that's right.

13                   MEMBER PFISTER: See, I think that  
14      the -- the comment made earlier about in a lot  
15      of ways the bundling of this in terms of like  
16      do we measure it the right way would have been  
17      a more systematic way to do this. And if I  
18      were to look at these three measures, I would  
19      say that that, firstly, that we measure it the  
20      right way. And actually the developer, while  
21      it's laid out very nicely in both 1857 and  
22      1858, that if we measure it the right way --

1 you know if we're doing that well, I would  
2 think that the nonuse would follow --

3 CHAIRMAN LUTZ: I guess the  
4 question is -- I mean are we breaking protocol  
5 too much if we go in the order we keep  
6 suggesting and do -- we're only at 11:50 in  
7 the morning. And should we do 1855 and then  
8 go back to 1858 and 1857? Is the developer  
9 okay with that? Because it sounds like --

10 MS. McNIFF: Absolutely. It makes  
11 good sense.

12 CHAIRMAN LUTZ: It might make more  
13 sense. And we can go on with this one and  
14 have the discussion, it should be easier. If  
15 we do that, if we could, maybe we should just  
16 do -- 1855 is the one we're talking about,  
17 right? Yes. Can we just do 1855 and go from  
18 there? Maybe we can just do it now, because  
19 I think we're saying this would come third in  
20 order. Is that going to mess you up? Is that  
21 all right? Let's do that. Because then we'll  
22 go in the order. We're do 1855 and then 1858

1 and then 1857 and then we'll have everyone --  
2 I'm sorry, 1878. So shall we start from 55 or  
3 78?

4 MS. McNIFF: I'm not sure whether  
5 the CAP -- I mean the CAP -- we're not the  
6 stewards for or the owners of 1855, so that's  
7 a little bit more of a --

8 CHAIRMAN LUTZ: So should we do  
9 then 1878 then is the one? We can do that?  
10 Can you do that one?

11 MEMBER CHOTTINER: 1878 is the  
12 percentage of patients with invasive breast  
13 cancer who receive HER2 testing. The  
14 numerator is HER2 testing performed and the  
15 denominator is all adult women with invasive  
16 breast cancer. The only exclusions are  
17 history of metastatic disease or multiple  
18 primaries.

19 This is a process measure.

20 The level of analysis is  
21 clinician, group practice, clinician team.

22 The importance to measure, I know

1 this is a large group of women and the testing  
2 is both prognostic and predictive in that it  
3 helps to determine the prognoses and predicts  
4 the response to trastuzumab.

5 The evidence level is high. The  
6 scientific acceptability I think we thought  
7 was high during the work group. It's a new  
8 measure, so the only performance gap we have  
9 demonstrated again is from the QOPI data with  
10 the same caveats that these were high  
11 performing groups and that although the  
12 performance measures were high, there's a  
13 concern about generally.

14 The useability and feasibility we  
15 thought were moderate to high.

16 The questions that came up during  
17 the work group in addition to the performance  
18 gap had to do with the statement that we do  
19 this testing for all women with invasive  
20 breast cancers and the only exclusion  
21 pathologically is too little tissue to test.  
22 And I think the issue is that the clinical

1 trials that have looked at trastuzumab have  
2 been the adjuvant setting and have, for the  
3 most part, been for women who nod negative or  
4 women who have two nods that are more than one  
5 centimeter. But you can correct me if I'm  
6 wrong, but I think that MD Anderson did some  
7 retrospective studies and we do that for  
8 tumors between .6 and 1 centimeters there is  
9 some prognostic value to the testing and that  
10 these patients that can be considered for  
11 trastuzumab. But there are really no data for  
12 smaller tumors.

13 And I think that's the biggest  
14 issue we had with that: Should we really be  
15 doing HER2 testing in women with DCIS with  
16 microinvasion or local DCIS or very small  
17 tumors? And my personal experience in the  
18 community hospital where I worked before I  
19 went to U of M is that this was something that  
20 we took up our pathologist because it does add  
21 to the expense of reading these and it really  
22 doesn't make much sense to be doing the HER2

1 testing on these very small tumors if it's not  
2 going to impact treatment outside of a  
3 clinical trial.

4 I do know that there are trials  
5 now looking at HER2 testing in DCIS and we  
6 participated in those and just called our  
7 pathologist and had done on a reflex basis.

8 CHAIRMAN LUTZ: Were there any  
9 comments from the work group that discussed --  
10 Robert?

11 MEMBER MILLER: So I generally  
12 agree with what Elaine said. But I think --  
13 I'm not sure with how this relates to what  
14 we're voting on, but I'll just say that there  
15 are the same MD Anderson series and others I  
16 believe looking at even smaller tumors. The  
17 T1a subgroup did seem to show that there was  
18 important prognostic value to HER2, so  
19 particularly in the ER positive group. So the  
20 HER2 positive T1a tumors or less than 5  
21 millimeters clearly did much less well. We  
22 don't have the predictive information in that



1 group because the randomized trials almost all  
2 used patients who were centimeter or larger or  
3 ne positive. But I think that, again, I'm not  
4 sure how this goes back to a measure and  
5 whether we should require this or not.

6 On the call, I was the one that  
7 brought it up saying that I was just  
8 questioning whether we wanted to be sure if  
9 we're holding people's feet to the fire to do  
10 this test, is it relevant? And maybe that was  
11 more rhetorical or not, so I can give both  
12 sides of the street. But I would say that I'm  
13 not even sure the that T1a tumors are  
14 necessarily excluded from the discussion.

15 MEMBER HAMMOND: Based on the  
16 information that's coming out in the guideline  
17 panel that's now redoing the HER2 guideline  
18 again, it appears that there's a lot of  
19 heterogeneity in breast cancer. That  
20 metastatic disease has to be retested.

21 So from a perspective and also the  
22 data that Robert just brought up, I think from

1 a perspective of looking at it for the benefit  
2 of patients in the long run it's better for  
3 patients to have this data available to them  
4 and for their physicians to have that data  
5 available to them when they recur, if they do,  
6 for the purposes of prognosis and so on.

7 And to make exclusions into this  
8 measure will make it more difficult to -- or  
9 it will encourage people not to do it maybe in  
10 situations where they should. So, I would  
11 argue against having that exclusion in the  
12 measure.

13 CHAIRMAN LUTZ: Elaine?

14 MEMBER CHOTTINER: I think the  
15 issue I have coming from 20 years in a  
16 community hospital originally was that for one  
17 thing, you have to take costs into  
18 consideration. And I think that this  
19 particular Committee can't really be  
20 proactive. I mean, I think that we need to  
21 look at the data. And if you look at the NCCN  
22 guidelines, they're very specific about the

1       indications for treatment.  And although I  
2       agree that I have treated patients with two  
3       millimeter tumors with Herceptin, but on a  
4       case-by-case basis.  And I think to  
5       incorporate it into a generalized priority  
6       measure at this point in time is premature.

7                   MS. FRANKLIN:  I just wanted to  
8       say that if the evidence changes for this  
9       measure after we've endorsed, we can also do  
10      a review of the measure at that time.

11                   CHAIRMAN LUTZ:  Does anyone else  
12      have a statement on that topic or other?  
13      Bryan?

14                   MEMBER LOY:  A couple of things.  
15      I guess I'm a little bit perplexed about the  
16      lack of having sort of a time element to this  
17      measure.  I think I heard you say  
18      heterogeneity issue and the proximity --

19                   MEMBER HAMMOND:  Well, yes.

20                   MEMBER LOY:  -- to treatment  
21      issue.  I mean if you've got three year old  
22      data, you meet the measure you know because

1 you got it routinely in an early stage and  
2 then it recurred. And that's a little more  
3 troublesome.

4 And then I'm also just wondering  
5 if you all spent any time talking about the  
6 work we've talked about, those folks that  
7 perhaps wouldn't be candidates for trastuzumab  
8 because of cardiac function, for example?

9 MS. KHAN: We do talk about that  
10 in the actual --

11 MEMBER LOY: I'm sorry?

12 MS. KHAN: -- treatment.

13 MEMBER LOY: Okay. But I'm just  
14 saying to myself, you know if it's -- again  
15 from the payer perspective prognostic, okay so  
16 I'm getting news but if it's actionable news,  
17 what's the clinical utility would be the next  
18 set of questions. And if there's an answer,  
19 would love to hear it. But if it's predicted  
20 but predicted only for one regime that would  
21 excluded, that would be important.

22 MEMBER HAMMOND: I don't know what

1 the data's going to show in the long run, but  
2 I think it has differential significance in ER  
3 positive versus ER negative patients.

4 We also do this test  
5 retrospectively on patients. So putting a time  
6 exclusion on it would not be a good idea  
7 because sometimes you go back and measure  
8 their tumor from a long time ago so we don't  
9 want to put a time exclusion on it.

10 MEMBER LOY: Then I would ask how  
11 reliable is that information --

12 MEMBER HAMMOND: Very reliable.

13 MEMBER LOY: -- from a tumor that  
14 was three years old that has gone through  
15 chemotherapy, do we have good data that says  
16 that a recurrent disease that was even HER2  
17 negative three years ago is now the same and  
18 vice versa in the face of chemotherapy. But  
19 we already got a heterogeneity issue, and now  
20 we're going to introduce a chemotherapy issue.  
21 That's --

22 MEMBER HAMMOND: Well people are

1 using that information. I don't if that --  
2 that doesn't help you, I know. But in fact  
3 the testing does get done, mostly in people  
4 who never had it done in the first place is  
5 the problem.

6 So doing it, say if we're  
7 recommending in the new guidelines that  
8 metastatic disease be tested specifically, and  
9 that would argue that it should be proximate  
10 to the treatment. So I guess I agree with  
11 you.

12 MEMBER MALIN: I would just say, I  
13 think that is an evolving area. I mean, that  
14 actually may be pushing the envelop. I mean,  
15 and there's been some recent studies, you know  
16 smaller studies that have suggested that  
17 there's maybe more tumor heterogeneity than we  
18 thought previously. But until now the  
19 standard of care has been that when someone  
20 recurs, you use their original pathologic  
21 information and you don't go in and rebiopsy.  
22 And that's what would be required in a

1 situation is to rebiopsy someone to get newer  
2 tissue information.

3 MEMBER HAMMOND: Well, I think  
4 that's under active consideration in the redo  
5 the HER2 guideline, but we don't have the data  
6 yet and it could be changed when the measure  
7 changed.

8 CHAIRMAN LUTZ: David, did you  
9 have anything?

10 MEMBER MALIN: And I guess the  
11 other thing is I don't know if there was some  
12 concern that we would be over testing HER2,  
13 but I mean one would have to think about it in  
14 terms of a cost standpoint given that probably  
15 most people need the test, it's probably less  
16 expensive that it's just a routine then to  
17 have to request it on a case-by-case basis.  
18 And so I think the system has moved to it  
19 being routine like ER and PR positive.

20 MEMBER PFISTER: Okay. I would be  
21 cautious regarding the -- unless it's very  
22 clear that it should be tested, and that's

1 going to guide therapy. But clearly there's  
2 a harm to boxes that are done and bad things  
3 happen. So if it's something that's clearly  
4 part of the state-of-the-art, that's one  
5 thing. But some of it is going to leverage  
6 behaviors to do biopsies that aren't  
7 necessarily that established, I think would be  
8 I think a potential downside of leveraging  
9 behavior that way.

10 CHAIRMAN LUTZ: Well, this may be  
11 a little bit down the rabbit hole, but  
12 actually I think is evolved as the new  
13 standard of care in breast cancer that  
14 biopsies should be done for metastatic sites.  
15 I mean, I know it's not published in the CAP  
16 guidelines yet, but I think practically  
17 speaking that's what everyone is saying ought  
18 to be done now. And, you know there are  
19 certain sites that I've found don't lend  
20 themselves well to biopsies. But I think  
21 we've just seen practically I think the  
22 discordance rate is something like 10 or 12



1 percent with HER2, and I forgot what it is for  
2 ER. So increasingly at all of our tumor  
3 boards at my institution that's what it is.

4 So, again, maybe not relevant to  
5 this, but just clarify.

6 CHAIRMAN LUTZ: Bryan?

7 MEMBER LOY: I just want to go  
8 back and you're on the end of the spectrum  
9 that I think I appreciate what you're saying,  
10 but I also want to go back to the comment to  
11 the comment that was made earlier about the  
12 smaller lesions. I'm wondering if perhaps we  
13 might be promoting overtesting and still in  
14 that arena that we talked about. But I'm  
15 hearing the argument of don't exclude that  
16 because you might need it later and I'm  
17 thinking feels like we're asking for it to be  
18 both ways.

19 So, get the information now or  
20 skip later in a world where we don't quite yet  
21 know.

22 MEMBER MALIN: So I think that, I

1 mean at least in my experience this is usually  
2 obtained even on the core biopsy. It just done  
3 routinely up front before you know what the  
4 size of the tumor is. So, I mean I think the  
5 cost savings for not doing it for those few  
6 people where maybe you don't need it would be  
7 more than offset by the administrative burden  
8 of having to say "Oh, well what size is this  
9 tumor? Do we need to get it or not?"

10           And then secondarily, I think you  
11 know, I mean obviously this isn't the forum  
12 but I don't think the decision about whether  
13 or not to rebiopsy someone should be based on  
14 whether or not just their markers have  
15 changed, right, a ten percent change in  
16 marker? Because in metastatic setting you  
17 basically assess response within two months of  
18 treatment. So, you know you'd have to show  
19 that having to wait to assess that response  
20 results in a worse outcome than treating --  
21 you know treating empirically and assessing  
22 outcome with potentially inaccurate marker

1 data on ten percent of the population  
2 sometimes results in a different outcome than  
3 re-biopsying and narrowing your chance of  
4 having a response a little bit better.

5 CHAIRMAN LUTZ: Karen?

6 MEMBER FIELDS: Just to comment on  
7 treatment of metastatic disease, though. If  
8 you're usually giving combination chemotherapy  
9 and not Herceptin alone so if you didn't  
10 understand your HER2 status, you might be  
11 giving a drug that didn't need to be given and  
12 not being able to understand which that drug  
13 the patient was responding to.

14 So, the tendency tends to be HER2  
15 ne positive patients stay on Herceptin for  
16 life adding a variety of different synergistic  
17 drugs, and that may not be even most rational  
18 use of our health care dollars.

19 But I would just echo that I think  
20 trying to interpret what the next set of  
21 recommendations today is make it very  
22 difficult for us to proceed with any quality

1 guidelines.

2 CHAIRMAN LUTZ: Is there anybody  
3 on the line with anything to offer? Are you  
4 still there, Rocco? I didn't forget about  
5 you. Heidi? Larry?

6 DR. HASSETT: Can you hear me?

7 CHAIRMAN LUTZ: Yes.

8 DR. HASSETT: My name is Michael  
9 Hassett I'm with ASCO and I'm a medical  
10 oncologist, and I just make a couple of  
11 comments about this measure.

12 I think it's an important  
13 discussion that's been going. And I would say  
14 that regard to the DCIS and the metastatic  
15 occurrence setting at least the way I read the  
16 measure I don't view this as part of this  
17 particular measure because it was what was  
18 done in invasive breast cancer. And I would  
19 agree there's debate about whether to test  
20 DCIS cases or microinvasion cases for HER2  
21 positivity, but this measure is really  
22 focusing on the invasive breast cancer cases

1 and the denominator describes that.

2           So the small T1a cancers, the  
3           invasive cancers, I feel that the information  
4           is potentially in type of forms of treatment  
5           while I'm not commonly giving trastuzumab-  
6           based adjuvant therapy to patients with 2 or  
7           3 millimeter cancers, it does have some  
8           prognostic import for those patients. And I do  
9           consider that information when I figured out  
10          their risk of occurrence and a potential  
11          magnitude of benefit from anti-estrogen  
12          therapy as well.

13                 I also think just from a  
14                 generalizability perspective, interpretability  
15                 perspective I think it might be more confusing  
16                 to have a measure that is excluding a small  
17                 focus of cancer cells and there are a number  
18                 of nonrandomized trials that are suggesting  
19                 the potential for benefit for HER2 directed  
20                 therapy in the T1a/T1b subset of patients.

21                 So, I would argue strongly in  
22                 favor of having the measure apply to all

1       invasive cancers and not excluding the small  
2       cancers.

3                   CHAIRMAN LUTZ:   Elizabeth?

4                   MEMBER HAMMOND:   The current  
5       guideline doesn't exclude anybody from  
6       treatment. It says it should be a routine test  
7       just like just ER/NPR. And that's the current  
8       guidelines. That's not future. That's not  
9       going to change in the next iteration either.

10                  MEMBER ALVARNAS:   This is Joe  
11       Alvarnas. I would like to add to that  
12       sentiment as well. I think we have to be  
13       careful about exclusions and we can always  
14       base upon data and we re-evaluate this at the  
15       time of its renewal later.

16                  CHAIRMAN LUTZ:   Okay. Thank you.

17                         So, is there anything that --

18                  MEMBER DONOVAN:   That's my  
19       agreement as well.

20                         This is Heidi.

21                  CHAIRMAN LUTZ:   Oh, thanks, Heidi.

22                         Does anybody have anything else

1 they want to discuss or go on to further  
2 discussion before we vote, or are we good to  
3 vote on this one? All right. We'll vote.

4 So just to be clear as we're  
5 making sure of the voting for the phones.  
6 Heidi, you're there.

7 I didn't not hear Rocco, did you  
8 answer?

9 MEMBER RICCIARDI: I am still  
10 here.

11 CHAIRMAN LUTZ: Okay. So we got  
12 Rocco and Heidi are left for voting.

13 Larry Marks I think is not on  
14 anymore. And Dr. Laver is gone. Dr. Alvarnas  
15 has joined us. Good.

16 MEMBER ALVARNAS: Are we sending  
17 in votes via the gmail thing to Lindsey?

18 MS. KHAN: Okay. All right. So  
19 we're going to --

20 MEMBER ALVARNAS: I'm sorry, I  
21 apologize.

22 CHAIRMAN LUTZ: She said yes. She

1 said you can channel your votes straight  
2 through her.

3 MEMBER ALVARNAS: Okay. Thank  
4 you.

5 MS. KHAN: So voting on 1a impact.  
6 High, moderate and low or insufficient  
7 evidence.

8 So you have 13 for high, three  
9 moderate and zero for low and zero for  
10 insufficient.

11 Voting on 1b performance gap.  
12 High, moderate, low or insufficient evidence.

13 You have four high, seven  
14 moderate, four low and one insufficient  
15 evidence.

16 Looking at the evidence, yes, no  
17 or insufficient.

18 So you have 15 yes and one no.

19 And going on to reliability 2a.  
20 High, moderate, low or insufficient evidence.

21 I think we're missing one person.

22 MEMBER DONOVAN: I'm going to put



1 my phone on mute when we're not talking.

2 MS. KHAN: So that's 10 high and  
3 six moderate, zero low, zero insufficient.

4 Looking at 2b validity. High,  
5 moderate, low or insufficient evidence.

6 So nine high, six moderate, one  
7 low and zero insufficient.

8 Looking at usability, high,  
9 moderate, low, insufficient.

10 Seven high, eight moderate and one  
11 low, zero insufficient.

12 Feasibility, high, moderate, low  
13 or insufficient.

14 Can we do it one more time?

15 Ten high, five moderate, one low  
16 and zero insufficient.0

17 And overall suitability for the  
18 endorsement, does the measure meet NQF  
19 criteria for endorsement, yes or no.

20 So 15 yes and one no, the measure  
21 will pass.

22 CHAIRMAN LUTZ: All right. So

1 just to be clear, since we're going out of  
2 order and some of the folks on the phone might  
3 not have heard all that, so we started with  
4 1878, which was measure HER2/ne. We're going  
5 next to 1858 which is appropriately treat  
6 positive, and then we'll go to 1857 which is  
7 appropriately not treat negative.

8 So next will be 1858 and we'll let  
9 the developer tell us what we need to know and  
10 then I think David is going to be the one to  
11 describe the Subcommittee's thoughts.

12 MS. McNIFF: Yes, I would be happy  
13 to.

14 All of what I said before applies  
15 to this one, too. There is a change that was  
16 made that was an error that was identified in  
17 the work group call. And that is in the  
18 finding of the trastuzumab administration  
19 within one year. That change has been  
20 reflected. It's within one year, 12 months of  
21 diagnosis.

22 CHAIRMAN LUTZ: David?

1                   MEMBER PFISTER: I was not  
2 actually on the subgroup call, so those that  
3 were certainly feel free to chime in.

4                   I think that, again, the  
5 discussion of this overall as a measure I  
6 think is probably so as to not to sort of  
7 repeat a lot of what has already been said, I  
8 think is perhaps best done in the context of  
9 its relationship to the prior measure. So I  
10 think that one of the issues that came up on  
11 the importance, the available data is  
12 dissimilar, the performance gap issue is  
13 similarly -- at least basic data provided it's  
14 smallish, but not as small as it is for 1857

15                   Kristen clarified the issue that  
16 came up about the timing of the Herceptin.

17                   It also did come up in the call  
18 that, you know given the potential cardiac  
19 morbidity of the Herceptin that the exclusions  
20 are not super explicit about that. You know,  
21 my sense is it's probably purposely made that  
22 way because to overly explicit is probably

1 going to be ultimately overly explicit. And,  
2 you know it gets into the realm of judgment.

3 I think, again comparing the votes  
4 for the suitability of the measure for 1857  
5 versus 1858, at least on the all there seemed  
6 to be that the preliminary assessment for the  
7 suitability for the most part seemed to be  
8 uniformly yes as opposed to the prior it was  
9 uniformly or seemed to be weighted the exact  
10 opposite direction.

11 CHAIRMAN LUTZ: Thank you.

12 Is there anyone on this call that  
13 wants to assure the facts of the Subcommittee?

14 Steve?

15 MEMBER EDGE: I note that the  
16 exclusions include the contradiction or other  
17 clinical exclusions. A consideration the NQF  
18 might want to have a consideration of making  
19 these analogous to the American College of  
20 Surgeons measures where those patients were  
21 not excluded from the denominator, but rather  
22 were considered concordant with the measure if

1       there was appropriate documentation that they  
2       should not receive appropriate treatment.

3               I think it would be confusing to  
4       users to be having to figure out who to  
5       exclude from their denominator rather than  
6       taking all people who have HER2 positive  
7       cancer who meet these criteria and then  
8       providing a reasonable either they got  
9       treatment or didn't get treatment rather than  
10       allowing the provider to choose who to report  
11       as a member of the measured group of patients.  
12       I think it'll be easier for the user. I think  
13       it will be more open and transparent. And I  
14       think it will allow granularity of the  
15       collection of data as to why that person was  
16       excluded. And it will allow them to have a  
17       uniform set of way of applying these measures.

18               CHAIRMAN LUTZ:   Yes?

19               MS. McNIFF:   Can I respond to  
20       that?

21               CHAIRMAN LUTZ:   Yes.

22               MS. McNIFF:   So that is actually

1 the way; it's analytical exclusion. The data  
2 are collected on every patient so that  
3 exclusion happens in the analytic of the  
4 measure. You know, we will collect this on  
5 every patient and the provider has to actually  
6 submit to us if there's a contraindication  
7 and it's pulled out analytically. And you can  
8 actually look in the -- you know, by that  
9 methodology you're actually able to look and  
10 see how often you're reporting the exclusion  
11 and have that date as well. But we absolutely  
12 do not -- I mean, I agree with you, Dr. Edge,  
13 that is not the approach that we take.

14 MEMBER EDGE: I think the NQF  
15 ought to look at this carefully and make this  
16 a homogeneous way of doing this rather than  
17 having us to go back and forth between those  
18 two different mechanisms for reporting. And I  
19 would argue for the American College of  
20 Surgeons' mechanism rather than the other, but  
21 I would recommend the NQF look carefully at  
22 that question when these are actually

1 operational.

2 MS. McNIFF: Just in response, I  
3 think that's actually a pretty significant  
4 change. And a lot of the changes I think we  
5 can bring back fairly confidently saying that  
6 the ASCO Committee would be happy make  
7 reporting a contra -- rereport clinical trial  
8 as a yes and for the numerator if the  
9 treatment was not done, by reporting a  
10 contraindication as a yes that the treatment  
11 was given is a conceptually major change. And  
12 so that one we would definitely need to do  
13 some real thought and work. ASCO does not  
14 specify that way.

15 CHAIRMAN LUTZ: Jennifer?

16 MEMBER MALIN: I mean, I think is  
17 value to harmonizing the approach so that  
18 exclusions are either handled in the numerator  
19 or the denominator. I think, you know  
20 personally as someone who has spent most of my  
21 career working on these kinds of things, I  
22 think it's much cleaner to do it through the

1 denominator because in the numerator it's open  
2 to a lot more interpretation. Essentially you  
3 end up having to count any notation that  
4 treatment was considered or recommended as  
5 passing the indicator, whereas excluding it  
6 from the denominator usually the criteria are  
7 much stricter.

8 MEMBER EDGE: If somebody is  
9 excluded because the doctor says they have a  
10 low ejection fraction and I'm not going to  
11 give them trastuzumab, how is that different  
12 whether they're excluded from the denominator  
13 or the numerator? Why is it more strict if  
14 they're excluded from the denominator? I'm  
15 sorry, I don't understand that one.

16 MEMBER MALIN: Because generally  
17 speaking, I mean it may not be operationalized  
18 this way in the American College of Surgeons  
19 data platform, but usually when the numerator  
20 statement says "Treatment was considered" or  
21 "Treatment was recommended", any notation in  
22 the charts that treatment was discussed,



1 recommended without any indication provided as  
2 to why it wasn't given is usually considered  
3 sufficient to pass the indicator.

4 MEMBER EDGE: But wouldn't that be  
5 just as equally sufficient to pass the  
6 exclusion from the denominator? I mean, the  
7 College of Surgeons could switch around and  
8 analyze it the other way as well. But if NQF  
9 thinks that that's a better way to do. But,  
10 I'm sorry, but I don't understand why the  
11 doctor is saying that it's excluded because  
12 the patient is too sick to get the therapy is  
13 any different whether the doctor excludes it  
14 and we choose to put it in the numerator or  
15 the doctor excludes it and we choose to do it  
16 from the denominator.

17 MEMBER MALIN: I guess it wouldn't  
18 be different -- well, the ratios can appear  
19 different.

20 MEMBER EDGE: That's true,  
21 reportedly different.

22 MEMBER MALIN: But the numerator

1 statement I think is different if you say  
2 receive treatment unless the following, or  
3 have documentation that there was a  
4 contraindication, any of the specific  
5 exclusions. But if the numerator statement  
6 says "Consider treatment" or "Recommended  
7 treatment," that's much broader than received  
8 unless, which is the way essentially this --

9 MEMBER EDGE: The only value with  
10 putting this is in the numerator is that it  
11 allows you to see for an individual provider,  
12 institution, however you tend to attribute  
13 this whether that organization has a problem  
14 in that a high fraction of their patients are  
15 refusing therapy or they're choosing not to  
16 give therapy. So if an institution has 30 or  
17 40 percent of their patients -- and Mr.  
18 Stewart alluded to this in his presentation.  
19 If that institution has a very high proportion  
20 of patients who are choosing not to get  
21 therapy, then that institution has got a  
22 quality problem in how they're presenting --

1 or a potential quality problem in how they're  
2 presenting that information to patients.

