

NATIONAL QUALITY FORUM

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RESOURCE USE PROJECT:

PHASE II CANCER TECHNICAL ADVISORY PANEL

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TUESDAY

JUNE 28, 2011

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The Technical Advisory Panel met at the National Quality Forum, Suite 600 North, 601 13th Street, N.W., Washington, D.C., at 8:30 a.m., David Penson, Chair, presiding.

PRESENT:

DAVID PENSON, MD, MPH, Vanderbilt University
Medical Center, Chair

ROHIT BORKER, PhD, GlaxoSmithKline

STEVEN CHEN, MD, MBA, University of

California-Davis

TIMOTHY GILLIGAN, MD, Cleveland Clinic Taussig
Cancer Center

DWIGHT KLOTH, PharmD, Fox Chase Cancer Center

LOUIS POTTERS, MD, FACR, North Shore-Long
Island Jewish Health System

JAY SCHUKMAN, MD, Anthem Blue Cross and Blue
Shield

JOHN SKIBBER, MD, University of Texas-MD
Anderson Cancer Center

LOUISE WALTER, MD, University of California-
San Francisco

NQF STAFF:

TAROON AMIN

HEIDI BOSSLEY, MSN, MBA

LAURALEI DORIAN

SARAH FANTA

CAMILLE PRESBURY

SALLY TURBYVILLE, MA, MS

ASHLIE WILBON, MPH, BSN

CARLOS ALZOLA, NQF Statistical Consultant

ALSO PRESENT:

TODD LEE, PharmD, PhD, American Board of
Medical Specialties (ABMS) (via phone)

ROBIN WAGNER, ABMS (via phone)

KEVIN WEISS, MD, ABMS (via phone)

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

2 8:39 a.m.

3 MS. TURBYVILLE: Welcome,
4 everyone. We are going to start this morning
5 with just some welcome and introductions, and
6 then we will go into the disclosure of
7 interests.

8 So we are so pleased that you are
9 here today. We are really thrilled with the
10 work that we have done with you all so far,
11 and we are really looking forward to
12 evaluating and moving through the measures
13 today and hearing what your thoughts are on
14 the measures that have been submitted, and
15 capturing your ratings as we move through the
16 meeting.

17 I want to give Heidi Bossley, who
18 is our Vice President, Performance
19 Measurement, an opportunity to welcome you as
20 well, and then I will turn it over to your
21 Chair of this Technical Advisory Panel. You
22 don't want to --

1 MS. BOSSLEY: No. You have to
2 tell me what I am supposed to do disclosures,
3 too. But we are thrilled to have you here,
4 truly appreciate the amount of work we are
5 asking you to do. We have recognized that,
6 and it is truly appreciated by NQF. Thank
7 you.

8 MS. TURBYVILLE: So, David, if you
9 wouldn't mind.

10 CHAIRMAN PENSON: Yes, sure.
11 Thanks, Sally. I think the way to do this to
12 begin with is probably to do introductions,
13 and then maybe do the disclosures first, if
14 there are any. Then we can talk a little bit
15 about our goals today, and sort of the
16 process.

17 So why don't we around the table
18 and introduce ourselves. I will start. My
19 name is David Penson. I am at Vanderbilt
20 University, Nashville, Tennessee. I am a
21 urologic oncologist who also does health
22 services research, and I run our Center for

1 Surgical Quality and Outcomes Research at
2 Vandy.

3 DR. WALTER: I am Louise Walter.
4 I am from the University of California-San
5 Francisco. I am a geriatrician, and I am also
6 a health services researcher at the San
7 Francisco VA.

8 DR. SKIBBER: I am John Skibber.
9 I am a surgeon at MD Anderson Cancer Center,
10 and I am the Chief Surgical Quality Officer
11 there.

12 DR. POTTERS: I am Louis Potters.
13 I am a radiation oncologist. I chair
14 Radiation Medicine for the North Shore LIJ
15 Health System on Long Island.

16 DR. BORKER: I am Rohit Borker. I
17 work for GlaxoSmithKline. I am in the U.S.
18 Health Outcomes Group, Director, Oncology.
19 Are we also doing disclosures?

20 MS. TURBYVILLE: We will do that
21 after. We have instructions. Thanks.

22 DR. SCHUKMAN: Good morning. I am

1 Jay Schukman, Senior Medical Director of
2 Anthem Blue Cross and Blue Shield here in
3 Virginia and a Regional Vice President with
4 WellPoint for the East Region.

5 MS. BOSSLEY: Heidi Bossley, VP of
6 Performance Measures in charge of the CDP
7 process.

8 MS. DORIAN: And I am Lauralei
9 Dorian. I have recently started here at NQF,
10 and I am happy to be working on this project.

11 DR. KLOTH: Dwight Kloth, Director
12 of Pharmacy, Fox Chase Cancer Center and
13 Secretary of the Pharmacy and Therapeutics
14 Committee which has a lot of linkages to Joint
15 Commission, compliance, quality and so forth.

16 DR. CHEN: I am Steve Chen. I am
17 oncologist at UC-Davis for a few more days,
18 and then I will be at City of Hope, and a
19 health services researcher as well.

20 DR. GILLIGAN: I am Tim Gilligan.
21 I am a medical oncologist at the Cleveland
22 Clinic.

1 MS. WILBON: Good morning,
2 everyone. I am Ashlie Wilbon. You have all
3 received a lot of emails from me probably. It
4 is nice to see you all, and I am a Project
5 Manager for this project.

6 MR. AMIN: Hi, everybody. Taroon
7 Amin. I am a Senior Director here working on
8 both work with the CDP and on the Measures
9 Application Partnership.

10 MS. TURBYVILLE: And I am Sally
11 Turbyville. I am the Senior Director on this
12 project in performance measures, and again
13 just thrilled to have you here, and also want
14 to make sure I try to take a moment to thank
15 the team for all their hard work in getting us
16 ready for this meeting today.

17 CHAIRMAN PENSON: Great. Thank
18 you, everyone. I will echo what the NQF folks
19 have said. Really, everyone did a yeoman's
20 effort getting the reviews done in advance.
21 I think that will help us today, I hope.

22 Before we get into that, we

1 probably should do the disclosures now.

2 MS. BOSSLEY: Okay. This normally
3 is done by our General Counsel, and I have
4 been given a script just to make sure I do it
5 correctly.

6 As you may remember, we asked you
7 to fill out a disclosure form a while ago, and
8 we are asking you to orally disclose. You
9 don't need to include everything that you put
10 on your form. I would just include those
11 things that are relevant to this project. So
12 if you have any grants, receive any speaking
13 engagements with any organization that would
14 be relevant to cancer care, I would probably
15 just include that.

16 I would also remind you, you all
17 are here as individuals. You are not
18 necessarily here on behalf of your
19 organization, and we do ask you to represent
20 yourself with your expertise.

21 We are going to have you go
22 around. You all have introduced yourselves.

1 So I would just say whether you have any
2 disclosures or not, and then we will actually
3 follow up and make sure if anyone has any
4 questions for anyone who has disclosed
5 something, we will give you an opportunity to
6 do that as well.

7 DR. KLOTH: We should reiterate
8 what we had previously submitted
9 electronically?

10 MS. BOSSLEY: If it is relevant to
11 the project, yes. Yes. So why don't we
12 start.

13 DR. WALTER: I have no
14 disclosures.

15 DR. SKIBBER: John Skibber
16 disclosure is I am on the NCCN Executive
17 Committee for their colorectal cancer
18 database.

19 MS. WILBON: I'm sorry. Could you
20 just say your name before you have your
21 disclosures for our transcription, so we can
22 associate whose disclosure goes with who.

1 Thank you.

2 DR. SKIBBER: That was John
3 Skibber.

4 DR. POTTERS: Lou Potters. I have
5 no disclosures.

6 DR. BORKER: Rohit Borker. I work
7 for GlaxoSmithKline, and I have stock
8 ownership in GlaxoSmithKline, Amgen, and other
9 pharmaceutical companies.

10 DR. SCHUKMAN: Jay Schukman, no
11 disclosures.

12 DR. KLOTH: Dwight Kloth. I am on
13 two guidelines panels for NCCN, antiemetics
14 and myeloid growth factors. I have done
15 speaking or consulting for Amgen, SI,
16 Novartis. I think that would cover the
17 relevant parameters.

18 DR. CHEN: I am Steve Chen. I
19 have a few disclosures. I do have a grant for
20 the California Breast Cancer Research Program.
21 As far as industry disclosures, I have a
22 research contract with Agendia, Inc. With

1 Genomic Health I have a pending research
2 contract, and with LifeCell, I have a protocol
3 under review.

4 DR. GILLIGAN: Tim Gilligan. A
5 couple of things to disclose: I chaired a
6 panel for the American Society of Clinical
7 Oncology on the use of tumor markers for germ
8 cell tumors. I am on the NCI PDQ Adult
9 Treatment Editorial Board that writes
10 treatment summaries for all adult cancers.

11 I am oncologist at Cleveland
12 Clinic, who has a big stake in this, and I in
13 2010 received a one-time fee for speaking from
14 Pfizer.

15 CHAIRMAN PENSON: And this is
16 David Penson. I have pharmaceutical
17 disclosures or industry disclosures. I do
18 service as the Vice Chair for Health Policy
19 for the American Urological Association and,
20 as such, I am a paid consultant to the Board
21 of Directors for the AUA.

22 MS. BOSSLEY: Okay. Does anyone

1 have any questions for any of their colleagues
2 on anything they have disclosed? Thank you
3 very much.

4 MS. TURBYVILLE: Are there any
5 panel members on the telephone as of yet?

6 CHAIRMAN PENSON: All right. A
7 few people are in the room but not at the
8 table. If you all would like to introduce
9 yourselves, that would be great.

10 (Audience introductions.)

11 CHAIRMAN PENSON: Thank you. Is
12 anyone on the phone? All right, I think it is
13 just us.

14 So let me just say a few words
15 about this process. I also double as a member
16 of the Steering Committee. So I get double
17 the work and half the fun, I would say.

18 So my goal today, I was telling
19 Sally beforehand, is to get through all four
20 measures, so we don't have to do a painful
21 conference call. That will be the reward and,
22 as such, what we are trying to do here -- We

1 will try to stay as close to the agenda as
2 possible.

3 I would like everyone to feel free
4 to speak their mind, but at the same time, I
5 would like to encourage people not to repeat
6 what others have said, just for the sake of
7 time.

8 These measures, compared to some
9 of the others we have seen in this arena, are
10 relatively straightforward. So I hope that
11 the discussion will be relatively streamlined,
12 and the work that everyone did in advance was
13 really helpful; but again, that being said, I
14 want to ensure that everyone has a chance to
15 say what is on their mind and their thoughts.

16 Going through the agenda, we will
17 start -- we are actually running a little bit
18 ahead -- with the colon cancer measures this
19 morning. We will go through the colonoscopy
20 measure first, and we have left about an hour
21 and a half for that.

22 We will take a break, and then we

1 will do the episode of care for treatment of
2 localized colon cancer at 11:15. We will have
3 some time at 12:25 for members and public
4 comment, folks on the phone, if anyone joins
5 us. We will take a lunch break at 12:30 and
6 start again at 1:00 with the breast cancer
7 measures.

8 We have two breast cancer measures
9 to do. I think everyone has been through
10 these. One is episode of care around a case
11 of newly diagnosed breast cancer, an episode
12 of care around a breast biopsy, and then again
13 we will have time for public comment and any
14 member comment, and then we will wrap up.

15 The way this works, my
16 understanding of it -- Sally, correct me if I
17 misunderstand -- is that as the TAP we go
18 through these measures and provide our opinion
19 as to whether it meets the criteria, high,
20 medium or low or insufficient, as it were, and
21 these recommendations then go up to the
22 Steering Committee and then go up to even a

1 committee above that for final approval.

2 My suspicion is that what this TAP
3 says will probably swing the Steering
4 Committee. So it is important, as you put
5 your votes through, to understand that what
6 you say here will determine whether or not
7 this gets NQF endorsement.

8 With that in mind, I want to just
9 say a few words about how these measures are
10 evaluated. As part of the Steering Committee,
11 this was a new realm for NQF. I don't know
12 how many of you all have served on NQF panels
13 before. Having served on patient outcome
14 measures and other quality measures, those
15 are easy compared to these.

16 I think the Steering Committee
17 really had a hard time wrapping themselves
18 around some of these issues. For example,
19 because they are cost measures, there wasn't
20 the level of evidence required for a quality
21 measure, because it is fairly generic. A
22 dollar is a dollar, within reason, obviously.

1 So as you go through this, that level of
2 evidence isn't required.

3 Another key point that I think, as
4 a Steering Committee member, those of us on
5 the committee who are clinicians had a hard
6 time accepting was the concept of we are just
7 looking at dollars, and we are not looking at
8 quality, and we really want to get efficiency
9 and value.

10 One of the key points, one of the
11 key principles of NQF, is that these should
12 not be used in isolation. They need to be
13 used with a quality measure, but I want, for
14 lack of a better way to put it, folks to
15 suspend disbelief today and accept that. It
16 is hard to do. I am with you on that.

17 It was really -- There was a very
18 long discussion in the Steering Committee, and
19 I think a lot of us, myself included, were
20 very uncomfortable and still are
21 uncomfortable, but have gone from very
22 uncomfortable to the only way we are going to

1 do this is if we accept that. I think that,
2 if we can get this piece done, we can start
3 talking about efficiency and value in the next
4 iteration.

5 As far as the criteria, I won't go
6 through them, because when I saw the responses
7 that people gave -- I had originally thought
8 may be I would send out an email to everyone
9 until I saw your responses. I think people
10 really do understand what we are trying to get
11 at here.

12 In some ways, I was telling Sally,
13 we took the measure -- the criteria that --
14 the existing criteria that they used for the
15 quality measures and put them into the cost
16 measures. To some degree, it is a round peg
17 in a square hole, and to some degree it was
18 sort of taking an octagon and knocking it into
19 a circle.

20 I think the Steering Committee did
21 as best a job as they could without completely
22 reinventing the wheel. So we really have

1 these four areas to deal with: The importance
2 to measure and use, with its four subcriteria,
3 and I won't go through it unless there are
4 questions or discussions that people want to
5 have with it.

6 There is the acceptability, which
7 I think is going to be the majority of our
8 discussion. I don't think people are going to
9 argue a whole lot about importance. There may
10 be some discussion, but I think the issue
11 really comes up around scientific
12 acceptability, and to some degree usability
13 and feasibility, but it really is in the
14 scientific acceptability; risk adjustment,
15 does this make sense; accountability issues.

16 So I think we are going to spend
17 the majority of our discussions with each
18 measure on criteria number two, and I think
19 that is appropriate.

20 The other thing I would say --
21 and, Sally, correct me -- we will obviously go
22 through each measure and each criteria and

1 each subcriteria in turn. Do you want us to
2 vote on each subcriteria at the end of a
3 discussion?

4 MS. TURBYVILLE: Yes. So what we
5 have done in the past, and it worked pretty
6 well, is to have all of you using the clickers
7 that were handed out, rate each subcriteria
8 once the discussion of the criteria is
9 complete, so that we can keep moving through
10 the whole process.

11 So we are going to do a little
12 recap on some presentations, have people talk
13 a little bit about how the voting works
14 following, but as we go through, so that we
15 don't have to wait until the end of the day
16 and then go back and recap.

17 One of the things that staff will
18 do as you move through measures is try and
19 make sure we don't have rating creep, so that
20 we are not getting harder or easier as we move
21 forward in other measures, and we will kind of
22 remind you what you thought before. Doesn't

1 mean you can't go back and say, well,
2 actually, now we need to change that. It is
3 just to try and help you find that consistency
4 throughout the day.

5 CHAIRMAN PENSON: To that end, I
6 sort of -- This is a personal opinion. The
7 way I approached the high, medium, and low or
8 insufficient, which I think is another
9 criteria, was I looked and I said, in my mind
10 using sort of the NIH criteria for a grant
11 review, if it is high, there are really almost
12 no weaknesses or just it's fine.

13 If it was moderate, my feeling was
14 that the strengths outweighed the weaknesses.
15 The weaknesses were moderate at most, but it
16 wasn't enough to kill it, in my mind. It was,
17 when you got to low or insufficient low, where
18 it was just basically, this ain't going to
19 fly, it doesn't pass the smell test, or
20 insufficient, I just wasn't convinced, but
21 perhaps it can be addressed.

22 I think that, if you sort of keep

1 to that mentality -- and I think everyone did
2 when they were going through this at home --
3 I think we will be okay.

4 So I am trying to think if there
5 are any other issues that need to be
6 addressed. We do have a report from our
7 statistical consultant, and I think that will
8 also be very helpful, who just walked in the
9 room. So do you want to introduce yourself?

10 MR. ALZOLA: I am Carlos Alzola.
11 I have been involved with this process for a
12 few number of measures now, and I met with
13 Sally and some other people here.

14 CHAIRMAN PENSON: Thank you. The
15 only other thing I will say as far as -- and
16 then I will turn it over to Sally and the
17 team: You know, we have this Excel
18 spreadsheet in front of us, and I can see it,
19 and I think everyone else can see what
20 everyone else voted on.

21 I don't want to call people out.
22 So in other words, looking at some of the

1 results, there are places where everyone said
2 high or medium or one person said low, and I
3 will just basically, instead of saying, you
4 know, so and so, why did you rate it low, I
5 will let you guys speak out, because it may be
6 as the discussion goes on, you change your
7 opinion, and if you had changed your opinion,
8 that is good. We are trying to arrive at some
9 sort of general consensus.

10 MR. AMIN: As we sort of walk
11 through the discussion, if there are elements
12 that are rated more low or insufficient, the
13 more detail that we can get on the rationale
14 for that scoring process, the better we can
15 provide that feedback to the measure
16 developers.

17 CHAIRMAN PENSON: Okay. Sally, go
18 ahead.

19 MS. TURBYVILLE: So I am going to
20 hand it over to Ashlie. We want to spend a
21 little bit of time making sure we are all on
22 the same page. So I know some of you have

1 seen this before. We might speed up and slow
2 down as we go through, when are hitting on
3 something new, try to slow it down. That
4 said, if we are going too fast or too slow,
5 feel free to signal to us, please.

6 DR. SCHUKMAN: I just had a
7 question on the resource use, how that will
8 ultimately tie to the quality measures, and
9 how granular can you get tying those two
10 together at a high level. I am just trying to
11 understand what the work product is going to
12 look like or if we know that yet.

13 MS. TURBYVILLE: We don't know
14 that yet, and I appreciate David's perspective
15 in the Steering Committee. I think there is
16 a very strong guiding principle, both from the
17 Steering Committee in resource use and,
18 certainly, the TAP is welcome to echo that
19 sentiment if it is agreed upon, and then there
20 is also a principle from NQF that quality
21 should be a part of this.

22 What we learned as we went into

1 developing the criteria and thinking through
2 evaluating measures is that where we are now
3 today, both in the industry as well as our
4 conceptually evaluating, we needed to at least
5 get resource use measures evaluated as a
6 building block as we move toward value, and
7 knowing that we have over 600 quality measures
8 currently endorsed.

9 So I don't know that we know what
10 the exact match is, and I don't think all the
11 developers know this yet either. So,
12 hopefully, this will continue to encourage us
13 to get there. So it is really to kind of push
14 us to keep on thinking about value and
15 efficiency, I would say.

16 CHAIRMAN PENSON: The only thing I
17 would add to that, because, Jay, I am with you
18 110 percent on this -- How long did we spend
19 on this? A good hour, and it is heated. The
20 one thing that gives me a little bit of relief
21 in this committee is that, where cancer is
22 concerned, there are a lot of quality measures

1 specifically tied to colon and breast cancer.

2 So you could see the start of a
3 value ratio developing here. It is much more
4 problematic, speaking as a Steering committee
5 meeting, where we are looking at non-condition
6 specific measures. You know, general episode
7 groupers for care in a managed care population
8 over the course of a year, it is easy to
9 measure what resource use is there, but what
10 is the denominator there, and that is a bigger
11 problem.

12 So it is no consolation. Again, I
13 will ask you to suspend disbelief to some
14 degree.

15 While folks are getting set up,
16 there is one other thing as I look through my
17 papers. The NQF team had assigned the panel
18 sort of lead reviewers for different elements.
19 If people are comfortable with that, I will
20 ask each person as we go through that to sort
21 of lay out their thoughts in two or three
22 minutes, and then have an open discussion.

1 That may facilitate things a little bit. Go
2 ahead. Thank you, guys.

3 MS. WILBON: Good morning,
4 everyone. We just have a few presentation
5 kind of introduction slides, as Sally
6 mentioned, to kind of get us all on the same
7 page. We are going to go over a little bit
8 just a couple of slides on the consensus
9 development process. You can figure out and
10 kind of visualize where this TAP fits in the
11 overall process for these measures.

12 Then we will go into an overview
13 of the criteria and the subcriteria, and then
14 a little bit about the meeting process toward
15 the end.

16 So for the meeting, we do hope
17 that in evaluating the measures -- you guys
18 are the second TAP to meet -- that we will be
19 able to, hopefully, at the end draw out some
20 lessons learned and be able to move that
21 forward through the other TAPs that are going
22 to be meeting. So any feedback that you have

1 throughout the process for how we can improve
2 things and, hopefully, make things more
3 efficient, we are welcome and open to that.

4 So the consensus development
5 process is approximately an eight step
6 process. We have already done the first two
7 steps that are in gray, which is for a call
8 for nominations, which is what got you all
9 here, and the call for candidate standards.

10 We are now in the consensus
11 standards review process, which for this
12 project we will go into a little bit later.
13 It is a little bit longer and more elaborate
14 than most projects.

15 Then after we have recommendations
16 from your ratings and then the recommendations
17 from the Steering Committee, we put those out,
18 and the measures back out for public and
19 member comment. Those comments are usually
20 integrated back -- or sent back to the
21 developer for any improvements or changes that
22 are needed, and then we put the measures out

1 for member voting.

2 All of that goes on to our CSAC,
3 and the CSAC is our Consensus Standards
4 Approval Committee. They are an oversight
5 body that we have here at NQF that oversees
6 all the projects, the consensus development
7 projects, and ensures that the process was
8 followed and that the recommendations that
9 were made were in alignment with the criteria.

10 The CSAC decision is then passed
11 on to the Board for ratification, and then
12 after -- and at that point the measures would
13 be endorsed. After the endorsement process,
14 we do actually -- endorsement stamp of
15 approval -- we do actually have a 30-day
16 appeals period where developers or public can
17 send in any concerns for how the measures or
18 the outcome of the project.

19 So this is just a pictorial of how
20 the process works. obviously, what is in
21 yellow is kind of where the Technical Advisory
22 Panels feed into the process.

1 So this is just a brief slide to
2 kind of -- so everyone understands what is the
3 definition we ended up with, particularly
4 through our work with the Steering committee
5 in the first year of this project, that
6 resource use measures are broadly applicable
7 measures that compare health service counts in
8 terms of units or dollars, that can be applied
9 to a population or event, and are broadly
10 defined to include diagnoses, procedures or
11 encounters.

12 Those counts can be the frequency
13 of defined health system resources. some may
14 further apply dollar amount, allowable
15 charges, etcetera, to each unit of resource.

16 So for this particular project, as
17 I said, we have a little bit more of an
18 elaborate process or standards review process.
19 We realize that because these were new
20 measures, the first time we have ever
21 evaluated them, that we wanted to give
22 ourselves a little bit more lead time with the

1 first effort, which was with our
2 cardiovascular diabetes TAP.

3 They have already met, and we are
4 still working through those measures, and that
5 was what we kind of coined as Cycle 1, and
6 with a little bit of lead time on Cycle 2
7 where we would, hopefully, be able to kind of
8 feed in any lessons learned for the remaining
9 TAPs that we have started now.

10 So you guys are the first TAP in
11 Cycle 2. You will be followed by the bone
12 joint and the pulmonary TAP in the next few
13 weeks.

14 So these are just -- I won't spend
15 any time on this, but it is just kind of a
16 high level timeline of how we hope to get
17 through each of the cycles for each of the
18 consensus development process steps.

19 So this is the process, the
20 general review process that we aimed to use
21 for this process, and we do do a brief staff
22 review when the measures come in to make sure

1 that they are complete, to the best of our
2 ability. We try to do follow-up with the
3 developer for any empty fields or things that
4 don't make sense, cut and past errors.

5 We don't catch everything, but we
6 do try to do a little bit of clean-up before
7 they go out to the panel, and then to send in
8 to the statistical consultant, who is Carlos,
9 and send that feedback to you guys so that you
10 can, as you begin your review, have that
11 additional -- any guidance around the
12 scientific acceptability to help you further
13 evaluate the measures.

14 So for those measures that are
15 condition specific, they go to the TAP first,
16 and then, as Dr. Penson mentioned, your review
17 will then be forwarded to the Steering
18 committee for final recommendations.

19 So the role of the TAP is really
20 to evaluate each of the subcriteria, identify
21 strengths and weaknesses of the measures, and
22 particularly focus on the clinical construct

1 of the measure.

2 Our Steering Committee was built
3 with a little bit of different expertise. So
4 our TAPs are specifically built with clinical
5 experts and methodologists to really give the
6 measure -- to ensure that the measures have
7 that technical review.

8 So what we are planning on doing
9 today in terms of the review and with the TAPs
10 is to do a systematic criteria by criteria
11 evaluation. We will start with importance,
12 and then move sequentially through each of the
13 criteria and subcriteria, and to really be
14 focused on how well the developer has
15 demonstrated that the criteria has been met.

16 You will rate the criterion, and
17 we will kind of go into, in some later slides,
18 about how the electronic voting tool works.

19 So I will hand it over to Sally.

20 MS. TURBYVILLE: So what we are
21 going to do today is finalize the evaluation
22 and rating of the four submitted measures

1 using the subcriteria that we sent out earlier
2 to all of you, was finalized last year with
3 guidance from the Steering Committee, as David
4 mentioned, and we do ask the TAPs to focus on
5 the subcriteria, which then will help the
6 Steering Committee, as Ashlie mentioned, make
7 determinations about the overall criteria.

8 So as you know, there are four
9 major criteria. They are: The importance to
10 measure and report -- specifically, is the
11 topical area that is being selected an area
12 that is of interest to think about measurement
13 of resource use; certainly, the scientific
14 acceptability, which has the reliability and
15 validity component of your evaluation, as well
16 as thinking about the risk adjustment
17 approach, and other kind of components of the
18 measure construct; how usable is the measure
19 itself, you know, the final results; and then
20 feasibility.

21 I already briefly talked about the
22 measure to report, how important it is. We

1 are looking at four subcriteria: A national
2 goal -- is it a problem area with
3 opportunities for improvement? Is the purpose
4 and objective, as submitted by the measure
5 developer, clear to you as the reviewers of
6 the measure, and do the resource units that
7 they are capturing for the resource use
8 measure make sense to you as experts in this
9 area?

10 So it is feasible that the area
11 would be important, but the resources that
12 they are requesting be captured as part of the
13 measure potentially don't jive. So we ask you
14 to think about that.

15 Scientific acceptability, as we
16 talked about, reliability, mainly: Are the
17 results consistent? Can they be reproduced or
18 are they not -- have they not been able to
19 demonstrate some kind of reliability or
20 generalizability as far as it being able to be
21 something that we would run the specifications
22 and see the results as they should be?

1 How credible is it? There are a
2 couple of areas in validity, both for the
3 measure itself, and then when we tie it back
4 to importance -- Importance, remember, is a
5 topical area. Validity is the opportunity
6 where you say, well, in how they constructed
7 the measure and the area that is presumably
8 important to measure, are those tied together?
9 So that we will ask you to talk about that,
10 and disparities, if and when applicable. We
11 can talk about that a little bit more as we
12 get to that discussion.

13 So as David mentioned, when we are
14 thinking about the rating, we just wanted to
15 provide you a little bit of guidance on high
16 and moderate and low, mainly focusing on the
17 liability and validity, but I think you can
18 see some of the gradations between high,
19 moderate and low, or when we are thinking
20 about high reliability, there should be both
21 clear specifications that could be implemented
22 in a standard way. So they would have to be

1 unambiguous.

2 There would have to be someone
3 that a user could take and then implement the
4 measure, and that there is empirical evidence
5 of the reliability of the measure, both for
6 the data elements -- so the data that are
7 being captured -- as well as the measure
8 score. So can the score that the measure is
9 producing -- do they demonstrate that it is
10 reliable?

11 Validity has the same kind of both
12 things happening at the same time. So are the
13 measure, as I have said, specifications
14 consistent with what they described important,
15 and then is there empirical evidence of the
16 validity, both for the data elements that are
17 required in order to specify the measure, as
18 well as the measure, and then whether flex to
19 validity are empirically assessed. That is a
20 high.

21 So as David said, really, you
22 don't feel there are any weaknesses in the

1 measure as it is submitted. The testing that
2 they submit is relevant, makes sense, and is
3 complete.

4 Moderate would be that the
5 specifications are unambiguous, but for
6 reliability they may empirically demonstrate
7 only that one of the two, the data elements
8 are reliable or the score. So we are looking
9 for one or two, and then validity similarly.
10 You have the empirical evidence of validity,
11 but again there is this "or" about the score
12 or the data element itself. Still, there
13 should be some assessment of flex.

14 Then low: Really, this is when
15 the specifications perhaps have some ambiguity
16 or requires some improvement, and that the
17 empirical evidence doesn't demonstrate
18 reliability. Same with validity, it doesn't
19 reflect the evidence or the intent as
20 described in the measure importance, doesn't
21 jive with all of you, or the empirical
22 evidence is demonstrating that the measures

1 are actually not valid or flex and validity
2 have not been assessed.

3 As David mentioned, there is also
4 insufficient evidence. If it is just an
5 inappropriate method or scope of reliability
6 testing, and you want these developers to
7 either take the time in this project or in
8 future projects to do different testing, that
9 will be a signal to that, as well as the
10 validity.

11 Any questions about that before we
12 move on? I just want to make sure we are all
13 on the same page as you move through your
14 voting of the measures. I think everybody
15 understands that pretty well, from the
16 expressions.

17 So I just want to briefly touch on
18 how we thought about resource use measures.
19 We did want to make sure that we were able to
20 capture different types. So we have episode
21 based measures, procedure measures, population
22 based measures. I believe all four of these

1 measures are episode based measures. So under
2 the project, though, we did collect other
3 types of measures as well.

4 I don't want to spend too much
5 time on this, because all of you did do the
6 preliminary review, and as David said, based
7 on the notes we got, it seemed like there was
8 a good grasping on what they are.

9 We had four areas that we asked
10 developers to submit guidance or
11 specifications on. So we had data protocol:
12 What data are needed? Data cleaning steps.
13 Clinical logic has to be specifications, has
14 to be unambiguous. As Ashlie said, certainly,
15 as a good group of clinicians here in cancer
16 care, we really want you to take a deep dive
17 into the clinical logic of the measures.

18 The construction logic, which are
19 those steps that are beyond the clinical
20 logic: Sometimes there aren't any steps
21 beyond the clinical logic, but sometimes there
22 are, that are just parameters around the

1 measure, time periods, etcetera, that need to
2 be applied. Then certainly, the risk
3 adjustment and costing methods, and then
4 reporting guidelines. How do you attribute
5 the results of the measure? How do you define
6 the peer group in order to create your
7 benchmark for resource use?

8 This is just an illustration of
9 what we were talking about, and I don't want
10 to spend too much more time on this. You can
11 see that, where the general methods were
12 submitted, that was just to help us
13 understand. It is not the part that is
14 subject to your evaluation. However, it does
15 inform you so that you can then evaluate the
16 data protocol, the resource units, the
17 clinical logic, and the construction logic,
18 the adjustments for comparability, and then
19 the reporting.

20 So we already talked about the
21 reliability and the validity. As you can see,
22 there are two subcriteria for reliability, and

1 there are six subcriteria for validity, and we
2 will walk through this.

3 What is going to come in real
4 handy -- could I borrow this for a second? --
5 is as we are walking through the measure, if
6 you just pull this out as we are evaluating it
7 and have it in front of you, in our experience
8 it is really helpful, because we will use it
9 to guide us through the rating process.

10 Again, there are these six
11 criteria, subcriteria, for validity.
12 Disparity: Just to note, one of the TAPs
13 before talked about disparities, in particular
14 race, ethnicity, socioeconomic status, and to
15 us typically, we don't want these types of
16 things to be risk adjusted away. We want to
17 reveal these kinds of differences, but we may
18 ask developers to stratify by the population
19 so that action can be taken.

20 What we have had discussions about
21 so far, and we are going to ask the Steering
22 Committee to further discuss it, and they

1 started their conversations about it, is
2 whether it really makes sense for resource use
3 at this time. The evidence isn't really
4 clear. These resource use measures are not
5 measures of appropriateness, so something that
6 we would certainly welcome your expert input
7 as well, once we get there, and what your
8 thoughts are on that.

9 Then usability. I want to talk a
10 little bit about usability here. So this is
11 the spectrum of what we think about when we
12 want to -- when we are talking about measures.
13 You can see all the way on the left is
14 benchmarking. When we are saying
15 benchmarking, we are talking about those
16 internal quality improvement measures.

17 Those are the type of measures
18 that NQF doesn't endorse, because they don't
19 need that national standardization for
20 implementation. They are within a system or
21 within a network, and it is just being used
22 for quality improvement and tracking.

1 As we move over to the right for
2 accountability, these are the measures that we
3 are interested in endorsing and making sure
4 that there is a standard specification, so
5 that people can implement them in the same
6 way, compare results, etcetera.

7 So as you can see, when we talk
8 about usability and we talk about public
9 reporting, we are not just talking about the
10 very end, which will be public reporting to
11 all, but we are also talking about these
12 accountability models as well.

13 I don't want to spend too much
14 time on this, because I think David did a
15 fantastic job of recapping both the Steering
16 Committee's sentiment about what this project
17 is doing and how it fits into this concept of
18 efficiency and value as well as NQF's
19 position.

20 Also, you can see here, if we
21 think about our integrated measurement
22 framework, certainly, we realize that the

1 resource use measures and cost can be
2 examining slices of a clinical episode or it
3 can be looking at the entire episode or
4 trajectories from the episode. So just a
5 contextual illustration. We don't have to
6 spend too much time on this.

7 I think we have enough complicated
8 things to think about.

9 CHAIRMAN PENSON: I love that
10 cartoon.

11 MS. TURBYVILLE: Is it a snail or
12 is it a -- I'm not sure -- caterpillar
13 perhaps? Okay.

14 Then feasibility: We certainly
15 want to make sure any measure that is endorsed
16 by NQF is something that can be implemented
17 today. So while we understand that there are
18 measures that we certainly are very interested
19 in but the data perhaps aren't quite
20 available, I don't think that is an issue
21 typically for the measures that we have seen
22 come through, because they have all been

1 claims based.

2 So just as a reminder, we will
3 pause here and there to make sure that we are
4 opening it up for public and member comment as
5 well as the public and members who are here in
6 the audience, and we may also at times try --
7 you know, if we think we are getting too off
8 time, to try and avoid conference calls, we
9 might try and see if there are any other
10 inputs, and I know David is certainly going to
11 help guide us through that as well.

12 We will ask the measure developers
13 to briefly introduce the measure. They should
14 be available to ask questions, and I think
15 they might be on the phone now. Then we will
16 ask you to weight this criteria.

17 I think we went through the
18 evaluation's process. We start with
19 importance and then move -- We will probably
20 have feasibility go pretty quickly, because it
21 is administrative claims data, and then dive
22 into the areas where there really should be

1 some distinct differences measure by measure.

2 These are the measures we are
3 looking at. Thank you again for all the
4 reviewers on these measures, and then I think
5 at this point I am going to hand it over to
6 Sarah to make sure you get the instructions
7 that you need in order to rate the measures,
8 because it is an application.

9 MS. FANTA: Good morning,
10 everyone. All right. So each of you should
11 have received a little remote. That was
12 particularly assigned to you, so we know which
13 way everyone voted. We will be using these as
14 we go through and rate each subcriteria.

15 I actually have the receptor on my
16 computer. So as you vote, if you want to just
17 point in my direction, I can pick up the votes
18 very easily.

19 As you can see, the keypad is
20 numbered zero through nine, and there is a
21 caution symbol in case you want to delete your
22 entry, change your rating. Then if you just

1 press Send after you make your selection, and
2 point at me, then I will get the rating.

3 Then here is just an example of
4 the types of things you will be voting on. So
5 one, Yes, and two, No. You would just press
6 it on your keypad, and point to me. This is
7 just an example.

8 If you want to modify your
9 response, you can just press the Caution
10 button, press the number you meant to send,
11 and then press Send. You will have 60 seconds
12 to vote, and there will be a live tally,
13 letting you know how much time is left, and
14 then once everyone has voted, the voting
15 results will be displayed on the screen.

16 MS. WILBON: There is also a
17 little handout in your folder that gives you
18 instructions on how the -- if you kind of get
19 mixed up, if you want to refer to it before we
20 vote, you can do that as well.

21 MS. FANTA: All right. Here is
22 just our next steps and upcoming dates. We

1 actually have a Steering Committee meeting
2 tomorrow and on Thursday. So we have been
3 very busy. I will be discussing the CV
4 diabetes measures as well as non-Commission
5 specific measures, and as far as this meeting
6 goes, NQF staff will serve as the liaison
7 between this TAP and the measure developers.

8 So if there is any follow-up
9 needed or any questions that need to be
10 answered, we will definitely be communicating
11 with them and then reporting back to you any
12 progress that has been made.

13 Your final TAP ratings will also
14 be sent to the Steering Committee to help
15 inform their decision as they go through the
16 cancer measures, and we will schedule any
17 follow-up calls as needed, but hopefully, we
18 will get everything done today.

19 CHAIRMAN PENSON: I am optimistic.
20 I really am. All right. So far, so good;
21 don't jinx it.

22 All right. So I guess we really

1 should start. The first measure we are going
2 to look at is 1583, which is episode of care
3 for a 21-day period around colonoscopy.

4 Is someone on the phone from ABMS
5 Foundation?

6 DR. WEISS: Yes. Kevin Weiss is
7 here. We also have Robin Wagner and Todd Lee.

8 CHAIRMAN PENSON: Great. Good to
9 hear from you, Kevin. It's Dave Penson. What
10 I will ask you to do, as Sally had mentioned,
11 is maybe spend just a minute or two or three
12 just discussing -- introducing the measure to
13 the panel, and giving us sort of a broad
14 overview.

15 I think everyone in the room has
16 poured through the materials pretty well. So
17 I don't think you have to go into great
18 detail, just the high points to get our
19 discussion started, if you would.

20 DR. WEISS: Sure. That would be
21 great, and maybe give a framing. Also, just
22 a note, which I appreciate that you noted that

1 this was coming from the ABMS Research and
2 Education Foundation, not from the ABMS per
3 se.

4 This project was funded by the
5 RWJ. We looked at types of care measures, and
6 the philosophy of the project. You will be
7 looking at several measures today from the
8 project. So I can maybe give you that
9 general, and won't have to repeat it later.

10 It was to develop measures that
11 were physician led around the cost of care,
12 and in doing so, we looked at the areas that
13 will have priority, and we were pleased that
14 this particular measure and several others met
15 the needs of NQF in that prioritization.

16 We have -- In looking at this
17 measure, we have looked at one or two types of
18 measures we present. One would be high
19 frequency measures that are very common across
20 the health care system, but maybe not large in
21 individual cost, but recognized that there was
22 a perception of variability.

1 To develop these measures, we
2 brought together a multi-disciplinary team of
3 physicians and non-physicians to have us vet
4 what they thought was an important measure
5 that could be linked to a quality measure at
6 some point, recognizing that the cost of care
7 measures by themselves do not provide enough
8 information and could actually provide wrong
9 information if not paired with quality
10 measures.

11 In asking them to look at the
12 issue of colon cancer and colonoscopy opt-out;
13 and the measure that we present to you today
14 here looks at the concept of an episode of
15 care around colonoscopy, it was felt that
16 there was enough variability in the process of
17 colonoscopy, both in types of approach in
18 terms of -- specifically, in terms of whether
19 anesthesia was used and also in terms of
20 numbers of biopsies and approach to pathology
21 within that process, so that all those
22 collectively warranted enough perceived

1 variation that they wanted to, and did,
2 develop the measure which we present today.

3 The episode begins before -- just
4 before the colonoscopy, recognizing that there
5 may be some preparatory work which is
6 involved, and then follows up through a period
7 that was felt to be appropriate in terms of
8 when the acute complications might arise, and
9 correctly follow from colonoscopy.

10 I will stop there, just to check
11 and see if Todd Lee, who is our health
12 economist, would like to add anything.

13 DR. LEE: No, Kevin. I think you
14 have captured all of the important factors.

15 DR. WEISS: Great. Probably the
16 only other thing that is worth noting is that
17 we will be presenting in this model a risk
18 adjustment model for trying to manage the
19 issue of the complexity of individual
20 patients, and that model is one that is
21 consistent to other models. So you may or may
22 not decide to spend extra time on that part of

1 the discussion, because otherwise, you know,
2 if you repeat it to other measures you will
3 see today.

4 Was that the type of overview that
5 would be helpful?

6 CHAIRMAN PENSON: Yes, I think
7 that is very helpful, and I just -- I will ask
8 the people in the room, is everyone
9 comfortable with the measure, their
10 understanding of the measure? Any questions
11 right off the bat for the ABMS Foundation
12 folks? Okay. Well, I have got noes around
13 the table, Kevin. So I think everyone is with
14 us here on the same page.

15 So I guess we will start the
16 discussion around the measure. This measure
17 specifically, when we talk about
18 distinguishing this, in the afternoon, from
19 the breast cancer measures, is accountable to
20 the level of the provider, and I think that is
21 going to shape the discussion, and I think the
22 risk adjustment piece -- we are going to spend

1 probably some time on that.

2 Let's start with the importance to
3 measure and report. The first subcriteria,
4 1a, deals with whether or not this is
5 addressed as a national health goal or
6 priority or is a high impact aspect of health
7 care.

8 Pretty much across the board,
9 everyone rated this as high. There was one or
10 two people who said it was moderate. I will
11 open up the floor to any comments. I think we
12 all know this is a fairly common condition.
13 Colonoscopy is very widely used. It runs up
14 a bill in many places.

15 Do other folks have things to add
16 to that?

17 DR. GILLIGAN: Just briefly, I
18 think we probably get the high, just based on
19 what we know walking into the room. The
20 application itself here actually didn't
21 provide any evidence that it is high. I think
22 most of us just believe it is high.

1 The first paragraph talks about
2 breast cancer, which was probably a typo, and
3 then the rest of it talks about colon cancer
4 treatment costs, and colon cancer treatment
5 costs have very little to do with colonoscopy
6 costs.

7 So I think we kind of threw them a
8 bone on this one and said, well, we know it is
9 important, even though you haven't actually
10 shown us any evidence that it is important.

11 CHAIRMAN PENSON: Yes, I think you
12 are right about that, Tim, and I do think that
13 comes up in some of the other criteria. I
14 notice you and I kind of hit on the same
15 thing, but I think in the overall impact, I am
16 getting the impression that everyone felt
17 pretty unanimously that that was high.