3 And an exclusion from the  
4 denominator we lose the potential to identify  
5 that quality problem. And that's one of the  
6 reasons why I think this is -- I actually  
7 don't agree with you that there's any  
8 different where you exclude them in terms of  
9 the indications on how it's documented. And  
10 I think there's added granularity and added  
11 quality evaluation and added opportunity for  
12 quality improvement by including in the  
13 numerator and separately reporting those  
14 patients who are not treated and considered  
15 excluded based on medical indication or  
16 patient choice.

17 CHAIRMAN LUTZ: So you are saying  
18 that this one is, as per the ASC --

19 MEMBER EDGE: I would recommend  
20 that the NQF look at this carefully, and it  
21 probably goes beyond our ability to make the  
22 answer today. But I would suggest that when

1 operationalizing this through NQF and through  
2 CMS that this course should be more carefully  
3 reviewed. I think it's a really important  
4 question. I don't think we came prepared to  
5 address the question today. And I don't think  
6 we're fully prepared to answer the question  
7 today. I think you've got some concept from  
8 Dr. Malin and myself and others. But I think  
9 this is a really important one that the NQF  
10 may want to address.

11 MS. McNIFF: I was just going to  
12 say, so I just wanted to clarify that this  
13 particular piece of the conversation is  
14 regarding recommendations as to what you would  
15 like to see in the future. And we're looking  
16 at the measure in front of us. Is that a  
17 recommendation for changing --

18 MEMBER EDGE: I personally would  
19 recommend my recommendation --

20 MS. McNIFF: Right.

21 MEMBER EDGE: -- and I suspect it  
22 will be taken today for this approval. But my

1 recommendation would be that they be switched  
2 and I would recommend that the NQF and with  
3 this measure have those cases excluded from  
4 the numerator and not from the denominator.

5 I would recommend that we turn  
6 this back to the developer with that  
7 recommendation.

8 MS. McNIFF: Okay.

9 MEMBER EDGE: But after the fact,  
10 I think this is something the NQF should look  
11 at very carefully before these kind of  
12 measures are implemented.

13 MS. McNIFF: Karen, did you have  
14 anything?

15 MS. PACE: So, yes. Exclusions is  
16 a big topic of interest and it is something  
17 that our Consensus Standards Approval  
18 Committee is going to be looking at a little  
19 more closely.

20 Currently our guidance  
21 specifically about the issue of patient  
22 preference or patient declining is that the

1       measure if that's include in a measure, it  
2       should be transparent. So the ways that that  
3       could be transparent is exactly as you've  
4       talked about: Is a numerator category. The  
5       other way is that you have to report both  
6       rates -- both with and without those  
7       exclusions because of the very reason you're  
8       talking about. If one provider has a higher  
9       rate of patients declining in treatment, you  
10      know what's going on there?

11                 So, it is certainly a broader  
12      issue than this project or these particular  
13      measures.

14                 In terms of the harmonization, I  
15      think that's something that you'll be talking  
16      about later if individual measures on their  
17      own merits meets the criteria, then you know  
18      if these are big issues in terms of related  
19      measures, you know how they would define the  
20      denominator and exclusion populations. That's  
21      something that the Steering Committee can  
22      certainly weigh in terms of when they're

1 addressing related and competing measures.

2 CHAIRMAN LUTZ: Yes, Karen?

3 MEMBER FIELDS: So to the  
4 developer. At the beginning you summarized  
5 what changes you made in response to our  
6 previous discussion. And the only one that I  
7 heard was you changed it from a four month  
8 window to a year window. You still didn't go  
9 through and do our recommendations about more  
10 clarity in cardiac exclusions, correct?

11 MS. McNIFF: So I would ask Dr.  
12 Hassett to comment on that.

13 DR. HASSETT: I think one of the  
14 challenges with -- and you guys have been  
15 having this conversation, is how to rank  
16 corporate exclusions into the mix for these  
17 folks.

18 The vast majority of -- this  
19 measure is targeting folks who receive  
20 chemotherapy for breast cancer, and the vast  
21 majority of these folks will have already had  
22 preexisting cardiac evaluation. So, at least

1 from my perspective, the probability of that  
2 cardiac evaluation in addition to including  
3 the characteristic of chemotherapy receive  
4 cardiac evaluation would be very unlikely to  
5 leave somebody out of this because they  
6 wouldn't have gotten in the measure in the  
7 first place, because they probably would have  
8 gotten chemotherapy.

9 MS. McNIFF: And to add to that,  
10 there is a clinical exclusion option, right?  
11 So that goes --

12 DR. HASSETT: Oh, yes. Yes. And,  
13 of course, yes, if there is a clinical  
14 comorbid condition option.

15 MS. McNIFF: Right. It's already  
16 there.

17 DR. HASSETT: So we felt that with  
18 those elements that the concern about getting  
19 folks into this measure who shouldn't be there  
20 for cardiac issues were addressed.

21 MEMBER EDGE: One quick comment,  
22 Kristen, is that I would suggest you also



1 change the title on this measure just like we  
2 did for the other one to reflect that this is  
3 trastuzumab administered with adjuvant  
4 chemotherapy for a patient with AJCC staging  
5 and for clarity for the user. That this  
6 measure isn't intended to be addressing people  
7 with metastatic disease. The fact that they  
8 have AJCC stage I to III cancer, the stage  
9 doesn't change when they have metastatic  
10 disease, so that does not clarify that. I  
11 would add the same thing for consistency and  
12 clarity.

13 MS. McNIFF: Yes. And I meant my  
14 opening comments to reflect both of the  
15 measures. We will absolutely do that, make  
16 that change.

17 And the page, Dr. Fields, is 9 --  
18 oh, but I'm looking at a different document.  
19 It's 2a1.8.

20 MEMBER FIELDS: For those of us in  
21 the room that have prescribed it, are the  
22 label indications do they say cardiac

1 exclusions? I don't remember. Just I mean,  
2 I think there's some very clear cut ones where  
3 we don't worry about necessarily remeasuring  
4 the ejection fraction. If somebody had  
5 congestive heart failure or some -- you know,  
6 a history of those things, those are  
7 contraindications that are pretty well  
8 standard. And so I still am disturbed that we  
9 don't enumerate that a little bit in the  
10 exclusion criteria rather than the general  
11 statement. But maybe just changing the title  
12 and making sure everybody understands that the  
13 quality measure isn't punitive, it's more  
14 meant to just be a quality measure will help  
15 that problem.

16 MEMBER PFISTER: How do the  
17 measures here handle when, you know sometimes  
18 I see these things come through where, you  
19 know have it tested at one place, it's  
20 registered HER2 negative, it's tested in  
21 another place it's another place it's HER2  
22 positive. And how does one trump the other or

1 is basically that, you know any positive will  
2 count as a decision to justify giving it and  
3 any negative will be justification to the  
4 other measure?

5 CHAIRMAN LUTZ: I think, isn't  
6 that in the directions we printed out when I  
7 asked a similar question for the other one?  
8 That's in the directions for use the following  
9 definitions to determine status.

10 MS. McNIFF: Actually in the  
11 instructions, Bob, information from the most  
12 recent report.

13 MEMBER PFISTER: So it's going to  
14 be whatever the most recent report is?

15 CHAIRMAN LUTZ: Robert?

16 MEMBER MILLER: I don't know if  
17 it's relevant to the discussion, but the  
18 answer to Karen's question, the label does not  
19 list any contraindications but cardiac is a  
20 boxed warning, it's listed under warnings. So  
21 it's technically not contraindication.

22 MEMBER PFISTER: Is there data

1 that suggests the most recent report is the  
2 most accurate report, or is that just you did  
3 it for a feasibility measurement?

4 MS. McNIFF: This is a feasibility  
5 issue. I mean others in the room many want  
6 to comment data about which report. But it  
7 was done for feasibility instruction.

8 MEMBER HAMMOND: I don't think  
9 there's any data about that.

10 CHAIRMAN LUTZ: So just to be  
11 clear, so Stephen made a plea that we submit  
12 this back without a change in the exclusion  
13 criteria. Are we comfortable to go ahead? Do  
14 we discuss further whether to give that back  
15 to the medical? I guess that's the unanswered  
16 question in my mind. Are we moving it to a  
17 vote or are we agreeing and saying we should  
18 move back and have those definitions more  
19 clear?

20 MEMBER EDGE: I would say this is  
21 a feasibility issue and I wouldn't actually  
22 necessarily insist or ask that you take a vote

1 on delaying the other votes. I think this is  
2 a broader question when you look at these  
3 clinical contraindications that I think the  
4 NQF ought to very carefully make these the  
5 same. And I think there's arguments on both  
6 sides.

7 But I'm not sure, for the purpose  
8 of practicality, that I would suggest that you  
9 insist on turning this back to the developer  
10 while you have that discussion, because I  
11 don't think the developer is going to  
12 recommend that they change it at this point.

13 MEMBER MALIN: I mean, I would  
14 certainly recommend that we defer on the issue  
15 of addressing harmonization because I think it  
16 goes beyond just the numerator/denominator  
17 issue. It goes to the issue of the specific  
18 categories themselves.

19 And then also, you know, what we  
20 haven't explicitly here is are these measures  
21 for a defined data set or not? So, for  
22 example, the College of Surgeons measures have

1       been implemented using their data, but I don't  
2       know that there's anything about NQF  
3       endorsement of the measure that says that they  
4       only think it's valid with their data set.

5               And so the exclusion criteria are  
6       going to get operationalized potentially  
7       differently in different data sets. And so, I  
8       mean, I think it's a broader topic that  
9       probably should be gone into in more detail.

10              CHAIRMAN LUTZ: I have been told  
11       we are allowed to vote as to whether we're  
12       going to vote, so if you want to -- but I  
13       certainly agree. I mean, I don't know that I  
14       made attention to the exclusion criteria that  
15       closely in all the other ones we've done, so  
16       it's sort of stopping procedure for this one  
17       measure for this one developer, whereas I  
18       don't recall whether we've gone that far in  
19       depth in any of the others. So I'm not sure if  
20       it's fair to put them under the criteria.

21              But, yes, we can vote as to  
22       whether we'd like to vote.

1                   MEMBER HAMMOND: I would like to  
2                   make comment that based on what Bob said about  
3                   the labeling requirements that we can't  
4                   really. I would like to see more specificity  
5                   about the cardiac exclusions, but since the  
6                   labeling don't have it, I don't think it's  
7                   fair to do that to providers.

8                   MS. McNIFF: And would you feel  
9                   more comfortable if there was a specific  
10                  notation along with the clinical exclusion  
11                  contraindications that, for instance, cardiac?

12                  MEMBER HAMMOND: Yes, heart  
13                  failure for example.

14                  MS. McNIFF: Yes. Right.

15                  MEMBER HAMMOND: I mean, you can  
16                  measure that with an ICD-9 code, it's not  
17                  difficult to get that data. I would feel more  
18                  -- but I'm not sure that it's fair to require  
19                  it because the labeling requirement doesn't  
20                  say that. So --

21                  MS. McNIFF: If it's more of an  
22                  instructional -- but clearly there as an

1 instruction instead of a data element?

2 MEMBER HAMMOND: An instruction  
3 would be great.

4 MS. McNIFF: Okay. I mean that we  
5 can certainly do.

6 MEMBER ALVARNAS: This is Joe  
7 Alvarnas. I was away, so I wasn't sure if the  
8 developer is in the room.

9 And I know last time when we met  
10 we wanted the developers to walk away, come  
11 back an hour later and push back a respond.  
12 Are they available for us to put this on hold  
13 for a little while, let them rethink and  
14 either push back or suggest modifications?

15 MS. McNIFF: Hi. This is Kristen  
16 McNiff talking representing ASCO as the  
17 measure developer. And I think we're fine  
18 right now.

19 MEMBER MALIN: Are we just looking  
20 for a motion to vote on whether we should vote  
21 on this? I move to vote.

22 MEMBER EDGE: Second.



1                   CHAIRMAN LUTZ: We're voting,  
2 folks.

3                   MS. KHAN: So we are voting on 1a  
4 impact high, moderate, low or insufficient?

5                   MEMBER EDGE: Is it true that the  
6 NQF can make these kind of adjustments if they  
7 felt they were to put those clinical  
8 indication exclusions into the numerator or  
9 the denominator, they could modify this after  
10 the fact to do so?

11                   Oh, that's a different matter  
12 then, because then I would retract my second  
13 to this motion because if you can't then take  
14 these and harmonize them so that they can be  
15 operationalized to the public in a  
16 consistently uniform fashion, I think that's  
17 a serious matter, actually. I'm then in  
18 disagree with it.

19                   MS. PACE: And I'm sorry. I  
20 didn't introduce myself. I'm Karen Pace on  
21 NQF staff and work with the measure evaluation  
22 criteria on different methodology issues.

1                   So the measure stewards own these  
2                   measures. And so you're reviewing the  
3                   measures as they were submitted. And  
4                   basically we can't change measures. The  
5                   Steering Committee cannot change measures.

6                   If there is something that you  
7                   think is a fatal flaw in terms of measure  
8                   meeting the NQF criteria, then your voting  
9                   should reflect that. So if you feel that the  
10                  exclusions make this really an invalid  
11                  performance measure in terms of being able to  
12                  identify differences in quality, then that  
13                  should be reflected in your vote for validity  
14                  or ultimately whether the measure is  
15                  recommended.

16                  Now, you know you can if a measure  
17                  goes down, you know you can then talk about  
18                  conditions for your recommendation for  
19                  endorsement. And so the Steering Committee  
20                  could say that, you know we think this measure  
21                  should be recommended on the condition of  
22                  X,Y,Z and then the measure steward needs to

1 respond to that. And, you know it may be that  
2 they agree and we'd change it. It may be that  
3 they disagree and they give their rationale  
4 for that. It may be that, you know it's such  
5 a major change that it would require  
6 additional testing to really implement that  
7 kind of change.

8           So, there's no kind of one black  
9 and white thing, but NQF does not change  
10 measures after they're endorsed. The Steering  
11 Committee has some ability to recommend  
12 measures on certain conditions that the  
13 measure stewards reply to you about, and then  
14 you make a decision on that.

15           You know, your suggestion about  
16 NQF and having some standardized approach to  
17 exclusions, you know that's a much broader  
18 issue and it goes to making changes in our  
19 criteria, and that's a much longer process in  
20 getting that implemented across all topics and  
21 all measure developers, it's going to be a  
22 much longer process.

1                   So, you know what you have at hand  
2                   is the measure that's before you and voting on  
3                   whether the measure before you meets the  
4                   criteria based on what they've submitted in  
5                   terms of the reliability and validity testing  
6                   and how it's specified, and you know whether  
7                   there's evidence that backs how it's  
8                   specified, et cetera. And if fails, then, you  
9                   know, you could recommend it on a condition  
10                  and see what the measure developer's response  
11                  is tot hat.

12                  CHAIRMAN LUTZ: Elizabeth and then  
13                  Bryan. Just don't want to skip you. Bryan?

14                  MEMBER LOY: Just a comment.

15                  (1) It feels like some of the  
16                  discussion that we're having now is largely  
17                  around the harmonization. I think I heard the  
18                  developer say that didn't own all of these.  
19                  So, it would be kind of hard on a measure-by-  
20                  measure basis to really execute upon what you  
21                  just described.

22                  (2) I'd just comment to the group

1       it feels like this isn't the first time that  
2       this has come up. I mean, we've kind of all  
3       throughout our deliberations here have asked  
4       ourselves the question: So how good is good  
5       enough in terms of adhering to these measures?  
6       And it feels like to me at some level we've  
7       kind of acknowledged all along the way that  
8       there's some imperfections and some exclusions  
9       and maybe some things that we haven't  
10      completely contemplated.

11               And I don't know what it is about  
12      this measure that kind of brings that --  
13      escalates it to a higher level, but it seems  
14      that at some level we ought to be  
15      acknowledging as a group that a 100 percent  
16      compliance is maybe not the --

17               MS. PACE: So let just clarify  
18      other thing. As I mentioned, what you're to be  
19      doing now is reviewing each individual measure  
20      against the NQF criteria. If after you go  
21      through this and you have related measures  
22      with the same target population, then that

1 becomes a harmonization issue if you know the  
2 denominator is specified differently, if the  
3 exclusions are specified differently. And that  
4 can be brought back at that time to go back to  
5 the developers.

6 Your vote today is really not a  
7 final recommendation. It's preliminary pending  
8 addressing any harmonization and competing  
9 measures issues. So I don't know if this  
10 measure has related measures that are targeted  
11 to the same population or you're just talking  
12 in general about --

13 MEMBER HAMMOND: No. No, just  
14 about the broader issue.

15 MS. PACE: -- the method of doing  
16 exclusions? Okay.

17 So you're right, harmonization and  
18 competing measures need to be addressed later,  
19 but this not about specific measures that are  
20 related or competing, but just the broad  
21 concept of how to do exclusions, I believe.

22 CHAIRMAN LUTZ: Karen?

1 MEMBER FIELDS: So this is a new  
2 measure and explain to us how the new measures  
3 get adopted. Because before we were talking  
4 about new measures have a year of review or --

5 MS. FRANKLIN: No. This measure  
6 has been tested, so it would be fully  
7 endorsed--

8 MEMBER FIELDS: Okay. So some of  
9 the other ones where there's --

10 MS. FRANKLIN: -- if that's the  
11 Committee's decision.

12 MEMBER FIELDS: -- no testing  
13 date--

14 MS. FRANKLIN: Those are time  
15 limits.

16 MEMBER FIELDS: Okay.

17 CHAIRMAN LUTZ: Yes?

18 MS. FRANKLIN: And we have a  
19 comment from --

20 MS. McNIFF: A point of  
21 clarification. We do in fact, these three  
22 measures ASCO does own. I think maybe there's

1 one from CAP that's related.

2 And I just want to make sure, a  
3 point of clarification. NQF does not dictate  
4 how exclusions are handled and in fact has  
5 endorsed many measures that handled exclusions  
6 by pulling them from the denominator  
7 analytically, is that correct?

8 MS. PACE: Yes. We don't dictate  
9 measure specifications. We do have criteria  
10 about exclusions that say patient preference  
11 should be transparent.

12 So to what extent that has been a  
13 key issue for any one measure, it has varied.  
14 In some cases it has been. So there is a  
15 criterion about that that would apparently  
16 apply to your measure. But in general we have  
17 measures that -- I would say that most of them  
18 are, you know excluded from the denominator.  
19 But we have examples of measures where there  
20 are numerator categories and it really depends  
21 on, you know the particular measure and  
22 measure developer. But right now our criteria



1 do not require one way or the other.

2 The only criteria that the  
3 exclusion should be necessary, they should be  
4 identified in the evidence or they should be  
5 of sufficient frequency that it's really worth  
6 the data collection effort, or if patient  
7 preference is one of the reasons for an  
8 exclusion, that it should be transparent.

9 MEMBER EDGE: Well in my mind,  
10 first of all, I'm not sure that patient choice  
11 is an exclusion. It's a concordance with the  
12 measure. You appropriately consider that the  
13 patient should consider trastuzumab in this  
14 situation and it's been decided actively not  
15 to do so for a specific reason.

16 Based on what you just said, I'm  
17 feeling even stronger that the way that this  
18 is handled, this specific "exclusion" is  
19 handled in this measure reduces the value to  
20 the public, the value to the providers for  
21 quality assurance and reduces the  
22 transparency. So if the goal is transparency

1 to the public and transparency to users for  
2 the purpose of quality improvement, the way  
3 that these exclusions, the way that this is  
4 included as an exclusion reduces the  
5 transparency because you can't see how many  
6 people were considered, how many people were  
7 eligible for the treatment, how many people  
8 received it and now many did not receive it  
9 because of valid medical reasons.

10 CHAIRMAN LUTZ: We'll see how many  
11 folks you swayed in voting. Time to vote.

12 MS. McNIFF: I mean I don't want  
13 to draw out this conversation, I think it  
14 needs to go to vote. But that seems to me to  
15 be a reporting issue and that by reporting out  
16 either the numerator categories or the  
17 exclusions that go with the denominator, each  
18 way you're able to demonstrate the impact of  
19 patient preference and the impact of  
20 contraindications.

21 MEMBER EDGE: I would agree with  
22 you that that could be dealt with in a

1 reporting way as long as the data are  
2 collected. Are you currently reporting that  
3 to your providers in that fashion?

4 MS. McNIFF: Yes, we actually  
5 report this measure and we report recommended  
6 and received and you're able to drill down to  
7 look at the information exclusions. Now  
8 that's within QOPI. This, you know it's  
9 recommended to be --

10 MEMBER EDGE: Is that recommended  
11 in this document for how this should be  
12 reported? The developer be willing to put in  
13 a reporting recommendation that the number of  
14 patient are excluded because of those kind of  
15 clinical issues be reported?

16 MS. McNIFF: I don't think that's  
17 an option, is it?

18 MS. PACE: The question again?

19 MEMBER EDGE: Can the measure have  
20 rules for reporting that say that you report  
21 the people who are eligible based on including  
22 the exclusion that if the patient says no,

1 they won't be in the denominator? And that  
2 they will also be reported how many people are  
3 excluded from the denominator because of that,  
4 which is the way the developer specifically is  
5 reporting to that providers now in their data  
6 reporting system.

7 MEMBER MALIN: I need a  
8 clarification. I don't recall in any of the  
9 other measures that we've reviewed where the  
10 exclusions were in the numerator that the  
11 reporting was going to stratify how the people  
12 passed the measure. So it's not like that's  
13 providing people at a reporting -- you know,  
14 if you're talking about quality reporting that  
15 people are going to use, nobody's talking  
16 about stratified results. So it's not like,  
17 you know if 50 percent pass a recommended  
18 measure because the doctor discussed it with  
19 them and they refused, you would have no way  
20 of knowing that.

21 MEMBER EDGE: Well, we actually  
22 did discuss that, not quite so in detail when

1 we were discussing the American College of  
2 Surgeons measures. And specifically we  
3 discussed how those data were collected and  
4 whether the specific data element included,  
5 whether it was because the patient refused or  
6 the doctor said no, or there are other  
7 reasons. And that's why I was suggesting that  
8 after -- I think we're going too far down this  
9 road right here, but I think that this is  
10 something that would be valuable to harmonize  
11 across these measures so there's a consistent  
12 method of reporting so that the public get a  
13 consistent report. So the public when they see  
14 these data don't have to dive into the  
15 methodology about how one measure was defined  
16 and how another measure was defined. Our goal  
17 here is for transparency to the public.

18 MEMBER MALIN: Are you able to  
19 identify those who refuse?

20 MEMBER EDGE: Yes. We  
21 specifically discussed that with Mr. Stewart,  
22 and you might want to invite Mr. Stewart to

1       come back to the table to discuss how that is  
2       collected if you want. But, yes, the answer  
3       is yes.

4               And, again, our goal is  
5       transparency to the public, and I think we're  
6       losing that transparency with this measure.

7               MS. PACE: So let me just clarify  
8       a couple of things. First of all, NQF  
9       endorses the measures, how they're implemented  
10      which includes reporting currently is not part  
11      of the endorsement. So we don't attach  
12      guidelines on how the measure is reported.

13              If the measure was actually  
14      specified that there's numerator component,  
15      that would be part of the measure and the  
16      expectation would be that's how it would be  
17      implemented.

18              So, you know we don't attach  
19      reporting guidance to say that information  
20      goes back to the provider or that that  
21      information could be available. It's not part  
22      of the measure.

1                   So what you're voting on is the  
2                   measure as specified. And if for some reason  
3                   the measure does not receive a preliminary  
4                   recommendation for endorsement and someone  
5                   wants to bring up a condition on which you  
6                   might want to push it forward, that could be  
7                   done at that time. But again, you know I  
8                   don't know if this has been an exclusion in  
9                   other measures that you've taken a look at,  
10                  but you need to think about some of that  
11                  balance in terms of how you've been looking at  
12                  measures.

13                  And again, whether this one  
14                  element is in your mind a fatal flaw or not,  
15                  then you vote that accordingly.

16                  I think your general  
17                  recommendation about harmonization of methods,  
18                  not just of the actual specifications, is  
19                  something that you could discuss as a Steering  
20                  Committee about whether you want to make that  
21                  recommendation, and certainly we can have some  
22                  discussions about the developers about that.

1 But that's really a separate issue and it's  
2 something that we ask all Steering Committees  
3 to come up with recommendations regarding  
4 performance measurement, whether it's  
5 identifying areas where we need additional  
6 performance measures or if it's specifically  
7 about methods that apply across measures.  
8 You're certainly encouraged to do that.

9 MEMBER ALVARNAS: I know that you  
10 had scheduled a discussion of streamlining the  
11 process for how measures are evaluated. Would  
12 it be worthwhile including this as part of  
13 that much broader discussion?

14 MS. PACE: Yes, we'll certainly be  
15 looking at this for sure. Thanks.

16 CHAIRMAN LUTZ: All right. Shall  
17 we vote, see if this sinks or swims? We're  
18 getting to it. Yes, we did measure and then  
19 appropriately treated and then appropriately  
20 not treated. Right, but it's a different  
21 developer.

22 MS. KHAN: So voting on 1a impact.



1 High, moderate, low, insufficient evidence.

2 So you have 14 high, two moderate,  
3 zero low and zero insufficient evidence.

4 And measuring performance gap.

5 High, moderate, low, insufficient evidence.

6 Can everyone put their vote in one  
7 more time, please?

8 So you have three high, nine  
9 moderate, two low, two insufficient evidence.

10 Looking at the evidence, yes, no  
11 or insufficient.

12 So you have 15 yes and one  
13 insufficient evidence and zero for no.

14 Looking at reliability. High,  
15 moderate, low, insufficient.

16 You have six high, eight moderate  
17 and two low, zero insufficient evidence.

18 Looking at validity. High,  
19 moderate, low, insufficient evidence.

20 Five high, seven moderate, four  
21 low, zero insufficient.

22 We're moving on to usability,

1 high, moderate, low, insufficient evidence.

2 Four high, eight moderate, four  
3 low, zero insufficient information.

4 And Feasibility high, moderate,  
5 low, insufficient information.

6 Five high, nine moderate, one low,  
7 one insufficient.

8 And overall suitability for the  
9 endorsement, does the measure meet NQF  
10 criteria for endorsement, yes or no.

11 So 13 yes and three no, So the  
12 measure will pass.

13 CHAIRMAN LUTZ: Shall we do member  
14 and public comment and then hit lunch.

15 MEMBER HAMMOND: Yes.

16 MS. FRANKLIN: 1857.

17 CHAIRMAN LUTZ: Do you think we  
18 discussed 1857 enough to go ahead and vote?  
19 Okay.

20 MS. KHAN: So. Okay. So 1a  
21 impact. High, moderate, low, insufficient  
22 evidence.

1                   MEMBER LOY: Just so I understand,  
2                   are we voting on 1857 with the revised  
3                   language or is it as is? There was use of the  
4                   word appropriate. So we do we handle it like--

5                   MEMBER DONOVAN: Yes, they already  
6                   said what they'd do.

7                   MEMBER LOY: Okay. So could you  
8                   put it back up on the screen one more time?

9                   MEMBER DONOVAN: Maybe we can hear  
10                  it again out loud?

11                  CHAIRMAN LUTZ: So if I'm  
12                  understanding correctly, so it now says:  
13                  "Trastuzumab appropriately not administered to  
14                  breast cancer patients when human epidermal  
15                  growth factor receptor is negative or  
16                  undocumented." So the additional is medicine  
17                  appropriately now administered versus simply  
18                  saying not administered? What was that  
19                  change? And then was there an adjuvant  
20                  therapy in addition to that as well?