18 MS. TURBYVILLE: Can I ask a
19 question? So given that these are the experts
20 here, and this would be potentially an
21 application that would go out to the general
22 user, is the missing information because there

1 isn't as much literature and evidence of that,
2 and so the experts here are able to say, even
3 though the literature provided was more
4 downstream, as people in the field we know
5 there is variation; or is there an opportunity
6 for there to be evidence cited, not clinical
7 evidence but evidence of variation, to support
8 the importance of the measure a little bit
9 more directly?

10 CHAIRMAN PENSON: Well, Sally,
11 let's -- The variation piece comes up in the
12 next subcriteria. So let's table that for just
13 a minute, because I have an issue there.
14 Let's just start right into very high impact
15 piece of it. Rohit?

16 DR. BORKER: Hi. This is Rohit
17 again. I'm sorry. I wanted to -- We agree
18 with what Tim and David were saying. I think,
19 in terms of high impact, the literature that
20 would be really needed that will help us is it
21 is not just the cost of colonoscopy, but what
22 proportion of total colorectal costs are --

1 colonoscopy costs; because if they are
2 minimal, then doing anything in colonoscopy is
3 not going to help reduce that total burden.
4 So that is the missing link, to me.

5 CHAIRMAN PENSON: And I do think
6 we are going to come to that in the next
7 piece.

8 So just to keep us moving along --
9 Sorry, Jay, go ahead.

10 DR. SCHUKMAN: I was just -- You
11 had mentioned something earlier. Is the
12 denominator going to be at the individual
13 level? Is that correct?

14 CHAIRMAN PENSON: So if you look
15 in the report, what you basically see is
16 reported out by provider, and my understanding
17 is I interpreted the measure -- and we can ask
18 the folks on ABMS Foundation on the phone, but
19 it is actually probably going to be attributed
20 to the provider who performs a colonoscopy,
21 would be my guess.

22 DR. SCHUKMAN: Okay. Is that

1 going to be generally true for all these
2 measures?

3 CHAIRMAN PENSON: No, sir.

4 DR. SCHUKMAN: Okay. I just
5 wanted to be clear on that.

6 CHAIRMAN PENSON: Yes. So this is
7 just for this measure. it will be accountable
8 to the -- most likely, the gastroenterologist
9 who performs the colonoscopy or the colorectal
10 surgeon.

11 DR. SCHUKMAN: The other question
12 I had, to follow up on that, is how we are
13 going to gain access to the administrative
14 data to do this.

15 CHAIRMAN PENSON: Well, I will ask
16 Kevin and the team from ABMS Foundation on the
17 phone. I am assuming it is probably publicly
18 available data like Medicare, etcetera. But,
19 Kevin?

20 DR. WEISS: I don't -- Let me ask.

21 CHAIRMAN PENSON: I'm sorry?

22 DR. WEISS: I don't understand the

1 nature of --

2 CHAIRMAN PENSON: So the nature of
3 the question was -- and we are sort of getting
4 ahead of ourselves here, because we will come
5 to this a little later, but we might as well
6 just address it now.

7 As far as administrative data used
8 to populate the measure, can this be done from
9 publicly available data like Medicare or
10 Ingenix, etcetera?

11 DR. WEISS: Correct. It can be
12 gotten from administrative data available that
13 would either come from a private or public
14 payer. It could come from a health system, if
15 they have got comprehensive use of those
16 administrative data or a health system that
17 has all the different data elements.

18 CHAIRMAN PENSON: Jay, does that
19 answer your question?

20 DR. SCHUKMAN: Yes, it does.

21 Thank you.

22 CHAIRMAN PENSON: So the question

1 is, if you -- I think that we will keep moving
2 along, because there are going to be other
3 issues. Do you want to vote now on each or
4 later at the end? Okay, great.

5 So let's move on to 1b, and b is
6 the demonstration of resource use or cost
7 problems in opting for improvements. So this
8 is really where you say there are issues with
9 variation in delivery of care across providers
10 or groups.

11 There is a little bit more
12 variation here. I probably was one of the
13 people who was most sort of had problems with
14 this, and I would share with you my thoughts
15 on this and then open it up to the floor.

16 There is no doubt in my mind that
17 there is going to be variation in care around
18 colorectal cancer geographically by provider,
19 etcetera, but understand that the inciting
20 episode here is colonoscopy, and you going
21 around a 21 day period around colonoscopy.

22 I wonder if there is going to be

1 variation in costs based by colonoscopy,
2 because everyone is going to have had a
3 colonoscopy. What I think is going to drive
4 it, as Dr. Weiss implied, are things like
5 differences in anesthesia use, potentially how
6 many biopsies are taken, and in my mind I am
7 not sure that is meaningful.

8 So at least in my preliminary
9 read, I read that as a low, because I wonder
10 if, in fact, there may be appropriate
11 variation, and we are not going to capture
12 that. That was why I was sort of less
13 enthusiastic. I will open the floor now.

14 DR. POTTERS: I had a similar
15 concern. I didn't see any evidence presented
16 that there was variation. I can believe that
17 there probably is, and again I have doubts
18 about how significant that variation is going
19 to be. I would like to see more data on that.

20 CHAIRMAN PENSON: Other folks?
21 Jay?

22 DR. SCHUKMAN: I just had a

1 question. It is going to look at a 21-day
2 segment, but in terms of variation, say, over
3 a period of a year -- I am just asking, you
4 know. There is going to be those who do it
5 probably more frequently than they should, and
6 I am just curious how that would be captured.

7 CHAIRMAN PENSON: Well, it won't,
8 because the inciting event is colonoscopy. So
9 each episode is colonoscopy and the 21-day
10 period around it. Louise?

11 DR. WALTER: I guess it just
12 depends on what the important question is. If
13 it is really about anesthesia and
14 complications, that sounds like that is what
15 they are trying to go after versus who
16 actually -- you know, the disparities that
17 exist with colonoscopy use.

18 CHAIRMAN PENSON: So is that
19 meaningful? That is the question.

20 DR. GILLIGAN: I guess, in their
21 defense, it is meaningful in the sense that
22 this is a screening procedure. So it is done

1 to millions of people. So even a small
2 difference has a huge multiplier here. So
3 small differences in cost could have a big
4 impact on dollars spent.

5 DR. SKIBBER: That is a good
6 point. I am not clear exactly from the
7 developers that they are only restricting
8 themselves to screening procedures, and that
9 is going to have a -- as evidenced by their
10 references and by the attached article, that
11 is going to have a significant impact, I
12 think, on the variation in cost between
13 providers.

14 If you look at their article at
15 the end, inpatient costs for surgeons to do
16 colonoscopy, in one of their slides, is five
17 times that of other providers, and I can tell
18 you why that is. It is because they are sick
19 patients who are having a clearly diagnostic
20 or therapeutic colonoscopy, and they are in a
21 high risk group for perforation and bleeding.

22 That is not accounted for anywhere

1 in this measure. Now if they want to say we
2 want to study the costs associated with
3 screening colonoscopy in appropriate age
4 groups, or something, that is going to be a
5 much cleaner question.

6 I think this overall suffers in
7 the way it is going to impact on providers'
8 sense of do I need to improve, because they
9 don't make that designation between a
10 screening procedure and a therapeutic or
11 diagnostic procedure.

12 CHAIRMAN PENSON: So let me just
13 interrupt for one minute, because I think we
14 have the measure developer on the phone. So
15 let's just confirm that that is the case.

16 Kevin, is there any possibility or
17 are we misinterpreting it? There is no
18 exclusion criteria for a prior diagnosis of
19 colon cancer?

20 DR. WEISS: Todd Lee is around --

21 CHAIRMAN PENSON: We can't hear
22 you. I'm sorry. You are sort of breaking up.

1 We are really losing you here. Maybe take it
2 off speaker for a minute.

3 DR. LEE: This is Todd Lee. I can
4 try and answer the question. They are asked
5 whether or not the episode includes prior
6 colon cancer.

7 CHAIRMAN PENSON: Well, the
8 question becomes, basically, is this a
9 screening -- or what you are hearing from the
10 panel is concern that, if this is a screening
11 colonoscopy versus a surveillance colonoscopy,
12 you are going to have major differences in
13 cost. So one thing that could really limit it
14 to screening colonoscopy might be an exclusion
15 of patients who have a prior diagnosis of
16 colon cancer.

17 So the question is: Does this
18 measure only apply for screening colonoscopy,
19 surveillance? Have you thought about this at
20 all?

21 DR. LEE: It actually -- So the
22 current measure captured --

1 CHAIRMAN PENSON: Are you on a
2 speaker phone? You kind of keep going in and
3 out.

4 DR. LEE: Sorry. It is a handset.

5 CHAIRMAN PENSON: We can hear you
6 pretty good right now.

7 DR. LEE: It is intended to
8 capture both groups, the way the current
9 measure is currently specified. We realize
10 that there might be differences in cost.
11 However, it is difficult within an
12 administrative dataset to differentiate with
13 exact clarity whether or not an individual
14 would have had a previous diagnosis of colon
15 cancer versus a screening colonoscopy.

16 Our work group felt that it was
17 best to include the entire spectrum of
18 colonoscopies as events in this episode.

19 CHAIRMAN PENSON: Is there any way
20 to at least capture that in the risk
21 adjustment?

22 DR. LEE: Well, what I don't know

1 is how good the administrative data are and
2 being able to differentiate the different
3 screening versus a colonoscopy done in a
4 person who has had previous colon cancer.

5 CHAIRMAN PENSON: Okay. Steven,
6 question, comment?

7 DR. CHEN: I think my comment
8 would be I actually gave this a better score
9 here on 1b, which is that there are
10 opportunities for improvement. However, I
11 would be much more concerned when we get to
12 the scientific validity of this, that I think
13 that the way that they have constructed this,
14 particularly things like there is going to be
15 a huge cost difference between people who get
16 a colonoscopy with no biopsies and a
17 colonoscopy with biopsies that is going to
18 engender pathology reports and what-not.

19 That may or may not have anything
20 to do with the provider as opposed to the
21 person who they are screening. On top of
22 that, people who are lower cost may actually

1 be providing a lower quality colonoscopy,
2 because they are not finding the polyps, to
3 begin with. So you say, wow, I am really
4 cheap.

5 CHAIRMAN PENSON: So what I am
6 hearing -- Lou, go ahead.

7 DR. POTTERS: You know, there is
8 also in the broader context the patient who
9 gets screened on an assigned frequency versus
10 the patient who never gets screened and then
11 presents with a disaster.

12 So, you know, if you are going to
13 try to understand the cost of somebody who
14 gets screened on a regular basis against the
15 inpatient who has, obviously, got an advanced,
16 previously unscreened lesion, that that
17 creates conflict.

18 So in the broader context of
19 trying to understand how they teased out the
20 data, which I guess we will get into, is by
21 provider and not by patient, it creates that
22 conflict. I don't know how they could get

1 that data or tease it down, and it doesn't
2 sound like they can, and that is one of the
3 issues.

4 CHAIRMAN PENSON: So what I am
5 hearing, just to reiterate, because I think
6 there are some concerns here, is that there
7 may be opportunities for improvement here, but
8 the problem becomes the way the measure is
9 developed, because we can't look at screening
10 versus surveillance colonoscopy, and there are
11 some issues with risk adjustment, that any
12 variation seen may actually be appropriate
13 variation and that, in fact, we may be
14 rewarding providers who provide worse care, as
15 Steven pointed out.

16 I personally am not convinced that
17 there really is evidence of variation around
18 these costs with colonoscopy specifically, but
19 that being said, if there is evidence of
20 variation and with the proper methodology,
21 there may be some opportunity for improvement
22 here. Is that a fair assessment? Okay.

1 DR. GILLIGAN: Can I ask on
2 question, because one of the things that came
3 up for me here was -- I mean, if this was a
4 grant application, we expect them to make the
5 case, not us to have to make the case for
6 them. So that kind of surprised me here.

7 CHAIRMAN PENSON: Yes, and I think
8 that that is a good point. I will cut them
9 some slack, only because they have a form they
10 have to fill out, and there is an element of
11 trying to be sort of terse. I think it is
12 fair for us to bring our knowledge in. We
13 don't have to act in a vacuum, as if we were
14 in a study section.

15 I think that reflects our response
16 to 1a, which was I think everyone in the room
17 felt that was important, even though we didn't
18 get our five-page diatribe on why. I think we
19 all know that. But here, you know, Tim, I
20 agree with you. I would have liked to have
21 seen evidence that there is variation, because
22 I am not feeling it, for lack of a better way

1 to put it.

2 Okay. If people are comfortable
3 with 1b, I will move on to 1c. The purpose
4 and objective of the resource use measure and
5 the construct is clearly described. I think
6 that, for the most part, everyone felt that
7 was a true statement or a moderately true
8 statement. I thought it was fairly
9 straightforward myself. I will open it up to
10 discussion.

11 All right. I am not hearing
12 anyone. So I think we all can agree that
13 probably was the intent, and the description
14 was reasonable.

15 The last piece in the importance
16 to measure realm is the resource use service
17 categories that are included are consistent
18 with and represent the conceptual construct of
19 the measure.

20 So just to start the discussion
21 here, I thought that this -- When I was
22 considering this measure, 1d and 1b tracked

1 very closely, because my gut feeling was that
2 the variation was going to be related to
3 exactly what everyone was saying, which was
4 use of anesthesia, use of pathology services
5 and, to some degree, complications.

6 So the question is, was that
7 meaningful? I wasn't convinced, for the same
8 reason that I wasn't completely convinced with
9 1b. I may have been a little harsh, as people
10 are talking, but I am curious to get other
11 people's opinion on the service use categories
12 -- the resource use service categories. Did
13 folks think that the -- I think it was eight
14 categories, that the costs were divided into
15 were reasonable?

16 DR. BORKER: I have a opinion on
17 that. So I am not a clinician, but it does
18 seem, based on what the developer submitted,
19 that anesthesia is used without any sufficient
20 evidence that it works, but especially in the
21 light of colonoscopy.

22 So, to me, that is appropriate to

1 look at those resource use and at some point
2 connect it to the outcome. I know we are not
3 doing it at this forum, but --

4 CHAIRMAN PENSON: Yes. I
5 completely agree with you. Again, I think at
6 some point this becomes a numerator of a value
7 ratio, and I think we just have to sort of
8 take NQF at its word. I am looking at Sally.
9 I am blaming you for everything Carolyn Clancy
10 has ever done, for better, for worse. But I
11 think we have to take them at their word.

12 Like I said, the only thing that
13 gives me some sort of relief here is that,
14 with colon and breast cancer, there is just a
15 litany of quality measures out there, but I
16 agree with you that you need to consider both.
17 John?

18 DR. SKIBBER: I think that that
19 gets back to that issue, though, of not
20 separating screening colonoscopy from a
21 therapeutic one. It gets into all these
22 issues, and it does even get down to the point

1 of attribution.

2 You know, when you read the
3 developer's submission, it implies that the
4 anesthesia is some sort of a patient
5 preference or they ask repeatedly if the
6 patients would pay out of pocket.

7 That may or may not be, and it is
8 not clear to me that the evidence or even the
9 rationale for that statement is correct. It
10 may be a patient preference issue, and it may
11 be a provider issue or it may be clearly
12 indicated, and their rationale, to me, seemed
13 like it went back and forth, and there is not
14 a clear statement about that.

15 Again, this speaks more probably
16 when we get into the attribution.

17 CHAIRMAN PENSON: But let me stand
18 up for a moment just to sort of reiterate what
19 you are saying so that that way the measure
20 developer gets feedback, because it is
21 resonating with me, as you say.

22 I think other people around the

1 table are shaking their heads, which is, you
2 know, that inability to break up a screening
3 versus a surveillance colonoscopy is really
4 problematic. Is that a fair statement?

5 DR. SKIBBER: It is not even
6 clearly the issue of surveillance. It also
7 speaks to the issue brought up by one of the
8 other members, which is there are a lot of
9 instances, actually, where a patient is
10 undergoing a colonoscopy without a diagnosis
11 of cancer preceding that. However, they have
12 symptoms. They have obstructive symptoms or
13 whatever, and those are not going to be in the
14 same risk category as a patient who is turns
15 50 and shows up for an asymptomatic
16 colonoscopy.

17 I think several times now we are
18 getting back to that issue.

19 CHAIRMAN PENSON: And that may
20 have an impact on this anesthesia question.

21 R. POTTERS: I think one positive
22 attribute is that we are probably going to see

1 geographic variation as a significant driver.
2 You know, practicing in the northeast, I can
3 tell you that the expectation is that you are
4 going to get anesthesia with your colonoscopy,
5 and it is interesting in the context of just
6 talking about this with some colleagues and
7 laypeople.

8 At least on Long Island and
9 Manhattan, you are going to see a huge
10 geographic variation against this data.

11 CHAIRMAN PENSON: You know, the
12 other point I would add to that is, thinking
13 about this as someone who is approaching the
14 age to have a screening colonoscopy, if you
15 are going all the way to the right colon, then
16 I sure as heck would like some anesthesia, but
17 it may be that, yes, there is less anesthesia
18 used and the colonoscopy could potentially
19 only look at the descending colon, and it gets
20 to the point where we do need to think about
21 quality here as well at some point, but I
22 think you are going to see geographic

1 variation. It is provider and patient
2 preference and community standards, but that
3 is value. That is value, documenting that.
4 Steven?

5 DR. CHEN: Again, I think I would
6 renew my comments about 1b, which is to say
7 that I had less problem with this as far as
8 how they divided up the categories than I do
9 with how they are going to use the categories.
10 I will reserve the rest of my comments for
11 when we get there.

12 CHAIRMAN PENSON: So I think,
13 again -- Tim, do you have a comment?

14 DR. GILLIGAN: Well, no, just very
15 briefly. I think that, if there are practice
16 patterns and people on Long Island like
17 general anesthesia -- my experience in Boston
18 was that we did it with conscious sedation and
19 didn't have a lot of discomfort, and it worked
20 just fine.

21 That is kind of the sort of thing
22 that we do want to find, because if we are

1 spending a lot of money on anesthesia and we
2 can do just as good a job without it, then we
3 should know that and reward people for more
4 efficient care.

5 CHAIRMAN PENSON: So I think it is
6 important. There are a couple of points I
7 want to reiterate to the group, because what
8 I am hearing from everyone is that this
9 actually goes back to the 1b discussion we
10 were having before, that even though there is
11 not a lot of evidence that there is variation,
12 if there is, we would like to know that. So
13 that has some value.

14 I think Steven's comment about
15 breaking up 1d and 1b is critical. When you
16 vote on 1d, what you are really voting on is
17 the -- I hate to use the term validity,
18 because it comes into number 2, but from a
19 clinical component, do the service categories
20 resonate with you; whereas, the opportunity
21 for improvement is where you want to vote on
22 1b. So I would urge you to sort of break

1 those two up.

2 What I am hearing is, actually,
3 more positive than negative here, if that is
4 a fair statement. I do hear the concerns
5 about screening versus -- I don't want to keep
6 harping on that, John, but screening versus
7 surveillance, that it is symptoms when people
8 come in the door, and perhaps that is a
9 discussion that we can get to when we do risk
10 adjustment, because I think that will be a big
11 discussion coming down the pike.

12 Any other comments on importance,
13 the criteria 1 in general? Steven?

14 DR. CHEN: Just one other thing,
15 and again I am having trouble sorting out
16 whether these go to the ones or the twos, but
17 I did have one concern as far as how they did
18 their categories, where they include things
19 like inpatient stays and things and other
20 imaging that may or may not relate to the
21 colonoscopy at all.

22 They are excluding people once

1 they hit two days before their colectomy, but
2 what day you get your colectomy is heavily
3 probably dependent on what day your surgeon is
4 available as opposed to how long it takes for
5 real. So if you are doing other preoperative
6 staging studies, that may or may not fall
7 within the two days before surgery or outside
8 the two days before surgery, and that has
9 almost nothing to do probably with what the
10 gastroenterologist did in their colonoscopy.

11 CHAIRMAN PENSON: Yes. And I
12 think that may actually fall into the 1d
13 criteria here. So I think it is reasonable to
14 consider that when you put in your vote for
15 1d, and I think that is a well taken point,
16 and we will get into accountability. I mean
17 why does the gastroenterologist get
18 potentially penalized for what the colorectal
19 surgeon does? Maybe that is just the nature
20 of the beast.

21 Okay. I think I am not seeing
22 anyone looking to holler anymore. So let's

1 vote on criteria 1.

2 MS. TURBYVILLE: So if you look at
3 the flat screen right there as a reminder, we
4 are looking at high impact. One on your
5 clicker is high; two is moderate; three is
6 low, and four is insufficient. Point don't
7 Sarah.

8 CHAIRMAN PENSON: Don't forget to
9 hit Send. That is what I just learned.

10 MS. TURBYVILLE: We are missing
11 one.

12 CHAIRMAN PENSON: We've got nine
13 responses. Is that everyone?

14 MS. TURBYVILLE: There you go.

15 CHAIRMAN PENSON: Good. Great.
16 So I think the majority of the panel felt this
17 was high. A few folks felt it was moderate.
18 That is reasonable.

19 Let's move on to 1b, and the next
20 one we are going to talk about is the
21 performance gap. This is demonstration that
22 there was variation over or less than optimum

1 performance across providers or population
2 groups. So let's go ahead and vote on that.
3 Remember to hit Send.

4 MS. TURBYVILLE: And point toward
5 Sarah. There we go.

6 CHAIRMAN PENSON: Okay, great. So
7 this is interesting. The group sort of split
8 up. I'm sorry? People migrated down, for
9 better, for worse. So there is some
10 discussion here.

11 Let's move on to 1c. Let's go
12 ahead and vote on that. This is the purpose
13 and objective of the measure and the construct
14 being clearly described.