21                  MS. McNIFF: Yes. The use of the  
22                  word -- I hate to wordsmith at the moment.

1 The use of the word "appropriate" has it's own  
2 specific meaning, and we can put that in there  
3 but I think that'll probably be fine.

4 We can certainly change the title  
5 for clarity, absolutely.

6 MS. BOSSLEY: Right. What we can  
7 do is I think we can let ASCO go back and kind  
8 of wordsmith and recirculate it, but let's if  
9 everyone's comfortable have you vote, assuming  
10 that there will be some language in there  
11 that's appropriately or whatever terminology.  
12 If you have concerns with what they circulate  
13 again, we can redo the vote or send it back to  
14 them.

15 But I mean I think they've heard  
16 it, they're going to make the change. So if  
17 you're comfortable, we can just vote that way.

18 MEMBER LOY: Given the discussion,  
19 I feel I'd be remiss not to at least look at  
20 the exclusions on this measure. Can we take  
21 a look at those?

22 MS. BOSSLEY: So for those on the

1 phone the exclusion is just patient transfer  
2 to practice after initiation of chemotherapy.

3 MEMBER ALVARNAS: Thank you.

4 MS. KHAN: All right. 1a impact.  
5 High, moderate, low, insufficient evidence.

6 So you have nine high, three  
7 moderate, four low and zero insufficient  
8 evidence.

9 1b performance gap. High,  
10 moderate, low, insufficient evidence.

11 Can we have everyone press it one  
12 more time, please.

13 You have two high, six moderate,  
14 seven low and one insufficient evidence.  
15 That's eight and eight, so it doesn't pass.

16 MS. BOSSLEY: So it is actually a  
17 split.

18 MS. KHAN: Yes.

19 MS. BOSSLEY: So in the instance  
20 of this typically we have you go on and  
21 continue voting and let's see how the rest of  
22 this plays out. Because what staff will do is

1 make sure reflects at the moment that you all  
2 really didn't come to consensus on this one  
3 subcriteria at the moment.

4 Are we on reliability or -- 1b,  
5 I'm sorry. I lost track. Walking in after  
6 being on a webinar makes me lose track. Sorry.

7 So in this instance all three  
8 subcriteria must be met to pass importance. So  
9 the impact, the opportunity for improvement  
10 and then also the evidence.

11 Here we've actually got a split.  
12 I don't think we can say whether this  
13 subcriteria was or was not passed because it's  
14 50/50. So we should move on to the evidence  
15 piece and see if it passes that component. And  
16 then I think we should have a discussion again  
17 to make sure that are all in agreement. And  
18 usually what we typically do is you have a  
19 split vote on one of the subcriteria, it in  
20 essence doesn't quite pass but it's one of  
21 those that it's hard to tell, you'll move on  
22 to scientific acceptability if it passes

1 evidence. I think that's the next thing that  
2 we need to do.

3 This is one where it's always fun  
4 when we have a split vote on a subcriteria,  
5 and it's really let's move it through the rest  
6 of the process and see how it plays out  
7 against the remaining subcriteria.

8 Does that make sense? All right.

9 MS. KHAN: So looking at evidence,  
10 yes, no or insufficient.

11 So you have 13 yes, two no and one  
12 insufficient evidence.

13 So we're going to go forward,  
14 right?

15 MS. BOSSLEY: So again because you  
16 did have a split vote there's no real way to  
17 know. I think we just need to follow the  
18 stream and let's do scientific acceptability  
19 and move it through the rest of the process.

20 MS. KHAN: So voting on  
21 reliability. Again, high, moderate, low or  
22 insufficient evidence.

1                   It's six high, seven moderate,  
2                   three low, zero insufficient.

3                   Looking at validity. Again, high,  
4                   moderate, low or insufficient.

5                   So four high, eight moderate, four  
6                   low and zero insufficient evidence.

7                   Moving on to usability. High,  
8                   moderate, low or insufficient.

9                   So five high, eight moderate,  
10                  three low and zero insufficient information.

11                  Feasibility.

12                  So you have six high, six  
13                  moderate, four low and zero insufficient.

14                  And overall suitability for the  
15                  endorsement, does the measure meet NQF  
16                  criteria for endorsement, yes or no.

17                  So you have nine yes and seven no,  
18                  so the measure will pass.

19                  MS. BOSSLEY: So I think -- I  
20                  wasn't here for most of the discussion, so I  
21                  apologize. But I want to make sure that staff  
22                  have enough of a kind of a rationale to



1 understand why people voted and we had a split  
2 vote on the opportunity for improvement. So  
3 if -- again, more it's more to Angela and  
4 Lindsey if they have enough information.  
5 Because we want to explain kind of where we  
6 landed on this.

7 Again, it was a close vote, but it  
8 did pass and we have the split vote in the  
9 opportunity for improvements.

10 Feel like you do? Okay. ASCO  
11 feel comfortable? Okay.

12 I just want to make sure because I  
13 wasn't in the room.

14 CHAIRMAN LUTZ: All right. So any  
15 public comments or any NQF comments from the  
16 group or on the phone?

17 MS. TIGHE: Of you could open all  
18 lines, please?

19 OPERATOR: At this time there are  
20 no questions.

21 CHAIRMAN LUTZ: Shall we vote on  
22 whether to eat lunch?

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MEMBER ALVARNAS: I Vote yes.

MS. BOSSLEY: Any comments in the  
room? Okay.

(Whereupon at 1:15 p.m. the above-  
entitled matter went off the record and  
resumed at 1:47 p.m.)

1 A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

2 1:47 p.m.

3 CHAIRMAN LUTZ: All right. So  
4 we're going to get started again with 1855,  
5 which is another HER2 discussion. We have our  
6 submitting group here. And I think Heidi was  
7 going to give us thoughts about how we should  
8 have the work group sort of present as we  
9 vote.

10 MS. BOSSLEY: So I have a request.  
11 You all might not like it, but it is a  
12 request. To standardize across our different  
13 committees across the different topic areas,  
14 it's most helpful if we have you discuss  
15 importance. So all three set criteria first  
16 and then vote on importance. Then move onto  
17 to scientific acceptability. Discuss that.  
18 Then vote. That's what we did the last time.  
19 And again, for consistency's sake, we kind of  
20 got away from it this morning. I'd like to  
21 bring us back and have us do that.

22 I don't think it will take more

1 time, but it really helps people -- I think  
2 the developers follow the discussion. It  
3 helps staff to be able to capture the  
4 rationales. And when we go back to try to  
5 capture and make sure we got it all, it's much  
6 easier to track that way and it is better in  
7 mind a thought process. So if you all are  
8 willing, my request is that we go back and do  
9 it that way. No, not repeat. Not at all.  
10 Starting from 1855. I would never ask you to  
11 do that. I promise.

12 CHAIRMAN LUTZ: She means 1855,  
13 the submission, not the year.

14 MS. BOSSLEY: Right.

15 MS. FRANKLIN: So if we could have  
16 the developers for 1855 give us an overview.  
17 And I would just like to note that this is  
18 also a time limited measure, or it's eligible  
19 for a time-limited recommendation for  
20 endorsement.

21 MS. BOSSLEY: Everyone remember  
22 when it's time-limited what that means? No,

1 everything -- I wanted to make sure. So for  
2 time-limited it means they've provided all the  
3 information with the exception of reliability  
4 and validity data. So under reliability and  
5 validity for site specific acceptability, you  
6 will specifically just look at whether they've  
7 provided precise specifications. That's it.  
8 Because you won't have anything else. So on  
9 that one I think we have provided specifically  
10 for that so you're sure you know what you're  
11 voting for. Make sense?

12 (No response.)

13 MS. BOSSLEY: Okay.

14 DR. SPEIGHTS: Are we ready?

15 Okay. 1855 is a quantitative HER2 evaluation  
16 by immunohistochemistry. Uses a system  
17 recommended by the ASCO/CAP guidance.

18 MS. FRANKLIN: Sorry. Sorry to  
19 interrupt.

20 DR. SPEIGHTS: That's okay.

21 MS. FRANKLIN: Could the  
22 participants on the phone please mute your

1 lines if you're not speaking? Thank you.

2 DR. SPEIGHTS: Ready? Okay. In  
3 discussion of the last three measures we saw  
4 that HER2/neu testing is essential in  
5 determining whether patients do or do not  
6 receive trastuzumab. Our measure does not  
7 focus on which patients should receive HER2  
8 testing as much as if we're going to do it we  
9 need to do it right and report it in a  
10 reproducible and clinically relevant manner.

11 Several years ago it was noted  
12 that when people -- when patient samples which  
13 were tested for HER2 at one facility were  
14 subsequently retested at a reference facility,  
15 then there was discrepancy in a set to 25  
16 percent of the cases. This led to the  
17 ASCO/CAP guidelines for all phases of HER2  
18 testing being published in 2007.

19 In 2010; actually two years ago  
20 this month, there was a survey of about 700  
21 labs which showed about 84 percent of them  
22 were using the CAP/ASCO recommended

1 guidelines. So we see that there is a  
2 performance gap. We feel this is a very  
3 important measure. Obviously, we've talked  
4 about the large numbers of people with breast  
5 cancer and the high impact of appropriate  
6 therapy for these patients and the need for  
7 selecting the appropriate patients to be  
8 administered trastuzumab.

9 We see then that it basically is a  
10 very important measure in the sense that it  
11 has very important implications for patient  
12 care, there is a documented performance gap,  
13 and that we are focused on assuring that the  
14 key information from the pathology testing for  
15 HER2/neu is done in a standard manner and  
16 reported in a standard manner. You've already  
17 seen some of the criteria for HER2/neu  
18 reporting in discussion of other measures. So  
19 basically, we feel that IHC evaluation of  
20 HER2/neu should be reported in a consistent  
21 manner as indicated by the ASCO/CAP  
22 guidelines.

1 CHAIRMAN LUTZ: Okay. And I think  
2 -- who is our discussant for this one?

3 MEMBER FIELDS: I am.

4 CHAIRMAN LUTZ: Karen.

5 MEMBER FIELDS: So I think that  
6 was an excellent summary. And I just wanted  
7 for the group to add a couple of other issues.

8 So the measure itself measures the  
9 percentage of patients with quantitative  
10 breast HER2/neu IHC evaluation who either use  
11 the ASCO/CAP recommended either manual system  
12 or computer-assisted system with an algorithm  
13 that includes when to --

14 (Whereupon, there was interference  
15 from participants on the phone line.)

16 MEMBER FIELDS: You want to try  
17 again?

18 MS. FRANKLIN: To those  
19 participants on the phone, if you're not  
20 speaking, please mute your lines. And,  
21 Arnika, could you let us know if you can mute  
22 that line?



1 OPERATOR: Yes, one moment.

2 MS. FRANKLIN: Arnika?

3 OPERATOR: Yes, one moment.

4 MS. FRANKLIN: Okay.

5 MEMBER FIELDS: Okay. So the  
6 numerator is all patients receiving  
7 quantitative HER2 IHC testing according to the  
8 guidelines, and the denominator is all  
9 patients who got HER2/neu IHC testing. So  
10 there were no exclusions. And as we noted,  
11 it's a new measure.

12 I think for the group to  
13 understand the reason for the performance gap  
14 also is the FDA indications and the  
15 manufacturing recommendations for the  
16 measurements differ from the ASCO/CAP  
17 guidelines. So ASCO recommends to call a  
18 positive IHC test. It's 30 percent of the  
19 cells completely take up the dye, and then  
20 it's positive. Less than 30 percent, then we  
21 recommend FISH testing or we recommend HER2  
22 CEP17 testing just to verify whether or not

1 HER2 is over or under-expressed in those  
2 tumors. And then less than 10 percent is  
3 negative. The manufacturers recommend more  
4 than 10 percent is positive. So that's the  
5 difference between the disparity and why some  
6 labs may not adequately be reporting.

7 Also, a comment from a clinical  
8 standpoint. Usually it falls on the clinician  
9 to go back and request the testing if you get  
10 the equivocal results rather than it's an  
11 automatic. The pathology department  
12 automatically follows those guidelines. At  
13 least that's been the way over the years it's  
14 evolved for trying to get those equivocal  
15 tests redone so that the provider could use  
16 the information about whether or not to treat  
17 a patient with trastuzumab or not.

18 So we'll discuss section 1,  
19 impact. Obviously, breast cancer, there's a  
20 very high number of diseases. It's costly to  
21 treat and trastuzumab is one of our most  
22 costly drugs and contributes to the overall

1 cost. So I thought that the impact was high.

2 The opportunity for improvement I  
3 think was well described by the developers,  
4 that only 84 percent of the labs surveyed used  
5 the ASCO/CAP guidelines.

6 And the evidence. I'll make a  
7 comment on evidence. I think that there's no  
8 direct evidence about comparing a tumor  
9 marker, in different ways use a tumor marker.  
10 It's all direct evidence. The clinical trials  
11 where we're describing whether a patient was  
12 more or less likely to respond, the measure is  
13 an indirect measure because there's central  
14 review of the tumors and going back and  
15 reanalyzing who was going to respond. So  
16 there's a huge body of indirect evidence  
17 related to using trastuzumab in these  
18 patients, that the ones that truly respond are  
19 the patients that have the true positives or  
20 have evidence of over-expression of the gene.

21 So this is a guidelines-based  
22 recommendation and the guidelines are very

1 well written and understandable. So I think  
2 that I would have rated the literature as the  
3 quantity of the literature was high. The  
4 quality was moderate because it's indirect,  
5 not direct. And the consistency is high. And  
6 so, I felt that it was reasonable -- that's a  
7 -- importance to measure was yes, but I open  
8 it up for discussion from my other group  
9 members and any other comments from the  
10 investigators, or the sponsors.

11 MEMBER HAMMOND: I agree with  
12 Karen has said. She has documented in her  
13 remarks another source of this performance  
14 gap, and that is that in the guideline it  
15 specifically says what you're supposed to do  
16 if the test is equivocal. It specifies that  
17 clearly that you have to do certain specific  
18 things, and clearly that's not happening. So  
19 the goal of this performance measure is for us  
20 to document and try to improve the problem we  
21 have with this testing and not following the  
22 guideline recommendations, which would, we

1 hope, make a big difference in what happens to  
2 these patients and the accuracy of the  
3 testing.

4 CHAIRMAN LUTZ: Jennifer?

5 MEMBER MALIN: I had a couple of  
6 questions. So under numerator details it says  
7 that you report one of the following CPT  
8 Category II codes. The first one, 3394F, is  
9 quantitative HER2 IHC evaluation, but the  
10 second one is quantitative non-HER2 IHC  
11 evaluation; e.g., testing for ER, for estrogen  
12 and progesterone receptors. I don't  
13 understand how that would be a passing  
14 criteria for the HER2 testing.

15 DR. SHAMANSKI: It's because with  
16 the codes you cannot differentiate the two  
17 types of testing. So we had to have a  
18 separate reporting code for testing that was  
19 not for HER2.

20 MEMBER MALIN: But why would  
21 quantitative testing not for HER2 meet the  
22 criteria for the --

1 DR. SHAMANSKI: Because if you're  
2 coding with breast cancer and with IHC codes  
3 and pathology aren't -- they're not specific  
4 to HER2.

5 MEMBER MALIN: But here it says  
6 specifically 339 -- am I just --

7 DR. SHAMANSKI: Those are the  
8 reporting codes.

9 MEMBER MALIN: Right?

10 DR. SHAMANSKI: Those are not the  
11 -- the denominator codes --

12 MEMBER MALIN: Right. No, I'm  
13 saying but the numerator codes. So those are  
14 the measure that's specific to HER2, correct?

15 DR. SHAMANSKI: Correct, but you  
16 have to have some way of picking up those  
17 cases that are not HER2. They're going to get  
18 picked up in the denominator, so you have to  
19 have some way of reporting them.

20 MS. BOSSLEY: But for performance  
21 it's only the 3394 that counts?

22 DR. SHAMANSKI: Right.

1 MS. BOSSLEY: Correct?

2 DR. SHAMANSKI: Correct.

3 MS. BOSSLEY: So actually --

4 DR. SHAMANSKI: For reporting,  
5 it's for both of them so that you can account  
6 for those cases, which are approximately 50  
7 percent of the cases.

8 MEMBER MALIN: Okay. So maybe  
9 this just needs to be clarified.

10 DR. SHAMANSKI: Yes.

11 MEMBER MALIN: Because the way  
12 this is worded, it looks like if you --

13 MS. BOSSLEY: Right.

14 MEMBER MALIN: Yes.

15 MS. BOSSLEY: Right. It looks  
16 like -- right now if you read this, I would  
17 interpret that both of these would count for  
18 the numerator.

19 MEMBER MALIN: Right.

20 MS. BOSSLEY: But that's actually  
21 not the case.

22 MEMBER MALIN: It's basically --

1 MS. BOSSLEY: So I think we need  
2 to --

3 MEMBER MALIN: -- having either  
4 one of those --

5 MS. BOSSLEY: Yes.

6 MR. MALIN: -- puts you in the  
7 denominator. And then the only thing that  
8 counts for the numerator is -- so we can work  
9 with the developer to make sure that's clear.

10 MS. BOSSLEY: So we can work with  
11 the developer to make sure that's clear.

12 MEMBER MALIN: Okay.

13 MS. BOSSLEY: Yes.

14 MEMBER MALIN: Okay. I think I  
15 may have just missed this. Is this a time-  
16 limited one?

17 MS. BOSSLEY: Yes.

18 MEMBER MALIN: Okay.

19 CHAIRMAN LUTZ: Okay. I think  
20 Elizabeth and then David. David?

21 MEMBER PFISTER: It was a little  
22 unclear to me. Is the denominator here any



1 pathology reading? So for example, let's say  
2 that someone has their slides evaluated  
3 locally, then kind of goes to another place,  
4 has their slides reviewed. The second place  
5 probably sort of sees what was done the first  
6 time and may dispense with certain things  
7 because they sort of view it already been  
8 done. And how is that captured as not being  
9 non-compliant?

10 DR. SHAMANSKI: So the measure is  
11 physician-specific. So it's just saying as a  
12 physician if you're doing this sort of  
13 evaluation you are using the ASCO/CAP  
14 guidelines regardless of whether there's been  
15 previous studies or not. I don't understand  
16 why you would not want to do that.

17 MEMBER PFISTER: No, I was just  
18 saying if it is physician-specific. So I'm  
19 good with that.

20 DR. SHAMANSKI: Okay.

21 MEMBER PFISTER: So but then let's  
22 say you've got two different pathologists that

1 cross paths on this case. And so, you have  
2 pathologist 1 that maybe was the first intake  
3 and follows the guidelines and gets it done.  
4 Then the second pathologist might confirm a  
5 diagnosis of breast cancer, might kind of be  
6 mindful of what had been done already with the  
7 other pathologist. And how is that  
8 eventuality sort of captured in a way that  
9 doesn't penalize the second pathologist?

10 DR. SHAMANSKI: If the second  
11 pathologist is actually not doing a HER2  
12 evaluation, it won't get picked up in the  
13 denominator.

14 MEMBER PFISTER: Yes.

15 MEMBER HAMMOND: It wouldn't be  
16 able to charge for that.

17 MEMBER PFISTER: Yes.

18 MEMBER HAMMOND: Those are  
19 charging codes.

20 MEMBER PFISTER: Yes.

21 MEMBER HAMMOND: So they would not  
22 be able to charge for HER2 and therefore they

1 would not be measured about it. That code  
2 would never be in the system. That clear?

3 MEMBER FIELDS: So I guess what  
4 you're saying is the trigger is always when  
5 you order HER2 IHC and then it needs to be  
6 done correctly?

7 MEMBER HAMMOND: It's not when you  
8 order. It's when you do it.

9 MEMBER FIELDS: When you do it?

10 MEMBER HAMMOND: Yes, you do it.

11 MEMBER FIELDS: When you do it?

12 MEMBER HAMMOND: Yes. Right.

13 MEMBER FIELDS: And so, then any  
14 other ordering of FISH or variations on  
15 amplification isn't related to this measure?

16 MEMBER HAMMOND: Correct.

17 MEMBER FIELDS: Okay. Is that --

18 DR. SHAMANSKI: Yes.

19 MEMBER PFISTER: So then, I mean,  
20 I'm just thinking in real time like how these  
21 things kind of come through. Maybe Steve can  
22 comment on this. But like, let's say one of

1 the breast pathologists might submit some  
2 slides. They kind of put in like the order.  
3 It gets kind of processed. And arguably they  
4 may end up doing a HER2 that's redundant on  
5 what's been done previously. And then they  
6 don't do any for the work of knowing what's  
7 been doing previously. But having done that  
8 HER2, then even though they're not following  
9 up on it further because it would be  
10 redundant, they're going to get penalized for  
11 having done in the first place.

12 DR. SPEIGHTS: I mean, our measure  
13 really just focuses on whether the pathologist  
14 uses the ASCO/CAP guidelines for  
15 interpretation. Other problems such as not  
16 knowing a previous result, repeating the test,  
17 difference in interpretability and  
18 interpretation between pathologists are not  
19 really the focus of this.

20 MEMBER EDGE: On this test when  
21 you did the HER2 test you used the guidelines  
22 for testing as recommended by ASCO/CAP, NCCN,

1       whatever? And then that should be documented  
2       in the path report?

3                   MEMBER HAMMOND: Right, and the  
4       guideline states that anybody who looks at a  
5       HER2 test should be using the guideline  
6       recommendations. So anybody who does that  
7       first or second time, it doesn't matter. They  
8       should be using the same criteria.

9                   MEMBER EDGE: So is this something  
10      that should be measured on a case-by-case  
11      basis, or is this --

12                   MEMBER HAMMOND: Yes.

13                   MEMBER EDGE: -- something that is  
14      better measured on a laboratory-by-laboratory  
15      basis? Like, you know, if I have my blood  
16      sugar measured, I'm supposed to be in a  
17      laboratory that has documented that they  
18      measure blood sugars accurately. Shouldn't  
19      the same thing be true for this? Isn't this  
20      a CLIA issue?

21                   MEMBER HAMMOND: Well, there are  
22      two parts to the test. In the guideline, this

1 is made clear. So there's laboratory  
2 component and there's pathologist component.  
3 This measures only the pathologist component.  
4 We need to have a measure -- and hopefully the  
5 measure developers are hearing me say this.  
6 We need a measure for the laboratory component  
7 as well. That's whether or not the test was  
8 accurately done and the specimen is handled  
9 correctly. So by institution. We should have  
10 a measure by institution as well as a measure  
11 by physician, just like we've talked about  
12 with these other measures that we've discussed  
13 previously.

14 DR. VOLK: Dr. Hammond, this is  
15 Emily Volk. I'm part of the Measure  
16 Development Team here. I think we certainly  
17 appreciate the content of that comment. I'm  
18 a little unclear on how we would  
19 operationalize that with the parameters set by  
20 the PQRS program.

21 MEMBER HAMMOND: Well, I don't  
22 know. The answer is, Emily, I really don't

1 know, but I know there have been measures that  
2 we've discussed where they were institution-  
3 specific. Maybe CAP is not the one to make  
4 this measure, but it would be nice if we had  
5 measures that were measuring whether or not  
6 laboratories were compliant with this  
7 guideline. That means that they're watching  
8 the fixation of the sample, the way in which  
9 the test was done, the quality indicators for  
10 that laboratory's performance. That's not  
11 what this measure is about. This measure is  
12 completely about the other part of the test,  
13 which is just pathologist-specific.

14 DR. VOLK: Agreed. Agreed. I'd  
15 love to talk to you about that more off line.

16 CHAIRMAN LUTZ: Bryan, did you  
17 have something?

18 MEMBER LOY: I just want to make  
19 sure I understand. You showed us a part of  
20 the screen that showed some alphanumeric codes  
21 that really made the distinction between HER2  
22 and non-HER2.

1 (Off mic comments.)

2 MEMBER LOY: Well, I thought I saw  
3 them up here on the numerator statement.  
4 There. They're alphanumeric. As a payer,  
5 that gives me a little bit of pause because  
6 not all systems process those codes.

7 And then the second question that  
8 I had was that there's a CPT code that I'm  
9 kind of worried about because it's not  
10 necessarily specific for HER2/neu that folks  
11 use probably even more frequently than they  
12 would the alphanumeric codes that are much  
13 broader. They do HER2 and ER/PR and others.  
14 How are we dealing with that in terms of --

15 DR. SHAMANSKI: So just to be  
16 clear, the CPT billing codes and ICD-9 codes  
17 are the codes used to determine the  
18 denominator. These are reporting codes. And  
19 so, the reason you have the second code for  
20 non-HER2 IHC is to exactly address the problem  
21 you're talking about, is that those CPT codes  
22 are not specific. So we have to account for



1 those other cases in some way.

2 MEMBER LOY: Got it.

3 DR. SHAMANSKI: And this is the  
4 best way.

5 MEMBER LOY: Okay. So in order to  
6 even be measurable, you have to submit these  
7 reporting codes, is that correct?

8 DR. SHAMANSKI: Correct.

9 MEMBER LOY: Okay. So one other  
10 question. If I report 3394F in my numerator,  
11 does that mean that clinically I've met the  
12 ASCO/CAP recommendation?

13 DR. SHAMANSKI: Correct.

14 MEMBER LOY: Or is there a further  
15 review of the actual pathology report that's  
16 required to meet that criteria?

17 DR. SHAMANSKI: Well, by reporting  
18 that code, it indicates that that was done,  
19 that the report meets the criteria.

20 MEMBER LOY: Okay. Thank you.

21 CHAIRMAN LUTZ: Is there anybody  
22 online that has a question? I don't know, if

1 Rocco, Heidi, Joe -- if any of you are there,  
2 but we don't want to forget you. Anybody?

3 (No response.)

4 MEMBER DONOVAN: We're here. I  
5 don't have anything to add.

6 CHAIRMAN LUTZ: Okay.

7 MEMBER LOY: One other question.  
8 FISH. Is there any --

9 MEMBER FIELDS: What about FISH?

10 MEMBER LOY: Pardon?

11 MEMBER FIELDS: FISH is not --

12 MEMBER ALVARNAS: No comments on  
13 my end.

14 MR. LOY: So if somebody chose to  
15 do FISH instead of IHC -

16 MEMBER FIELDS: It wouldn't  
17 qualify for --.

18 MEMBER LOY: So we're just going  
19 to exclude that out of the universe for this  
20 purpose?

21 MEMBER FIELDS: Yes.

22 MEMBER LOY: Okay.

1 MEMBER HAMMOND: It's just IHC.

2 MEMBER FIELDS: Then I don't  
3 understand the measure at all, because I  
4 thought that it was when to use FISH  
5 appropriately to quantify your IHC.