15 One person voted low on this, and
16 I don't want to call people out, but I just
17 want to make sure you meant to vote low on
18 this. So this was basically the purpose of
19 the resource use measure and construct are
20 clearly described. If you voted low, I didn't
21 really feel that there was a lot of negativity
22 here. So whoever voted low on that --

1 DR. KLOTH: I was on the fence, to
2 be quite honest.

3 CHAIRMAN PENSON: Okay. And that
4 is not a problem, voting. I don't want to
5 influence your vote. I just want to just have
6 for the record why, so the staff can report
7 back to the -- You vote the way you want to
8 vote. All right? But I just -- and it can be
9 because you didn't like the color of the
10 paper. That is okay, but I just want to have
11 it on record so that the NQF team can report
12 back to the measurers. It is a matter of
13 public record. So if you don't mind.

14 DR. KLOTH: Well, I was really
15 ambivalent about voting 2 versus 3, and I was
16 very persuaded by some of the discussion about
17 the level of documentation and justification.
18 Sitting on research review for so many years,
19 I perhaps get too fussy at times and too
20 picky.

21 CHAIRMAN PENSON: So what you are
22 saying is you were concerned when you heard

1 the discussion regarding documentation and how
2 it is defined, that basically you felt that
3 perhaps this wasn't clearly defined enough.
4 Is that what you were sort of --

5 DR. KLOTH: That's right, and we
6 had a lot of discussion about screening versus
7 diagnostic and all the variables, and really
8 parsing that out so that we are really
9 measuring what we think we are measuring in
10 the way that we really do intend to measure
11 it.

12 CHAIRMAN PENSON: Okay. Thank
13 you. Again, I don't mean to call you to the
14 table, but we just didn't have that discussion
15 at this point. I want to make sure that we
16 are properly documented.

17 Let's move on to 1d. So this is
18 the service categories that are included are
19 consistent with and representative of the
20 conceptual construct represented by the
21 measure. So this breaks down to the various
22 A categories, etcetera, and I will open it up

1 for voting. All right, we are all done there.

2 I think this is consistent with
3 the discussion we had where we had sort of a
4 spread. Most of us felt it was moderate.
5 Okay, next. I think that's it. so we don't
6 have a yes/no for this one at all. Okay,
7 great.

8 So we are making pretty good time,
9 relatively. We are going to now move on to
10 the scientific acceptability of the measure,
11 and for this one we do have assigned folks.
12 We will go through each of these and have a
13 discussion.

14 The first one, 2a: Was the
15 measure well defined and precisely specified
16 so that it can be implemented consistently
17 within and across organizations for
18 comparability? I was the assigned reviewer
19 for 2a.

20 I felt it was. When I reviewed
21 the measure itself, it made a lot of sense to
22 me. Someone has done a fair amount of

1 research in administrative databases that I
2 could identify patients undergoing
3 colonoscopy, that I could define the seven-day
4 period beforehand, the 14-day period
5 afterward, etcetera.

6 With regard to inclusion and
7 exclusion criteria, I have to say that that
8 was my only sort of hook on this, was that --
9 and I think Lou Potters noticed this either on
10 this or one of the other measures, that the
11 concept of having two years continuous
12 coverage in some respects is problematic,
13 because how was that chosen? What does that
14 mean?

15 On the other hand, if you don't
16 have it, it is a problem as well. I think it
17 is more critical for some of the other longer
18 measures as opposed to this one, which is only
19 two or three weeks, but I do think that, if
20 you know someone is about to lose their
21 insurance in a few months, it is going to
22 affect the way you do business as a provider.

1 So I think it is an imperfect but reasonable
2 exclusion criteria.

3 So that is why I actually voted
4 this high. I will throw it open to the floor.
5 Tim?

6 DR. GILLIGAN: I just had a brief
7 comment. I am not an expert on this, but I
8 think the reason we need that two-year role in
9 this is to make sure that you know who the
10 patient is and whether or not they have
11 exclusion criteria and stuff like that. I
12 think that is why they have it so long. Maybe
13 others know more than I do about this.

14 CHAIRMAN PENSON: No, and that is
15 exactly right. You need to have some sort of
16 background information for the risk
17 adjustment. You need to -- There are a number
18 of reasons why you want to have that. It is
19 imperfect, as I think Lou mentioned, but it is
20 making the best of a bad situation.

21 DR. GILLIGAN: Right. I mean,
22 there is no way around it. So it is just

1 stating -- It is sort of just stating a fact,
2 that that is what it is.

3 CHAIRMAN PENSON: Yes. I'm sorry,
4 Louise.

5 DR. WALTER: Yes. I also wanted
6 to say, on the specifications, actually, the
7 other reason I rated it high is because it
8 actually based the claims and specifications
9 on an Annals of Internal Medicine article by
10 Warren et. al, which I thought that was an
11 impressive part of that, too.

12 CHAIRMAN PENSON: This works, in
13 my assessment, and anyone -- I don't want to
14 say anyone disagrees. It sounds so
15 heavyhanded. But any negative comments on
16 that? I thought this was straightforward, but
17 I have been wrong before.

18 DR. BORKER: A quick comment. It
19 is nothing negative about this particular
20 approach, but one of the issues -- and I am
21 not a statistician either; so you have a
22 statistician here. But whenever we are

1 analyzing the costs, there is obviously that
2 issue with being able to compare one cost or
3 point estimate of a cost to another point
4 estimate, because of all the non-delaying
5 distributions which are not pretty
6 straightforward.

7 So what I would like to see
8 additionally is -- and those are finally --
9 This is going to get used to compare costs at
10 regional level or even at a wider level --
11 some level of developer's recommendation in
12 terms of what adjustments we need to make, in
13 addition to just assigning one dollar to all
14 the zero dollar claims.

15 CHAIRMAN PENSON: I think I can
16 put your mind at ease, because I do use
17 standardized costs and, in fact, in this
18 measure they are actually risk adjusted costs.
19 We will talk about whether or not that
20 particular methodology is reasonable in a
21 little while, but I think that the
22 standardized cost and methodology is pretty

1 accepted out there.

2 DR. BORKER: Right. My issue is
3 not around the standardized costing. So the
4 standardized costing will assign a unit cost
5 to a particular resource use. It is comparing
6 provider one to provider two. Let's assume
7 provider one comes up at \$10,000; provider two
8 comes up with \$13,000. To me, that comparison
9 needs to be more explicitly stated.

10 CHAIRMAN PENSON: So I will ask
11 you to table that, because I think that comes
12 up in the risk adjustment.

13 DR. BORKER: Okay.

14 CHAIRMAN PENSON: Because I think
15 one of -- I don't want to bias the discussion.
16 So I will just say that I think we need to
17 talk about the risk adjustment. So I will ask
18 you to table that, because I think it comes
19 later. We are just talking about A-1 right
20 now. Any other comments about A-1; that is,
21 just sort of specifications and sort of the
22 basic sort of guts of the measure? All right.

1 Hearing none, I am going to move
2 on to A-2,k which is reliability testing.
3 Reliability testing, it says, is also
4 repeatable and produce the same results a high
5 proportion of the time. Lou Potters, you were
6 the primary reviewer for that.

7 DR. POTTERS: So I voted high, but
8 then this weekend I sort of looked at it, and
9 I guess I agree with the consensus of more of
10 a moderate.

11 These are commercial claims that
12 are then filtered down by provider. They have
13 a single reference that was noted on a
14 publication, but the reliability of this
15 across, I guess, the dataset, the market
16 scanned dataset, is a compilation, and that is
17 going to be used as the base. But it is not
18 completely clear that this is going to work
19 across the board.

20 CHAIRMAN PENSON: So would you
21 change your sort of view from high to moderate
22 or high to low?

1 DR. POTTERS: Yes, from high to
2 moderate.

3 CHAIRMAN PENSON: Before the panel
4 chimes in, I will ask Carlos to just give his
5 sense on this, particularly your thoughts on
6 reliability and validity. But let's start
7 with reliability.

8 DR. ALZOLA: Reliability?

9 CHAIRMAN PENSON: Yes.

10 DR. ALZOLA: When I looked at
11 these measures and I look at the data
12 derivation process and how, as someone who is
13 going to implement the measure, going to do
14 it, they have two kinds of measures. Some of
15 them apply a commercial software, and those
16 have been tested, and using administrative
17 data they can be reproduced. No question
18 about it, and essentially true in this case.

19 So the only problem that I find is
20 that this depends a lot on who is going to
21 implement it. So the specifications are
22 clear, but there is always room for reading

1 something a little different than the way the
2 measure developers did.

3 So in that respect, there is --
4 Even though I consider it reliable, but there
5 is some room for not being able to reproduce
6 things exactly the same way that the
7 developers did.

8 In terms of the data, the data
9 itself -- you know, it is claims data. It is
10 not always very reliable, but there is not
11 much anyone can do about it.

12 DR. POTTERS: You know, it was an
13 iterative process that they went through, and
14 to me, when you go to write software code to
15 get your result, if that formula isn't
16 formulaic in the sense that that is what you
17 have really proven, people can write that
18 formula multiple different ways and get
19 different answers.

20 CHAIRMAN PENSON: Steve?

21 DR. ALZOLA: And most -- More than
22 the formula, usually where the differences can

1 happen is when someone is extracting the data
2 from the database. Interpretations that look
3 very crisp and clear on paper, when one goes
4 to put it in computer code, the difference is
5 going -- different interpretations can happen.

6 CHAIRMAN PENSON: Let me ask one
7 question, Steve. I can't find this. I was
8 looking. In the one article that they talk
9 about, was that Joan Warren? Was that
10 Medicare data? So, remember, the Medicare is
11 one dataset, and Healthscan, Ingenix is
12 another dataset, and they may or may not work
13 equivalent.

14 I have a lot of faith in Joan and
15 the NCI team where Medicare is concerned, but
16 it is Medicare. They are the maestros at
17 that. Whether or not it works in Ingenix, I
18 don't know. Steven?

19 DR. CHEN: Yes. The question that
20 is asked is, is this reproducible; and I think
21 the answer is yes. the one thing that I would
22 have as far as reliability is that they allow

1 each place to do their own data cleaning, and
2 there is no discussion as to how they should
3 do this data cleaning, which allows you the
4 potential for gaming with garbage in these
5 situations. So I will probably switch my vote
6 down, too, as well.

7 DR. POTTERS: And I guess that is
8 a different question, which is how much of
9 that is reliability versus validity in a
10 sense. If they tell you what to do, but then
11 you do something different, which category
12 does that fall into? It is a semantic.

13 CHAIRMAN PENSON: I am not sure it
14 falls into either one. I mean, that is just
15 dishonesty.

16 DR. POTTERS: No, I am not saying
17 they are dishonest. I am just saying they
18 just don't care.

19 DR. CHEN: And I would point out
20 that you could be highly reliable and totally
21 wrong.

22 CHAIRMAN PENSON: Let's focus on

1 the reliable piece for now, and what I am
2 hearing is that there are some concerns here
3 that this may not always be reproducible each
4 time, even when someone is doing their very
5 best effort to do so.

6 The question I would ask is: Does
7 anyone want to disagree with that statement
8 and say, no, it is, or does anyone want to
9 say, actually, that is true, and it so bad
10 that it is a problem and that we should be
11 voting low, because I am hearing this sort of
12 consensus in the middle. Rohit?

13 DR. BORKER: So I put low here,
14 only because it hasn't been demonstrated that
15 this is -- that this method is reproducible in
16 another dataset. I mean, to me, they did a
17 very good process with it being a data
18 process, but that process was applied to the
19 same database again and again. There is no
20 evidence of it being reproducible somewhere
21 else.

22 CHAIRMAN PENSON: So I would just

1 advise you that that insufficient as opposed
2 to low. In other words, it is not that the
3 evidence speaks against it. It is just that
4 there is not enough evidence. So if that is
5 your opinion, then you would vote
6 insufficient.

7 DR. BORKER: Okay.

8 DR. TURBYVILLE: And just to
9 remind everyone, and not to sway what your
10 rating here is, that NQF doesn't prescribe to
11 the developer how to do the reliability
12 testing. So, clearly, your input is
13 important, but we do allow, especially at the
14 first time of endorsement, to think about the
15 ability for developers to test it.

16 You know, real life or out in
17 multiple databases, we acknowledge, is
18 limited. I think ratings probably should
19 reflect that, if it is something that you are
20 very concerned about, and we would capture
21 that. In follow-up, we would hope that it
22 would have been tested in more expansive data

1 sources.

2 CHAIRMAN PENSON: Other
3 discussions with regard to reliability
4 subcriteria 2a(2)? So just to sort of again
5 recapitulate the discussion I have heard,
6 since I know also the ABMS Foundation team is
7 on the phone, is that what I am hearing is
8 that, for the most part, people are feeling
9 that this probably is reliable, but they are
10 not 100 percent swayed.

11 There are some concerns, mostly of
12 a moderate nature, both that the formulas are
13 created from a good process, and there may be
14 room for error there, and also it has not been
15 adequately tested in other datasets. For some
16 people, that may be okay, and for others they
17 may view that as real major problem, and that
18 will be reflected in the voting.

19 Did I miss anyone's thoughts,
20 comments? Excellent.

21 MS. TURBYVILLE: You could vote on
22 the two reliability criteria.

1 CHAIRMAN PENSON: That would be
2 fine. So let's do the 2a variables. So let's
3 start with 2a(1), which is: Is the measure
4 precisely specified so it can be implemented
5 consistently, and again it is high, moderate,
6 low or insufficient. Looks like we got that
7 there.

8 So I think most people felt that
9 was high or moderate.

10 Let's move on to the 2a(2), which
11 is reliability: Are the results repeatable,
12 produce the same things?

13 Let's just vote again. We are
14 down one person. We got it. Okay, well,
15 consensus. So moderate. That's good.
16 Consensus is excellent.

17 So then we have to have an overall
18 reliability. I didn't know we had to do this.
19 I apologize. So, basically, based on those
20 two subcriteria, what is your overall feeling
21 about reliability, based on this discussion?
22 Okay, we have everyone. You got to like that.

1 It is all about consensus. Very good. All
2 right, excellent.

3 Is that what I wanted? It is not
4 what I want you to do. What I want is just to
5 send a -- If we send a consistent message, I
6 think that is useful for both the ABMS
7 Foundation folks, and it is also very useful
8 for the Steering Committee. Excellent.

9 So now we are going to move on to
10 the 2b issues, which include validity an risk
11 adjustment. The first one is 2b(1), and that
12 is that -- We are not going to vote. So don't
13 worry -- the measure specifications are
14 consistent with the evidence presented to
15 support the focus of the measurement under the
16 criterion. The measure is specified to
17 capture the most inclusive target population
18 indicated by the evidence.

19 I think Tim's comment before about
20 the fact that there is not a lot of evidence
21 here -- let's remember that a lot of us in the
22 room are content experts, and if you feel that

1 it meets your take of the evidence, I think
2 that is reasonable.

3 So the reviewer for 2b(1) was me,
4 and I felt that this did sort of capture what
5 they intended to capture. They were
6 specifically focused on costs around
7 colonoscopy, not around colon cancer
8 treatment, and I think that is a key thing.

9 If you accept the argument and the
10 evidence, you are going to have to make a leap
11 of faith, but I think we have made that leap
12 of faith already. There may be an opportunity
13 for room for improvement here, and this is
14 something worth studying.

15 I did feel that the data elements
16 captured what they were trying to capture and
17 the evidence, and with that I will open it to
18 the floor. Okay, I am not hearing anyone
19 argue on that, and I guess that is good.

20 Now we will move on to 2b(2),
21 which is the validity testing demonstrates
22 that the data elements are correct and that

1 the measure score correctly reflects the cost
2 of care.

3 What I will do is I will ask Lou,
4 who is responsible for that, to comment. Then
5 I will ask Carlos to add his thoughts. So,
6 Louis?

7 DR. POTTERS: So again this was
8 like the weekend switch. In terms of validity
9 testing, I thought they did a better job than
10 the reliability testing, because the data just
11 is what it is, and they have the publication.
12 They have gone through their breakdown in
13 terms of standard deviation and how they
14 fractionated everything, and I thought it
15 actually worked out okay.

16 CHAIRMAN PENSON: Carlos?

17 DR. ALZOLA: Yes. I don't have
18 much to add to that. I just look at how the
19 costs were distributed in terms of what lines
20 of service were responsible for the major
21 costs. They seem to make sense to me. Of
22 course, you clinicians know better than I, but

1 they all seem consistent with what you would
2 be expecting.

3 CHAIRMAN PENSON: All right. And
4 Steven, we will open up to the floor.

5 DR. CHEN: So this is where I
6 actually start to have issues with precisely
7 what is being included, and I think that is
8 where this goes. Right?

9 For instance, I have concerns
10 about in the seven-day run-up to the
11 colonoscopy, which is included, including
12 things like ER visit. I can't imagine how
13 scheduling a colonoscopy generates an ER visit
14 that is attributable to that provider. If
15 anything, it is the opposite.

16 I will renew my concern about the
17 cancer work-up, things like CTs and MRIs,
18 after colonoscopy. It is unlikely that that
19 is what you are using to look for free air.
20 You may use a CT scan at some point, but an
21 MRI of the liver is almost certainly not part
22 of the colonoscopy. That is the colon cancer

1 work-up.

2 Then again, my concern about
3 including as a mix people who have biopsies
4 and therapeutic polyp excision with people who
5 just had a straight screening colonoscopy, are
6 two radically different populations that I
7 don't think risk adjustment handles well. I
8 think that does need to be a stratification,
9 not a risk adjustment.

10 CHAIRMAN PENSON: So what I would
11 say to the last comment is let's -- that last
12 piece, let's table that and discuss that in
13 the exclusions, the next subcriteria, because
14 what I am hearing is perhaps these patients
15 either should be substratified or excluded
16 altogether. Is that a fair statement? But I
17 think the two other points are worth
18 discussing further, because I think they do
19 fall into this subcategory.

20 Is it valid to include that
21 information there? It is going to be
22 attributed to the individual performing the

1 colonoscopy, but that may not be a valid cost
2 associated with a colonoscopy per se. It may
3 be a valid cost associated with the diagnosis,
4 is what you are saying.

5 What I would ask you is if you
6 feel that that is such a major problem that it
7 really is going to cause you to vote low, for
8 lack of a better way to put it, because I
9 think it makes a difference.

10 DR. CHEN: I think as it is
11 currently constructed, I would probably vote
12 low, but its remedy-able. You know, it is
13 able to be remedied.

14 CHAIRMAN PENSON: So what I am
15 hearing is that that, as currently written, is
16 a major problem that causes you to really
17 question the validity of the measure, but it
18 could be fixed. Can you just comment again
19 for the NQF team how you would think about
20 fixing it?

21 DR. CHEN: Reexamining that -- For
22 instance, an MRI of the abdomen probably has

1 fairly similar cost to the professional fee of
2 the colonoscopy, if not more. So it could
3 quite easily be imaging aspect could overwhelm
4 the entire episode of colonoscopy of an
5 otherwise uncomplicated colonoscopy that is
6 done without anesthesia.

7 Similarly, I worry about
8 attribution. While the gastroenterologist may
9 choose to do anesthesia, how the anesthesia is
10 performed may or may not be within their
11 purview as to which drugs and what-not as
12 well. So again, I worry about attribution as
13 it pertains to the validity, because if the
14 validity has to do who it is being attributed
15 to, then there are things out of their
16 control.

17 CHAIRMAN PENSON: So I wonder if -
18 - One of the key things that I am hearing here
19 as you are speaking and I am thinking about
20 this, and you are certainly making me think
21 about this, is that you would be able to
22 capture a new diagnosis of colon cancer

1 immediately following the colonoscopy, and
2 that certainly is something that would be
3 worth stratifying by, because that is going to
4 affect things.

5 If someone does have a diagnosis
6 of colon cancer, it is going to affect the way
7 they are imaged. It is going to affect other
8 resource utilization, even up to a colectomy.
9 I am not a colon cancer surgeon or deal much
10 with colon cancer in the clinical setting. Is
11 that a fair statement?

12 DR. SKIBBER: Again, it speaks to
13 an issue that I have a little bit that is
14 similar, is the fact that even in the attached
15 article, they don't account for -- They
16 account for inpatient costs as part of this
17 model. However, inpatient costs that may be
18 generated even before the patient has the
19 colonoscopy would be captured.

20 What I am referring to there is a
21 patient admitted for a symptomatic problem,
22 then undergoes a colonoscopy. I think that is

1 going to distort some of the provider
2 attribution, and it is a similar point.

3 CHAIRMAN PENSON: Do you think
4 that is something that could be fixed in a
5 risk adjustment model? Steven's comment is
6 you would just have to stratify. There is no
7 way to risk adjust.

8 DR. SKIBBER: I would have to ask
9 the developer on that. I don't know. Did
10 they have any -- Does the developer have any
11 idea if this was addressed by their working
12 group?

13 CHAIRMAN PENSON: So I would ask
14 Dr. Weiss and the ABMS Foundation team on the
15 phone. Are you guys there?

16 DR. WEISS: We are. However, the
17 phone is in and out. So if you could repeat
18 the question.

19 CHAIRMAN PENSON: So the question
20 was: There was concern regarding attribution
21 of costs, that certain patients are going to
22 have more imaging. Some patients are going to

1 come into a hospital symptomatic, and there is
2 no real indication to us in reviewing the
3 measure that that was considered by the
4 working group.

5 Was that considered by the working
6 group in the discussion? Is there any sort of
7 risk adjustment for that? Is there discussion
8 about stratifying analyses? Where was that
9 with regard to your working group?

10 DR. WEISS: So I will start and,
11 hopefully, Todd can jump in, in terms of the
12 risk adjustment model which he is intimately
13 familiar with.

14 The working group recognized that
15 the older someone -- of these colonoscopies
16 would be for screening activity, that there
17 would be a small portion that would be done
18 for other reasons, and that -- and that in
19 here that that should be relatively balanced,
20 and that more severe patients require -- risk
21 adjustment. So they did not want to, didn't
22 feel the need to, recognizing that --

1 CHAIRMAN PENSON: Kevin, you are
2 breaking up a little bit there. I'm sorry.
3 Could you repeat that last part? It may be a
4 tech problem on our end. We just don't know.
5 We don't think so. Maybe if everyone here
6 could turn off their microphones, maybe that
7 will help.