6 DR. SHAMANSKI: No, we require  
7 that laboratories -- well, we don't require  
8 it, but we like to have them provide to us a  
9 score, which is sort of semi-quantitative, and  
10 a quantitative number for the  
11 immunohistochemistry as well as the FISH.  
12 Both of those could be quantitative tests.

13 This particular measure only  
14 measures the immunohistochemistry part. It  
15 doesn't measure the FISH part. So another  
16 measure would have to be created to measure  
17 whether or not the pathologist is compliant  
18 with the FISH codes.

19 MEMBER FIELDS: But the guideline  
20 itself tells you when to use FISH?

21 DR. SHAMANSKI: Yes. Yes, the  
22 guideline --

1                   MEMBER FIELDS: So how can we have  
2 a measure that measures if you're doing the  
3 guideline if you don't --

4                   DR. SHAMANSKI: Well, because this  
5 is --

6                   MEMBER FIELDS: -- do the whole  
7 test?

8                   DR. SHAMANSKI: -- one element of  
9 the guideline. It's not the entire guideline.  
10 As we talked about a moment ago, you know,  
11 there are laboratory components, there are  
12 FISH components, there's immunohistochemistry  
13 components. There are many components of the  
14 guideline. One could look at this as a  
15 surrogate for all ASCO/CAP guideline  
16 compliance. We need measures that tell us  
17 whether people are complying with this and get  
18 rid of that gap. And so, this is our first  
19 effort to try to start to get there.

20                   DR. SHAMANSKI: I think there's a  
21 word missing here in the measure title. It's  
22 the scoring system, not the system, which was

1 in our original measure. Just that word seems  
2 to have gotten dropped. But, so we're  
3 measuring that aspect of the guidelines.

4 MEMBER FIELDS: Okay. Well, so to  
5 get to real quality improvement then, we need  
6 the labs to start appropriately interpreting  
7 the pathology and ordering the appropriate  
8 rest of the work-up, because otherwise we're  
9 leaving it to the clinicians to interpret that  
10 for treatment decisions. I mean, that's not  
11 the point of today. I understand now. You're  
12 eliminating it just to saying 1+, 2+, and 3+.  
13 That's all you're doing.

14 MEMBER HAMMOND: According to the  
15 guideline, which means that there are  
16 requirements in there for how they have to do  
17 the test. So they're not supposed to use that  
18 reporting code unless they are compliant with  
19 the guidelines. So we would assume that this  
20 is a surrogate for them doing all the other  
21 things you talked about, but we aren't  
22 measuring those other things. We're measuring

1 one element and hoping that it's a surrogate  
2 for all the other elements.

3 MEMBER FIELDS: Just as a  
4 clinician, the assumption that we can make is  
5 that once we get a 3+, we're done. We don't  
6 think about it again. And 2+, somebody's gone  
7 and is going to give us another report that  
8 tells us exactly what we needed to know.

9 MEMBER HAMMOND: And this report,  
10 if it's equivocal, should have a statement in  
11 it that says the IHC is 2+, the IHC HER2 test  
12 is 2+ positive. By the ASCO/CAP guideline,  
13 that requires that the test be confirmed by  
14 doing a FISH test on the same sample, and that  
15 report will be subsequently provided. And if  
16 those words are not in there, then they  
17 haven't complied with the guideline. That's  
18 part of the guideline.

19 MEMBER FIELDS: Okay. Then I  
20 guess you need to really change the title to  
21 say scoring, because that's a huge difference.  
22 Yes, okay. That's fine.

1                   MEMBER HAMMOND: So this is just a  
2 surrogate. It's measuring one part of this  
3 whole guideline. And we're hoping that it  
4 will address the performance gap and make it  
5 better in the future.

6                   CHAIRMAN LUTZ: All right. So  
7 I'll defer to my NQF brethren here. We've led  
8 a little bit further ahead. I don't know, in  
9 terms of voting whether you want to --

10                   MS. BOSSLEY: So, I do. I think  
11 we should have a vote on the importance  
12 because there's clearly a discussion around  
13 the evidence and as the measure that's before  
14 you. So let's do that and then let's see how  
15 it goes against that. And then we'll move  
16 onto scientific acceptability, because you  
17 moved right into that already. Then we'll  
18 move onto the rest, usability and feasibility  
19 -- Well, we talked about the -- you did it.  
20 You weren't the one who moved into scientific  
21 acceptability. Others did. But that's okay.

22                   MS. KHAN: So voting on 1a,

1 impact.

2 MEMBER FIELDS: Dr. Ricciardi, are  
3 you still on the line?

4 MEMBER RICCIARDI: Yes, I am on  
5 the line. Sorry.

6 MEMBER FIELDS: Okay. We're just  
7 waiting for your vote.

8 MS. KHAN: Okay. So, we have 11  
9 high, 4 moderate, 1 low and 0 insufficient  
10 information.

11 Moving onto performance gap, 1b.

12 We're missing two people.

13 Five high, eleven moderate, zero  
14 low, and zero insufficient.

15 And going onto evidence. Yes, no,  
16 or insufficient.

17 Can we press them one more time,  
18 please?

19 So, we have 14 yes, and 2 no.

20 MEMBER FIELDS: So moving onto  
21 reliability and validity. So the question No.  
22 1 is is the measure precise? And now that we



1 understand all of the differences in CPT codes  
2 and reporting codes, I think that the measure  
3 is precise and you would be able to measure  
4 it.

5 Reliability. There's no  
6 reliability testing available. But because  
7 this is adopted for a one-year period to test  
8 the reliability, I think that makes it  
9 acceptable for approval.

10 Validity has to be determined once  
11 we determine whether or not it's a Reliable  
12 measure. It seems like a valid tool for me as  
13 a clinician and as somebody that uses this  
14 information to make treatment decisions. So  
15 I would assume that it meets validity  
16 criteria, or it's worth discussing that.

17 And the disparities in healthcare  
18 don't apply in this measure.

19 CHAIRMAN LUTZ: Any further  
20 discussion on those things? I know we already  
21 covered a lot.

22 (No response.)

1                   CHAIRMAN LUTZ:   Okay.  Can we vote  
2                   on those?

3                   MS. KHAN:   So we are going to be  
4                   voting on reliability and validity for  
5                   untested measures.  The measure  
6                   specifications, numerator, denominator and  
7                   exclusions are unambiguous and likely to  
8                   consistently identify who is included or  
9                   excluded from the target population, identify  
10                  the process, condition or event being measured  
11                  and compute the score.  And they should also  
12                  reflect the quality of care problem in 1a and  
13                  1b and the evidence cited in support of the  
14                  measure focus, 1c.

15                  So we're going to vote 1, yes or  
16                  2, no.

17                  I think we're missing two people.

18                  So, we have 15 yes and zero no.

19                  And moving onto usability.  High,  
20                  moderate, low or insufficient.  You want to  
21                  discuss it first?

22                  CHAIRMAN LUTZ:   Karen, we

1 definitely need to hear what you have to say  
2 about that.

3 MEMBER FIELDS: Usability? I  
4 don't know that I understand what the public  
5 reporting implications would be at this point  
6 in time. I think it's a useful measure for  
7 quality improvement, however. So I would say  
8 that it seems to meet the usability criteria.

9 And not feasibility yet, so --

10 CHAIRMAN LUTZ: Anything else  
11 about usability?

12 MS. KHAN: So usability. High,  
13 moderate, low or insufficient.

14 I think we're missing one person.

15 All right. Six high, five  
16 moderate, two low and two insufficient.

17 MEMBER FIELDS: And feasibility.  
18 Yes, it's definitely data that's generated as  
19 a byproduct of the process. It should be  
20 available on electronic formats. And I would  
21 assume that it has a moderate susceptibility  
22 to inaccuracies, but it should be fairly

1 reliable. And I think that the strategy that  
2 they outlined to collect the data is feasible.

3 CHAIRMAN LUTZ: Anyone else?

4 (No response.)

5 CHAIRMAN LUTZ: Okay.

6 MS. KHAN: Feasibility. High,  
7 moderate, low or insufficient.

8 So, we have 4 high, 11 moderate  
9 and 1 low.

10 And overall suitability for  
11 endorsement. Does the measure meet NQF  
12 criteria for endorsement? Yes or no.

13 Fifteen yes and one no. So the  
14 measure will pass.

15 CHAIRMAN LUTZ: All right. Not to  
16 confuse anyone, but the next one I think by  
17 virtue of who's available to be moved up in  
18 line is 0391. I know, Elizabeth, you have to  
19 leave in four minutes, correct? Do you have  
20 the capability in four minutes and four  
21 seconds to tell us what we need to know?

22 MEMBER HAMMOND: I think I can.

1 MS. FRANKLIN: Sorry. If there's  
2 a developer on the line from AMA-PCPI, could  
3 we please open their lines, or from College of  
4 American Pathologists? Or if they're in the  
5 room? Okay. There they are. Okay. There  
6 they are. Sorry. Okay.

7 MEMBER HAMMOND: All right. This  
8 is a maintenance measure that was originally  
9 endorsed in 2008. It is a measure that seeks  
10 to show that the staging information is being  
11 collected on all patients with breast cancer  
12 resection specimens. It has been shown over  
13 and over again in the literature that staging  
14 information is very critical to patients.  
15 We've talked about this in other cancers at  
16 our last meeting. And the data and the way in  
17 which this is presented is very analogous to  
18 those other sites. So staging information is  
19 used to treat patients and this is an attempt  
20 to collect that staging information and to  
21 demonstrate whether or not it's present.

22 The impact of breast cancer is

1 high. There is a performance gap related to  
2 proposing this or recording this staging  
3 information. As we said last time when we  
4 were talking about other places, we know that  
5 the outcome of a patient is directly related  
6 to stage, but whether or not the recording of  
7 stage relates to outcome is not necessarily  
8 known. This is a process measure and it is  
9 supported only by indirect data, but there's  
10 a lot of indirect data that supports it.

11 Because I'm going to be leaving, I  
12 would like to just go on and mention my  
13 thoughts about acceptability. I think the  
14 reliability of this measure is very high. The  
15 data is collected in a meaningful way and the  
16 measure is a valid measure, although I would  
17 rate its validity as being moderate. The  
18 information would be meaningful to the public  
19 because staging information hopefully is  
20 something understood by the public. So I  
21 think it has a high usability criteria. It is  
22 feasible to collect since the data is

1 generated during clinical care. So I believe  
2 that this measure should be accepted for  
3 endorsement.

4 And there were no specific issues  
5 that I felt needed to be addressed. Let's  
6 see. Oh, the only thing that was brought up  
7 that I think is really a serious problem that  
8 can't be addressed by this particular  
9 performance measure is that often there's  
10 staging information embedded in several  
11 pathology reports, and one of the difficulties  
12 is how do you decide which pathology report  
13 you would use.

14 Typically that's the latest  
15 pathology report is usually the one that is  
16 usually used, but in some cases it's the  
17 initial report. And because we don't have  
18 valid codes to measure a summary report or we  
19 don't even have a form of a summary report  
20 yet, that issue cannot really be adequately  
21 addressed. But it occurs across all of  
22 pathology reporting. It's not specific to

1 this breast cancer measure.

2 So basically, the situation is  
3 very similar to the measures we passed at our  
4 last meeting related to other cancers and  
5 staging measures. Does anybody have any  
6 questions for me before I run out the door?

7 MEMBER MALIN: Maybe I missed  
8 this. What happens if it's just an excision  
9 and the lymph node biopsy hasn't happened yet?

10 MEMBER HAMMOND: Well, if it's  
11 only an excision, there won't be any lymph  
12 node status. But typically in that situation  
13 what should be said is that the lymph node  
14 status would be designated as an X, which  
15 means that the person writing the report has  
16 no understanding about the status of the lymph  
17 nodes at that time. So if you look at all the  
18 pathology staging reports, you should find one  
19 where there's the most information, and that  
20 most information should be the one that's  
21 used.

22 So if you're only looking at an



1       excision specimen, it will be pT with a  
2       number, pN with an X, and pM for metastasis  
3       with an X. But if there are lymph nodes, it  
4       will be both.

5                       (Off mic comments.)

6                       MEMBER HAMMOND: Oh, there isn't?

7                       (Off mic comments.)

8                       MEMBER HAMMOND: All right. Well,  
9       I should have left before I -- Well, then I  
10      was not --

11                      MEMBER EDGE: There is no such  
12      thing as MX. So they will not be listed as  
13      MX. I'm sorry.

14                      MEMBER HAMMOND: So what do you do  
15      in the situation where you have no knowns? Do  
16      you record it as being --

17                      MEMBER EDGE: No, M. M.  
18      Metastases. There is no MX.

19                      MEMBER HAMMOND: Oh, there's no M?  
20      Okay. But there is an NX?

21                      MEMBER EDGE: A patient is either  
22      clinically M0 pathologically --

1 MEMBER HAMMOND: Oh, good.

2 MEMBER EDGE: -- M1 or clinically  
3 M1.

4 MEMBER HAMMOND: All right.

5 MEMBER EDGE: There is no such  
6 thing as MX.

7 MEMBER HAMMOND: Okay. So there  
8 is a way to tell.

9 CHAIRMAN LUTZ: Thank you,  
10 Elizabeth, and safe travels.

11 MEMBER HAMMOND: Thank you.

12 MEMBER LOY: If you caught them in  
13 a slice time where they had gotten an  
14 excisional biopsy and they wrote down p and  
15 NX, would that be counted as compliant before  
16 they'd gotten the full specimen?

17 MEMBER HAMMOND: Yes, because they  
18 might never get another specimen.

19 MEMBER LOY: Right. Right. Okay.

20 MEMBER HAMMOND: It would.

21 MEMBER LOY: So as long as they  
22 have used the appropriate notation --

1 MEMBER HAMMOND: Codes.

2 MEMBER LOY: -- no matter where  
3 you've gotten them --

4 MEMBER HAMMOND: Right. Right.

5 MEMBER LOY: -- they could --

6 MEMBER HAMMOND: Right. There is  
7 a strong meet though; and we talked about this  
8 on the conference call, for something called  
9 an integrated report, which would be at the  
10 end where all the information was recorded in  
11 one place. The College of American  
12 Pathologists is actually working on this  
13 through their electronics interfacing  
14 groups trying to come up with something like  
15 that. And at that time, when we ever get it,  
16 that will be something we can bring back for  
17 a measure.

18 CHAIRMAN LUTZ: I know we're a  
19 little out of order, but do our AMA or CAP  
20 folks have anything to say?

21 DR. SPEIGHTS: I don't think we  
22 have anything to add. Emily?

1 DR. VOLK: Nothing to add.

2 CHAIRMAN LUTZ: Okay. Then I  
3 guess we need to go first to importance.

4 MS. KHAN: So, voting on 1a,  
5 impact.

6 CHAIRMAN LUTZ: Is there any  
7 further discussion on importance?

8 (No response.)

9 MS. KHAN: Oh, we are voting on  
10 1a, impact. So if you could send your votes  
11 in to Lindsey.

12 Twelve high, three moderate and  
13 one low.

14 CHAIRMAN LUTZ: Anybody have  
15 comments about opportunity for improvement?

16 (No response.)

17 MS. KHAN: So voting on 1b,  
18 performance gap.

19 So it's nine high, five moderate,  
20 one low and one insufficient.

21 And voting on the evidence. Yes,  
22 no, or insufficient.

1                   CHAIRMAN LUTZ: Any further  
2 comment on evidence?

3                   (No response.)

4                   CHAIRMAN LUTZ: Okay.

5                   MS. TIGHE: Dr. Marks, can you  
6 send your vote, please?

7                   MEMBER MARKS: Sorry.

8                   MS. KHAN: We have 14 yes and two  
9 no.

10                  CHAIRMAN LUTZ: Any discussion  
11 about reliability?

12                  (No response.)

13                  MS. KHAN: Voting on reliability.

14                  Can everyone just press it one  
15 more time, please?

16                  So that's 10 high, 4 moderate, 1  
17 low and 1 insufficient.

18                  CHAIRMAN LUTZ: All right.  
19 Anything additional about validity testing?

20                  (No response.)

21                  MS. KHAN: Voting on 2b, validity.

22                  So we're missing two votes. If

1 you could press it one more time.

2 So four high, eight moderate, two  
3 low and one insufficient.

4 CHAIRMAN LUTZ: Anything about  
5 usability? Bryan?

6 MEMBER LOY: One shortcoming we  
7 might have identified here in the process is  
8 that we may not have complete information. It  
9 seems to me in order for this to really be  
10 linked to a health outcome, even indirectly,  
11 you would want what Dr. Hammond had advanced  
12 before, and that is, you really want the  
13 complete integrated report. So if we give  
14 somebody credit for something, meaning they  
15 did the appropriate pathologic staging on an  
16 excisional biopsy but that didn't get it  
17 accomplished when they actually did the node  
18 dissection and all the accompanying pieces of  
19 it, we might find that our results might not  
20 reflect what we're really trying to measure.

21 Have you all given any thought to  
22 that, measure developers? I mean, I

1 understand it doesn't need to be perfect. I'm  
2 not trying to say that it's still not useful.  
3 It just seems as though it kind of clouds the  
4 issue, if that makes any sense.

5 DR. SHAMANSKI: Can I just add one  
6 point? This is on resection. Biopsies are  
7 not included in this measure.

8 MEMBER LOY: Okay. Well, I  
9 misunderstood her, then. I thought that if it  
10 was an excisional biopsy and it was staged  
11 properly, that you got credit in the  
12 numerator, is what I thought I heard. Is that  
13 not true?

14 PARTICIPANT: No.

15 MEMBER LOY: So only when you have  
16 a complete --

17 DR. SPEIGHTS: If an excisional  
18 biopsy or lumpectomy, tylectomy, whatever  
19 names it goes under, can completely remove a  
20 tumor, it may or may not be accompanied by  
21 lymph nodes.

22 MEMBER LOY: Correct. Okay.

1 DR. SPEIGHTS: With this, as with  
2 any measure, all we can report on is what we  
3 have. And we really need to have the complete  
4 tumor resected and the margins free to really  
5 say the T category (telephonic interference)  
6 big it is.

7 MEMBER ALVARNAS: I'm sorry, but  
8 how is that related if the path report doesn't  
9 have an N stage result? For example, how do  
10 we differentiate just a T stage, but not an N  
11 stage? How do we differentiate that? How are  
12 we differentiating not meeting the criteria  
13 versus not having nodes submitted, for  
14 example?

15 DR. VOLK: Again, you would use  
16 the NX designation if nodes were not  
17 submitted. This is Emily Volk from the  
18 Baptist Health System in San Antonio, and I'm  
19 a practicing pathologist here. And I think  
20 what this measure does is encourages the most  
21 accurate up-to-date staging at every point  
22 along the way in the patient's journey.



1 DR. SHAMANSKI: And I would just  
2 add; this is Fay Shamanski from CAP, that it's  
3 breast cancer resection pathology reporting.  
4 The CPT codes that are included in the  
5 denominator are 88307 and 88309, if that means  
6 anything to you. Those are not biopsy codes.

7 MEMBER ALVARNAS: Are those breast  
8 surgeries or axillary surgeries, or both?

9 DR. VOLK: Both. Any time there's  
10 a margin that needs to be evaluated, it  
11 changes the code from a biopsy code to a  
12 resection code.

13 MEMBER ALVARNAS: So for example,  
14 a patient goes in for axillary surgery, but  
15 they don't enter the breast again, is that  
16 going to be captured? Because that would be  
17 a pX if they don't have the old report, for  
18 example.

19 DR. SPEIGHTS: Again, the most we  
20 can report on is what we have. It is possible  
21 that the tumor may be resected at one  
22 facility. Patient goes elsewhere and then has

1 an axillary dissection in which the lymph  
2 nodes are removed.

3 MEMBER MARKS: But (telephonic  
4 interference) so the pathologist is given  
5 appropriate credit, if you would, reporting  
6 what they have based on the information  
7 available to them.

8 DR. VOLK: This measure would  
9 capture that.

10 MEMBER FIELDS: So we had this  
11 same question. I brought it up on the group  
12 call. And in breast, it's very common that  
13 they have multiple re-resections. So I think  
14 unless we get to the point of really trying to  
15 have summary reports, it still won't give us  
16 the level of quality we need in this  
17 particular disease. It's true that other  
18 diseases have multiple resections for margins,  
19 but in breast it's pretty traditional that you  
20 have the lumpectomy. And returns to the ORs  
21 are not that uncommon. And there's multiple  
22 stage procedures. So that was our --

1                   MEMBER MARKS: But I think the  
2 majority of patients have read the synoptic  
3 report, the synoptic path report. Right?

4                   MEMBER FIELDS: So I don't think  
5 the resection code issue answers or solves the  
6 problem about getting to the quality end point  
7 that we need, which is we need to know what  
8 the TNM stage is before we make a treatment  
9 decision.

10                  MEMBER MARKS: Do you have any  
11 clinicians who actually make the decision  
12 based on the path stage given the path report  
13 as opposed to the later staging based on  
14 assimilation of the two or three path reports  
15 that we have in the clinic?

16                  MEMBER FIELDS: I would say I know  
17 a whole bunch of clinicians, because we're  
18 relying on the pathologists to tell us what  
19 the stage was. I'll let the surgeon answer  
20 that.

21                  MEMBER EDGE: I think the question  
22 was does he know a clinician who rely on the

1 single path report rather than both the  
2 aggregate of all the path reports, plus the  
3 imaging studies, plus the clinical examination  
4 that goes into it? And I don't ever make a  
5 recommendation --

6 MEMBER MARKS: Right.

7 MEMBER EDGE: -- based on a single  
8 path report. To me unfortunately it makes me  
9 concerned that this measure -- this is why  
10 this measure really isn't linked to outcome.

11 MEMBER MARKS: Right.

12 MEMBER EDGE: And it makes me  
13 really struggle with whether we should be  
14 approving the measure. Did the person write  
15 down on a piece of paper as opposed to did the  
16 doctor provide a treatment that was  
17 appropriate for the true stage of the patient?  
18 But that's another question.

19 MEMBER MARKS: No, I agree.

20 MEMBER MALIN: I mean, I think,  
21 you know, some of the times the pathologist-  
22 specified T stage can be misleading. So let's

1 say it's the third excision, or whatever. And  
2 I've seen this happen before, you know, either  
3 it was a different pathologist at the same  
4 institution or a different institution that  
5 they didn't aggregate across. And then you  
6 see on the third path report, you know, a  
7 specific, you know, T stage that's just  
8 reflecting the tumor that they got out of that  
9 specimen, not the two other things that  
10 happened before, and it can be wrong. And so  
11 if you as the clinician aren't making sure  
12 that you've checked it -- so at least  
13 personally I don't ever rely just on the  
14 pathologist-specified stage. I always  
15 calculate myself.

16 MEMBER FIELDS: Well, I mean, I  
17 think -- but you have to have all of the  
18 information. And --

19 MEMBER MALIN: But have you looked  
20 at what they gave you?

21 MEMBER FIELDS: Except for the  
22 most common scenario where the pathology stage

1 is what you needed or the timbers that had  
2 positive margins, but you go back in the --  
3 there were close margins and the margins were  
4 clear. And so, the bottom line is somehow we  
5 need to get to the point where somebody does  
6 a summary of the data that we have so that  
7 it's not in multiple stages. And there are  
8 some pathologists that are very compulsive  
9 about that and do that. And then there are  
10 some that just don't do that.

11 And so I guess opportunities for  
12 the future would be getting to that level of  
13 reporting so it's helpful. And it's true, you  
14 have to use everything. You have to use  
15 physical exam, radiographic images, and  
16 everything else. But there's lots of times  
17 where you had a close margin. You go back  
18 because the margins were close. There's  
19 nothing there. The path stage is the stage.  
20 So the answer is yes lots of time.

21 MEMBER MALIN: But if it's that  
22 one report -- I mean, maybe this is being

1 harsh, but how much added value is it for them  
2 to go ahead and put it in a category versus  
3 just seeing the tumor size there on that  
4 report?

5 MEMBER FIELDS: If it's in a  
6 summary document, it would be lots of value.

7 MEMBER MARKS: But there is no  
8 construct beyond that summary document.

9 MEMBER FIELDS: We're just saying  
10 that that was our request.

11 MEMBER MARKS: I agree it would be  
12 nice if they read the summary document, but if  
13 there is a mechanism to generate that, I'm not  
14 sure of the validity of this metric.

15 MEMBER LOY: I can't disagree with  
16 what you just said, but I have to say given  
17 where we are -- and we live in a world where  
18 we don't have that synthesis of all path  
19 reports -- this certainly has to be more  
20 desirable to have this document than to not be  
21 documented. So it certainly seems like a  
22 valuable step given where we are today, but it

1 certainly seems like we should be making  
2 recommendations for the future world.

3 CHAIRMAN LUTZ: So necessary but  
4 not yet sufficient, or not yet comprehensive?

5 MEMBER LOY: I would agree with  
6 that.

7 CHAIRMAN LUTZ: Okay.

8 MEMBER MARKS: I'm not sure if  
9 this would come into your discussions or not,  
10 but on the opportunity costs. And yes, this  
11 might be a good first step, but this is -- you  
12 know, perhaps other measures that may be --  
13 one could spend one's energy on that might be  
14 more useful in the pathology realm. I don't  
15 know what those are, but I'm just saying, it  
16 seems like a good step forward doesn't mean  
17 necessarily we should do it because there are  
18 opportunity costs.

19 MEMBER FIELDS: Just one final  
20 comment though. I think they showed us a huge  
21 performance gap which was --

22 MEMBER MARKS: That's true, yes.



1                   MEMBER FIELDS: -- 32 percent of  
2                   the reports don't have all the elements. And  
3                   then there's another report that's similar to  
4                   that. So I'd have to say mom and apple pie  
5                   comes first and then we get to better levels  
6                   of reporting and quality.

7                   MEMBER MARKS: That's fair.

8                   CHAIRMAN LUTZ: All right.

9                   DR. SPEIGHTS: Obviously, you  
10                  know, we have to report on what we have. We  
11                  can't say the tumor size unless we have a  
12                  completely resected tumor. And sometimes we  
13                  just have to say that according to an outside  
14                  report there was a one-centimeter tumor seen  
15                  that involved the margins elsewhere. We have  
16                  another centimeter tumor here and we have to  
17                  give our best assessment of the final T stage  
18                  based on what we see.

19                  Now our path reports, at least in  
20                  my institution, say something to the effect  
21                  that this staging information is based on the  
22                  pathology specimen. There can always be a

1 lung CT or something that shows a metastasis  
2 that we aren't privy to that could upstage.  
3 But I think what we're trying to do is to  
4 close the gap so that we give appropriate T  
5 and N categories whenever we can.

6 CHAIRMAN LUTZ: All right.  
7 Anything else? We're actually -- Elaine?  
8 Sorry.

9 MEMBER CHOTTINER: Is there any  
10 attempt to incorporate the clinical staging in  
11 any way because of the larger number of  
12 patients who are receiving neoadjuvant therapy  
13 where the clinical stage is actually going to  
14 be more accurate? Is that reflected in the  
15 reports?

16 DR. SPEIGHTS: If the patient has  
17 received previous treatment, it should be a Y,  
18 and there should be a Y in front of the T,  
19 receiving neoadjuvant or what have you, which  
20 implies a caveat that we report again what we  
21 see pathologically, but that hopefully the  
22 neoadjuvant treatment has downstaged the

1 disease.

2 CHAIRMAN LUTZ: All right. I  
3 think we left off on voting on usefulness. Is  
4 there anything else to add for that?

5 MEMBER MARKS: Did we actually  
6 vote on that yet?

7 CHAIRMAN LUTZ: We're just about  
8 to.

9 MEMBER MARKS: Okay.

10 MS. KHAN: So voting on usability.  
11 You can go ahead and send your votes in now.

12 So we have four high, eight  
13 moderate, three low and zero insufficient.

14 CHAIRMAN LUTZ: Is there any  
15 additional discussion about feasibility?

16 (No response.)

17 MS. KHAN: And voting on  
18 feasibility.

19 So we have five high, eight  
20 moderate, two low and zero insufficient.

21 And overall suitability for  
22 endorsement. Does the measure meet NQF

1 criteria for endorsement? Yes or no.

2 I think we're missing one vote.

3 So we have 12 yes and 2 no. So  
4 the measure will move forward.

5 CHAIRMAN LUTZ: All right. Then  
6 the same logic applies in terms of who's  
7 available to present for us.

8 Next one is 0392, which would have  
9 been after the break, but we'll do it now.  
10 Anything from our AMA or CAP folks to give us  
11 the framework?

12 DR. WITTE: This also is a  
13 maintenance measurement. It was developed by  
14 a broad multi-disciplinary group convened by  
15 the AMA and supported by the College of  
16 American Pathologists Use Guidelines. It's  
17 been in use in multiple places. It's been in  
18 the PQRS program. Obviously colon cancer is  
19 frequent. The gap in the most recent data was  
20 about 25 percent. It focuses on guidelines  
21 and it focuses on those elements of the  
22 guideline (telephonic interference) useful in

1 guiding therapy. And it has been useful and,  
2 we believe, reliable.

3 CHAIRMAN LUTZ: All right. We  
4 have John and Bryan listed as double-teaming  
5 this one.

6 MEMBER GORE: So basically when we  
7 look at importance, we discussed the  
8 prevalence of colon cancer, being a very  
9 common cancer among men and women and the need  
10 for accurate pathology reporting. As for  
11 example, distinguishing between stage 2 and  
12 stage 3 colon cancer, it is very important to  
13 delivery of adjuvant therapies. And in terms  
14 of performance gap, the surprising  
15 identification of inaccurate complete  
16 pathologic staging in up to 25 percent of the  
17 pathology reports missing elements such as  
18 grade or nodal status. And so, in terms of  
19 importance, our work group universally  
20 declared this to be an important measure to  
21 report.

22 Bryan, did you have anything to

1 add?

2 MEMBER LOY: No.

3 MEMBER GORES: In terms of  
4 disparities, there's not really much on there,  
5 but in terms of importance to measure and  
6 performance gap.

7 CHAIRMAN LUTZ: Anybody have  
8 anything to add on importance?

9 (No response.)

10 CHAIRMAN LUTZ: All right. Should  
11 we vote on 1a?

12 (No response.)

13 CHAIRMAN LUTZ: So for those of  
14 you on the phone, we are voting on 1a.

15 MEMBER ALVARNAS: Thanks for  
16 clarifying.

17 CHAIRMAN LUTZ: So we're going to  
18 go back to square one on voting on 1a. One  
19 moment.

20 MS. KAHN: Importance to measure  
21 in our report. Impact. One high, two  
22 moderate, three low, four insufficient.

1                   We need three more votes. If you  
2 could try voting again.

3                   DR. TIGHE: Dr. Marks, if you  
4 could send me your vote.

5                   CHAIRMAN LUTZ: I'm sorry, David.  
6 Did you have something to --

7                   MEMBER PFISTER: Yes, in my  
8 colorectal -- in a trip, we make sense,  
9 because you know obviously grade and reports,  
10 but what management decision is association  
11 with grade of a cancer?

12                  DR. WITTE: I'm sorry, could you  
13 repeat that?

14                  MEMBER PFISTER: Yes, like it  
15 certainly makes sense that they use the T and  
16 N data to make a management decision, but  
17 under what circumstances does grade affect  
18 that management decision? You know, once  
19 you've got a diagnosis of invasive cancer?

20                  MEMBER RICCIARDI: This is Rocco  
21 Ricciardi from Lahey. The only thing I could  
22 think that would be of any value that we use

1 would be with a T1 tumor based on the depth of  
2 invasion in the submucosa and the grade of the  
3 tumor.

4 MS. FRANKLIN: You faded out.  
5 Hello? You faded you just a bit.

6 MEMBER RICCIARDI: Oh.

7 MS. FRANKLIN: Could you repeat  
8 that?

9 MEMBER RICCIARDI: Yes, what I was  
10 saying is that based on the grade and  
11 sometimes the level of invasion into the  
12 submucosa we'll base a decision about a T1  
13 rectal tumor as to whether or not treat it  
14 locally versus a more extensive resection.

15 DR. SPEIGHTS: Following up,  
16 sometimes when colon polyps are locally  
17 resected whether it's poorly differentiated or  
18 not can be determinative of whether to do a  
19 more extensive resection or not.

20 MEMBER GORE: One thing, we also  
21 were curious on the call was about why it's  
22 just T, N and grade and not margin status?



1 DR. WITTE: We are trying to  
2 remember the discussion on that. I apologize  
3 for not being able to bring back five-years-  
4 ago discussion. I think part of the reason  
5 was there wasn't -- when we reviewed the data,  
6 if I remember correctly, that what was missing  
7 was not that, so the gap -- we tried to pick  
8 the stuff that was higher gap, is what I  
9 recall, but I'd have to go back and review  
10 that.

11 CHAIRMAN LUTZ: Jennifer?

12 MEMBER MALIN: I think, you know,  
13 similarly to some of the discussions we've had  
14 about some other measures, you know, it might  
15 be worth considering updating this measure.  
16 You know, grade is not so important, but  
17 number of lymph nodes evaluated is. And I  
18 think certainly margin status is arguably more  
19 important. And then other things like, you  
20 know, if you want to look at things that  
21 actually impact outcomes. Things like  
22 lymphovascular invasion, you know, evidence of

1 rupture, things like that would be more  
2 relevant.

3 MEMBER LOY: Yes, I think we're  
4 going to get there, but further on we're going  
5 to hear some other things that might be more  
6 contemporary like KRAS testing, etcetera. I  
7 think all signs; at least in my view, are  
8 pointing towards a more synthesized report  
9 that encompasses all the clinically and  
10 important and molecular diagnostic predicted  
11 biomarkers, et cetera, into one report. And  
12 I just don't think we're there yet.

13 MEMBER MALIN: But I think this is  
14 just kind of a global issue. You know, with  
15 a lot of these measures that we're seeing for  
16 re-review, they were sort of barely reaching  
17 a threshold the first time they were, you  
18 know, endorsed for being kind of relevant and  
19 driving improvement. And for, you know, what,  
20 is it five years later, to not have something  
21 that's trying to move the bar, I personally  
22 find disappointing. So I think it would just

1 be, you know, good to re-look at the evidence,  
2 not just to bring back the same measure, but  
3 to have a little more responsibility on the  
4 part of the measure developers to see really  
5 what needs to be done to move the bar.

6 CHAIRMAN LUTZ: John?

7 DR. WITTE: We certainly are  
8 sensitive to the synthesization of the report  
9 as we were on the previous measure, and that  
10 certainly is in our docket, as Dr. Hammond  
11 indicated. There still remains a performance  
12 gap for this measure. I think the criticisms  
13 are registered and taken to heart.

14 MEMBER ROSS: So I have a question  
15 on the performance gap. So is that the data  
16 that was originally presented in 2008, or is  
17 that current data? I'm confused about that,  
18 the 21 percent.

19 MEMBER GORE: Looking at 1b, the  
20 data does give for the demonstration of  
21 performance gap is 2008.

22 MS. CHRISTENSEN: Yes, so the data

1 there, the 10th percentile, the 25th, 50th,  
2 75th and 90th percentile is 2008 data, which  
3 is unfortunately the most recent that CMS has  
4 been able to make available for us to report  
5 publicly.

6 MEMBER ROSS: So I agree with  
7 Jennifer about raising the bar. And we've now  
8 -- at last meeting and this one have sat  
9 through a number of those in which we're  
10 validating staging, which is the essence of  
11 oncology care. And I still remain surprised  
12 that in 2012, we're revalidating staging.

13 But this doesn't seem to make  
14 sense, because in the last four years there  
15 have been so many presentations at all of the  
16 oncology meetings, NCCN, addressing the points  
17 that you're talking about, Jennifer; number of  
18 nodes, how the resections are done. And to  
19 just go ahead and validate another staging  
20 that is at least four years old in terms of  
21 the data that documents a gap that may no  
22 longer exist doesn't make sense to me.

1 DR. ANTMAN: Mark Antman speaking  
2 for the PCPI. So unfortunately, as Keri was  
3 saying, we can only report the most recent CMS  
4 data that we have for the PQRS system. And  
5 obviously if we had more recent data, we would  
6 provide that.

7 If I may jump off of what Dr.  
8 Witte said a moment ago, this is very valuable  
9 feedback. This is a measure set. As we've  
10 been saying, it is five years old. And so  
11 that means that it is one of the measure sets,  
12 one of the PCPI measure sets that is certainly  
13 due for a review and for an update. And by  
14 all means, the recommendation of this steering  
15 committee will be paramount in the discussions  
16 of the work group in considering how to update  
17 the measures. So I think we have to defer to  
18 this committee as to whether or not you feel  
19 that the measure as it stands is still  
20 beneficial and is still better to retain  
21 endorsement rather than have no measure in the  
22 meantime until we're able to update it. But

1 by all means, these recommendations I think  
2 will be very useful for knowing exactly how to  
3 do that update.

4 CHAIRMAN LUTZ: Do Pat and then  
5 John.

6 MEMBER ROSS: Kind of a follow-up  
7 to that. So I guess I may not understand the  
8 process; and I should because we've now sat  
9 through three days of it and a few conference  
10 calls, but I'm a surgeon, so indulge me.

11 So in 2008 a committee like this  
12 validated this and said move this forward. Am  
13 I interpreting that correctly?

14 DR. WITTE: Yes.

15 MEMBER ROSS: No?

16 DR. WITTE: Well, partially I'd  
17 say.

18 MEMBER ROSS: So let me finish the  
19 question and then perhaps you can educate me.

20 DR. WITTE: Well, not much.

21 MEMBER ROSS: But how can we now  
22 say -- if we validated this, someone collected

1 the data, right? We've been collecting this  
2 data for four years and you can't give us any  
3 new news?

4 DR. WITTE: Well, let me just say  
5 that the data that was presented when this was  
6 originally approved was data that came from  
7 literature studies, not from performance  
8 measurement formal program studies.

9 MEMBER ROSS: But where's the data  
10 that's been collected for the last four years?

11 DR. WITTE: That's what Dr. Antman  
12 spoke to.

13 MS. CHRISTENSEN: So CMS is the  
14 organization that runs the PQRS program. And  
15 they provide information back to doctors, but  
16 they do not make that information publicly  
17 available. So we are unable to give you data  
18 because they don't make it available to us  
19 either. So they are collecting the data.  
20 They are looking at the data and they do make  
21 a determination every year about what measures  
22 they're going to keep and what measures they

1 will retire from their program, but we do not  
2 have the data that we are able to give to you  
3 for anything more recent than 2008 just  
4 because it's their data.

5 MEMBER ROSS: Does that make  
6 sense?

7 MS. CHRISTENSEN: We would very  
8 much like the data that is more recent, but  
9 unfortunately the government gets to make that  
10 decision.

11 CHAIRMAN LUTZ: The way it's been  
12 described to me is we give these measures,  
13 they sit up on a shelf, and based upon what  
14 Medicare sees from real-time data, they decide  
15 which ones to take off the shelf and use and  
16 which ones to put out in the trash. Is that  
17 too simplistic? That was the way it was  
18 described to me.

19 MEMBER ROSS: It seems somewhat  
20 not reasonable to just revalidate it. I don't  
21 know. Doesn't make sense.

22 MEMBER GORE: So, I mean, this is



1 a comment I was going to make: the question  
2 then becomes is this something analogous to  
3 what we did with the melanoma measures last  
4 time? I mean, there are clearly elements of  
5 this that are important and we all believe in  
6 accurate pathologic reporting, but there are  
7 more elements to the path report that we know  
8 are important that maybe were less useful five  
9 years ago. Do we just recalibrate the  
10 measure? You know, I don't know.

11 MS. FRANKLIN: We have to --

12 MEMBER GORE: I know we have to  
13 evaluate it as is.

14 MS. FRANKLIN: Yes, as is and go  
15 through the criteria and vote. If you find  
16 that you don't think the evidence is  
17 sufficient to support the measure, you can  
18 still make a determination as a steering  
19 committee, if you want to vote to move the  
20 measure forward if the benefits outweigh the  
21 harms.

22 MEMBER GORE: Yes, and I think the

1 hard part is I think it's important and I  
2 think it meets a lot of the criteria, but it  
3 could be better.

4 MEMBER ROSS: Right. So I guess  
5 to the sponsor, I mean, why isn't the burden  
6 on the six of you to have brought us an  
7 updated version instead of just bringing us  
8 one that is in a maintenance mode?

9 DR. SHAMANSKI: You know, the  
10 measure was developed in 2007.

11 MEMBER ROSS: Right.

12 DR. SHAMANSKI: And it was  
13 endorsed by NQF in 2008.

14 MEMBER ROSS: And none of us  
15 practice the way we practiced in 2007.

16 DR. SHAMANSKI: Okay. We then  
17 spent the next year-and-a-half testing these  
18 measures. So now we're already up into the  
19 end of 2010. There's only so much time, first  
20 of all, to get this stuff done. So I think  
21 there is a lag in --

22 MEMBER ROSS: A half a decade lag?

1 DR. SHAMANSKI: It takes a long  
2 time.

3 DR. WITTE: If you think this  
4 frustrates you, you should have been on our  
5 end of the testing.

6 MEMBER ROSS: Well, it does  
7 frustrate us, yes.

8 DR. WITTE: Believe we are taking  
9 your comments to heart, because I think they  
10 are very important. When this was developed,  
11 we had the data for about 10 elements, as I  
12 recall, in the colorectal cancer report and we  
13 selected the three that we thought were most  
14 important and had the biggest gaps.

15 Some of those other seven elements  
16 had very small gaps. And we thought, not to  
17 add to the burden of all of the record  
18 keeping, we'd just pick the three that we felt  
19 were most important either for guiding therapy  
20 or for being absent from the report.

21 Now we have not gone back to get  
22 another (telephonic interference) as far as

1 I'm aware. But that's how we got to the three  
2 that we have.

3           Going forward I think the  
4 suggestion that we have a summarizing path  
5 report is an excellent suggestion. And in  
6 fact, as Dr. Hammond said, the body of  
7 pathology agrees with that and it has groups  
8 of people working on how would we get to that?  
9 There are currently no mechanisms to have a  
10 code so we could keep track of it, and we're  
11 working on that.

12           But as far as being able to either  
13 tell you that there's more data after what the  
14 CMS has given us, we're kind of stuck. And I  
15 guess we don't have any other data, because  
16 our data would not be anywhere near as broad  
17 as what CMS could give us as far as --

18           MEMBER ROSS: No, I understand  
19 everyone's well motivated; and I apologize for  
20 being stuck on this, but I've been listening  
21 all day and perhaps I just needed to get it  
22 off my chest. My psychiatrist will be happy

1 that I'm doing this.

2           So I'm disappointed that we bring  
3 experts and interested parties to the table to  
4 validate something based on no data. We're  
5 trying to make a decision on whether something  
6 is worth collecting, and a stakeholder has  
7 that information but doesn't share it with us.  
8 The only information that can validate whether  
9 to reaffirm this is what's been collected in  
10 the last three years.

11           DR. WITTE: I'm not in your group,  
12 but it strikes me that you have another place  
13 to communicate that. We would certainly, I  
14 think, be in favor of you doing that.

15           DR. ANTMAN: And if I may add, so,  
16 Dr. Ross, we certainly share the frustration  
17 that you're expressing. I think as my  
18 colleagues have said, we are not the  
19 collectors of the data and we can only work  
20 with the data that we do have.

21           I will note; and I apologize if  
22 it's already been noted by this committee in

1 this discussion, but I think it's noteworthy  
2 that the performance gap that's cited in our  
3 documentation is from information that was  
4 collected in 2010. So that is somewhat more  
5 recent data that does note that the gap, the  
6 performance gap in the -- or the percentage of  
7 reports that are missing at least one of the  
8 required elements was still 21 percent at that  
9 point. And so at least we have that as more  
10 recent information that we can provide.

11 Although, as noted, we do not have more recent  
12 actual testing information.

13 CHAIRMAN LUTZ: All right. We'll  
14 let David get something off his chest, and  
15 then John's turn.

16 MEMBER PFISTER: No, I think that  
17 the -- you know, I think this is a very  
18 worthwhile discussion though. I think that in  
19 a lot of ways I think as Patrick implied,  
20 that, you know, while it may seem we spend  
21 disproportionate amount of time on this, on  
22 this particular measure, it's not unique to

1 this measure at all.

2 And I think that when it came up  
3 earlier about there being a venue where you  
4 look at certain process-related issues, like  
5 the exclusion of the numerator versus  
6 denominator, it's a more fundamental  
7 methodologic sort of approach, which, you  
8 know, applies across the board to multiple  
9 metrics.

10 Yes, I would certainly share my  
11 impression from the last meeting and this  
12 meeting that when things come up for  
13 reassessment that there's often very little  
14 that -- you could change the date on the  
15 submission form and it's basically the same  
16 submission form that was looked at the prior  
17 time. And that, you know, I think it may be  
18 worth, you know, being more explicit with the  
19 subsequent forms, not just for this, but for  
20 other measures as well that are coming up for  
21 sort of renewal. This is what's new. And it  
22 would at least leverage a little behavior to

1 say, well, if we don't have much out there,  
2 that's probably not a good thing, although it  
3 may be beyond your control in terms of  
4 providing what's new.

5 But I think that there is a  
6 certain kind of -- when things get past the  
7 first time, it's often on the presumption,  
8 well, more is coming. But by and large, I  
9 find that for a lot of the measures that come  
10 back that really more isn't coming. And it's  
11 sort of like we don't really raise the bar in  
12 our assessment of the measures  
13 proportionately. And I think that that's sort  
14 of something which I think is a general part  
15 of the process which I think is worth  
16 revisiting. It was sort of a touchstone for  
17 this particular measure, but I'm not sure this  
18 is in any way unique to this measure.

19 MEMBER GORE: So toward that, and  
20 this is maybe a better discussion for the kind  
21 of future directions of NQF, as they evaluate  
22 new processes for how the performance measure



1 process works, is there a possible process for  
2 essentially like amendments or updated  
3 modifications to measures?

4 MS. FRANKLIN: Yes, there's an  
5 annual update for the measures.

6 MEMBER GORE: Oh.

7 MS. FRANKLIN: As new information  
8 becomes available --

9 MEMBER GORE: Okay.

10 MS. FRANKLIN: -- the developers  
11 are able to amend their submissions.

12 MEMBER GORE: Okay.

13 MEMBER LOY: One more comment. I  
14 heard Angela say that, you know, you need to  
15 vote on this. You might want to consider  
16 voting that there's insufficient evidence to  
17 support. I think where I find myself is  
18 there's really insufficient data to even have  
19 an opinion at this point one way or the other.

20 So I just recommend that if  
21 there's a way to weight some of these  
22 questions in the renewal mode or the

1 maintenance mode -- because I for one would be  
2 very hesitant to say, no, take this away.  
3 Because at least in my view, and I think the  
4 point's already been expressed, this is table  
5 stakes at this, you know, time in 2012. If  
6 you don't document your pathology well, that's  
7 a very different expectation now than it was  
8 even five years ago.

9           And to the synthesis comment, you  
10 know, I heard you use the word criticism and  
11 I just wanted to pull back from that just a  
12 slight bit, because I don't think we're there  
13 yet and I think the measure developers have  
14 been contemporary in that we've kind of chosen  
15 the important things. We have measures yet to  
16 look at today that do address lymph nodes and  
17 do address KRAS. So I think those are very  
18 important.

19           Still, I think there's  
20 opportunity, but I also think there's  
21 opportunity for these maintenance pieces to  
22 have a stiffer requirement on some sort of

1 data. But again, I would be very hesitant to  
2 say, no, take it away, take the measure away  
3 because of insufficient data, because I don't  
4 know if the problems been solved yet or not.

5 MS. FRANKLIN: And, yes, just to  
6 answer your point, the steering committee can  
7 look at whether there's an impact, there's a  
8 high impact for this measure and whether or  
9 not there's still an opportunity for  
10 improvement, and whether there's a strong link  
11 to outcomes, or desired outcomes when making  
12 the decision as to whether you want to move  
13 the measure forward.

14 CHAIRMAN LUTZ: I think we had  
15 Karen and then David.

16 MEMBER FIELDS: So my question was  
17 process. So can we approve a measure and with  
18 a -- you had talked about we're allowed to  
19 make some suggestions or recommendations about  
20 it, or a caveat?

21 MS. FRANKLIN: Yes. Yes, you may.

22 MEMBER FIELDS: So we can do all

1 of that with this one vote? We can say we  
2 approve the measure, but we expect -- in one  
3 year we want the rest of these data elements  
4 in there and we need data. Is that how we do  
5 it?

6 MS. FRANKLIN: Yes, you would walk  
7 through the votes as usual. And if it looks  
8 like it's going to fail at the evidence level  
9 or at the importance level, you could make a  
10 vote or a decision as a committee to invoke  
11 the exception, which is that the potential  
12 benefits outweigh the potential harms. And at  
13 that time continue through the voting. And at  
14 the end we would talk about recommendations  
15 for future development. And if you had  
16 caveats as well for the developer, if the  
17 developer is able to address them in this  
18 measure, you could base your decision on those  
19 changes that could be made.

20 MEMBER FIELDS: So I think just  
21 for the summary issue, summary report issue in  
22 colon cancer, breast cancer is 31 years of

1       adjuvant therapy, or 30 years of adjuvant  
2       therapy where we've come up with what are the  
3       really key items. Colon cancer wasn't quite  
4       as far along in 2008 when they were developing  
5       that as far adjuvant therapies. In colon  
6       cancer it sounds like we need to get to a  
7       better standard of just reporting before we  
8       get to the more sophisticated summary reports  
9       because we've changed the therapy of breast  
10      cancer over the years.

11                So I think the caveat should be we  
12      need much better reporting across the board on  
13      preliminary data in colon cancer than even  
14      we're getting. That's all.

15                CHAIRMAN LUTZ: I think we're  
16      David and then back to Patrick.

17                MEMBER PFISTER: No, certainly I  
18      hear what you're saying about the difference  
19      between colon and breast. But, you know, in  
20      substance if you look at 0391 versus 0392, I'm  
21      not sure that that additional data explains  
22      the magnitude of the difference in comments

1 about one measure that was basically already  
2 passed here versus something which would  
3 generate 25 minutes of discussion. And I  
4 think a lot of the issues are basically  
5 identical for both measures. And that's why  
6 I say, I think it's a more fundamental issue.  
7 So some of the issues about, well,  
8 recommendations kind of go back to developers  
9 and assess its own merit. Those are, I think,  
10 equally applicable to the breast measure which  
11 we just passed. It's just that this  
12 discussion is occurring 30 minutes later.

13 MEMBER ROSS: Angela, I have a  
14 question to understand. So let's say that we  
15 vote down. I mean, so first of all, we'd have  
16 to question the judgment. Who's going to say  
17 that not doing appropriate staging on colon  
18 cancer is a good thing? It would not make  
19 good press for the Cancer Steering Committee  
20 to vote against it, right? But let's say we  
21 did it. When would this group of sponsors  
22 then have the chance to bring the new,

1 improved version forward? Is it a year from  
2 now?

3 MS. FRANKLIN: It would be during  
4 the next time that we have a project related  
5 to cancer.

6 MEMBER ROSS: So it's almost an  
7 impossibility to correct any of these --

8 MS. FRANKLIN: Therapy time,  
9 right.

10 MEMBER ROSS: -- in real time,  
11 right?

12 MS. FRANKLIN: Yes.

13 MEMBER ROSS: That's  
14 disappointing.

15 MS. FRANKLIN: Mark?

16 DR. ANTMAN: Thanks, Angela. Just  
17 a comment on the PCPI process, Dr. Ross, just  
18 to clarify our timing in working with our  
19 colleagues at CAP in updating these measures.  
20 Typically we convene our own work groups, our  
21 own panels of experts to consider the measure,  
22 and in this case, to update a set of measures.

1 Angela referred earlier to the annual updates  
2 that are available for all currently endorsed  
3 measures. We're able to use those annual  
4 updates only for situations where there has  
5 been a coding change to an element that's in  
6 a numerator or denominator of a measure where  
7 we can make a somewhat insignificant non-  
8 substantive change to a measure.

9 But if there's a substantive  
10 change, such as what's been discussed here,  
11 retiring, if you will, one element of a  
12 measure and replacing it with others, or  
13 perhaps adding new ones: that would require a  
14 very substantive discussion of our panel of  
15 experts. And so that's by way of saying that  
16 unfortunately that's not something that we  
17 could do in a very short time frame. It would  
18 require our reconvening the group. But it  
19 might be possible by the next time that NQF  
20 convenes the cancer group, depending on how  
21 much time passes at that point.

22 Typically our measure development



1 processes take in the neighborhood of a year  
2 or a little more or less, partly depending on  
3 the testing process involved, but it's not  
4 something we can turn around quickly because  
5 we need a panel of experts to approve it.

6 MS. CHRISTENSEN: If I can just,  
7 sorry, piggyback on that, these measures are  
8 a bit caught in the gap of our colleagues at  
9 NQF revising their process, which we have  
10 enjoyed the new process. But the timing on  
11 these hasn't come out quite the way that we  
12 maybe would have liked, and that's because  
13 when they were first endorsed we then went and  
14 did a testing project with our colleagues.  
15 And as Mark said, those can take somewhere  
16 between six months and a year. You guys I'm  
17 sure have all gone through the IRB process,  
18 and it's just harder to get done faster than  
19 that.

20 So once we had that information --  
21 that does go back to the work group when we do  
22 testing projects, things that we find that

1 need to be clarified and things that perhaps  
2 could be updated. We do take those back to  
3 our measure work groups. Unfortunately, in  
4 this case, if we had made changes to the  
5 measures, we would not have been able to  
6 submit them because they would not have been  
7 tested again in time for this policy. So it  
8 just is kind of a timing issue to figure out  
9 what are the best measures you can submit at  
10 any time. With the new process, we should be  
11 able to adjust our timing to fit that.