8 DR. WEISS: Oh, that sounds better
9 at my end, for sure. How much of what I said
10 was heard?

11 CHAIRMAN PENSON: We sort of lost
12 the last minute of it. I think we have
13 identified the problem. It has got to do with
14 microphones on On. So if you want to start
15 from the beginning, that is fine, too.

16 DR. WEISS: That sounds painful,
17 although it wasn't a very long answer.

18 The working group very much
19 focused on the fact that what we were really
20 capturing for the majority -- well, the
21 overwhelming preponderance is really
22 screening, and that there would be some non-

1 screening activity that goes in here, but that
2 the very complex patients who have lots of
3 comorbidity would be picked up in the risk
4 model adjusted for, and that hence the
5 comparisons would likely happen within peer
6 group, that there would probably be a tendency
7 to a more apparent random directional bias --
8 not random, but just directional bias in terms
9 of any variability in terms of patient
10 severity, recognizing that it was an imperfect
11 way to solve it, but that is the best possible
12 solution that was worked out.

13 To the risk model, we have got
14 Todd Lee on the phone, and I don't know, Todd,
15 if you want to -- if you can come off Mute and
16 talk a little bit about that as well.

17 CHAIRMAN PENSON: Before Todd goes
18 ahead, I just want to let you know, because
19 you can't see the visual cues. I am going to
20 state right up front that some of the clinical
21 experts in the room, when you mentioned the
22 distribution of screening versus surveillance

1 colonoscopy, were shaking their heads.

2 So it may be necessary at some
3 point for you to provide evidence that the
4 majority of colonoscopy is screening and that
5 the impact of a clinical surveillance
6 colonoscopy or colonoscopy for severe symptoms
7 or even moderate symptoms due to colon cancer
8 is minimal. Just to let you know, that is
9 what I am seeing here.

10 DR. WEISS: No, that is helpful.

11 CHAIRMAN PENSON: Todd, if you
12 want to mention a few words specifically as to
13 whether or not the risk adjustment piece
14 captures severity of symptoms, because we will
15 talk, I think, in great detail about the risk
16 adjustment model in a few minutes. But does
17 the risk adjustment model capture at all
18 severity of symptoms or, for that matter, new
19 diagnosis of colon cancer after the
20 colonoscopy?

21 DR. LEE: No, it only considers
22 information preceding the episode and is not

1 symptom based. Rather, it is going to risk
2 adjust for other coexisting conditions, and
3 that is really the focus of the risk
4 adjustment model, and looking at severity of
5 patients in terms of other concomitant medical
6 conditions.

7 CHAIRMAN PENSON: Okay, that is
8 great. Thank you. So I am going to sort of
9 keep us moving along for the sake of time.
10 I'm sorry, Louise.

11 DR. WALTER: No, no, the only
12 other thing I want to put on the validity is
13 I think the lack of testing in people 65 and
14 older is a concern for me. I put my
15 geriatrician hat on, and that will actually
16 come to some of my points in the exclusion
17 criteria.

18 CHAIRMAN PENSON: I think that is
19 a major concern. I agree with you.

20 So just to reiterate what I have
21 heard in the validity discussion, I am hearing
22 some real concerns here that are related, to

1 some degree, to the risk adjustment piece and
2 the inability to sort of capture: Is it valid
3 to capture, say, imaging in a patient who has
4 a new diagnosis of colon cancer that is going
5 to be attributed to a gastroenterologist that,
6 in fact, the gastroenterologist had nothing to
7 do with it?

8 I am mostly hearing some concerns
9 about symptoms at presentation, whether or not
10 that is going to affect the validity of the
11 measure. We will get to the inclusion
12 criteria, but these are all sort of intimately
13 related, for lack of a better way to put it.

14 Are there other comments or
15 concerns regarding validity?

16 DR. GILLIGAN: I am wondering if I
17 have interpreted this differently, because I
18 notice on this measure and also on 1584, I am
19 the only person who voted low.

20 When I looked at Carlos'
21 evaluation on 2b(2), it seems like all the
22 standards that were suggested there were not

1 met, to me. So has the data been compared to
2 other authoritative data sources? No. Has
3 the data integrity been checked? No. Is the
4 data representative of the target population?
5 Not really, because the target population is
6 over 65.

7 So that left me feeling like we
8 didn't really meet the criteria, but everyone
9 else felt like it did. So I am wondering if
10 I am using a different ruler here.

11 CHAIRMAN PENSON: No, I don't
12 think you are. I think it is a matter of
13 interpretation. I think that I could see why
14 you would vote that way, and it is just a
15 matter of reference setting. That is all.
16 But I think the comments you are raising are
17 quite reasonable, and I think that the
18 discussion reflects that.

19 MS. TURBYVILLE: And just to add
20 for your thought process, the minimum
21 threshold that we require for validity,
22 especially in consideration that this is the

1 first endorsement of these type of measures,
2 is face validity.

3 So that would be a minimum
4 threshold, that they demonstrated that face
5 validity in a systematic manner was met.

6 CHAIRMAN PENSON: Go ahead, Rohit.

7 DR. BORKER: I had a good comment.
8 So I completely agree with what Steven was
9 saying in terms of what is attributable, what
10 is not, but to what developers have produced
11 here, if the end was to look at absolute cost
12 of care for a given provider, definitely those
13 are valid concerns. But should we think about
14 what the instrument is getting used for or the
15 measure is getting used for? It is to compare
16 across providers.

17 So if one can assume that within a
18 certain setting, say community setting, if one
19 provider had a similar case mix of patients as
20 another, then shouldn't those differences get
21 neutralized, if you may?

22 CHAIRMAN PENSON: Well, I -- Go

1 ahead, Steven. I'm sorry.

2 DR. CHEN: I guess I would say to
3 that, there's two issues. One is small sample
4 size for a lot of providers. So you are going
5 to have case mix variation, just by pure
6 randomness.

7 The other is systematic bias. For
8 instance, colorectal surgeons do, I think, 10
9 percent of the colonoscopy or eight percent of
10 colonoscopy. They have a radically different
11 case mix than people who are doing screening
12 colonoscopy.

13 So to the extent that you are
14 using inter-specialty provider comparison as
15 well, that is radically different.

16 CHAIRMAN PENSON: Other comments?
17 I think we have beat validity to death, but we
18 are not done yet, because I think many of the
19 remaining points are going to come back to us.
20 So let's move on to 2b(3) which is the
21 exclusions, that basically these are supported
22 by the clinical evidence, and the

1 specifications for scoring include computing
2 exclusions and, finally, if patient preference
3 is a basis, there has to be evidence for that.

4 For this one, with the exclusions
5 2b(3), John, you were the primary.

6 DR. SKIBBER: I felt that the
7 exclusions expressed by the developer were
8 reasonable. They appear to be specified. The
9 exclusion of age less than 40 is arbitrary but
10 reasonable. The high cost condition exclusion
11 appears well stated and obvious. The issue
12 about colectomy for cancer within two days of
13 colonoscopy is reasonable.

14 You know, that is interesting,
15 though. You are going to lose a small number
16 of complications related to that, if one of
17 the objectives is to assess provider resource
18 use based on complications.

19 If you go back and look at their
20 article, the number that you are probably
21 going to exclude based on that is low, is very
22 low, in fact. So I think that is fine as an

1 exclusion.

2 The inflammatory bowel disease
3 exclusion is a reasonable one. We get back to
4 that insurance exclusion, which is their major
5 one. When you look at their article, they
6 exclude over 50 percent of the colonoscopies
7 in the database.

8 Just in an overall sense, I
9 realize that that is what they have to have in
10 order to record comorbidities and have
11 administrative data, but I have to tell you,
12 that completely excludes the ability to
13 address disparity. To me, that is not even
14 an issue, because of the way that they create
15 that exclusion. That cannot be addressed in
16 this at all.

17 CHAIRMAN PENSON: So I will just
18 ask you on that, because I think that is a
19 very good point, but there is a specific
20 subcriteria for disparities. So let's come
21 back to that, and remember to bring that up
22 when we get to that.

1 DR. SKIBBER: That was all I had.

2 CHAIRMAN PENSON: Are there other
3 comments on exclusions? Steven?

4 DR. CHEN: So I have covered a
5 fair number of them. I do have some
6 questions. One was the exclusion includes
7 people who don't have coverage at least 320
8 days before and after for a 21-day measure.

9 I understand for the year before
10 you are using it for the comorbidity
11 adjustment, but for the year after I am not
12 exactly clear on why that would have any
13 effect, say, after, say, a few months after.

14 So going back to your question of
15 we are eliminating all these people, we end up
16 with a very small sample size. To the extent
17 of improving the sample size, it may be
18 worthwhile to consider cutting the back end,
19 because I don't think the back end has a lot.

20 The other comment I had, had to do
21 with -- Again, I was looking for ways to
22 consider excluding some people who I thought

1 were not the same, and then also re-including
2 some people that maybe aren't under active
3 treatment. So there is not really a reason to
4 think that their colonoscopy would be
5 performed dramatically differently, but the
6 issue has to then be whether that could be
7 risk adjusted away; because you will notice
8 that the number one medication given is anti-
9 lipid agent, which probably had nothing to do
10 with their colonoscopy cost. I am just
11 throwing that out there.

12 So you could do similar sorts of
13 things with something like HIV/AIDS. I don't
14 think we would necessarily perform their
15 colonoscopy any differently on face validity,
16 but their costs would be significantly
17 different.

18 So if you are going to include one
19 thing but not the other, why not CHF then as
20 a high cost. CHF is an incredibly costly
21 thing, to the point where they qualify for
22 hospice. So that's just my thoughts.

1 DR. WALTER: Building on that, I
2 had big trouble with the cost exclusions, as
3 you were talking about. Excluding people for
4 renal disease, HIV, and transplant might be
5 appropriate in younger people, but that would
6 completely not capture high use in older
7 people, which is more congestive heart
8 failure, dementia. There's a lot of other
9 high cost things. So I don't think that is
10 very inclusive.

11 CHAIRMAN PENSON: So I will put
12 out to the group, to Steven and Louise and
13 John who started this discussion, in your
14 mind, is that -- I mean, obviously, it is
15 remediable, but is that a major limitation
16 that affects your feeling that this is
17 appropriate. Would it lead you to vote low,
18 is basically what I am asking?

19 DR. WALKER: Yes.

20 CHAIRMAN PENSON: All right.

21 DR. SKIBBER: Again, a lot of that
22 concern -- and I agree with both the members -

1 - is this issue of not identifying screening,
2 because if you look at their article again,
3 their cost, their phenomenal amount of costs
4 are related to management of cardiovascular
5 conditions, which again is just going to muddy
6 any interpretation of provider attribution and
7 may, in fact, muddy your ability to draw any
8 distinctions based between even institutions,
9 if not regions. It is a concern.

10 CHAIRMAN PENSON: We are going to
11 get to this in a minute, but my question to
12 everyone in the room -- and we are talking
13 about exclusions, but we are sort of bouncing
14 back and forth -- does that affect the
15 validity, because you have included these
16 costs which may have nothing to do with the
17 colonoscopy that are related to CHF, and by
18 the same token, does the risk adjustment
19 methodology, which does include CHF, if I am
20 not mistaken, as one of the covariates,
21 adequately address that to the point where
22 your concerns are mitigated, I guess is the

1 term I want to use -- mollified?

2 DR. WALTER: Well, I guess I would
3 like better explanation for why they chose
4 certain things for exclusions and certain
5 things to risk adjust, because it just seems
6 like the exclusions are not appropriate for
7 older adults.

8 CHAIRMAN PENSON: So I think, on
9 that theme, what I would like to do -- and I
10 think the folks -- I am sure that Todd and
11 Kevin on the phone are hearing that discussion
12 specifically justifying why certain things
13 were excluded and why they were included in
14 the risk adjustment model or why they weren't
15 included at all.

16 I want to call the question or
17 move us on to the risk adjustment, and then
18 what I think we should do is vote on these
19 four, because they are related.

20 So we have talked about the
21 exclusion, and to reiterate, I think there are
22 some serious concerns there. Louis, I'm

1 sorry.

2 DR. POTTERS: Well, I had the
3 disparities. There is really not much to say
4 about disparities in the context of the
5 application, because they reference a section
6 that has like two sentences in it. It
7 basically just says that it is age related.

8 So it does get back to what John
9 was saying in terms of the insurance issue and
10 the filtering down. So we may want to take
11 that whole block.

12 CHAIRMAN PENSON: Oh, you mean all
13 the way down to disparities? I just think
14 that, just so we can remember what we did,
15 because it is a lot of information, although
16 I am open if people want to keep running. But
17 I think probably we can -- I think it is
18 better if we vote, because we will vote in
19 disparities in 10 minutes probably. But
20 before you vote now, I think we do want to do
21 the risk adjustment piece. That is the last
22 one, if people are okay with that.

1 So this one is 2b(4), and it is
2 the risk adjustment: Is there an evidence
3 based risk adjustment strategy specified or is
4 there a rationale that it does not need to be
5 included?

6 I think this is where you can ask
7 the question, does the risk adjustment
8 methodology pass the smell test, not just is
9 it there. I think that I will ask, just for
10 the sake of time -- we don't have to repeat a
11 lot of what we have already discussed
12 regarding things like screening versus
13 surveillance and CHF.

14 So with that, I will turn it over
15 to John, who is the primary reviewer.

16 DR. SKIBBER: The risk adjustment
17 use was the CMS version of eight ccs for
18 assignment of comorbid conditions based on
19 ICD-9 coding during the preceding 12 months.

20 This was adapted from a total cost
21 model to an episode based model. I have a
22 concern that this risk adjustment model treats

1 colon-specific comorbidities similarly to non-
2 colon related conditions, and that I am not
3 sure I see that this has been validated, for
4 all the reasons we just talked about.

5 I believe that the statistician,
6 who can speak for himself, has concerns about
7 the validity of the risk adjustment that
8 should be addressed.

9 The other issue, I think, included
10 in this measure was the stratification. That
11 was based on a task force recommendation of
12 stratification of 40-75 years or greater than
13 75 years. Again, I am not sure that this is
14 totally valid.

15 One interesting point is they
16 based some of this on that Warren article, and
17 if you read that, that article is for
18 outpatient colonoscopy. It is not for all
19 colonoscopy, and I think it is going to speak
20 to the issues brought up by one of the
21 members.

22 CHAIRMAN PENSON: I will ask

1 Carlos to say a word or two about the risk
2 adjustment, then throw it open to the masses,
3 as it were.

4 DR. CHEN: Thank you. The main
5 thing about the risk adjustment is that there
6 is a lack of information here about how the
7 model was fit and some statistics on how we --
8 especially how it calibrates to the
9 population, how the predictive relates to the
10 observed, and also are there measures of
11 goodness of fit.

12 The other that seems curious to me
13 is that, if you look at the model, it is
14 adjusted for lots of conditions, and
15 apparently they intend to select those risk
16 factors. They just used some statistical
17 significant criteria.

18 I am not sure that all these
19 really should pass the test in terms of
20 clinical validity. So that is something to
21 reconsider.

22 Mostly, I felt a lot today that

1 people with cardiovascular conditions would
2 have really severe costs, much higher costs.
3 However, the coefficient for CHF is only \$88.
4 So it is not having any of these conditions.
5 It is only -- Most of them are less than \$100.

6 So if you take a base without any
7 comorbidities, it is going to cost -- The risk
8 adjustment is going to say \$1131. If you add,
9 if anybody is going to have may two or three
10 comorbidities, so their estimated cost, their
11 expected cost, is going to be just 1500, no
12 more than that, and yet, when we look at the
13 distribution that they observe, we have costs
14 in the upper range, over \$2,000.

15 So it seems to me that that is --
16 The model does not seem to be capturing those
17 high costs. It could be that those high costs
18 are not really appropriate, but I really would
19 need to see some evidence of calibration for
20 this model.

21 CHAIRMAN PENSON: Louise?

22 DR. WALTER: Well, probably

1 because it was in younger people versus older
2 people.

3 CHAIRMAN PENSON: Steven?

4 DR. CHEN: I would say, to what
5 Carlos said, I think the methodology they used
6 to create the risk adjustment is reasonable.
7 What we don't understand is they don't give us
8 an R-squared or some sort of idea of how well
9 does the model work.

10 In particular, risk adjustment
11 tends to really fall down at the outliers,
12 because a model will say, you know what, I am
13 just going to ignore that outlier, because,
14 well, we are just going to get that one wrong.
15 But in fact, what we are looking for in a
16 resource use thing is we are focused on
17 analyzing outliers.

18 So without understanding how the
19 fit is toward the edges, even a scattergram of
20 their the residuals of the first 75 percent
21 test set would be incredibly helpful in this
22 situation. So it is almost an insufficient as

1 much as anything.

2 CHAIRMAN PENSON: Yes. I am with
3 you. I actually felt it was insufficient.
4 When I looked at it before sort of Carlos'
5 review, I sort of -- you know, having played
6 in this space, and looking right off and
7 saying, well, they used a Delphi process,
8 well, you know, that is just 10 people's
9 opinion. I am fine with that. There's a lot
10 of people smarter than me. But the fact of
11 the matter is you are going to test that, and
12 I didn't feel like they had done a good job.

13 They have a very complicated
14 equation that has been -- they have done some
15 statistical maneuvering, but I just in my gut
16 didn't feel right. Then when Carlos as a
17 statistician sort of -- looking at his review
18 sort of confirmed that.

19 My feeling is that there may be
20 something here, but they haven't documented
21 that for me. Other comments? Wow, I thought
22 that was going to be a much longer discussion.

1 So I think that what I am hearing
2 is significant concerns from Carlos regarding
3 the risk adjustment, all the things we have
4 discussed already today vis a vis age, vis a
5 vis why the colonoscopy is performed, issues
6 with other comorbid conditions, attributing
7 one thing to another, attributing CHF costs to
8 colonoscopy and potentially not capturing
9 that.

10 I think that there was some
11 understanding of the risk adjustment
12 methodology and some sort of acceptance of it,
13 but by the same token, what I am hearing in
14 the room was that the evidence presented just
15 didn't get the ball over the goal line.

16 So I am going to sort of now ask
17 us to vote on these four criteria. Before I
18 call the vote for 2b(1) through 2b(4), are
19 there any other comments or thoughts people
20 want to add?

21 All right. We are down one panel
22 member. Should we just go ahead? I am

1 getting the "sure, why not." Sally, Louis is
2 out of the room. I think we still have a
3 quorum.

4 MS. TURBYVILLE: See if the
5 developer wants to provide any input.

6 CHAIRMAN PENSON: Okay. That is a
7 reasonable idea. Kevin and Todd, I think you
8 have been listening to the comments. Before
9 we take a vote -- we are waiting for one of
10 the panel members to come back in -- are there
11 any thoughts that you might want to add, any
12 comments, to what has been said?

13 DR. LEE: Sure. This is Todd Lee.
14 I will take a couple of minutes to address a
15 few issues that I heard, one around
16 exclusions.

17 We have standard exclusions that
18 are applied across all of our measures. So if
19 we consider this measure in a suite of an
20 additional measure -- I know you are not
21 evaluating it as a suite, but we felt that
22 there was value in having some consistency

1 across all of our measures, so that if folks
2 wanted to implement these as a suite of
3 measures, it would reduce the possibility of
4 errors.

5 For that reason, we have the
6 standardized time window, the one year before
7 and the one year after. Realizing that we may
8 not need the one year after to capture all the
9 resource use related to a colonoscopy episode,
10 we wanted to go with the strategy that we
11 wanted to keep this as consistent as possible
12 across all of our measures.

13 A similar sort of issue applies to
14 selecting these, quote/unquote, "high" cost
15 exclusions, HIV/AIDS, active cancer, renal
16 failure, transplant status, and again this is
17 a standard across all of our measures.

18 That is consistent with several
19 other resource use measures, and again it was
20 an acknowledgment on our behalf to try and
21 have some consistency across the measures to
22 reduce, again, the likelihood of errors when

1 individuals or groups might be implementing
2 these measures. It is essentially a standard
3 set of code that you could use across all of
4 our measures to exclude individuals.

5 I fully acknowledge what Dr.
6 Walter said about this probably being more
7 applicable to a younger population than it is
8 to an older population. There is a big caveat
9 around all of the information that you are
10 seeing in that this is a commercially insured
11 population in which we tested these episodes.

12 So we don't have the evidence on
13 those people that are older than 65, and we
14 would fully acknowledge that.

15 The final thing that I will touch
16 on is the risk adjustment issues that you all
17 just talked about, and think that you captured
18 the information very accurately.

19 We certainly have fit information
20 in terms of observed predicteds and how each
21 of these 12 different models that we evaluated
22 with our work groups fit.

1 We went through a process of
2 having them say, hey, what is clinically
3 important, and then we went through another
4 process of saying, okay, what if we used some
5 statistical fitting methods and seeing how
6 those two things differ.

7 What we found out is we ended up
8 falling on this risk adjustment model that
9 used whether or not things were associated
10 significantly with resource use.

11 We know that we are not going to
12 predict -- or be able to predict all of the
13 variation in the observed -- and we don't want
14 to, because some of that, as was noted, might
15 be due to difference in practice patterns and
16 not differences in coexisting conditions.

17 It is not surprising to me, given
18 that we are focusing on a 21-day period, that
19 these coefficients are small. The
20 coefficients that you see with other chronic
21 conditions in our risk adjustment model are
22 small, simply because we are talking at a very

1 constrained time period.

2 Finally, we have all of the
3 information that you might want around risk
4 adjustment model performance. We just did not
5 submit that as part of our initial
6 documentation, and again as we have done for
7 other measures, we could submit that as part
8 of the response to all of your comments.