12 CHAIRMAN LUTZ: Do Jennifer then  
13 David.

14 MEMBER MALIN: Maybe it is just  
15 because I'm steeped in oncology that I feel  
16 like oncology changes more rapidly than other  
17 fields, but it does seem like, you know,  
18 things change pretty -- I mean, guidelines get  
19 updated several times a year. And so I wonder  
20 if maybe there's something with the NQF  
21 process where instead of the committee  
22 reviewing just the final set of measures,

1 saying up or down on this measure, if there  
2 couldn't be six months ahead of time someone  
3 who reviews how well do these measures fit the  
4 context of what's happening in breast cancer  
5 today.

6 MS. FRANKLIN: That's part of what  
7 our new CDP two-stage process that we're  
8 piloting will do. But that hasn't come on  
9 line now. And unfortunately, I think this  
10 project kind of falls in the gap. We don't  
11 anticipate seeing another cancer project for  
12 at least a year, or more than a year.

13 MEMBER MALIN: Okay. Well, that's  
14 good. Maybe that will help some of --

15 MS. FRANKLIN: But that is  
16 contemplated in the new process.

17 CHAIRMAN LUTZ: All right.  
18 Anybody else? Anybody on the phone have any  
19 additions?

20 MEMBER RICCIARDI: Yes, this is  
21 Rocco Ricciardi. Just a couple things. One  
22 I'd say that I still get path reports today

1 that don't include this information, so I  
2 think it's still valuable today. I know  
3 that's anecdotal, but I think, you know, I can  
4 comment that my colleagues and I do still see  
5 this. And two, it looks like we have a metric  
6 or a measure that looks at measuring the  
7 number of lymph nodes, which I believe is very  
8 important. Thank you.

9 MEMBER ALVARNAS: This is Joe  
10 Alvarnas. I agree. I think that we do want  
11 more perfect measures, but I think given that  
12 there's a performance gap, sadly, with even  
13 this level of measure, I think we should just  
14 vote upon that gap rather than become  
15 paralyzed because the measures may in fact not  
16 be perfect.

17 At the same time, I think we have  
18 to be able to plan for measures that are  
19 brought forward in a more timely fashion to  
20 maintain the currency. Because you're right,  
21 in oncology and hematology the state of the  
22 art evolves so rapidly that five-year cycles

1 may be way too long for these things to  
2 maintain their complete relevance.

3 CHAIRMAN LUTZ: Very good. Thank  
4 you. If someone could remind me where we are  
5 on the voting.

6 PARTICIPANT: 1b.

7 CHAIRMAN LUTZ: 1b?

8 MS. KHAN: So voting on  
9 performance gap, 1b.

10 So we have seven for high, five  
11 for moderate, zero for low and one  
12 insufficient.

13 And 1c, the evidence. Yes, no or  
14 insufficient.

15 So 12 yes, and 2 insufficient  
16 evidence.

17 Voting on reliability.

18 CHAIRMAN LUTZ: Does anyone have  
19 anything else that they want to say about  
20 reliability in this? John?

21 MEMBER GORE: So there was, I  
22 think, fairly robust evidence presented of the

1 reliability of ascertainment of this measure.  
2 The working group had no concerns about  
3 reliability. And we go to validity now, too,  
4 correct?

5 MS. KHAN: Yes.

6 MEMBER GORE: In terms of  
7 validity, this was one of the measures where  
8 there was an expert panel that kind of decreed  
9 the importance to report. And there was  
10 pretty uniform consensus about the importance  
11 of the measure and the validity of the  
12 measure.

13 MS. KHAN: So we're going to go  
14 ahead and vote on 2a, reliability.

15 So we have five high, and nine  
16 moderate, zero low and zero insufficient.

17 Voting on 2b, validity.

18 So we have five high, seven  
19 moderate, two low and zero insufficient.

20 And did you want to have a  
21 discussion on usability?

22 CHAIRMAN LUTZ: Say anything else

1 on usability, John?

2 MEMBER GORE: I don't think  
3 there's much to say about usability. And it's  
4 a little bit pursuant to some of our previous  
5 conversation, but the working group didn't  
6 have any concerns about the usability of the  
7 measure. The accurate pathology report  
8 definitely can be used to evaluate pathology  
9 labs, institutions, whatever.

10 MS. KHAN: So voting on usability.

11 Can we have everyone press their  
12 button one more time?

13 Still missing one vote. If you  
14 could push your votes again.

15 So you have four for high, nine  
16 moderate, zero low, and one insufficient.

17 And feasibility?

18 CHAIRMAN LUTZ: Say anything on  
19 feasibility?

20 MEMBER GORE: The elements are all  
21 easily abstracted on. For example, electronic  
22 health record and our standard parts of a

1 synoptic path report.

2 MS. KHAN: And voting on  
3 feasibility.

4 So you have nine high, five  
5 moderate, zero low and insufficient  
6 information.

7 And overall suitability for  
8 endorsement. Does the measure meet NQF  
9 criteria for endorsement? Yes or no.

10 Thirteen yes and one no, so the  
11 measure will pass.

12 CHAIRMAN LUTZ: So is there  
13 anything else, any recommendations beyond what  
14 we've said for our developers who want to give  
15 thoughts, suggestions on this one? Karen?

16 MEMBER FIELDS: So I guess we  
17 wanted to make a recommendation that they try  
18 to add some other pathologic elements to the  
19 list of elements that they're measuring, if  
20 that's feasible, although it sounded like for  
21 next year's measure that's not feasible  
22 because they could only replace new elements.



1 But perhaps histologic grade needs to be  
2 replaced with something a little more  
3 contemporary, like margins.

4 And then number two, we also would  
5 like for the next year's data -- the caveat  
6 would be we need to see the data from the  
7 period up to that time.

8 MS. TIGHE: And just for my notes,  
9 is this recommendation only for 0392, or for  
10 0391 also?

11 MEMBER FIELDS: I think 0391 had  
12 some different issues. I think that we  
13 thought that the requested pathologic elements  
14 were broader. These were just three elements  
15 that we didn't think were sufficient, unless  
16 someone disagrees with me.

17 MEMBER PFISTER: I mean, I think  
18 it was equally applicable to both measures.  
19 I mean, I think the pathologic elements,  
20 looking at both measures, are identical,  
21 right? I mean, it's T, M, grade, you know?

22 I think you're absolutely right

1 that, you know, there's a longer line of -- to  
2 the extent you're hoping to have some  
3 correlates without them here just because  
4 there's more adjuvant data. There's going to  
5 be more correlation with outcome, but I think  
6 that, as I think has been implied by other  
7 discussions, there's certainly other factors,  
8 albeit different for the diseases which are  
9 kind of raising the bar in terms of what  
10 oncologists look at when they're trying to  
11 make these management decisions now. I think  
12 making some of the old paradigms, probably  
13 just that, old paradigms. And some of the new  
14 paradigms which are now being actively used.

15 And so I think, you know, some of  
16 the updating issues, some of the relevance to,  
17 of let's say the applicability of something  
18 like grade, which is a historic-sort of  
19 cultural thing that often drives decisions.  
20 And I'm not saying there aren't particular  
21 circumstances where it sort of does factor  
22 into what you do, but is that on the same

1 footing as some of the other markers which are  
2 now like very heavily vetted? You know,  
3 that's a larger discussion. But I would say  
4 some of the caveats, I think, are very similar  
5 for both 0931 and 0392.

6 MEMBER FIELDS: So I'll respond to  
7 that. So in breast, though, we still know  
8 that the major prognostic indicators are TN  
9 and then ER/PR status and HER2 status, and I  
10 think some of the previous measures addressed  
11 some of those issues. Whereas in colon, I  
12 think we're just now getting to understanding  
13 KRAS and a little bit more information about  
14 nodal status.

15 So I do think they're a little bit  
16 different. But I agree, all of them need to  
17 be up to date, all of them need to reflect  
18 modern therapies, and the fact that we use all  
19 these data now for treatment decisions where  
20 we used them perhaps less at the time in colon  
21 cancer from that era.

22 I have a question, though. Are we

1 allowed to go back and make a recommendation  
2 without the group that voted on the breast  
3 thing? Or we can just make a caveat on both  
4 of those right now and we vote that and make  
5 that as a recommendation?

6 MS. FRANKLIN: We can make it a  
7 recommendation for 0391. Add that as a  
8 recommendation for 0391. We don't have to  
9 vote again. I don't think --

10 MEMBER FIELDS: Okay. So we must  
11 make --

12 MS. FRANKLIN: Right.

13 MEMBER FIELDS: These aren't  
14 voting things? These are recommendations?

15 MS. FRANKLIN: Right. They're not  
16 voting elements.

17 MEMBER FIELDS: Okay. That's all  
18 I needed to understand.

19 DR. ANTMAN: If I may just add, I  
20 do want to clarify that -- and I'll stand  
21 corrected if my colleagues at CAP disagree,  
22 but when we updated the measures, I don't

1 think any of us said that we would have to  
2 simply replace one element of the measure with  
3 another. Now we heard the recommendation to  
4 replace histologic grade with the margins.

5 MEMBER FIELDS: No, there was a  
6 statement; and maybe I took it out of context,  
7 that said we just try to replace measures  
8 rather than we add new measures.

9 DR. ANTMAN: Ah.

10 MEMBER FIELDS: Because it sounded  
11 like a huge process to add new elements to the  
12 measures.

13 DR. ANTMAN: I see.

14 MEMBER FIELDS: If you can add new  
15 elements to the measures, I think you're  
16 hearing our group calling for that.

17 DR. ANTMAN: Right. Okay. So all  
18 I wanted to clarify was that we're happy to  
19 take whatever recommendations you have on  
20 additional elements that you think should be  
21 in this measure, and that can all be part of  
22 the work groups in their deliberations.

1 DR. SPEIGHTS: And speaking from  
2 this side of the table, I think we can say  
3 that we have heard your concerns and we'll  
4 certainly work with the ongoing CAP efforts  
5 for integrated and comprehensive summary  
6 reports, and we'll certainly work on these.  
7 Thank you.

8 MEMBER MALIN: I know we've kind  
9 of beat this to death, but I wanted to sort of  
10 just in the spirit of thinking about the  
11 measurement process -- the point of these  
12 kinds of measures, especially -- these are  
13 really about communication between the team  
14 members. And really what you're trying to  
15 encourage is that pathologists and members of  
16 each institution have a process in place  
17 whereby they're making sure that they're  
18 documenting and communicating what's important  
19 to the person who's receiving the information.

20 So, and especially as we see new  
21 genomic tests, it would, you know, make these  
22 measures kind of useless if they're not

1 reflecting is this a pathologist who's keeping  
2 up and making sure he's providing the  
3 information that the clinicians need to make  
4 treatment decisions. It's not so much, I  
5 think, you know, about what the elements that  
6 are included in the measure are just one way  
7 to capture that.

8 CHAIRMAN LUTZ: Good. Our  
9 competing issues I think are folks from  
10 ActiveHealth with submission 0623 said they  
11 only have until 4:00. But then again --

12 PARTICIPANT: Do we have members  
13 from the ActiveHealth Team on the line?

14 (No response.)

15 PARTICIPANT: Arnika, could you  
16 please check to see if there's anyone from  
17 Active Health whose line may need to be  
18 opened?

19 OPERATOR: If so, could you please  
20 press star one?

21 The line is opened.

22 DR. CHIN: Hi, this is

1 ActiveHealth. Yes?

2 CHAIRMAN LUTZ: We're curious.  
3 Did someone from you guys say that we need to  
4 go over 0623 with some time frame in mind,  
5 like before 4:00 p.m., or how did that I

6 DR. CHIN: Yes, that's okay. No,  
7 we're fine.

8 CHAIRMAN LUTZ: Okay. If you  
9 don't mind then, we'll take a short break so  
10 everyone can kind of walk around their chair  
11 once.

12 DR. CHIN: Okay.

13 CHAIRMAN LUTZ: Thanks.

14 (Whereupon, at 3:45 p.m. off the  
15 record until 4:02 p.m.)

16 CHAIRMAN LUTZ: Okay. I think the  
17 request was made that the folks from  
18 ActiveHealth identify themselves by name.  
19 That was one of the first requests. If we  
20 could, please?

21 DR. CHIN: Sure, this is Dr.  
22 Lindee Chen from ActiveHealth Management, and



1 we have --

2 DR. PALACKDHARRY: This is Dr.  
3 Palackdharry, ActiveHealth.

4 DR. MENTHA: This is Laneesh  
5 Mentha. I'm the pharmacist. ActiveHealth.

6 CHAIRMAN LUTZ: Good. We  
7 appreciate that. And I think that if we're  
8 okay, I think we can go ahead and -- if you  
9 don't mind, if you can just go ahead and give  
10 us some background and framework for the  
11 submission. And then we'll go from there.

12 DR. CHIN: Sure.

13 MS. TIGHE: Sorry, just one quick  
14 point. For those in the room I had mentioned  
15 it. You have a copy of 0623 on the table in  
16 front of you. They have made some updates to  
17 it as a result of the work group call, and so  
18 we'd just ask them to point out those changes  
19 to you. Okay. Go ahead, Lindee.

20 DR. CHIN: Okay. Sure. So our  
21 measure is titled "The History of Breast  
22 Cancer - Cancer Surveillance." And we're

1 looking at the percentage of women with a  
2 history of breast cancer treated with curative  
3 intent who had breast cancer surveillance for  
4 a local regional recurrence annually. We  
5 updated the description of the measures to be  
6 more clear. I think there was some  
7 confusion about what types of cancers we were  
8 looking for exactly last time. So we updated  
9 the measure description, the numerator  
10 description and the denominator description.  
11 And we also had changed the numerator time  
12 window based on the preliminary work group  
13 suggestion as well. The other pieces that we  
14 had updated are the reliability and validity  
15 testing areas. We went back and looked at our  
16 data and did the statistical analysis that I  
17 think the group was asking for. I think we  
18 misunderstood the wording of the question, so  
19 we went back to our data and tried to give the  
20 statistics I think that the committee was  
21 looking for.

22 DR. PALACKDHARRY: This is Carol

1 Palackdharry. Did you want us to summarize  
2 how we updated it, or just that we updated it?

3 MS. BYRON: I would appreciate you  
4 describing how you updated it.

5 DR. CHIN: Sure. That would be  
6 better. Great. Okay. So in terms of the  
7 numerator statement, we're looking for women  
8 with a history of breast cancer treated with  
9 curative intent who had surveillance for  
10 breast local or regional recurrence annually.  
11 We updated the time window just a few months.  
12 It was 12 months before, but after the  
13 previous discussion with the preliminary work  
14 group it went back to 15 months.

15 We had 15 months in the past on  
16 our previous endorsement. We had moved it to  
17 15 months to align with sort of the annual  
18 recommendation, but then we went back to 15  
19 months because of the discussion around that  
20 women aren't going to get it within the 12-  
21 month window because of insurance reasons,  
22 that we need to give them a little bit more

1 time to get testing completed. So that was  
2 one of the changes that we had made.

3 The other piece that we wanted to  
4 emphasize in our descriptions is that we're  
5 looking for non-metastatic invasive breast  
6 cancer. So we just put that clarification in  
7 the description.

8 MS. BYRON: I just want to bring  
9 in, there was some question during the  
10 preliminary work group meeting about what the  
11 rules were pertaining to DCIS. And we wanted  
12 to make it clear that DCIS is -- all in situ  
13 breast cancers are excluded from this measure.  
14 It's invasive cancer only.

15 DR. CHIN: Okay. So we updated  
16 most of the descriptions to reflect that. And  
17 the other piece that we did in terms of the  
18 validity and reliability testing, like I said  
19 earlier, we added sort of the numbers in our  
20 test sample and their our statistics around  
21 it. So we had added our signal to noise  
22 ratio. We also added the other sort of

1 discussion around our sample size for our  
2 validity testing. And that's sort of more  
3 details around it that I think the committee  
4 was looking for.

5 CHAIRMAN LUTZ: All right. Thank  
6 you. I think if Heidi Donovan's on the line,  
7 I think she was going to give us our first  
8 overview of this. Are you there, Heidi?

9 MEMBER DONOVAN: I am here, yes.

10 CHAIRMAN LUTZ: Great.

11 MEMBER DONOVAN: Okay. So just  
12 everyone knows, I was not on the phone call of  
13 the small group discussion, so I hope others  
14 on the phone call will weigh in.

15 I guess we'll just start with the  
16 importance to measure. I think there were two  
17 discussions. One of them has been addressed,  
18 the question of whether 12 months was an  
19 appropriate timeline given some insurance  
20 restrictions. I think it's great that they've  
21 extended it to 15 months.

22 I think in terms of the importance

1 to measure, the other concern was that while  
2 everybody is very much in favor of annual  
3 screening and that meets -- that is  
4 appropriate and consistent with NCCN  
5 guidelines, there is not adequate evidence out  
6 there that screening does improve survival  
7 outcomes. And so I think that was one of the  
8 issues that came up. As I said, that's  
9 countered by the reality that we do find the  
10 early cancers in a group of patients who at  
11 high risk for recurrence.

12 I think that I'll stop there.

13 Let's see, they've addressed the issue around  
14 DCIS isn't excluded. I think there was some  
15 question about whether there needed to be an  
16 age limit for annual surveillance, and they  
17 have provided some rationale to not put in an  
18 age limit other than if women have short left  
19 expectancies. That's somewhat unclear that we  
20 can talk about that as well. So I'll stop  
21 there and let other people weigh in on this.

22 CHAIRMAN LUTZ: Okay. So I guess

1 we're looking for any other comments about  
2 importance. So I will say -- I hate to speak  
3 for him, but Dr. Marks wanted to strongly  
4 state that he doesn't think that this changes  
5 survival and was therefore not for it. Larry  
6 I think is not on the line, but asked us to at  
7 least mention that it was still his strong  
8 belief even after the changes.

9 But starting there, does anyone  
10 want to argue differently?

11 MEMBER FIELDS: So I had some  
12 questions for the developer. I guess your  
13 clarification about "invasive" probably needs  
14 to apply then to the description of the  
15 measure, the numerator statement and the  
16 denominator statement, because only the  
17 denominator statement says that it's invasive.  
18 And so the question is following the DCIS  
19 patients.

20 And then I had another question.  
21 I understand the intent, but I got confused  
22 about how you were trying to describe

1 reconstruction and whether or not those  
2 patients were candidates for follow up. It  
3 sometimes implied that they might have needed  
4 surveillance and they wouldn't -- I mean, I  
5 would assume they would need bilateral -- I  
6 mean, they met the criteria for bilateral  
7 mastectomies and therefore they weren't  
8 eligible. But there was some implication that  
9 you might follow them with MRIs or something  
10 like that.

11 And then my last question was  
12 there was sort of an interchange between  
13 screening, or follow-up mammograms and breast  
14 MRIs, and I didn't think that there was much  
15 literature or data to support MRIs as a  
16 follow-up or surveillance study in the  
17 patients.

18 So that was three big questions,  
19 but I'll stop and let you comment.

20 DR. PALACKDHARRY: Sure. This is  
21 Carol Palackdharry. So let me take those one  
22 at a time.



1                   In terms of the updated  
2 terminology, I just wanted to make it clear  
3 that in situ carcinomas were never included in  
4 this measure. It was always only invasive  
5 breast cancers. And so the coding that we use  
6 in our elements, we only use codes for  
7 invasive breast cancers. So does that answer  
8 that the first question?

9                   MEMBER FIELDS: It does. It's  
10 just you probably want to go through the  
11 document and make it consistent, because  
12 sometimes you say invasive and sometimes you  
13 say breast cancer.

14                  DR. PALACKDHARRY: Okay.

15                  MEMBER FIELDS: And that's the  
16 difference.

17                  DR. PALACKDHARRY: That's right.  
18 If you just look at the very first page, you  
19 have women with a history of breast cancer  
20 treated with curative intent. And the  
21 numerator statement says you have breast  
22 cancer treated with curative intent. And then

1 in the denominator it's a history of non-  
2 metastatic invasive breast cancer.

3 DR. CHIN: Yes, you know, that's a  
4 good point. We'll make that more clear.

5 DR. PALACKDHARRY: Yes.

6 DR. CHIN: So the second one, yes.  
7 And the second one, let me just clarify it by  
8 saying that in the revision that we submitted  
9 to you guys, we removed everything about  
10 reconstruction. And previously when we first  
11 -- meaning that we removed all women who have  
12 had bilateral mastectomy regardless of any  
13 kind of reconstruction from the denominator.

14 MEMBER DONOVAN: I mean, how do  
15 you measure previous local recurrences? Are  
16 they included in this or excluded?

17 DR. PALACKDHARRY: With previous  
18 local recurrence?

19 MEMBER DONOVAN: Right, so not  
20 metastatic.

21 DR. PALACKDHARRY: We do not  
22 exclude them if they've had a previous local

1 recurrence unless that recurrence led to a  
2 completion mastectomy which then gave them  
3 bilateral mastectomies. If you add, you know,  
4 two unilateral mastectomies together. But if  
5 they still have breast tissue left, if it  
6 wasn't coded as a full mastectomy, either  
7 bilateral at one time or two unilaterals, then  
8 they would still be included. Did that make  
9 sense to you?

10 MEMBER DONOVAN: Yes, just wanted  
11 to clarify.

12 DR. PALACKDHARRY: Sure. Thank  
13 you. And the last thing was we are not  
14 suggesting that women receive MRI, but we are  
15 counting MRI as a completion since some women  
16 are clearly recommended to get MRIs on the  
17 basis of dense breast tissue or radiation  
18 changes, or whatever. You know, and there are  
19 organizations that do recommend MRI for high-  
20 risk women in combination with mammography.  
21 But we're not recommending that. We're just  
22 taking that as a completion.

1                   CHAIRMAN LUTZ:   Okay.  We're going  
2                   to Bryan, Jennifer, Robert and John.

3                   MEMBER LOY:   Yes, and I think it's  
4                   just important for me to disclose that I do  
5                   have a working relationship with ActiveHealth  
6                   Management, that I disclosed last time.

7                   But I wanted to ask the question.  
8                   I heard Dr. Lutz say that Dr. Marks said that  
9                   there was no impact on survival.  Is that  
10                  correct?

11                  CHAIRMAN LUTZ:  He emailed us a  
12                  request to make that statement as a point that  
13                  he wanted to bring forth.

14                  MEMBER LOY:   And I'd just like to  
15                  hear the point of view of the other committee  
16                  members on that particular point, and if  
17                  ActiveHealth had a response to Dr. Marks'  
18                  concern.

19                  DR. PALACKDHARRY:  This is Carol  
20                  Palackdharry.  I actually do have a response  
21                  to that, because at least -- well, I'm an  
22                  oncologist, and so I would just say that when

1 I look at the data; not me, when we all look  
2 at the data which is looking at the survival  
3 of women with invasive breast cancers who had  
4 breast-conserving surgery with radiation  
5 therapy versus mastectomy, I think it's long  
6 been realized that although the survival 10  
7 and 20 years out is the same, the incidence of  
8 relapse-free survival is not the same. And  
9 the reason the overall survival becomes the  
10 same is because if you've detected a  
11 recurrence in the conserved breast, you can  
12 salvage that breast by mastectomy. That's the  
13 reason the overall survival is the same, is  
14 because they get salvaged with early  
15 detection. So I guess I would disagree with  
16 Dr. Marks' statement.

17 CHAIRMAN LUTZ: Please do.

18 MEMBER MALIN: There is no  
19 randomized trial data to support mammography  
20 improving survival in women who've already had  
21 breast cancer. And there have been several  
22 randomized trials that have looked at the

1 impact of intensive monitoring using imaging  
2 and laboratory data to see if there's an  
3 improved outcome in terms of survival. And  
4 those several studies are now probably 10-plus  
5 years old, but both of them were negative and  
6 showed no improvement in survival.

7 And so, you know, most of the  
8 time, you know, I think the rationale for  
9 doing it is that, you know, presumably people  
10 are at risk for contralateral disease and, you  
11 know, it's a low-risk procedure, so why not do  
12 it? But there's no evidence that it improves  
13 outcomes.

14 And at this point, you know, with  
15 modern radiation therapy techniques and  
16 hormonal therapy, local recurrence risks are  
17 in the low single digits. So something like  
18 two to three percent of women will have a  
19 local recurrence.

20 DR. PALACKDHARRY: But I think  
21 it's also important to point out that false-  
22 positive rate is higher --

1 MEMBER MALIN: Right.

2 DR. PALACKDHARRY: -- in the  
3 patient population overall.

4 MEMBER MALIN: So one of my  
5 concerns though is just how broad the  
6 denominator population is for this measure.  
7 So, I mean, it seems like you've excluded  
8 people who are at death's door, but you know,  
9 breast cancer is a very, very common disease  
10 and there are a lot of, you know, 80-year-olds  
11 and 90-year-olds who are unlikely to benefit  
12 at that point from having any breast cancer  
13 identified early. We certainly can identify  
14 it early, but whether it will, you know,  
15 decrease their morbidity or mortality at that  
16 point, given other things going on, you know,  
17 is questionable. And certainly most screening  
18 guidelines tend to put an upper limit on the  
19 age at which you would actively screen. And  
20 I guess I'd be interested in your thoughts as  
21 to why this population should be any  
22 different.

1 DR. PALACKDHARRY: This is Carol  
2 Palackdharry. Now none of the guidelines that  
3 I'm aware of actually have an upper age on the  
4 surveillance guidelines. It would be -

5 MEMBER MALIN: Well, NCCN  
6 guidelines specifically say that all of their  
7 recommendations should not be applied to  
8 anyone over age 70 because there's no data on  
9 that. Or there could be, but there's no  
10 absolute recommendation. So they have a  
11 general caveat across the whole guideline.

12 DR. PALACKDHARRY: Well, you know,  
13 we can take a look at that again. We'd be  
14 happy to put in an upper age limit of 70, if  
15 that's what the data supports.

16 MEMBER MILLER: So I also have  
17 some of the same concerns, but I guess maybe  
18 just to approach it from a different way and  
19 say that I think there are multiple data sets  
20 that show that if you're just talking about  
21 the breast conservation population, which is  
22 at least theoretically the population of



1 patients that you might expect to have the  
2 greatest likelihood of salvaging; however you  
3 want to define that, even that population of  
4 patients -- so patients that have had  
5 lumpectomy and radiation who have an  
6 ipsilateral breast tumor recurrence, they have  
7 a poor prognosis irrespective of what happens  
8 after that occurs. The NASBP has shown that  
9 in both node-positive patients -- and this is  
10 with modern systemic therapy. NASBP showed it  
11 even in node-negative patients that the chance  
12 of distance recurrence and death is very high.

13 So I guess I'm concerned that in  
14 the section -- it's 1c.1, which is the  
15 relationship between process and outcome -- I  
16 mean, again, we understand this is a process  
17 measure, but it has to speak to an outcome  
18 that's reasonable. The last sentence is  
19 simply factually incorrect. "Women who have  
20 had breast conservation have a higher chance  
21 of recurring within the remaining ipsilateral  
22 breast, but early detection allows for salvage

1       mastectomy and thus an equivalent overall  
2       survival."

3                       I'm sorry, that statement is  
4       simply not true. There are no data showing  
5       that. And I guess my whole concern is this  
6       whole measure is built on that assumption that  
7       you can identify something early and fix it.  
8       So I'm really troubled by the scientific  
9       assumptions based on this.