9 CHAIRMAN PENSON: All right. That
10 is very helpful, and I think, for the sake of
11 argument, we will move on to voting, if that
12 is okay.

13 MS. TURBYVILLE: If they could
14 email it to Ashlie, we might be able to keep
15 things moving so that you can adequately rate
16 today, if that makes sense to you.

17 CHAIRMAN PENSON: So I guess --
18 Why not? So what I would say is the sooner
19 you can get us that information specific to
20 this measure, because I think there is some
21 concern about the risk adjustment that matter.

22 We are going to call the vote now,

1 but certainly, we could circulate this either
2 through a follow-up phone call or even today
3 by the end of the day. So if you could email
4 that to us, that would be great, Todd.

5 With that, I am going to ask -- We
6 are all back in the room. So let's start
7 voting. We are going to start with item
8 2b(1), which is: Are the measures specified
9 consistent with the evidence or, if nothing
10 else, our clinical take on the evidence? If
11 everyone could vote now, that would be great.

12 So I think most people felt this
13 was high or moderate, and I think that
14 reflects the comments of the room.

15 Next is validity testing. This
16 is: Does the validity testing demonstrate the
17 measure elements are correct and the measure
18 score correctly reflects the cost of care and
19 resources provided? I do think there was some
20 discussion here. So let's go ahead and vote
21 here.

22 I think this reflects the

1 discussion fairly well.

2 The next one is 2b(2) and probably
3 2b(3). This is the exclusion question, and I
4 think there were some real discussion here
5 regarding age and other issues. So go ahead
6 and vote.

7 Okay, we got everyone.

8 Then the last, and certainly not
9 least, was the discussion around risk
10 adjustment, 2b(4), and again there was
11 discussion here as well.

12 I do think these scores reflect
13 the discussion as well. Okay.

14 Let's move on. I think we are now
15 officially behind, but hopefully, for the
16 remainder, I think these are a little bit less
17 controversial. We will go through what is
18 left in the scientific accuracy, and then we
19 will go through usability and feasibility,
20 hopefully, relatively quickly.

21 The next one is 2b(5), which is
22 differences: Data analysis demonstrates for

1 scoring that the differences -- you can
2 identify statistically significant and
3 clinically meaningful differences in
4 performance or there is evidence of over or
5 less than optimal performance. The primary
6 reviewer for this was John, 2b(5).

7 DR. SKIBBER: The data will be
8 provided in summary reports on each provider
9 and will be expressed as the proportion of
10 observed expected -- risk adjusted expected
11 ratios that are above the 75 percentile for
12 the peer group and overall.

13 The stewards proposed that this is
14 going to contribute to controlling for case
15 mix. Again, we spoke about that. It doesn't
16 appear that that is tested at all.

17 The main driver of this cost
18 difference is likely to be anesthesia use, and
19 this will be shown with -- I don't know how
20 this is going to directly impact on our
21 ability to truly identify clinically
22 meaningful differences between providers. It

1 is sort of like it is a fait accompli. They
2 already know that is what is going to show.

3 I do think that there is an issue
4 in anything like this of small numbers of
5 individual cases for individual providers that
6 is going to be profoundly affected by their
7 case mix. The steward does acknowledge this
8 in their submission. Other than acknowledging
9 it, they don't necessarily state that they are
10 going to account for it in any other fashion.

11 CHAIRMAN PENSON: Okay. Other
12 comments? I agree with you, John. I just --
13 Looking at this personally, I don't know what
14 to make what the differences is. First of
15 all, I am not sure what the differences are
16 going to be. I am sure they are going to be.
17 They always are, but I don't know how to
18 interpret the differences.

19 I didn't know whether that was
20 meaningful and whether I could interpret it,
21 which, if I could interpret it, I don't -- I
22 didn't know whether to score this low or

1 insufficient, but the bottom line is I don't
2 know what to make of it, and it is worrisome
3 to me.

4 CHAIRMAN PENSON: On 2b(5)? Okay,
5 we will move on to 2b(6). This is the one that
6 looks at multiple data sources, and is there
7 a demonstration that they can produce
8 comparable results? I think, John, you win
9 again.

10 DR. SKIBBER: This doesn't appear
11 to be fully addressed in the submission. An
12 additional concern is that the method they
13 describe in their description for getting
14 their resource use data only accounts for DRG
15 facilities, and there will be some facilities
16 that are currently at least DRG exempt, and
17 how their data is going to translate exactly
18 into the comparable data, while they propose
19 a model for that, I don't -- Maybe others
20 might know if that is a valid model.

21 MS. TURBYVILLE: I just want to
22 add something for your deliberations before

1 you get further into this conversation.
2 Typically, the way we think about this is, if
3 a developer is requesting for it to be
4 endorsed for use in different types of data --
5 for example, they are using both -- they tell
6 a user they could use both administrative data
7 and clinical enriched data, or differences in
8 that type of manner -- then we would want them
9 to demonstrate that, by specifying these
10 different data sources, that they have tested
11 them to see if the measure performs reliably
12 in that manner.

13 I think, certainly -- and we have
14 heard the conversation here that there are
15 issues with administrative claims data, that
16 that is, I think, going to be an issue
17 throughout the measure specifications and
18 concerns that administrative data itself, even
19 if it is just commercial, as they are looking
20 at it here, may have challenges. But for this
21 particular subcriteria, we are really looking
22 at when they have specified these distinct

1 data sources, and I do believe that they are
2 just looking at commercial administrative
3 data.

4 So we would endorse the measure if
5 it were recommended for that to be implemented
6 only in commercial data administrative
7 populations.

8 DR. WALTER: The problem is there
9 are many types of claims databases, like they
10 did not validate it in anything other than an
11 employer based, versus Medicare claims. So I
12 didn't know whether to rate this insufficient
13 or not applicable.

14 CHAIRMAN PENSON: Yes, I am with
15 you on that, because the question isn't -- You
16 don't have to meld Ingenix with Medicare to do
17 it, which is what you are getting at, Sally,
18 but what they have looked at is they have
19 basically looked at a commercial payer
20 dataset. I think it was Healthscan or
21 Ingenix, but does it work in Medicare?

22 It probably does, but there is no

1 evidence there to support it. So my gut
2 feeling was I would have liked to have seen
3 that evidence.

4 MS. TURBYVILLE: And just -- I
5 don't want to beat this up too much. We would
6 not endorse this measure if it were
7 recommended for implementation in Medicare
8 data. It would have to be endorsed for
9 commercial populations only.

10 I realize the measure goes 65 and
11 over, and that is a whole 'nother conversation
12 for this committee to have, but when it is
13 tested in a certain database, a commercial
14 population, that is all we can endorse it.
15 What you said, you know, there are variations
16 in commercial data. That is a question of how
17 representative the market scan that they used,
18 which is quite large -- whether that helps
19 address some of those concerns of all of you.

20 CHAIRMAN PENSON: So I guess what
21 I am hearing from you, Sally, for the panel is
22 that, if this was endorsed, it would only be

1 endorsed in the population -- It wouldn't be
2 used in Medicare, because it hasn't been
3 tested in that dataset. It would just be
4 Market Scan.

5 So in that respect, if you were
6 just looking at Market Scan, I guess it sort
7 of changes today for me. Others?

8 DR. WALTER: I guess I missed the
9 point of the question then, because I thought
10 it was about has this been tested in multiple
11 data sources, and it has only been tested in
12 one. Right?

13 CHAIRMAN PENSON: Right. So what
14 they are basically saying -- I know what you
15 are saying, Louise, and I think what Sally is
16 telling -- What I am hearing is, yes, if they
17 were looking at -- If they wanted to get it
18 endorsed for Medicare and for Healthscan, then
19 we would have to see them both, but it is only
20 going to get approved for the one.

21 DR. GILLIGAN: So this becomes not
22 applicable then?

1 CHAIRMAN PENSON: Yes, I guess it
2 becomes unapplicable. I think that is
3 reasonable.

4 DR. BORKER: Okay. So that
5 answers my -- My confusion was
6 generalizability versus testing.

7 CHAIRMAN PENSON: Okay. So I
8 guess, if it is not applicable, we can move
9 on. Lovely. So the next to the last one in
10 this set is disparities: If disparities in
11 care have been identified, did the measure
12 specification, scoring and analysis allow for
13 identification; that is, by race, ethnicity,
14 status and gender.

15 This is 2b(6), and John, this one
16 you have as well, with disparities.

17 DR. POTTERS: I had disparities.

18 CHAIRMAN PENSON: Oh, I am sorry.
19 I apologize. Sorry, Louis.

20 DR. POTTERS: There is not much to
21 say, because they really don't address it. I
22 interpreted that as -- which is why I raised

1 the issue under exclusions and risk
2 adjustment, because it gets back to the -- it
3 really gets back to the unknown denominator,
4 and we just said from an N/A -- you know, not
5 applicable -- for the previous section,
6 against other data sources.

7 Whatever the denominator is out
8 there is out there, and whatever is in, I
9 guess, this Med Scan data is going to
10 subdivide whatever is in there.

11 CHAIRMAN PENSON: But what I would
12 ask specifically, as I interpret it, was can
13 the current Market Scan data, and can the
14 current measure be used to address disparities
15 by gender, by race, by age?

16 When I read it, I didn't see any
17 evidence one way or the other.

18 DR. POTTERS: Right. Well, they
19 didn't really address it.

20 CHAIRMAN PENSON: Right. So that,
21 in my mind, is insufficient.

22 DR. POTTERS: Right.

1 CHAIRMAN PENSON: Other comments?

2 That is what I am hearing you are saying,
3 too, Louis.

4 DR. POTTERS: I went through the -
5 - I am going through this thing. I am like
6 where is the discussion on this, and there was
7 really nothing. So they don't look at it,
8 unless they want to comment.

9 CHAIRMAN PENSON: Kevin, Todd, did
10 you do any analyses, disparities analyses, by
11 gender, by race? Any evidence to help guide
12 us?

13 DR. WEISS: Yes. We have not done
14 anything by gender. We cannot in this dataset
15 do anything by race, not captured as part of
16 the Market Scan data. We did do some age
17 based analyses within the population.

18 Honestly, I don't have the data in
19 front of me to be able to tell you what
20 differences there were. I don't think we
21 found anything in, again, an under-65
22 population, but before I commit to that, I

1 want to dig up some data and make sure.

2 CHAIRMAN PENSON: Okay. I am
3 going to call the question, but I do want to
4 raise one point to the panel that you just
5 made, which is that you cannot do a
6 stratification by race or by socioeconomic
7 status. So if people feel that that is an
8 important piece to have here, then you would
9 want to have that reflected in your vote.

10 With that in mind, let's wrap up
11 the scientific piece. So let's do 2b(5),
12 which is the differences in performance. Are
13 they statistically significant, practically
14 and clinically meaningful differences in
15 performance? Let's go ahead and vote on that.

16 Okay. So just for the folks on
17 the phone, we have three votes for moderate,
18 four for low, and two for insufficient for
19 differences in performance.

20 2b(6) we are going to skip over,
21 because we felt that was not applicable, and
22 2c is disparities. Just to reiterate -- Oh,

1 I apologize. Yes, we have to do overall
2 validity.

3 So this basically encompasses the
4 evidence, the validity testing, the exclusion
5 criteria, the risk adjustment, the difference
6 in performance scores. I will ask everyone to
7 vote on that now.

8 We have everyone, it looks like.
9 So just again for the folks on the phone, and
10 I think this is reflected in the comments, for
11 overall validity we have five votes for
12 moderate and four votes for low.

13 Now we will move on to
14 disparities, which is the 2c: If disparities
15 in care have been identified, do the measures
16 specify scoring, etcetera, allow for
17 identification of disparities through
18 stratification or results? Let's go ahead and
19 vote now.

20 Everyone, re-vote. There we go.
21 So this one for disparities, we had two who
22 said it was moderate, two who said it was low,

1 and five who said it was insufficient
2 evidence.

3 So scientific accuracy. We are
4 running behind. My inclination is to plow
5 through this measure and then take a shortened
6 break, if that works for people. I am getting
7 yeses around the room. So that means
8 everyone's bladder is holding out, says the
9 urologist. Okay, great. Who invited the
10 urologist to a colonoscopy meeting, huh?

11 So next we are going to talk about
12 usability, and I think that, to some degree,
13 these are some of the quicker discussions, I
14 hope.

15 The first one is 3a, which is:
16 Are the performance results, measure
17 performance results, reportable to the public
18 at large in national and community reporting
19 programs at the time of endorsement or at
20 least by the time of endorsement maintenance
21 review?

22 So I will ask Tim, who is the

1 assigned reviewer, to discuss that.

2 DR. GILLIGAN: Yes. I don't think
3 there is a whole lot to say. What is
4 interesting here is that we are all over the
5 map on how we scored this, among the four who
6 rated it as insufficient, because it seemed to
7 me that this wasn't really addressed in the
8 proposal.

9 The standard here is whether the
10 measure performance was also reported to the
11 public at large in national or community
12 reporting programs, and they are not, really,
13 at this point. So I just got insufficient.
14 I don't know if there are people who voted
15 higher who will explain why they would give it
16 a high score on this, because I didn't think
17 I had any evidence or data to give it a score
18 other than insufficient.

19 CHAIRMAN PENSON: My question,
20 though, addressed to Sally and the NQF team,
21 is this is currently being sort of tested by
22 RWJ under the RWJ contract. So is this an

1 applicable issue now or is it something that
2 waits for endorsement maintenance review in
3 three years?

4 MS. TURBYVILLE: Very good
5 question. So what I would ask is to call your
6 attention to some revised language that we
7 have for usability. During the time that this
8 project was rolling out, concurrently the NQF
9 was reexamining some of the criteria,
10 including reliability, and it gets to exactly
11 what you are talking about.

12 So now it is: Does the submitted
13 information -- That is not right either.
14 Which one is right?

15 MS. BOSSLEY: Sally, why don't you
16 just -- The slide from before, can you put it
17 back?

18 MS. TURBYVILLE: I will. Thank
19 you.

20 MS. BOSSLEY: Let me just provide
21 a little background, too. So we are currently
22 looking at the usability criteria. So this is

1 a work in progress. So, hopefully, you all
2 will work with us as we go through this.

3 We have a task force that is
4 convening in the next month to take a look at,
5 as we advance and move more into public
6 reporting, actually different -- That is a
7 small piece in the spectrum, like Sally
8 showed, of accountability.

9 So how do we as NQF anticipate,
10 when we first have measures submitted to us,
11 what is the level of reporting that we expect
12 or accountability? Where should it fall
13 within that spectrum? It may not, and I think
14 that is what you are seeing with these
15 measures.

16 With these, I would also -- You
17 are looking at a piece that falls within the
18 efficiency framework. So I think we want to
19 move very cautiously in recommending that
20 these measures be put out there without that
21 context of the quality piece.

22 So I think you all need to balance

1 this with it is the first time we are looking
2 at these. These measures were just developed.
3 They are tested. They have been looked at in
4 many ways. They are being implemented within
5 some community. So your ratings may be low,
6 but it is in part because of just the state of
7 where we are with everything. David, did you
8 want to add anything?

9 CHAIRMAN PENSON: Yes. I don't
10 know how, given what you have said, that we
11 can vote anything other than insufficient,
12 because we just don't have any information
13 from the measure developer; and frankly,
14 because it is in flux with NQF, it is going to
15 make it very difficulty for us to make any
16 conclusions.

17 I would argue, perhaps tomorrow or
18 the next day or on a phone conference with the
19 Steering Committee, that I wouldn't dismiss
20 these measures just because we don't have this
21 level of evidence.

22 MS. BOSSLEY: And I think part of

1 what you will do in framing in the Steering
2 Committee will be part of this, as well as
3 framing that. This, again, is the first step,
4 and we, again, don't know what the
5 implications are, how this will work out, and
6 I think it is part of a broader look in the
7 way of resource use combined with quality, and
8 then in general.

9 This is something that most of our
10 steering committees struggle with when they
11 see new measures, because there is no
12 information most often on how they are being
13 used and how useful they are, how
14 understandable they are.

15 So you are not the first, and you
16 won't be the last to struggle with this. So
17 we do have a committee looking at this
18 specifically and, as we have more information,
19 we will provide it back to everyone.

20 CHAIRMAN PENSON: So I am going to
21 perhaps make a jump and wonder if anyone feels
22 that they would be able to vote anything other

1 than insufficient here. If so, that is okay,
2 but just holler out now. Steven?

3 DR. CHEN: I am fine with
4 insufficient. I do want to throw out
5 something when we get to 3b for the folks to
6 consider.

7 CHAIRMAN PENSON: Oh, absolutely.
8 We are going to go through each one
9 individually. I am not suggesting that we
10 blanket it, but at least for 3a, which is
11 useful to the public, we just don't know at
12 this point. Okay.

13 Then I will move on to 3b, which
14 is that the results are meaningful and
15 understandable and useful to the intended
16 audience for both reporting and quality
17 improvement.

18 DR. GILLIGAN; Yes. So I think,
19 for me, actually the discussion we have had
20 kind of sums up where I fall on this issue,
21 which is we have had a lot of debate about how
22 we interpret this and what the meaning is, and

1 my reading of the debate is it is really not
2 clear to us what the meaning of it is.

3 So I rated it low for that reason,
4 that it is just not clear yet what the outcome
5 of this is going to mean to anyone.

6 CHAIRMAN PENSON: So would that be
7 a low or insufficient?

8 DR. GILLIGAN: For me, that is a
9 low.

10 CHAIRMAN PENSON: Okay. I think
11 that is very reasonable. Steven, you had a
12 comment with 3b specifically.

13 DR. CHEN: Yes. It is somewhat of
14 what Tim was just saying. To the extent that
15 I have issues with validity, I also have
16 issues with portraying to the public a thing
17 that I consider potentially invalid. But on
18 top of that, I do want to throw out something
19 with standardized pricing as it pertains to
20 public reporting.

21 Standardized pricing, to me, makes
22 a lot of sense as a researcher, because I want

1 to equalize resource utilization. What the
2 public might actually care about, though, is
3 what they are going to be charged.

4 So if some hospital has an
5 extraordinarily high charge for something that
6 some other hospitals are an extraordinarily
7 low charge for, from the public's perspective
8 the resource utilization is dramatically
9 different, even if they do an identical thing.

10 DR. KLOTH: If I can inject some
11 additional thoughts on that question, that
12 very important question, as we move forward --
13 presently and as we move forward, there is a
14 nationwide recurring, ongoing problem with
15 drug shortages of a panorama of drugs which
16 are involved in the care of these patients,
17 including propofol.

18 So shortages and those related
19 issues and dealing with shortages can have
20 wildly fluctuating impacts on what the costs
21 are to the provider and, therefore, the cost
22 to get passed on to the patient.

1 In some cases, providers have to
2 go to what I would call the black market. It
3 is more generally called the gray market. You
4 could call it scalpers, but the question is,
5 when there is instability in the supply chain
6 of medications, it can have significant
7 impacts.

8 CHAIRMAN PENSON: I think those
9 are good points. I also wonder if, to some
10 degree, we have captured that already in the
11 validity piece with the standardized pricing,
12 but again, the question now is: Given that,
13 is it useful for public reporting?

14 What I am hearing is concerns.
15 The questions is whether or not those concerns
16 warrant a low vote or whether they warrant
17 just more evidence, and that is a matter of
18 personal opinion.

19 Other thoughts on reporting and
20 quality improvement vis a vis whether or not
21 these are meaningful? I would add, and I rate
22 insufficient, I think as a consumer, and a

1 consumer looks at what is a risk adjusted
2 score for a provider, what they cost, even if
3 you put quality on it, I am not sure a
4 consumer -- and I am not condescending to the
5 consumer, because I am a health care consumer,
6 too. I am not sure what to make of that.

7 If Dr. Smith versus Dr. Jones'
8 ratio is 1.2 versus 1.1, how do I use that?
9 Maybe there will be more evidence to tell me
10 how to do that. You know, I will get my
11 Consumer Report circle or something down the
12 road. That is where I think we are going to
13 end up, frankly.

14 That being said, for me I just --
15 I don't know what to do with this. So I am
16 between low and insufficient, leaning more
17 toward insufficient.

18 DR. POTTERS: I think it would be
19 unfair to -- this is just my opinion. It
20 would be unfair to vote insufficient, given
21 the fact that, for Section 2, we had a hard
22 time on the validity part of it.

1 So given the fact that we
2 understand this, to a large degree, more so
3 than the general public, to just say it is
4 insufficient and yet the validity doesn't
5 count or doesn't show at least a high vote
6 would not be right.

7 CHAIRMAN PENSON: I know exactly
8 what you are saying, and the question becomes,
9 did you capture that in the earlier vote or do
10 you want to -- I don't know a better way to
11 put it -- double jeopardy? I don't know. I
12 think in the end the whole thing is a Gestalt.
13 Whether it is low or insufficient, as Sally
14 alluded to when we started, if it is not
15 moderate or higher, the Steering Committee is
16 going to have a hard time running with it. I
17 will tell you that up front. Steven?

18 DR. CHEN: In distinguishing
19 between the two, I guess the way I meant to
20 think about it is I tend to vote insufficient
21 if I think the part has validity, and if they
22 just give me more information, I could vote

1 high. I vote low when I think this is
2 probably not fixable. Even if you manage to
3 fix the validity, I'm still not comfortable
4 that this should be released to the public.

5 CHAIRMAN PENSON: Yes, and that is
6 kind of where I am playing out in my mind,
7 too.

8 MS. TURBYVILLE: I just want --
9 Before you vote, that it is important to
10 remember that what we are talking about is
11 various types of public reporting as
12 demonstrated in this slide. So certainly, it
13 is important to think about the individual
14 consumer, but there are potential other uses
15 for the measure for you to deliberate as you
16 think about your potential ratings for this
17 measure.

18 CHAIRMAN PENSON: All right.
19 Let's keep plowing through the threes and
20 fours and get to a break, because even I am
21 getting tired now.