10                    DR. CHIN: I could perhaps point  
11       to a couple of publications, if you wouldn't  
12       mind. I'm looking at one right now from  
13       Breast Cancer Research Treatment in 2010. I'm  
14       just going to read some from the abstract.  
15       They followed 17,286 women for five years.  
16       Between 1996 and 2006 these women had a  
17       combination, some were DCIS, or they could  
18       have had early-stage 1 and 2 breast cancer.  
19       And what they found was that four percent had  
20       a second breast cancer event. There were 314  
21       recurrences in that and 344 second breast  
22       primaries; I am assuming in the other breast,

1       there.

2                   They state here when they went and  
3       identified that about a third of the  
4       recurrences, 37.6 percent, and the second  
5       primaries were not screen-detected, so two-  
6       thirds were screen-detected in there.

7                   MEMBER MILLER: I'm sorry, and  
8       your point regarding survival is? What are  
9       you getting at?

10                  DR. CHIN: Actually, yes, I  
11       thought that there was a survival statement in  
12       that one.

13                  MEMBER MILLER: Okay.

14                  MEMBER FIELDS: So the NCCN  
15       guidelines suggest mammography every 12  
16       months.

17                  DR. CHIN: They do.

18                  MEMBER FIELDS: And at 6 to 12  
19       months post-irradiation for the treated  
20       breast. And it's true that in an academic  
21       center where they pay attention to margins of  
22       local recurrence rates in the two to three-

1 percent range. In the general patient  
2 population the local regional recurrence rate  
3 is still in the range of 10 to 15 percent over  
4 a lifetime. And completion mastectomies then  
5 make long-term survival the same, whether you  
6 had a mastectomy or a lumpectomy, if you look  
7 at the long-term data from some of the early  
8 studies. So NCCN's still recommending annual  
9 mammograms in this patient population.

10 MEMBER MILLER: So certainly no  
11 dispute about that. I think I'm not sure you  
12 can prove cause and effect by those two  
13 statements. So I mean, you know, everything  
14 we've known since, whenever, the '70s, that  
15 lumpectomy in -- or '80s maybe, lumpectomy and  
16 radiation associated with, you know,  
17 equivalent survival to mastectomy.

18 I guess my concern is a  
19 justification for a quality measure in 2012,  
20 I just don't think you can use those data to  
21 justify that the surveillance act is what is  
22 going to make that difference. And I think

1 that's what I'm concerned, that the authors,  
2 the developers have put this in this abstract  
3 form without a reference as a matter of fact.  
4 And I'm just saying I don't think that's  
5 correct information, and I think this  
6 underpins their whole reason to put this  
7 measure forth.

8           So I'm not disputing at all that  
9 these women should have surveillance. Yes,  
10 it's just what's the outcome you're expecting  
11 from that? Are they going to live longer?  
12 Have the same outcomes as someone that never  
13 had an ipsilateral breast tumor recurrence?  
14 I don't think you can say that.

15           MEMBER FIELDS: Right. And then  
16 we still know that the risk of a new breast  
17 cancer in the opposite breast remains the same  
18 as it was in the first breast, unless you have  
19 a -- well, you become a higher-risk patient  
20 then. So we still recommend annual  
21 surveillance in that patient population.

22           So what you're disputing mainly is

1 the rationale and the literature support for  
2 the follow up rather than the need for the  
3 follow up?

4 MEMBER MILLER: I'm not disputing  
5 the need for the follow up -

6 MEMBER FIELDS: Right.

7 MEMBER MILLER: -- because it's  
8 consistent with guidelines.

9 MEMBER FIELDS: Yes, okay.

10 MEMBER MILLER: I'm saying I  
11 understand this is a process measure, but  
12 every process measure implies some type of  
13 outcome. I'm not sure I understand what --

14 MEMBER FIELDS: Okay.

15 MEMBER MILLER: -- outcome -- the  
16 outcome that is purported in this abstract  
17 document is -- I question its scientific  
18 validity.

19 MEMBER FIELDS: Okay. Okay. That  
20 was my question.

21 MEMBER MALIN: I think the other  
22 thing, too, is that there's already a quality

1       measure out there that all women of a certain  
2       age should get screening mammography, right?  
3       So the question is what's the added value of  
4       having an additional one specifically for  
5       breast cancer survivors that maybe focuses on  
6       a slightly different interval and has a more  
7       conservative interval.  Is that, you know,  
8       really meaningful and add to kind of the  
9       quality of reporting that's out there?

10               MEMBER DONOVAN:  I guess then the  
11       other measure that's just screening there,  
12       there is no measure for breast cancer  
13       survivors then.  That excludes people who've  
14       had a diagnosis.

15               CHAIRMAN LUTZ:  I'd say we'd have  
16       to look, but I'm not sure it does, because  
17       you're screening for a new cancer in the same  
18       breast and for a new cancer in the  
19       contralateral breast.  So it's still a  
20       screening situation, I believe.  I mean, we  
21       can double-check the wording, but I don't  
22       think someone's excluded from screening just

1 because they've already had active treatment.

2 DR. PALACKDHARRY: Yes, they are  
3 excluded.

4 MEMBER MALIN: Maybe someone from  
5 NQF staff could pull up the measure for us?

6 MEMBER FIELDS: In the denominator  
7 exclusion on the other measure we're going to  
8 evaluate next --

9 PARTICIPANT: Right.

10 MEMBER FIELDS: -- its says who  
11 had a bilateral mastectomy or for whom there  
12 is evidence of two unilateral mastectomies.  
13 It doesn't say that they had a diagnosis of  
14 breast cancer.

15 PARTICIPANT: Mastectomy--

16 MEMBER FIELDS: Yes, it's like you  
17 can't do it, right. Right.

18 CHAIRMAN LUTZ: David, I'm sorry,  
19 you've been waiting patiently. Did you have  
20 something?

21 MEMBER PFISTER: A couple of  
22 things just to reiterate some of the points



1 that have been made. I mean, on the first  
2 they talk about that the goal here has to do  
3 with local regional recurrence detection. But  
4 there doesn't seem to be a real, like,  
5 specification of a time frame. If the  
6 emphasis is on local regional failure  
7 detection, one would expect that most of those  
8 are going to be early events and that after  
9 the first five years it's probably going to  
10 mainly second primaries that you're going to  
11 pick up on surveillance.

12 I think that similarly the issue  
13 about what the impact of the imaging of a  
14 post-mastectomy breasts is on survival as an  
15 end point, I think, is not established. So,  
16 you know, I think that that's an assumption.  
17 I think as far as how this population fits  
18 into the screen recommendations, you know, I  
19 don't know that off the top of my head. I  
20 think it's worth asking though.

21 CHAIRMAN LUTZ: John, did you have  
22 something?

1                   MEMBER GORE: This is just more of  
2                   a question for the developer. And this isn't  
3                   pertinent to the question of the scientific  
4                   importance of therapy for local regional  
5                   recurrence, but it's a question about the unit  
6                   of measurement. And so who is expected to be  
7                   measured with this metric? Because, you know,  
8                   some of these women may be in the survivorship  
9                   phase of their breast cancer and it may be  
10                  unclear who is being assigned this quality  
11                  metric? Who is being evaluated with this  
12                  metric?

13                 DR. CHIN: So it's those women  
14                 that we find with a history of breast cancer,  
15                 invasive breast cancer with surgical or  
16                 radiation treatment in the year prior to the  
17                 measurement year. Because if there were --

18                 PARTICIPANT: I need you to answer  
19                 the --

20                 MEMBER GORE: What provider is  
21                 being assessed with this metric?

22                 DR. CHIN: It's the provider who

1 is coding for the breast cancer for the  
2 patient or whoever is caring for the patient.  
3 So we have an algorithm for which we try to  
4 identify providers who are coding that we seen  
5 claims for the breast cancer diagnoses. And  
6 then by default then it would probably go to  
7 the primary care provider if we don't need  
8 those codes. Those are sort of the algorithm  
9 that we go through.

10 MEMBER LOY: So outside of your  
11 algorithm would other entities be able to  
12 reliably attribute back to a provider in a  
13 similar manner, or is the measurability of  
14 this measure dependent upon your proprietary -  
15 -?

16 DR. CHIN: No. No, I mean, it's  
17 typically whoever you're finding that is  
18 coding for or treating the patient, or has  
19 treated the patient for the breast cancer, or  
20 actively caring for the patient. We don't say  
21 that you have to attribute this measure to  
22 anyone in particular.

1 MEMBER LOY: Okay. And --

2 DR. PALACKDHARRY: So that way if  
3 the person, if the woman were say transferred  
4 back to her primary care physician or her  
5 gynecologist after the acute phase of  
6 treatment, and if the oncologist or the  
7 radiation oncologist isn't coding at that  
8 point, so their follow up, that's the primary  
9 care-

10 MEMBER LOY: So what if they're  
11 seeing both? What if they're seeing a primary  
12 care doctor and a medical oncologist in follow  
13 up? Who gets the attribution?

14 MS. FRANKLIN: But so I just  
15 wanted to clarify that the level of analysis  
16 is current specified as the population level,  
17 the national population level?

18 MS. TIGHE: Yes, so correct me if  
19 I'm wrong, but ActiveHealth actually uses this  
20 measure for their clients and they use it at  
21 all different levels. The measure in front of  
22 you today is only specified for the population

1 level. So they're talking about their uses  
2 for it, but the NQF endorsed measure would  
3 only be used at a population level.

4 MEMBER LOY: Okay. And then the  
5 other question I might have being a non-  
6 medical oncologist, I heard the developer say  
7 that there was some value in relapse-free  
8 survival. Could you help us to understand if  
9 that's clinically meaningful, or in what way?

10 DR. CHIN: I guess relapse-free  
11 survival per se, I don't personally think is  
12 clinically meaningful. I think we could  
13 probably have another, you know, 10-hour  
14 discussion on what the literature says about  
15 that. But for this reason it's that women who  
16 have breast conservation do have a higher risk  
17 of relapsing within the breast tissue that's  
18 remaining. And if that is detected, then that  
19 breast can be removed by salvage mastectomy  
20 and that woman then is expected to have the  
21 same survival, overall survival, as a woman  
22 who was treated with mastectomy.

1                   MEMBER MALIN: I think the problem  
2                   with that sort of logic though is so we know  
3                   that people who have breast-conserving surgery  
4                   and radiation have the same survival as  
5                   mastectomy. There is no data. Presumably I  
6                   think most of it is because it's the distant  
7                   metastases that kill you, not the local  
8                   recurrences. And so even though we certainly  
9                   don't let local recurrences just lie there; we  
10                  treat them, and there's some retrospective  
11                  data that suggests giving those people  
12                  additional chemotherapy may improve their  
13                  outcomes, it's really very speculative. And  
14                  there's certainly no evidence of a process  
15                  outcome link there.

16                  Can we ask about or are we at the  
17                  point where we can ask questions about the  
18                  kind of reliability and validity of the  
19                  measure, or are we still on importance?

20                  CHAIRMAN LUTZ: I think we're  
21                  still on importance.

22                  MEMBER MALIN: Still on

1 importance?

2 CHAIRMAN LUTZ: John, did you have  
3 something?

4 MEMBER GORE: Just speaking to the  
5 structure process outcome link. And my  
6 question is just if this measure is relevant  
7 to a population, then how is it used for  
8 quality improvement?

9 CHAIRMAN LUTZ: Bryan and  
10 Jennifer, either one of you have anything?  
11 You're fine.

12 MEMBER GORE: Do the developers  
13 have a response?

14 DR. CHIN: Sorry. Can you repeat  
15 the question again?

16 MEMBER GORE: So if the unit is  
17 the population, if it's used to evaluate a  
18 population of patients, how is that used for  
19 quality improvement?

20 DR. CHIN: Well, you know, our  
21 clients or any sort of person using this  
22 measure would monitor their population of

1 people and how many of them are doing the  
2 surveillance on an annual basis. So I guess  
3 if they're performing well, they would either  
4 look at sort of what they're doing in terms of  
5 recommendations to patients to improve  
6 surveillance. Is that what you're asking?

7 MEMBER GORE: Well, with many of  
8 the metrics that we look at the unit analysis  
9 is such that you can discriminate quality  
10 among or between providers. And so if the  
11 unit of analysis is the entire population,  
12 then all you know about is whether your whole  
13 population is doing well or doing badly. And  
14 I wonder about the opportunity for quality  
15 improvement when it's looking at the whole  
16 without trying to drill down any deeper.

17 DR. CHIN: Well, since you  
18 clarify, I think we didn't say that this  
19 measure couldn't be used at those different  
20 levels. We do not do the level of analysis,  
21 the statistical analysis at those different  
22 levels for our measure. I think that we were



1       trying to answer the question on the form that  
2       says that if you're going to use this measure  
3       at those different levels you need to do the  
4       different types of analysis at those levels  
5       and the statistical analysis. And we do not  
6       have the time to do that level of analysis per  
7       provider and such. So that's why we said we  
8       went for the population endorsement. But it's  
9       not that this measure isn't being used by some  
10      of our clients to look at their providers and  
11      how they're doing on these measures.

12                   MS. TIGHE: So ActiveHealth is  
13      using it at all the different levels, but  
14      they've only provided reliability and validity  
15      information for the population level. So  
16      that's the only level that we can evaluate it  
17      at.

18                   CHAIRMAN LUTZ: All right. Is  
19      there anything else before we vote on  
20      importance?

21                   (No response.)

22                   MS. KHAN: So voting on 1a,

1 impact.

2 MS. TIGHE: Heidi or Rocco, if  
3 you're still on the line, you want me to send  
4 your votes?

5 MS. KHAN: We have zero for high,  
6 four for moderate, five for low and three  
7 insufficient evidence. So we are done.

8 MS. BOSSLEY: Let's do all of  
9 importance. Let's do the gap and the  
10 evidence, too. I think that would be helpful.

11 MS. KHAN: Okay. Moving onto  
12 performance gap.

13 We have one high, four moderate,  
14 one low and seven insufficient evidence.

15 And moving onto 1c, evidence.

16 We have zero for yes, seven for no  
17 and six insufficient evidence. So the measure  
18 will not pass.

19 MS. BOSSLEY: So this didn't pass  
20 importance. No need to move forward because  
21 this must pass.

22 CHAIRMAN LUTZ: All right. Let's

1 see. The next one is No. 0031, breast cancer  
2 screening. I think NCQA is going to give us  
3 the frame work and then Nicole is going to  
4 give us the details of the discussion.

5 MS. BOSSLEY: They are making  
6 their way to the table.

7 MS. BYRON: Hi, I'm Sepheen from  
8 NCQA. Mary Barton. The breast cancer  
9 screening measure is a HEDIS health plan-level  
10 measure. It's a longstanding measure in the  
11 HEDIS health plan measure set. And it looks  
12 at biennial, so that's once every two years,  
13 mammograms in women ages 40 to 69. And it's  
14 applicable to commercial, Medicaid and  
15 Medicare health plans.

16 CHAIRMAN LUTZ: Okay. Nicole?

17 MEMBER TAPAY: Yes, I would just  
18 add in terms of impact, there's potential high  
19 impact because of the benefits of early  
20 detection in terms of survival. There's  
21 actually significant room for improvement,  
22 even in the white population, and the African-

1 American population. We're only at 68  
2 percent, and it's even lower for other ethnic  
3 and racial minorities. The group found it to  
4 be a reliable measure with a high degree of  
5 usability. As was stated, it's being used  
6 right now for HEDIS.

7 I think a lot of the controversy  
8 was around the validity. As many of you know,  
9 there was a U.S. Preventative Services Task  
10 Force recommendation to only begin it at age  
11 50. And so the actual recommendation of the  
12 group was only three to two to recommend it to  
13 go forward. And I think largely because of  
14 that it wasn't clear from the explanations why  
15 there was a divergence. While they cited a  
16 number of other groups, ACOG, ACS, that  
17 concurred with this recommendation there  
18 wasn't really a clear rationale for keeping it  
19 at age 40.

20 CHAIRMAN LUTZ: All right. So is  
21 there -- please.

22 MS. BYRON: So NCQA is aware of

1 the differences between some of the national  
2 guidelines that are out there. And because of  
3 that, we are starting a reevaluation of the  
4 measure. And the difficult position that we  
5 find ourselves in is that there are national  
6 guidelines that are recommending different  
7 things. And for the task force, the  
8 recommendation for ages 40 to 49, that  
9 screening should be an individual decision  
10 based on shared decision making and other  
11 factors like that.

12 And so we did not feel that we  
13 could immediately change the measure. And  
14 what we anticipate is that we will be working  
15 with an advisory panel to discuss how we might  
16 address these issues. One possibility is that  
17 we might stratify the measure by different age  
18 groups so that we would be looking at 40 to 49  
19 and, you know, 50 and up, something like that,  
20 so that you could say what the rate for a  
21 health plan would be in these different age  
22 stratifications. And that might be one way

1 that we would have a measure that doesn't come  
2 into conflict with guidelines but is still  
3 able to produce some meaningful information  
4 for quality improvement.

5 MEMBER MILLER: So I have more of  
6 a procedural question, I guess. For example,  
7 if, say, the major objection that one of us  
8 were to have was strictly about the age issue;  
9 I'm just trying to think through, does that  
10 apply more to the importance to measure part  
11 of it, or is that really a  
12 reliability/validity question? I mean, I  
13 could argue both sides, but so is that --

14 CHAIRMAN LUTZ: I think it's hard  
15 to separate it.

16 MEMBER MILLER: -- overthinking  
17 it?

18 CHAIRMAN LUTZ: I had the same  
19 question because I keep arguing with myself  
20 there. I don't know what you guys think, but  
21 it seems like it's a little bit of both those  
22 things.

1 MS. BOSSLEY: I think the big  
2 thing will be, as we walk through this, to be  
3 clear on each criteria what the concerns are,  
4 because you could really raise them in both  
5 places. It's based on specifications as well  
6 as concerns with the measure as specified  
7 doesn't quite match the evidence that is  
8 important, if that's what you were thinking.  
9 Just have to be clear, yes.

10 CHAIRMAN LUTZ: Well, and then if  
11 I could, if we can say it in importance; and  
12 maybe this is the part I'm not supposed to  
13 say, but it concerns me that we might have  
14 something that's still being actively  
15 discussed and intelligently argued between  
16 respected bodies. And if we solidify this in  
17 a quality measure which can then be used as a  
18 payment issue, what we say can pull us onto  
19 one side or the other. And I'm not saying  
20 it's wrong. I'm not saying it's not a bad  
21 measure. It's just a real rough time given  
22 all of those disparities. I mean, you know,

1 we could probably intelligently argue about  
2 the 40 to 50 age group from either side for a  
3 long time.

4 Nicole?

5 MEMBER TAPAY: This would just be  
6 another clarifying question for NCQA. How  
7 long does your reevaluation process take?

8 MS. BYRON: For this measure we'd  
9 be reevaluating this summer. We plan to  
10 convene our advisory panel in July. The issue  
11 is we offer all of our measures for public  
12 comment. So because this is HEDIS plan  
13 measure, we align it with our HEDIS health  
14 plan publication and set. So that means that  
15 public comment would occur this coming spring,  
16 so it would be like spring 2013. And then any  
17 changes would be published in the HEDIS volume  
18 that summer.

19 MS. BOSSLEY: And just as a  
20 reminder, we have an ad hoc review process.  
21 So if this measure should go forward as it is  
22 now, if you all voted to maintain endorsement,



1 when NCQA brings back a revised specification,  
2 most likely that would go through what I would  
3 call an ad hoc review where a small group of  
4 experts review the evidence, the changes that  
5 they may or may not make, and determine  
6 whether the measure endorsement should  
7 continue. So there's a process to accommodate  
8 the change in the future. Again, just want to  
9 make sure you understand what the options are,  
10 maybe.

11 MEMBER LOY: I just want to make  
12 sure I understand the stewards' position on  
13 this. This is a maintenance endorsement,  
14 maintenance review. So did you all take a  
15 look at the same evidence that USPSTF took a  
16 look at and have a similar conclusion that 40  
17 to 49 is still appropriate, or was that part  
18 of the process?

19 MS. BYRON: What NCQA does when we  
20 develop measures is try to actually look at  
21 guidelines and trusting that the guidelines  
22 are following the process of basing their

1 recommendation on systematic reviews. You  
2 know, that said, we don't just take any old  
3 guideline. We do consider the USPSTF to be a  
4 highly-regarded and a very well-researched  
5 guideline that we usually trust.

6 We usually follow the  
7 recommendations that were put forth by the  
8 Institute of Medicine's "Guidelines We Can  
9 Trust." Guidelines for guidelines. And so we  
10 do try to look across the guidelines, see what  
11 they're saying, trust that they're basing it  
12 on systematic evidence reviews. We don't tend  
13 to do primary evidence reviews ourselves,  
14 because we are trusting the guideline  
15 developers to do that.

16 And so, you know, when a situation  
17 like this comes about, we find ourselves in  
18 the middle and we have to make those difficult  
19 decisions about what to do for the measure.

20 CHAIRMAN LUTZ: Karen, please.

21 Help me.

22 MEMBER FIELDS: So I guess your

1 statement before makes it even harder to have  
2 this discussion, because most of the oncology  
3 societies actually still are going around and  
4 endorsing 40 and above on an annual basis.  
5 And so even though there's some other data out  
6 there that's been confusing ACS, NCCN, ASCO,  
7 everyone is still endorsing that. So I guess  
8 until some of the big oncology societies start  
9 to think about changing those endorsements, I  
10 don't know that NQF endorsing a measure that's  
11 a maintenance measure makes us choose sides.  
12 I think the medical societies that represent  
13 us already chose sides. That's just an  
14 editorial comment. I don't know. And I value  
15 the other members' comments about that.

16 MEMBER PFISTER: You know, I think  
17 that, as you pointed out, there's clearly not  
18 consensus with the guidelines, and certainly  
19 the oncology societies have aligned with not  
20 changing the age range. And oftentimes not  
21 changing the age range is kind of a path of  
22 resistance in political hotbed situations like

1 this. I think what's a challenge here is that  
2 certainly the organization that's recommending  
3 a different age range is certainly not by any  
4 metric viewed as a non-credible source.

5           And, you know, I guess what I'm  
6 wondering is if you were -- and this is a  
7 quality measure where you are going to  
8 evaluate activities based on what would be  
9 widely appreciated, something should  
10 definitely be happening. And if in a certain  
11 decade of life there's a disparity among  
12 people saying what should happen, then I think  
13 that questions of the robustness of the metric  
14 is applied to that decade, whether the focus  
15 should be on those age groups, which there is  
16 no disagreement that they should definitely be  
17 getting it done.

18           It's such that the measurement is  
19 not a distraction from sort of like, oh, and  
20 by the way, when you looked at those  
21 performance gap statistics, they weren't  
22 looking very good in the area where they

1 should definitely be getting it done. And  
2 everyone agrees there, you know? And so, you  
3 know, sometimes situations like this can lead  
4 to the sort of distraction from stuff that  
5 there's broad consensus should be happening.

6 MEMBER GORE: I just wanted to  
7 clarify what provider is being measured here  
8 as well, because there's a part where it says  
9 it's a physician-level measurement. And so  
10 how is that determined which physician is  
11 being measured or evaluated by the screen of  
12 their patient population?

13 MS. BYRON: Well, the measure has  
14 been re-specified for electronic health  
15 records, and so that means that it is for what  
16 they call eligible providers. So I believe  
17 it's any providers, because this is a primary  
18 screening, or it's a secondary screening  
19 measure for a general population.

20 MEMBER GORE: So if this is for a  
21 population, how is it anticipated that this is  
22 used for quality improvement? Sorry to ask a

1 redundant question from my previous one.

2 DR. BARTON: Let me make sure I  
3 understand that question, if I might. So like  
4 for a population, for a health plan?

5 MEMBER GORE: So who are we  
6 evaluating with this measure? So if you're  
7 using this to understand rates of screening in  
8 your entire health plan, then my question is  
9 how is that then used for quality improvement?  
10 Because there's a part where it says it's a  
11 physician-level measure. How is that  
12 physician determined so that it's not, for  
13 example, punitive to someone who saw that  
14 patient once? That patient, like me, doesn't  
15 see a primary care doctor ever. And so how is  
16 that determined?

17 DR. BARTON: Well, I think NCQA's  
18 greatest experience is with the HEDIS set  
19 being applied in health plans. And I think  
20 that this is a conversation that Heidi and we  
21 go back and forth on a lot, is how we talk  
22 about measures that have been specified at

1 other levels where we may or may not have data  
2 to show their use in those areas, but where we  
3 want to make it available to people to use  
4 because we think there's good justification  
5 for using a measure on other levels than the  
6 one we use it for.

7 So I'll just say that for health  
8 plans, health plans are required to submit  
9 data on measures with the agreement that we're  
10 going to publicly report their results.  
11 They're compared on websites that NCQA  
12 maintains. They're published in Consumer  
13 Reports. So, and if I were a health plan and  
14 I saw that I had a poor overall score, I would  
15 certainly go to my component care groups and  
16 suggest that they be willing to compare  
17 publicly their rates so that there could be  
18 all of the boats, you know, working together  
19 to increase the rate for the health plan.

20 MS. BYRON: And also, NCQA does  
21 publish benchmarks for the measures, just so  
22 that health plans can compare themselves

1       against these benchmarks. So that said, we  
2       have actually seen a lot of work from health  
3       plans at our different conferences where they  
4       do best practices, and many of them have used  
5       this measure. They've looked at their rates.  
6       They've seen that they might not be as high as  
7       they would like, or they've stratified their  
8       rates according to different race/ethnicities  
9       or other, you know, socioeconomic status and  
10      they've seen maybe that their rates are good  
11      for some populations and not others. And so  
12      then they've been able to do quality  
13      improvement around that, like provider  
14      education or reminders sent out to patients,  
15      their members. So we've seen it go at  
16      different levels.

17                   MEMBER GORE: So how is the  
18      benchmark determined and is there a benchmark  
19      for this measure?

20                   MS. BYRON: There is; and I would  
21      have to look it up, and it's based on the data  
22      from all of the other plans.



1                   MEMBER GORE:  So it's an average  
2                   or a quartile?  Okay.

3                   MEMBER MILLER:  Yes, so not to be  
4                   redundant, but I just want to point out I  
5                   think the discussion we're having here is  
6                   reflective in part of the national discussion  
7                   we had between the Preventative Services Task  
8                   Force being comprised generally of people that  
9                   don't treat cancer patients.  And I think, not  
10                  everyone, but a number of us are oncologists  
11                  or predominantly deal with patients who  
12                  already have the established diagnosis.

13                  And so I guess, you know, I'm just  
14                  putting out there as an oncologist I have a  
15                  totally different perspective on this, that,  
16                  yes, I mean, I think 40-year-olds should be  
17                  screened because I see the bad end of it.  And  
18                  I understand the data and I understand this is  
19                  a controversy, but I think, who was it, I  
20                  think David said it, was, you know, maybe  
21                  focusing our attention on the people, the 52-  
22                  year-olds that aren't getting screened is

1 really where the money is.