22 So let's talk about 3c which is

1 the clinical and construction logic, and that
2 is basically, that the data and result detail
3 are maintained such that the resource use
4 measure, including in the clinical and
5 construction logic, defined in the measure can
6 be decomposed to facilitate -- and here is the
7 magic word when I reviewed this --
8 transparency and understanding.

9 Again, I will throw this to Tim.

10 DR. GILLIGAN: Yes. For me, that
11 is the key word at the end there. Most people
12 rated this moderate or high, and some curious
13 people still feel that way about it.

14 I think this O to E ratio and what
15 it means was a concern I had, which is why I
16 gave it a moderate, but I did think that with
17 more evidence -- I think that does have
18 meaning. It just needs to be spelled out a
19 little bit more as to what that is going to
20 mean, but I don't want to confuse 3b and 3c,
21 because I think we raised a lot of issues on
22 3b, and 3c is a separate issue, and we should

1 look at that cleanly.

2 I think, for my money, it deserved
3 a higher score than 3b, because I think the
4 problems there can be fixed with more data.

5 CHAIRMAN PENSON: So I was the
6 outlier here, looking at everyone's scores.
7 The reason I did was -- and perhaps I am not
8 being fair about this -- was something caught
9 my eye in looking at the provider report,
10 which was that you had reporting by specialty
11 type, and then the magic word, peer group; and
12 peer group was not well defined.

13 I think, as a clinician, I get
14 very nervous when something can be turned on
15 the -- maybe I shouldn't wear my clinician
16 hat, but I think that is why we are all --
17 those of us who are clinicians are here.

18 I think that needs further
19 discussion, because in the end, when you are
20 going to have accountability and comparisons
21 between providers, and you are going to have
22 potentially physician tiering, whatever it is,

1 you need to be completely transparent, and it
2 wasn't, to me. But I was probably a little
3 harsh. No getting around that.

4 Other comments with 3c? All
5 right, I will keep moving along to 3d. 3d --
6 what's that? It's N/A.

7 MS. TURBYVILLE: Right. So we
8 didn't ask the developers to try and harmonize
9 at this point. If we get in the process and
10 they need to, we will work with them to do
11 that.

12 CHAIRMAN PENSON: Terrific. All
13 right. So let's then vote on the threes now,
14 and then we will, hopefully, get through the
15 feasibility quickly and take a break.

16 So the 3a is regarding measure
17 performance, that there would potentially be
18 reported to the public at large and national
19 community reporting programs by the time of
20 endorsement maintenance review, and discussion
21 about exceptions.

22 This was the one where we stopped

1 and discussed whether or not there was no
2 evidence presented and that NQF is still sort
3 of moving on this. I think the general
4 feeling -- I don't want to sway -- I do want
5 to sway the vote. We sort of said it was
6 going to be insufficient. So let's go ahead
7 and vote. We stopped the discussion based on
8 it, and it's okay.

9 See, someone is messing with me,
10 okay? That's fine. As long as you meant to
11 do that, I'm fine with that. Dr. Potters --
12 it's always the radiation oncologist messing
13 with the urologist. I'm teasing you.

14 All right, let's move on to 3b.
15 So just for the folks on the phone, one person
16 voted moderate. The rest of the panel voted
17 insufficient. I would argue that I don't
18 think that is a negative reflection on the
19 measure.

20 3b is usability: Did the measure
21 results -- Are they meaningful,
22 understandable, and useful to the intended

1 audience, for public reporting, quality
2 improvement? We could have discussion here.
3 Go ahead and vote.

4 There we go. So this one, 3b, we
5 had six votes for low and three for
6 insufficient.

7 3c in usability is around clinical
8 construction logic. The resource use measure,
9 including the clinical construction logic for
10 defined measurement, can be decomposed to
11 facilitate transparency and understanding.

12 So here we have seven votes for
13 moderate and two for insufficient. And,
14 obviously, 3d was not applicable.

15 So let's see if we can't run
16 through the feasibility measures. I think
17 they will be relatively quick, and then we can
18 take a break.

19 We are going to 4a, which is
20 regarding the byproduct of care. For clinical
21 measures, the required data elements are
22 routinely generated and used during care

1 delivery. I don't think we have an assigned
2 reviewer here.

3 For the most part, looking -- It's
4 me.

5 MS. WILBON: So, David, the 4a and
6 4b, because it is administrative claims data,
7 they are kind of --

8 CHAIRMAN PENSON: They are
9 assumed?

10 MS. WILBON: Yes, you guys can
11 still vote, obviously, but --

12 CHAIRMAN PENSON: Basically, that
13 is what I was going to say, is I don't think
14 there is a lot of discussion, that these are
15 routinely capture. We will vote at the very
16 end. And administrative data, I don't think
17 anyone is arguing with that

18 With 4b, again obviously, the data
19 elements come from administrative data claims.
20 So they are going to be there. I don't think
21 anyone is arguing with that.

22 4c is susceptibility to

1 inaccuracies, errors or unintended
2 consequences related to measurement, and these
3 are judge to be either inconsequential or
4 minimized or, alternatively, they can be
5 identified and avoided. So, Tim?

6 DR. GILLIGAN: Yes. I didn't see
7 any issues here, except those that are
8 inherent working with administrative datasets,
9 which are imperfect by definition. So I
10 didn't see any way they could do more than
11 they had done, honestly, on either 4c or 4d.
12 I think there are limitations to this
13 methodology, but you have to work with these
14 datasets to get the data.

15 CHAIRMAN PENSON: Anyone have
16 anything to add to that, or disagree? All
17 right, excellent.

18 Then we will just briefly discuss
19 4d. The data collection management strategy
20 can be implemented as demonstrated by
21 operational use in external reporting programs
22 or testing did not identify barriers for

1 operational use.

2 So, basically, can it be done?
3 Can it be operationalized in a reporting
4 program?

5 DR. GILLIGAN: I didn't see any
6 reason why it couldn't. There are always
7 going to be cost and manpower issues, but
8 other than that, I didn't see anything
9 exceptional here.

10 CHAIRMAN PENSON: And I think our
11 votes reflect that. Anyone want to add to
12 that? Okay, why don't we vote on this, and
13 then we can take a 10-minute break.

14 So 4a: This is basically required
15 data elements generated and used during care
16 delivery in an administrative dataset. I am
17 tempted just to vote by acclamation here.

18 I think we will do these two by
19 acclamation from now on. Oh, there we go.
20 Okay. Insufficient -- I don't want to put
21 anyone's feet to the fire, but given the
22 discussion, did someone vote insufficient by

1 accident? If not, again, the person who voted
2 insufficient -- we certainly need to include
3 some sort of comment. So could someone take
4 credit for that?

5 DR. POTTERS: I voted
6 insufficient. It wasn't clear based on what
7 the intent was, you know, by Sally's comment.

8 CHAIRMAN PENSON: All right. So,
9 basically, just again, the idea here is that
10 these are sort of very feasibility issues. So
11 in other words, do the data in the
12 administrative datasets -- are all the
13 required data elements routinely generated in
14 an administrative dataset and used for care
15 delivery?

16 So if that is unclear to you, if
17 it is insufficient -- is that how you
18 interpreted it? It's clear. So --

19 DR. POTTERS: I would go with the
20 consensus.

21 CHAIRMAN PENSON: Okay. So again,
22 you don't have to, Lou. So can we just

1 reflect that? So it will be eight votes for
2 high, and one vote for moderate.

3 For 4b, I am going to vote by
4 acclamation. Can everyone agree that it is a
5 high probability that the required elements
6 are available in an administrative dataset?
7 Okay. So we voted -- all nine voted for high.

8 Now this is where I think we do
9 have to have a vote, which is 4c.
10 Susceptibility to inaccuracies, errors, or
11 unintended consequences related to measurement
12 are judged to be inconsequential or can be
13 minimized or can be monitored and detected.

14 There we go. We have nine. So we
15 have four votes for high and five votes for
16 moderate.

17 The last one is barriers to use,
18 that the data collection and measurement
19 strategy can be implemented as demonstrated by
20 operational use and external reporting
21 programs or testing did not identify barriers
22 to operational use. Let's go ahead and vote

1 on that.

2 We have all nine. So we have four
3 votes for high and five votes for moderate.
4 Then I think we have to vote for the overall
5 feasibility, if I am not mistaken. No, we
6 don't? Okay, great.

7 So let's do this. We are running
8 a little bit behind, about 15 minutes behind
9 schedule, as it is. Let's take a 10-minute
10 break and reconvene at 20 of 12:00, with hopes
11 of going through the next one somewhat
12 quicker, although perhaps not much.

13 (Whereupon, the foregoing matter
14 went off the record at 11:31 a.m. and went
15 back on the record at 11:46 a.m.)

16 CHAIR PENSON: So we'll get
17 started again. With any sort of luck this
18 will go a little quicker. The reason I think
19 this will go quicker is because we'll sort of,
20 to some degree, try to truncate our comments.

21 I'll ask people to really focus on
22 Criteria 2, the scientific piece of it. I

1 think that we can spend a lot less time on the
2 importance part and certainly much less time
3 on usability and feasibility, because this
4 measure, in many respects, sort of
5 recapitulates the earlier measure.

6 And with that in mind I will ask,
7 are the ABMS Foundation folks still on the
8 phone? Have we scared you guys away? They
9 finally said we've had enough of those people.
10 Okay, very good. Well that makes it move
11 along even faster.

12 So the next measure we're going to
13 talk about is episode of care around treatment
14 of localized colon cancer. I just need to get
15 my notes up here. But basically I think that
16 this should be an interesting discussion.

17 In many respects it's very similar
18 to the last measure. I'm actually trying to
19 get the measure up here, so forgive me. But
20 I'll start the discussion while I'm getting it
21 up.

22 With regard to Measure 1a, which

1 is the does this address a goal priority
2 identified by the partnership, is this a high
3 impact issue? I think most people voted yes
4 on that. Is there any real discussion, anyone
5 feel this isn't a high-impact topic?

6 I sort of figured we'd end up
7 there, I think everyone voted this as high.
8 The next one is 1b, A Demonstration of
9 Resource Use or Cost Problem and an
10 Opportunity for Improvement. Is there data
11 demonstrating variation, delivery of care,
12 cross providers and population groups.

13 And this, to me, even though I
14 don't remember seeing a whole lot of evidence
15 presented that there's opportunity for
16 improvement here.

17 It was sort of my take on this
18 that there probably is real variation in the
19 way colon cancer is treated across the United
20 States, and by extension there's going to be
21 variation in cost and there is room for
22 improvement here.

1 I'll open it up to the floor. I
2 think some people, actually there were one or
3 two people who voted low here, and so I wonder
4 if there are people who have different
5 thoughts?

6 DR. WEISS: Just to note on the
7 telephone, with apologies. Kevin Weiss here,
8 we were on the line but we were not able to
9 speak, they had us muted.

10 So we're available to you, it
11 seems that you're well on the way so we're
12 available to you as you go forward.

13 CHAIR PENSON: Okay. Great,
14 before you comment I'll just invite the
15 measure developers if you want to add anything
16 specifically about this measure now would be
17 a good time.

18 DR. WEISS: Probably the only
19 thing I would say is that as you can imagine
20 this is, as the working group was deliberating
21 this issue of cancer the stages of cancer
22 became very much the issue of clinical concern

1 right up-front.

2 And the way that this was
3 addressed by the Work Group in an obvious way
4 is to find localized colon cancer by way of
5 treatment exceptions and that's how this got
6 built. For the members of the group I'll just
7 let you know I'm an internist not an
8 oncologist nor a surgical oncologist.

9 So I can't give you any of the
10 nuances with it to how this was decided, but
11 that was the intent of this measure and it's
12 we did not look at the more advanced cancer
13 related to colon cancer because of the
14 inability entirely to manage the staging
15 question.

16 CHAIR PENSON: So I'll just, you
17 kind of went in and out, but I'll just repeat
18 for the group as what I heard in you saying
19 was basically that this was limited localized
20 disease as best you could because you felt
21 that that would make it more comparable among
22 patients, is that a fair statement?

1 DR. WEISS: Yes.

2 CHAIR PENSON: Okay. Louise, you
3 were going to say something?

4 DR. WALTER: I guess one quick
5 thing on the stage, it sounds like they're
6 using colectomy as a proxy for stage, but you
7 could still have really quite advanced disease
8 and get a colectomy.

9 So actually my main, the reason I
10 voted this low was I didn't see how this was
11 going to identify, without the very important
12 clinical characteristics like histology or
13 stage, how it would identify meaningful
14 differences or, you know, inappropriate
15 variation versus variation based on how sick
16 the person was, as far as their disease.

17 CHAIR PENSON: And I think that's
18 a very well taken point and I know it's going
19 to come up again when we talk about risk
20 adjustment.

21 And I guess, just to interpret
22 what you're saying, Louise, is that you think

1 that's such an overwhelming problem that it
2 actually affects your ability to look among
3 differences in use. Other folks want to add
4 to that?

5 Okay. So I'll move on, again, to
6 1c which is the purpose or objective of the
7 resource measure are clearly described. I
8 think in this respect I think the purpose and
9 the objective is clearly described.

10 And I think most people felt that
11 way, but not everyone, so I'll throw it open
12 to the group here.

13 DR. WALTER: I guess my main
14 question, because I just didn't understand, is
15 this just going to look at variation of
16 chemotherapy or what is it that they're
17 actually, they don't actually have a
18 hypothesis unlike the colonoscopy one which
19 actually said we think anesthesia is going to
20 be different, we think complications are going
21 to be different.

22 I didn't see any hypothesis

1 around what they thought was going to be the
2 driver of costs.

3 CHAIR PENSON: So I'll put that to
4 the measure developers on the phone that one
5 of our panel members is having some real
6 concerns with this, which I think to some
7 degree I share.

8 And I think others on the panel
9 may as well, that it's really hard without
10 adjusting for things like stage and grade to
11 interpret these things.

12 And so what are your thoughts on
13 this vis-a-vis, what do you expect to find
14 here?

15 DR. WEISS: So the workgroup was
16 again driven by oncologists on the group and
17 the general surgeon input was, general and
18 colorectal surgeon input, was that they felt
19 that there was a lot of variability in
20 complications associated with the surgery,
21 some of which appeared not really post op, but
22 actually took a number of months to evolve.

1 And that it was important to
2 capture a long episode cross associated with
3 it and that would be associated with the care
4 that would encompass the ability to look at
5 the various types of complications that were
6 fixable over a short period. And major
7 complications that actually led to severe
8 issues of patient compromise.

9 It's not a quality measure,
10 clearly, but they understood it associated
11 with initial procedure and that they would see
12 the variation in resource use attached to
13 this.

14 CHAIR PENSON: So let me sort of
15 summarize what I hear you saying, Kevin, for
16 the group. And sort of help us to sort of
17 focus on the importance piece. And I think
18 this helps you, Louise.

19 Because what I hear you saying is
20 basically by focusing on patients who have had
21 colectomies, specifically, you think that
22 you're probably selecting for patients with

1 localized disease, which I think many of the
2 people in the room might disagree with you on.

3 The surgeons in the room, I think,
4 definitely would. But that being said, I
5 think it's a rough proxy to some degree,
6 maybe.

7 But what you're really
8 hypothesizing here is that you're going to
9 capture differences in cost primarily related
10 to surgical complications after colectomy.

11 Either immediately, post
12 operatively or afterwards. And that certainly
13 you have some stratification, like
14 chemotherapy that may or may not help. So is
15 that a fair summary, Kevin?

16 DR. WEISS: Correct. And the fact
17 that the costs associated with care,
18 particularly if there is a complication,
19 really would rest outside of the usual, if you
20 did it on a short-term morbidity, a 30 or 60
21 day window you'd miss a lot of the care
22 complications that may end up in long-term

1 care or long-term care needs in some fashion
2 or another.

3 So that's why the episode was
4 built around that long duration. The term of
5 the episode was built because that is the
6 treatment term for a localized colon cancer.

7 Now in addition it's recognized
8 that if a person had just localized -- and by
9 way of my listening to the working group I
10 don't want to say that I don't have the
11 clinical expertise in this area.

12 That if they have localized colon
13 cancer without chemotherapy that would really
14 bespeak the this is probably an advanced
15 disease.

16 Although there are some times when
17 one would do a rescue, kind of some sort of a
18 salvage operation to a person with colon
19 cancer, who has very advanced, to do a
20 colectomy. But to do that without chemo would
21 bespeak a localized process.

22 CHAIR PENSON: Okay. So I think

1 I'm going to sort of discuss with the panel a
2 little bit about how to interpret this.
3 Because I think they're going to be -- I see
4 you, Steven, so give me a second.

5 I think there are going to be
6 issues here with validity and risk adjustment
7 we're going to get into. But I think that
8 when we're looking at this first criteria,
9 which is sort of the importance to measure and
10 report, we really should sort of focus on the
11 importance.

12 And what I would say is based on
13 what Dr. Weiss has told us that this is really
14 focused on looking at sort of sequelae of
15 colectomy in colon cancer patients. That's
16 how we're going to kind of end up interpreting
17 this, that's the de facto what this is.

18 Is that going to be important and
19 meaningful? So that would be my comment.
20 And, Steven, you had your hand raised.

21 DR. CHEN: Yes, I was going to say
22 as far as lb is concerned I do think that

1 there's a big opportunity here because I do
2 think there is a fair bit of variation. As
3 far as 1c I think that discussion just
4 reflects exactly why I put moderate.

5 Because I didn't have a good sense
6 of what were they attacking. Because one of
7 the big variations is actually do Stage II
8 colon cancers get chemotherapy or not.

9 Somewhere around a third of them
10 do. And then about a third of people who are
11 Stage III who are supposed to get chemo don't
12 get chemo.

13 So the stratification on that
14 leads you to big issues. And then, not to
15 mention Stage IV people who get colectomies
16 anyway. But having said that I would say 1b
17 for me was a high and 1c was a moderate best
18 because I don't think there's clarity here.

19 CHAIR PENSON: So again, what I
20 will tell you here is I hear what you're
21 saying, I agree with you 110 percent, but
22 wonder if that's a question for the next

1 section on validity and risk adjustment. But
2 maybe not.

3 DR. WALTER: Well I guess my main
4 feedback was there's nothing about this being
5 sequelae for colectomy in anything on the
6 section on impact importance. So the feedback
7 to the developers would be put that in there,
8 because there's nothing about that.

9 CHAIR PENSON: Right. And I would
10 add that it's also about given the long-term
11 followup it's about sequelae of chemotherapy
12 as well. And if you look at the
13 accountability piece, the surgeons are only
14 held accountable for the first six weeks and
15 the rest goes to the medical oncologist and,
16 again, I think we'll get into this discussion
17 a little later, but that's a concern.

18 So with that being said I am
19 hearing some concerns with 1c specifically and
20 perhaps a little bit with 1b.

21 Let's just quickly go through 1d
22 which is the resource use service categories

1 that are included are consistent with and
2 represent a conceptual construct represented
3 by the measure.

4 And I think that for the most part
5 people were on board with that, if I'm not
6 mistaken. The people thought that the
7 categories made sense. Any disagreement on
8 that? And most of the scores were high or
9 moderate.

10 So again, not to truncate
11 discussion, I think to summarize where we've
12 been with this I think in the room people feel
13 that this probably is important but there are
14 some concerns. Because what exactly are we
15 measuring here. And we will get into that
16 with validity for sure.

17 But let's just accept the fact
18 that there's no discussion about the sequelae
19 of treatment, whether it's surgical or
20 potentially chemotherapy and it's not really
21 discussed well there. And I think that gave
22 people some pause. Anything else to add to

1 that, the summary?

2 Okay. So let's vote on this then.
3 So the first one is on the impact. Does the
4 measure focus on a specific national health
5 goal/priority, or is there evidence to support
6 that it's high impact, or in our clinical
7 experience is this high impact issue. So
8 let's vote.

9 I have to say I don't love this
10 voting system. We're missing two. We're
11 missing one, one. Nine, we've got them all,
12 good. So not surprisingly everyone voted this
13 was a high impact issue.

14 Let's move on to 1b, which was
15 demonstration of resource use, or cost
16 problems and opportunity for improvement. So
17 in other words is there a performance gap or
18 is there variation?

19 It's always that last one. There
20 you go. And this was, again, fairly
21 acceptable. Five people voted high for 1b,
22 and four people voted moderate.

1 1c, was the purpose/objective of
2 the resource use measure, including its
3 components, and the construct are clearly
4 described.

5 And I think let's just vote on
6 that. There we go, we have all nine. And so
7 we have two who voted high, six who voted
8 moderate and one who voted insufficient.

9 And I think the person who voted
10 insufficient I think we've had that discussion
11 if you feel that, I felt it sort of makes
12 sense.

13 So let's do the last one which is
14 1d, the resource use service categories
15 included are representative of the conceptual
16 construct.

17 Well let's just vote on it, it's
18 quicker. There we go, we have all nine. And
19 so we had five who were high, three were
20 moderate and one who was insufficient.

21 I'm going to call out the person
22 who was insufficient, just felt that the

1 comments that we already discussed cover that
2 or if they want to add anything else.

3 (Off microphone discussion.)

4 CHAIR PENSON: Okay. All right.
5 Why don't we just re-vote so it reflects it
6 properly?

7 Should end up five to four now. I
8 like it when that happens. So five voted high
9 and four voted moderate. Okay, excellent. So
10 now let's move on to the scientific criteria.

11 And we're going to start with the
12 first one, which is the measure is well
13 defined and precisely specified so it can be
14 implemented consistently within and across
15 organizations. And the assigned reviewer for
16 this was John.

17 DR. SKIBBER: Okay. I felt that
18 the measure would benefit from a more explicit
19 statement of the meaning of localized, because
20 that's not clear. Also it's going to be
21 important to eliminate any costs related to
22 disease surveillance that may develop during

1 that first year.