2           And I just worry about this kind  
3 of distraction. We're coming to try to  
4 identify this as a quality measure that the  
5 individual physician at, you know, name the  
6 medical group is going to get dinged on  
7 because they didn't do their 42-year-old. I  
8 just worry that's going to be reflective of  
9 this whole national angst over this. And  
10 we're not smart enough to figure this out  
11 anyway. Certainly I'm not smart enough to  
12 figure this out.

13           CHAIRMAN LUTZ: Well, and I know  
14 we're not supposed to change, but just in  
15 terms of thinking about the processes, a  
16 hypothetical, if this has been brought simply  
17 with 50 to 69, would we have -- I mean,  
18 obviously we discussed the 40-year-olds and 40  
19 to 49 would be left out, but would we have any  
20 problem saying, well, that's a quality  
21 measure, or would that still be a confusing  
22 issue because we're not including the people

1 in their 40s? I mean, it seems a fair  
2 corollary to ask. I don't know.

3 Bryan?

4 MEMBER LOY: And to that point I  
5 would just say was there any consideration  
6 either by the developer; I guess to the work  
7 group as well, in terms of the shared decision  
8 making component of this, to say we had the  
9 discussion about shared decision making and we  
10 excluded that somewhere? I won't get into  
11 where it comes out of, numerator or  
12 denominator.

13 MS. BYRON: So this measure is  
14 actually an administrative measure only, so it  
15 only pulls from claims. So our data source is  
16 claims and there is not way that we would be  
17 able to capture that.

18 MEMBER LOY: Yes. Understood.

19 MS. BYRON: So we are balancing,  
20 you know, being able to capture all of that  
21 information but keeping it feasible.

22 MEMBER LOY: Got it.

1                   CHAIRMAN LUTZ: We've got David  
2                   and then John.

3                   MEMBER PFISTER: Yes, I mean, I  
4                   think that, you know, this is a very, I think,  
5                   passionate issue for oncologists, as you  
6                   pointed out. But, you know, I think that we  
7                   are a little bit at the mercy of what we see  
8                   and, you know, it's sort of whether it's, you  
9                   know, the last case we've seen and also the  
10                  morbidity we see. While there's certain  
11                  insights that oncologists have on this  
12                  particular issue, you know, I think in all  
13                  fairness there are certain insights that  
14                  people that aren't oncologists have in this  
15                  issue that look at, you know, health in a  
16                  different way, see the downside of some of the  
17                  false positives and never even make it to an  
18                  oncologist, you know? So, and I think it kind  
19                  of goes either way.

20                  And it's not that, as a provider,  
21                  following a given set of guidelines isn't a  
22                  very defensible thing to do here. You know,

1 certainly you have very credible organizations  
2 that, you know, say that this is the deal.  
3 It's just a matter of, if you're going to  
4 evaluate a health plan, an individual or so  
5 forth, when you have a pretty major player in  
6 this business saying, you know, that it's not  
7 so clear-cut in this group, and then we're  
8 having a pretty explicit quality measure which  
9 applies to that decade, it implies a  
10 certainty, or an evaluative certainty which I  
11 think it seems isn't so clearly there amidst  
12 the controversy. And I don't think we're  
13 going to resolve it in this room.

14 I think what the pressure on the  
15 situation is, is that it's a metric used to  
16 assess, you know, quality. And someone might  
17 say, one group will say, well, gee, not doing  
18 it in this decade is under-penetration.  
19 Another very reputable group will say it's  
20 actually over-penetration. So it's not even  
21 like a neutral thing. And so, you know, I  
22 think that's the quandary we're in here,

1 because this is something which -- you mention  
2 about evaluating the health plans, so how  
3 meaningful is that evaluation of a health plan  
4 in that decade of life in terms of being able  
5 to interpret that, except for the fact that  
6 two different guidelines panels disagree and  
7 you end up with a number that I'm not sure how  
8 actionable that number is?

9 CHAIRMAN LUTZ: I'm sorry, before  
10 we go to John, because directly to that, I  
11 mean, in practice if I see someone who's 40  
12 and is being seen, a female being seen for  
13 another reason, I start discussing the merits  
14 and drawbacks of screening at the age of 40  
15 and let them get screened if they want. And  
16 then I am much more dogmatic about starting  
17 screening at 50. I mean, I don't know.  
18 Again, I'm not trying to rewrite the  
19 submission, but I mean, in some ways there has  
20 to be some common sense to this.

21 MEMBER GORE: Yes, and I'm going  
22 to build upon that as well in that this

1 measure, it's not -- you know, the physicians  
2 who are going to be evaluated by this measure,  
3 either by their health plan or individually,  
4 are overwhelmingly going to be primary care  
5 physicians. And so when you look at survey  
6 studies of what informational materials  
7 primary care physicians use, they do  
8 predominantly use the USPSTF.

9 And so I think when you're feeding  
10 back to primary care clinicians about, you  
11 know, their breast cancer screening when their  
12 predominant guideline says to start at 50, I  
13 think they would be hard-pressed about being  
14 dinged for not doing it between 40 and 49.

15 MEMBER FIELDS: I guess the most  
16 important point is the median age of breast  
17 cancer in the United States is 51 or 52. That  
18 means that half the patients are below that  
19 age when they're diagnosed.

20 The median age of breast cancer is  
21 65? Okay. Then I am incorrect.

22 The problem with screening

1 mammography, the state of the art is such that  
2 the specificity of the test goes up with age  
3 and it's not specific in the younger patient  
4 population. Unfortunately, it's the test that  
5 we have. It's the widely-available screening  
6 tool. So there's a patient population in the  
7 ages of 40 to 50 that we just haven't  
8 addressed.

9           So that's the reason we have  
10 guidelines problems right now. And my only  
11 answer is I think that the main issue that we  
12 have as a problem is that we don't have a  
13 better way to screen that patient population.  
14 And that's where the disparity comes. I mean,  
15 that's where the issues come in.

16           I also think that there's a  
17 disparity problem between Medicare and  
18 commercial payors and Medicaid payors. And  
19 so, I don't know that this measure addresses  
20 that. I mean, the most important thing is to  
21 understand why Medicaid and Medicare patients  
22 aren't being screened at the same rate as



1 commercial payors if these guidelines are out  
2 there and available.

3 MEMBER MALIN: I think, you know,  
4 there's complex issues related to disparities,  
5 but I know from some of the work that the  
6 Quality of Care Department at WellPoint has  
7 done, you know, part of the challenges that --  
8 you know, screening requires an activated  
9 patient population as well. And, you know,  
10 often patients who are in under-served  
11 communities have more pressing needs in terms  
12 of survival than getting out for their  
13 screening. And so, you know, it's not  
14 necessarily having access and having  
15 physicians. I mean, there's a lot to get  
16 people in for their screening.

17 MEMBER LOY: Just to emphasize  
18 from the health plan perspective again, if  
19 HEDIS scores are valuable to employer groups  
20 and a health plan finds themselves with less  
21 than their competition, then there will be  
22 some pressure back to find out who those

1 segments are that aren't being screened. So  
2 I think it would be naive to think that there  
3 would not be some pressure back on the system,  
4 and it wouldn't be pressure to get towards a  
5 shared decision making or a conversation. The  
6 measure, as, you've already pointed out, would  
7 be addressed or acknowledged through claims  
8 payment. So I don't know of a claims payment  
9 mechanism that could overcome that shortfall.

10           And then the other point that I  
11 might make would be many commercial plans in  
12 the industry use USPSTF as their basis for  
13 screening coverage. And I don't know how  
14 folks are coping with that today. I don't  
15 know how regional versus the large plans are  
16 coping with that discrepancy today amongst  
17 different guidelines that exist out there. It  
18 is hypothetical, but I think that there could  
19 potentially be a situation where you've got a  
20 quality measure where there might not be  
21 commercial coverage that's available, if your  
22 commercial coverage allows for those

1 screenings that are acknowledged by USPSTF.

2 CHAIRMAN LUTZ: John?

3 MEMBER GORE: And to build on  
4 that --

5 CHAIRMAN LUTZ: I'm sorry, they  
6 want to respond to that. Sorry.

7 MEMBER GORE: Oh, sorry. Sorry.

8 DR. BARTON: I think it's true  
9 that there are insurers who look to the U.S.  
10 Preventative Services Task Force. I think  
11 though that an act of Congress that came along  
12 in 2009 instructing HHS to disregard the U.S.  
13 Preventative Services Task Force  
14 recommendation on mammography screening was a  
15 powerful message.

16 MEMBER CHOTTINER: I think,  
17 without trying to oversimplify. I'm looking at  
18 this, and in 2012, with the evidence that we  
19 have, I think it's hard to answer that first  
20 question about evidence with anything other  
21 than it's insufficient right now to recommend  
22 for or against in that patient population. So

1 the question becomes: do you judge the measure  
2 on that basis or is there any opportunity to  
3 modify the age range in the measure?

4 So did the developer want to  
5 respond?

6 MS. BYRON: So because the task  
7 force did not come out with an insufficient  
8 evidence -- it's actually a C grade for the 40  
9 to 49, and I think the issue is that across  
10 guidelines we don't necessarily have  
11 agreement. By stratifying the measure as 40  
12 to 49 and then, you know, 50 to 59, or 50 and  
13 up, we may be able to get around some of these  
14 problems that I think the entire medical  
15 community in addition to measure developers  
16 are struggling with here.

17 It's possible that if we are able  
18 to get that change for the measure, which I  
19 can't promise anything because, you know, we  
20 do rely on our advisory groups to help us go  
21 through that process, and you know, we would  
22 post it for public comment, and I imagine we

1 would get lots and lots of comments -- but by  
2 stratifying in that way, it may give us that  
3 ability to either disregard that age group for  
4 that stratification -- if I were someone  
5 implementing measures for whatever reason;  
6 quality improvement or payment, I might be  
7 able to say we would only like to focus on the  
8 50 and up age because that is where across the  
9 guidelines we have agreement.

10 For the 40 to 49, that could be  
11 something that you not use in a program or in  
12 a payment system. You know, that would be up  
13 to people implementing the measure, but would  
14 give people an opportunity to address the  
15 different age groups in different ways. So  
16 that is where we think we might be able to go  
17 with this measure.

18 CHAIRMAN LUTZ: So do we need to  
19 vote, or after the discussion do we have them  
20 go talk that over? I mean, what's the best  
21 way procedurally to deal with that?

22 MS. FRANKLIN: So we can go

1 through the votes for impact and opportunity  
2 for improvement. And if we feel strongly  
3 there is an opportunity for improvement and  
4 strong impact, but there is a weakness in the  
5 evidence base, we'll have to take that vote.  
6 And then if it fails at 1c, which is the  
7 evidence base, we can as a steering committee  
8 decide if we want to move the measure forward  
9 anyway and invoke the exception at that time.

10 MEMBER FIELDS: So the way the  
11 data was presented, it's hard to tell if there  
12 is an opportunity for improvement because the  
13 age range wasn't stratified in the way they  
14 gave us the data. So we can't necessarily say  
15 where the shortcomings in the data are, if  
16 it's in what age groups, unless you have a  
17 clarification on that.

18 MS. BYRON: That's true. For  
19 HEDIS, right now the measure is not  
20 stratified. So we anticipate that may be a  
21 possible change in the measure to allow for  
22 that stratification.

1                   One way you can look at it is that  
2                   you can compare across different product  
3                   lines. So commercial plans have a rate that's  
4                   right around 69-70 percent as a mean.  
5                   Medicare I think is around the same, if not a  
6                   little bit lower. And Medicare, it's down to  
7                   about 50 percent. So that's one way to think  
8                   about whether or not there's, you know, an  
9                   opportunity for improvement.

10                   MEMBER FIELDS: So the way you  
11                   could interpret that might be that the  
12                   Medicaid patients are the younger patient  
13                   group?

14                   MS. BYRON: Or disadvantaged.

15                   MEMBER FIELDS: So then that's why  
16                   they're falling outside of the guidelines?  
17                   Because the Medicare patients have it covered  
18                   as part of their coverage.

19                   MS. BYRON: For 65 and up. So it  
20                   probably is fair to say they're a little  
21                   younger, but they are also, you know,  
22                   disadvantaged in other ways. So I think it

1 would be hard to assign the reason to just one  
2 factor.

3 MEMBER FIELDS: It just makes it  
4 hard to follow that one recommendation, which  
5 would be since we can't interpret the data, I  
6 would think.

7 MS. KHAN: Voting on 1a, impact.

8 So we have eight for high, one  
9 moderate, zero for low and two for  
10 insufficient.

11 And voting on performance gap.

12 We have four high, four moderate,  
13 two low and on insufficient evidence.

14 And going onto 1c.

15 I'm missing one person.

16 So we have two yes, one no and  
17 eight insufficient evidence.

18 MS. BOSSLEY: So this is where  
19 again, as Angela said, there is the exception.  
20 It typically deals more with consensus-based  
21 guidelines that you're looking at.

22 I'm wondering, and again, just let



1 me throw out an idea, because you still have  
2 comments to come. And so one thing we could  
3 do is have you assess the measure against all  
4 the criteria. At the end of the day it could  
5 go out with you seeking additional input from  
6 the membership and the public before you make  
7 a final recommendation. We have done it in  
8 the past. It is an option before all of you.

9 Or if you feel like you have  
10 assessed this and you don't want to move  
11 forward, we won't move forward. But that is  
12 again another option you can run through. You  
13 can assess all the criteria and then see where  
14 we land, and then if you choose, we could  
15 actually put it forward for more input before  
16 you make a final final recommendation.

17 Throwing it out as an option.

18 MEMBER MILLER: I actually like  
19 that idea, and I'm not just saying that  
20 because it's 5:15. Again, maybe I'm speaking  
21 as a cancer doctor who sees people who already  
22 have a diagnosis of cancer and I have my bias.

1 We said it's a health plan measure. It's a  
2 primary care measure predominantly. And I  
3 would love for those stakeholders to have an  
4 opportunity to influence my opinion.

5 MEMBER PFISTER: Yes. No, I think  
6 getting more input is definitely the way to  
7 go. You know, this measure's been around a  
8 very long time. Okay? And obviously this is  
9 a very controversial area where there's been  
10 a lot of back and forth about it and I think  
11 that, you know, getting comprehensive input on  
12 this I think is particularly critical here.

13 MS. BOSSLEY: So in order to do  
14 that, often, especially at the end of the day,  
15 it's helpful if you could assess the rest of  
16 the criteria because that may be helpful when  
17 it goes out for comments. So they can see how  
18 you assessed it against scientific  
19 acceptability, usability, feasibility, and  
20 then the overall. Again, we can just put it  
21 out if everyone agrees that it would just be  
22 seeking additional input, you're not yet sure

1 what recommendation you should make, if that  
2 makes sense to everyone. Because I think  
3 everybody's in this dilemma and we just need  
4 more comment, it sounds like, from the  
5 external stakeholders.

6 CHAIRMAN LUTZ: Okay. So that  
7 means we continue on with the voting? Okay.

8 MS. KHAN: So moving on to -- are  
9 we going to have discussion?

10 MS. FRANKLIN: We're looking at  
11 2a, reliability, under scientific  
12 acceptability. And if there's any discussion  
13 about that?

14 (No response.)

15 MS. KHAN: So voting on  
16 reliability, 2a.

17 CHAIRMAN LUTZ: Nicole, do you  
18 have anything you want to say about  
19 reliability? You don't have to. We just  
20 didn't want to leave you out. Can someone  
21 nudge Nicole, wake her up?

22 MEMBER TAPAY: I mean, I think

1 that the group had felt that it was fairly  
2 clearly stated in terms of the reliability.  
3 The question was more around the validity and  
4 the age. So I don't have anything more to  
5 add.

6 MS. KHAN: So voting on 2a,  
7 reliability.

8 So we have six high, three  
9 moderate, zero low and two insufficient  
10 evidence.

11 And voting on validity.

12 I think we're missing one person.

13 So zero for high, six for  
14 moderate, two low, three insufficient  
15 evidence.

16 MS. FRANKLIN: All right. Moving  
17 on to a vote on usability.

18 But first, Nicole, did you have  
19 any comments around usability, and discussion  
20 from the group?

21 MEMBER TAPAY: We didn't really  
22 have any on that point.

1 MS. KHAN: So voting on usability.

2 We have two high, five moderate,  
3 two low and two insufficient information.

4 And feasibility. Was there  
5 anything?

6 (No response.)

7 MS. KHAN: Voting on feasibility.

8 That's nine high and two moderate,  
9 zero low, zero insufficient information.

10 And overall suitability for  
11 endorsement. Does the measure meet NQF  
12 criteria for endorsement?

13 So we have two for yes and nine  
14 for no.

15 CHAIRMAN LUTZ: All right. Just  
16 to prove how strong we are, there's one left  
17 and the developers have said that they're  
18 available to 6:00 and really requested if we  
19 could do it tonight, that would be good for  
20 them. Besides, Patrick said the dance bars  
21 downtown don't really get going until about  
22 9:30 or 10:00. So we got a lot of time.

1 That's what he told me.

2 (Laughter.)

3 MS. FRANKLIN: So do we have  
4 someone from AMA/PCPI who will tee up the  
5 measure for us?

6 MS. TIGHE: Actually, we may just  
7 want to actually let Dr. Miller go first,  
8 because he has to run off.

9 MEMBER MILLER: I have to catch a  
10 6:05 train.

11 MS. FRANKLIN: Okay. Dr. Miller,  
12 if you could start us off. Go ahead.

13 MEMBER MILLER: Yes. So very  
14 quickly, this is a measure similar to one we  
15 saw many hours ago. This is adjuvant therapy  
16 of hormone receptor positive breast cancer  
17 measure. This is the use of tamoxifen or  
18 aromatase inhibitor for appropriately selected  
19 patients, stage IC through IIIC, that are  
20 ER/PR positive. This is a process measure and  
21 the level of analysis is at the clinician, the  
22 individual physician group.

1                   In terms of the impact, little  
2                   doubt of the importance of this. The most  
3                   common type of breast cancer. Evidence very  
4                   high that the intervention is effective in  
5                   improving disease for survival and overall  
6                   survival.

7                   There is a performance gap in  
8                   terms of the QOPI measures. Performance was  
9                   at 94 percent, but other patterns of care  
10                  study, particularly in under-served  
11                  populations have been considerably less good  
12                  than that, 80 percent or so.

13                  And I'll just summarize very  
14                  quickly and say I didn't have any concern with  
15                  the evidence. It was high-quality evidence,  
16                  multiple studies. So I'll leave it at that.

17                  MS. FRANKLIN: Any comments from  
18                  the developer?

19                  DR. ANTMAN: My colleague Sam  
20                  Tierney is on the line, so I'll defer to her  
21                  to see if she wants to add anything.

22                  MS. TIERNEY: Thank you for your

1        comments. The only thing I would add; because  
2        it wasn't available at the time we submitted  
3        the measure, is that there was some data from  
4        PQRS in 2010 related to this measure that  
5        showed that the average performance rate was  
6        about 90 percent. So that information is not  
7        available in a range, so we're not sure of the  
8        range of variability within that, but I just  
9        wanted to also share that additional  
10       information from the recent use of the measure  
11       in PQRS.

12                    MS. FRANKLIN: Okay. Thank you.

13        So focusing on importance, do we have  
14        discussion around importance? Dr. Loy?

15                    MEMBER LOY: Just would say that  
16        point's already been made today. It feels  
17        like we're missing the compliance/adherence  
18        piece of this, rather than just the  
19        prescription. I just would say, as we move  
20        forward, if that's a consideration the  
21        developers would take away. I think that's  
22        contemporary.



1 MS. FRANKLIN: Additional comments  
2 about the importance? Karen? Okay. Any  
3 other comments?

4 (No response.)

5 MS. FRANKLIN: Then we're ready  
6 for a vote.

7 DR. HASSETT: Can I make a  
8 comment?

9 MS. FRANKLIN: Oh, yes. Sorry, on  
10 the phone?

11 DR. HASSETT: I'm sorry. This is  
12 Michael Hassett. I'm a medical oncologist in  
13 breast cancer.

14 Two quick comments, one about the  
15 gap issue. There are a number of studies that  
16 I've looked at compliance relative to this  
17 measure in other patients that would suggest  
18 that there are some particularly disparity-  
19 focused populations where compliance is much  
20 lower, probably in the 60-percent range.

21 And with regard to the adherence  
22 issue, I would certainly support the concept

1 of an adherence-related measure as well. I  
2 think we actually probably need both on the  
3 market, an initiation measure and an adherence  
4 measure.

5 MS. FRANKLIN: Thank you.

6 DR. HASSETT: Thank you.

7 MS. FRANKLIN: Any other comments  
8 from those on the phones?

9 (No response.)

10 MS. FRANKLIN: No? I think we're  
11 ready to vote. All right. Then we're ready  
12 to move to a vote on 1a, impact.

13 MR. CUNNINGHAM: Okay. Now voting  
14 on 1a, impact.

15 We have 10 high, one moderate.

16 Moving onto 1b, performance gap.

17 Seven high, four moderate.

18 Moving onto 1c, evidence.

19 Ten yes, one insufficient.

20 CHAIRMAN LUTZ: So any discussion  
21 about reliability?

22 MEMBER MILLER: So none about any

1 of the other measures felt comfortable with  
2 our discussions. My own analysis, we met all  
3 the other criteria.

4 MEMBER FIELDS: I just had a  
5 question. When you looked at the expert panel  
6 for validity, 80-90 percent of them put it in  
7 category four or five, and we're sort of used  
8 to seeing higher validities there. And I  
9 assume they're saying it was because there was  
10 a high exception rate to who wouldn't get the  
11 drug, but I just wanted to ask how to  
12 interpret that, or any comments. Because it  
13 seems to me like a very valid measure.

14 MS. CHRISTENSEN: Yes, we didn't  
15 actually ask for comments on that. That's  
16 something that we've changed since then to  
17 find out more if it's not a four or a five,  
18 you know, what their particular thing was.  
19 There were two people on here that put a  
20 three, which was -- just make sure I get the  
21 word right, sorry -- neither disagree nor  
22 agree. So it's not disagreeing. It's just

1 not very high.

2 MEMBER FIELDS: That was like 30  
3 years of data on disparity in healthcare. I  
4 just didn't understand if there was something  
5 we were missing about --

6 MS. CHRISTENSEN: Yes, we felt the  
7 same thing.

8 MEMBER FIELDS: -- the validity of  
9 the test. Okay.

10 MR. CUNNINGHAM: Onto 2a,  
11 reliability.

12 Ten high, one moderate.

13 Moving onto 2b, validity.

14 One more vote.

15 Eleven high.

16 Any more discussion?

17 MS. BOSSLEY: I get the feeling  
18 you all feel you've discussed this enough.  
19 You want to just vote? Okay. We'll vote.

20 MR. CUNNINGHAM: All right. Cast  
21 those votes.

22 Eleven high.

1 Moving onto feasibility.

2 We need one more. Please hit it  
3 again.

4 Nine high, two moderate.

5 Moving onto overall suitability  
6 for endorsement.

7 Eleven yes, zero no.

8 CHAIRMAN LUTZ: It is incumbent  
9 upon us to ask for public comment. Anyone for  
10 public comment?

11 (No response.)

12 CHAIRMAN LUTZ: All right.  
13 Hearing none, we will see -- oh, go ahead.

14 DR. CHIN: Hi.

15 CHAIRMAN LUTZ: Go ahead.

16 DR. CHIN: Hi. This is Lindee,  
17 Dr. Lindee Chin from ActiveHealth again. I  
18 just had a suggestion for the steering  
19 committee about our measure again.

20 CHAIRMAN LUTZ: Go ahead.

21 DR. CHIN: So I just wanted  
22 clarification that if we're basing our measure

1 on an NCCN guideline that's as recent as --  
2 it's been updated as of January 2012, still  
3 recommending surveillance for this group of  
4 people -- I guess I'm confused as to what  
5 other data that you would have liked to have  
6 seen to qualify the importance of this  
7 measure.

8 CHAIRMAN LUTZ: I'm not sure if  
9 there was data, so much as there's so many  
10 different options as to things that can be  
11 considered in quality measures. And I think  
12 it's trying to put some gradation on the  
13 things that are most pressing and things that  
14 are important, but maybe not the most pressing  
15 in terms of measurement. I'm not sure there  
16 was anything missing as much as it's sort of  
17 put upon us to find the things that are  
18 emergent and important and topical right now.  
19 I don't know if that helps.

20 MEMBER MALIN: Also, I think the  
21 rationale for surveillance in the NCCN  
22 guidelines for breast cancer, for colorectal

1 cancer, for lung cancer is based on the data  
2 in the non-impacted population. And so it's  
3 harder to make a case, I think, that there's  
4 evidence to support a different indicator for  
5 the affected, the survivorship population  
6 rather than just using the same indicator that  
7 you would use for the general population.

8 DR. CHIN: And I guess our concern  
9 is, though, then if you just put these people  
10 under the bucket of screening, then the other  
11 measure, you're not going to capture those  
12 people that are under the certain age limit  
13 that you're capturing with screening.

14 MEMBER MALIN: So you're saying  
15 that maybe we need a measure for young breast  
16 cancer survivors?

17 DR. CHIN: Perhaps. I'm not sure.  
18 That's why I'm trying to figure out how do we  
19 capture that population, because the screening  
20 measure's going to miss those people who are  
21 younger than the screening guidelines.

22 MEMBER MALIN: Well, currently

1 they wouldn't, right? I mean, although we  
2 just voted down the measure. But the current  
3 measure starts at age 40 and the number of  
4 women with breast cancer who are younger than  
5 40 is incredibly small. If the general  
6 screening measure gets revised to be 50 and  
7 above, then I think you may have a case to be  
8 made to come in with a targeted measure for  
9 breast cancer survivors who are under age 50  
10 who wouldn't fall into the regular screening  
11 guideline.

12 DR. CHIN: And I guess my other  
13 question is, I'm just wondering why this was  
14 endorsed a couple of years ago, but now it's  
15 not. And we didn't really change the measure  
16 that much because we were applying the same  
17 guidelines. So I'm just confused as to why in  
18 the past it was believed to be more important  
19 than it is today.

20 MS. FRANKLIN: And this is Angela.  
21 Our criteria here at NQF has changed and  
22 become a little more stringent over the last



1 couple of years, and it would have been a  
2 different level of review then than there is  
3 now. So our criteria have changed, and that's  
4 what the committee is looking at in reviewing  
5 the measure today.

6 DR. CHIN: Okay. Thank you.

7 CHAIRMAN LUTZ: Any other public  
8 comment?

9 (No response.)

10 CHAIRMAN LUTZ: What are you  
11 thinking? I'm good with 8:30. Depends  
12 whether Pat will be over his dancing or not.  
13 No, I'm good.

14 MS. FRANKLIN: So for tomorrow we  
15 have a motion on the table to start with a  
16 working breakfast at 8:30 tomorrow morning and  
17 the review of the measures will begin during  
18 that area. So we'll start tomorrow at 8:30  
19 with our discussions. Thanks, all.

20 (Whereupon, the meeting was  
21 adjourned at 5:37 p.m.)

22

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Cancer Endorsement Maintenance  
Steering Committee

Before: NQF

Date: 05-23-12

Place: Washington, DC

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