2 It's very common that patients are
3 going to followup for surveillance during the
4 first year, in fact it's in all the
5 guidelines. There's no accommodation for
6 eliminating those costs.

7 The one thing that's not
8 mentioned, and it may be an assumption by the
9 developer, is that from my experience of
10 looking at administrative databases that
11 differentiate colon from rectal cancer, that
12 is ill defined at best. They don't mention it
13 at all.

14 And I think they at least need to
15 acknowledge that the treatments are different
16 between those and that rectal cancer should
17 not be included.

18 The general approach is clearly
19 stated. The target population, that note was
20 not filled out on their submission sheet, but
21 I would assume is going to be fine. Data
22 inclusion and exclusion criteria are clear.

1 CPT coding for a colectomy is
2 extensive, to say the least, and includes a
3 number of procedures that are not commonly
4 done for colon cancer.

5 And I would say that when you look
6 at the way that they created an exclusion for
7 inflammatory bowel disease in the initial, the
8 colonoscopy set, and then you compare it with
9 this they completely ignored that.

10 So what that means is there is a
11 number of those, actually relatively high-cost
12 procedures that are done for either IBD,
13 polyposis, a variety of things that they don't
14 limit their colectomy definition to.

15 And that muddies the patient
16 population somewhat. I'd like to either, they
17 should at least either acknowledge this or
18 recreate this in some fashion.

19 CHAIR PENSON: So maybe I'm
20 misinterpreting this. But are you saying that
21 basically there are going to be patients who
22 are included in this measure who did not have

1 a colon cancer diagnosis?

2 DR. SKIBBER: They might have had
3 it, however the setting in which this cancer
4 was found and treated is going to be
5 substantially different than, what I think is
6 the purpose and a very worthwhile one, which
7 is to look at the patient who's undergoing a
8 routine colectomy. So that might be a
9 consideration.

10 CHAIR PENSON: So let me just
11 state this so I understand and also so that
12 the measure reviewers, your concern is that a
13 patient comes in with say IBD and is having a
14 total colectomy for symptoms and they find a
15 unexpected colon cancer and that patient's
16 included?

17 DR. SKIBBER: Yes.

18 CHAIR PENSON: Okay.

19 DR. SKIBBER: And you know, the
20 procedures that they have described some of
21 them are very high-end technical procedures
22 for patients with unusual conditions, like you

1 just described. I'm sure their working group
2 is well aware of this and probably felt that
3 it wasn't important, but --

4 CHAIR PENSON: And, John, how
5 important do you think it is? I mean is it a
6 fatal flaw, is it a minor point?

7 DR. SKIBBER: No it's a fixable, I
8 would consider it's a fixable thing. If I was
9 trying to do something that was really going
10 to be resource efficient and really look at
11 the issue of localized colon cancer I would
12 adjust that.

13 But just to carry on and not
14 belabor that, the way that they capture costs
15 appears to be reasonable and clear. To get
16 into the risk adjustment it's a similar, for
17 me at least, it's a similar set of problems.

18 CHAIR PENSON: Right.

19 DR. SKIBBER: To the colonoscopy
20 issue. Probably more important here, the
21 comorbidity is, the way this adjustment is
22 used, again the statistician can address his

1 concerns, I'm not aware of any valid way to
2 take into account the way that they created
3 their risk adjustment strategy, as said
4 before.

5 CHAIR PENSON: So just for the
6 sake of process, because I think we're going
7 to have that discussion when we get to the
8 specific risk adjustment sub-criteria, but
9 let's table that.

10 And by the way it's very similar
11 to the last measure and I think we're going to
12 come up with a lot of the same things.

13 Let's just focus just on that 2a1
14 to start with, which really is, if you feel
15 that it's well defined and precisely
16 specified. And I'm hearing that it's not
17 perfect but it's okay?

18 DR. SKIBBER: Right.

19 CHAIR PENSON: Other comments?

20 DR. KLOTH: A couple of questions.
21 I just can't figure out if these patients that
22 are collected as part of this measure will be

1 patients receiving adjuvant chemotherapy, yes
2 or no?

3 And if so I can't find if they're
4 going to stratify per KRAS testing, which is
5 a vital component of determining what is
6 optimal therapy. I just couldn't, if those
7 portions are there I just couldn't see them.

8 CHAIR PENSON: So they're not, as
9 best I could tell. And I'll let the folks on
10 the phone correct me if I'm wrong. They do
11 control for adjuvant chemotherapy in that they
12 stratify their analysis by date the patient
13 received chemotherapy or not afterwards.

14 Now whether or not the people in
15 this room feel that's adequate is another
16 discussion which I think we're going to have
17 in a little while.

18 But as far as KRAS testing, you
19 know, I mean I suppose that could be captured
20 in an administrative data set, so I'll ask the
21 folks on the phone, did you guys attempt to
22 capture that at all?

1 DR. WEISS: Let me see if Todd Lee
2 is available. He was on mute and I'm not sure
3 he's been able to get off mute.

4 DR. LEE: So can you hear me now?

5 CHAIR PENSON: Yes, we can.

6 DR. LEE: Okay. Good. I didn't
7 mean to be a Verizon commercial, sorry. Yes,
8 all of the testing as part of the standard
9 care of the patient undergoing a colectomy is
10 intended to be captured.

11 So the KRAS testing will be
12 captured as long as it's captured in one of
13 our CPT codes that's listed here or it has a
14 eligible ICD-9 associated with that claim. We
15 do not stratify the population by receipt of
16 a KRAS test.

17 CHAIR PENSON: All right. I think
18 that answers Dwight's question, thanks Todd.
19 Steven?

20 DR. CHEN: All right, since this
21 has to do mostly with implementability and
22 reproducibility, I think my concern, one of

1 them harkens with John was saying as far as
2 the reliability of people who, they get a
3 colectomy for a large sessile polyp or
4 whatnot, partially colectomy and then it's
5 found to be cancer later, whether they're
6 going to be included or not.

7 Because the measure says that they
8 have to have ICD-9 code and the operation on
9 the same claim-line. Now some institutions
10 will go back and change the ICD-9 code and
11 bill it properly. Some institutions quite
12 frankly are too lazy to do that. So I have
13 worries about reproducibility as it pertains
14 to that.

15 The other issue I have goes back
16 to the colon and rectal issue. They're
17 radically different diseases, I think for
18 reproducibility and for reliability sake you'd
19 want to separate them.

20 But the more you separate them the
21 less reproducible it's going to get. And
22 that's a conundrum I don't think is --

1 CHAIR PENSON: Well I actually
2 think so we will get to sort of the
3 reproducing and reliability piece. But just
4 stick on this first part, this 2a1, I think
5 that it critical.

6 Because if you don't feel that you
7 can group colon versus or not the measure
8 specified the right pop rectal patients
9 together that speaks to whether population on
10 the measure.

11 And I'll defer to both you,
12 Steven, and you, John, as colorectal surgeons
13 whether or not you feel that's an appropriate
14 grouping.

15 And if you say no, it fatally
16 flaws it, I think that's something that the
17 panel needs to know. We rely on you guys for
18 your clinical opinion on that.

19 DR. SKIBBER: I think there's two
20 points there. One is that the ICD-9 coding is
21 different. So within the limitations of that
22 that's fine.

1 The other thing is that, and I
2 think I got this from the initial presentation
3 by the developers, was that their working
4 group decided, as many of the working groups
5 do on this, decided to say it's really almost
6 an intention to treat.

7 If they were treated as a colon
8 cancer then they were, you know, then that's
9 the way it's going to work out for this
10 measure, which is fine. I don't have a big
11 problem. But there definitely will be some
12 overlap.

13 One thing that might be helpful
14 though is to exclude any radiation therapy.
15 I don't see that addressed. Commonly rectal
16 cancer is treated with that and that's a big
17 difference than colon.

18 And so if that could be either
19 considered as an exclusion that might be
20 helpful in clarifying that.

21 DR. CHEN: Yes, I do think they
22 need to be separated. In every paper I've

1 every written about colon, I've written about
2 colon specifically. In every paper I've
3 written about rectal I've written about rectal
4 specifically.

5 The papers that have combined the
6 two I've criticized heavily at meetings to say
7 that you're mixing apples and oranges.

8 CHAIR PENSON: Okay, and can that
9 be done with administrative data comfortably
10 for you guys? So I wonder and, Sally, are we
11 better off voting after each discussion with
12 the sub-criteria or taking it on whole do you
13 think?

14 MS. TURBYVILLE: There's a benefit
15 of moving through maybe 2a2, but if you think
16 the conversation is so lengthy that you want
17 to capture it quickly we're fine with that.
18 But it may be worthwhile to go 2a1, 2a2. And
19 then we can dive into validity after that.

20 CHAIR PENSON: Okay. I'm fine
21 with that. So what I'm hearing, to wrap up on
22 2a1, is that on the one hand the measure is

1 well defined, it is specified and it can be
2 implemented consistently.

3 But I'm also hearing some real
4 concerns from the clinical experts that the
5 way it's defined and the way things are
6 grouped may not be acceptable.

7 There's another way to put it.
8 And I'm hearing real concern, basically no, I
9 can't do it from Steven and at least moderate
10 concern from John.

11 And so I think that that's
12 something worth considering when we take into
13 votes. Certainly if you accept that you can
14 do colon and rectal together I think it's
15 certainly specified and clear.

16 Let's talk a little bit about
17 reliability and repeatability. I think many
18 of the issues here are going to be the same as
19 what we saw in the earlier colonoscopy
20 discussion.

21 So what I'll ask to do is I'll ask
22 Jay, who has been assigned to talk about

1 reliability, to add anything. And if you
2 think it's the same as the earlier measure
3 just say so and then ask Carlos to add.

4 DR. SCHUKMAN: I think it's
5 primarily the same as the earlier measure
6 there. You know there was a comment,
7 something earlier on in here and you
8 referenced it earlier, is the issue between
9 the surgeons and the oncologists and splitting
10 them up and looking at it.

11 Because attribution is always an
12 issue. Always an issue going forward and I
13 want to put that out there.

14 CHAIR PENSON: Yes, I agree. I
15 think this is a real concern here. You know
16 the question becomes at least, and I think
17 we'll come into that particularly when we get
18 to reporting in 3. But can you reliably and
19 reproducibly assign to a surgeon and a medical
20 oncologist? I worry about that.

21 DR. SCHUKMAN: Yes, I do too.

22 CHAIR PENSON: I really do.

1 Carlos, your comments and your review on the
2 reliability piece?

3 MR. ALZOLA: No I feel that the
4 same comments as for the other measures apply.
5 In the sense that how reproducible it is for
6 someone who wants to implement the measure.
7 But I guess I agree that the attribution is
8 going to be a problem.

9 CHAIR PENSON: Okay. Other
10 comments on reproducible or reliability?
11 Dwight.

12 DR. KLOTH: A question. This is
13 stimulated by a discussion we had at Med Onc.
14 Faculty meeting just yesterday. And the
15 pending mandatory conversion to ICD-10 coding
16 rather than ICD-9.

17 What I see in the document is ICD-
18 9 and I can't find any reference to ICD-10 and
19 if or how they're going to address that.

20 CHAIR PENSON: You know this is
21 where my grandmother would look and go "Oy" so
22 --

1 MS. WILBON: So if I can,
2 actually, I did a project here in NQF last
3 year on ICD-10 coding. We actually have
4 gathered a group to think about how we might
5 be converting our whole portfolio of measures
6 at this point that are based on ICD-9 codes,
7 use 9 codes and we're going to have to convert
8 them at some point all to ICD-10.

9 So we actually have some processes
10 that we're putting in place now to work with
11 measure developers to get those measures
12 converted. And at this point just where this
13 project happens to fall we won't be requiring
14 them to submit ICD-10 codes until October.

15 So we'll be working with them
16 through maintenance and annual updates
17 processes that we have imbedded in our NQF
18 review process.

19 CHAIR PENSON: So yes, Sally says
20 don't worry about it now. Which I kind of am,
21 but is it safe to say, because Dwight I think
22 you raised an important point. Not just for

1 this panel but unfortunately for everything we
2 do.

3 But is it safe to say that we can
4 proceed on ICD-9 only and in the maintenance,
5 assuming it's endorsed in review, they'll deal
6 with the ICD-10 question, is that a fair
7 statement?

8 MS. WILBON: Yes, that's fair.

9 CHAIR PENSON: So I'll ask you, I
10 mean, Dwight, it's a great question. I have
11 no clue how I see it, God knows, oy. But
12 let's just go on the assumption that ICD-9 is
13 okay with this, if that's all right with you
14 all.

15 (Off microphone discussion.)

16 CHAIR PENSON: Yes, it's going to
17 be ugly, it's going to be really ugly. Other
18 questions about reliability/reproducibility,
19 comments? All right. Not having heard any.

20 So what I'm hearing, we talked a
21 little bit about, we're going to vote now on
22 2a1 and 2a2. I'm not hearing overwhelming

1 concerns about reliability/reproducibility,
2 but going back there are some that Carlos
3 raised earlier with the colonoscopy measure,
4 and I think there are some here as well.

5 And I think are reflected in an
6 earlier discussion. So let's go ahead and
7 vote. First on 2a1, which is the
8 specifications.

9 And again, this is the one where
10 basically I think, if I can summarize. If you
11 feel comfortable grouping colon and rectal
12 together then you probably are okay with this
13 and if you feel that's a fatal flaw you want
14 to reflect your vote here.

15 DR. LEE: Can I, this is Todd Lee
16 from ABMS.

17 CHAIR PENSON: Yes, sure.

18 DR. LEE: Can I ask a clarifying
19 question there? Because our measure focuses
20 solely on colon cancer from a diagnostic code
21 standpoint. The intent was to focus on colon
22 cancer.

1 We realize folks with rectal
2 cancer may get in. So am I hearing that that
3 would have been the preference that we would
4 have explicitly excluded people with a rectal
5 cancer, ICD-9 code?

6 Because right now that group is
7 not included unless they also have a colon
8 cancer diagnostic code.

9 CHAIR PENSON: So, Todd, I'm glad
10 you jumped in there. Your timing is very,
11 very good. So looking at the colorectal
12 surgeons they would have preferred that those
13 were specifically excluded.

14 The question becomes is, if a
15 patient has both a colon cancer code and
16 rectal cancer code, because if they just have
17 a rectal cancer code what you're saying, Todd,
18 is that they will not be included in the
19 measure, correct?

20 DR. LEE: That's exactly correct.

21 CHAIR PENSON: Okay. So my
22 question to the content experts in the room

1 is, all of the patients have a colon cancer
2 code. Some of them will also have a rectal
3 cancer code as well. What do you think about
4 that, Steven?

5 DR. CHEN: Yes, that's still going
6 to be a problem. Because you're still going
7 to treat their rectal cancer with radiation
8 oncology.

9 They have much higher incidence of
10 using chemo at lower stages. It's a dramatic
11 difference in their resource utilization to
12 have any rectal cancer component.

13 CHAIR PENSON: And if you either
14 excluded them or at least stratified them
15 would that make you feel better about the
16 world? So Steven said yes. Just so Todd and
17 Kevin you hear that. John do you agree with
18 that?

19 DR. SKIBBER: Yes, I think if
20 there's an explicit exclusion that's clear
21 it's fine.

22 CHAIR PENSON: Okay. So I think

1 with those comments we can vote now. So for
2 the benefit of the folks on the phone, seven
3 people voted moderate and two people voted
4 low.

5 And I would strongly suggest that,
6 I think I know who voted where. I would
7 strongly suggest that you consider the
8 comments of the two people who voted low.

9 And next we'll vote on 2a2, which
10 is reliability. Does reliability testing
11 demonstrate the results are repeatable and do
12 they get the same results the high proportion
13 of the time when assessed in the same
14 population and the same period.

15 Let's go ahead and vote on that.
16 Okay. And so you have eight votes for
17 moderate and one vote for insufficient. And
18 I think that's based on prior discussions
19 which have been had. We'll keep moving along
20 then.

21 (Off microphone discussion.)

22 CHAIR PENSON: Oh, sorry. We

1 have to -- thank you, vote on overall
2 reliability. Was the overall reliability
3 testing both based on the two prior.

4 And here we have nine people who
5 voted moderate, so I guess we consensus. Not
6 what I expected, I don't know why, but okay.
7 Very good, I guess that's a good straw for
8 that.

9 So let's keep moving along. At
10 some point I'll get hungry and then get cranky
11 and then we'll really be in bad shape.

12 (Off microphone discussion.)

13 MS. TURBYVILLE: Did you try and
14 plow through some scientific acceptability and
15 then --

16 CHAIR PENSON: Yes, let's try to,
17 let's see where we're at, but I think what
18 we'll probably do is we'll plow through the
19 scientific acceptability. Break for five
20 minutes to get lunch and then do a working
21 lunch to hopefully catch up.

22 So let's look at the evidence

1 question that measure specifications are
2 consistent with the evidence presented, or at
3 least your clinical spin on the evidence, to
4 support the focus of measurement.

5 And that the measure is specified
6 to capture the most inclusive target
7 population indicated by the evidence.

8 And so this may be another area
9 where we can talk about that colon versus
10 colon versus rectal piece. And this will be
11 John.

12 DR. SKIBBER: I basically said my
13 piece on this before. So if they take that
14 into account I am happy with where they
15 include patients. You know this also works
16 down to the issue of the, well, I think it's
17 fine basically.

18 CHAIR PENSON: All right, did
19 others have new information to add? I think
20 we've covered a lot of this. I'm sorry, go
21 ahead.

22 DR. CHEN: Is this where we talked

1 about the stage issue, here? Or should I hold
2 that for validity testing?

3 CHAIR PENSON: I would hold that
4 for validity or even risk adjustment, I think
5 that's a critical piece. I wonder if that's
6 not in the risk adjustment piece.

7 But in the end, because it can't
8 be fixed in the risk adjustment, it may be a
9 validity issue.

10 But here it's basically that the
11 evidence presented, you know, supports the
12 focus of the measurement and it captures an
13 inclusive population. So I think the staging
14 piece should probably wait. Other comments?

15 DR. KLOTH: A question.

16 CHAIR PENSON: Yes, sir.

17 DR. KLOTH: And maybe there's
18 other portions where this would be applicable
19 but I'll ask it now. And if the authors are
20 on the line.

21 How will they track chemotherapy
22 costs delivered in the hospital outpatient

1 department. Because that's not, I see
2 reflected ambulatory, take-home tablet costs.

3 That's by NDC code. But I don't
4 see where they're going to track the actual
5 chemotherapy resource utilization?

6 CHAIR PENSON: So I will refer
7 that to the folks on the phone. To some
8 degree it goes back to something we discussed
9 earlier with the service categories. But Todd
10 or Kevin, could you answer that question?

11 DR. WEISS: Yes, we have a long
12 list of J codes in the specification that are
13 intended to capture those chemotherapies that
14 are delivered in an outpatient chemo unit or
15 something like that.

16 CHAIR PENSON: Okay. Thanks, I
17 appreciate that, Todd. So I think we've
18 discussed 2b1 regarding the specifications
19 being consistent with evidence.

20 I think we should move on to 2b2,
21 which is validity. Where we're going to have,
22 I think, a more sort of interesting

1 discussion.

2 Now to remind you validity testing
3 demonstrates that the measured data elements
4 are correct and that the measure score
5 correctly reflects the cost of care and
6 resource provided. So in other words are we
7 capturing what we say we're capturing.

8 And I don't think is where we have
9 a discussion about staging, which I think
10 comes in sort of, but maybe it does come here
11 as well, it really comes into risk adjustment.
12 But I'll throw open the floor and I'll ask
13 Carlos to comment on this.

14 Let me actually do this the same
15 way we've done it. Dwight, you were the
16 primary reviewer for this. Do you have
17 anything to add? And then I'll ask Carlos to
18 comment.

19 DR. KLOTH: I'm going to disclose
20 that I didn't get to, I did not complete my
21 homework assignment.

22 CHAIR PENSON: You're a good man

1 to admit it and you are forgiven. You are
2 smarter than me. Jay?

3 DR. SCHUKMAN: I just have a
4 comment here on J codes. Particularly when
5 you collect J codes. I mean there are a lot
6 of administrative data limitations around J
7 codes.

8 Because you're not going to
9 capture all of them, particularly in hospital
10 outpatient facilities. Because of the revenue
11 codes. You just simply aren't going to
12 capture those J codes. So I already see and
13 issue with that here.

14 The other thing I noticed here is
15 that despite the robust database that they had
16 our there, you know, there were only 1,843
17 episodes that qualified, which I think is a
18 limitation right there.

19 That's a fairly limited number of
20 episodes that met the inclusion criteria. The
21 other thing that's interesting, as you might
22 imagine, the chemotherapy group was much

1 higher in cost that the non-chemotherapy group
2 overall. So while the average was 65,000
3 they're way out there on the tails.

4 CHAIR PENSON: So those are really
5 key points and that's right where we are now
6 with this validity discussion. Because what
7 you're basically saying is that capturing,
8 we're not measuring what we think we're
9 measuring. Or we're not doing a good job
10 doing it.

11 So I think those are very
12 important points. Let me just, before we, let
13 me just ask Carlos to chime in on his thoughts
14 on validity here.

15 MR. ALZOLA: Well, again, for
16 validity the same thing I look at is whether
17 the distribution of the cost along the
18 different lines of service made sense.

19 And again, I think we found that
20 what made sense that the chemotherapy group
21 was, in the cost, was a lot higher than for
22 the other group.

1 And within those lines, I think
2 that, again, for the non-chemotherapy group
3 the majority of the costs were attributed to
4 the inpatient stays and the colectomy
5 qualifying.

6 So again, in terms of tests what
7 seemed clinically reasonable in terms of which
8 are the components of the cost, that made
9 sense to me.

10 CHAIR PENSON: Other comments on
11 validity? Louise.

12 DR. WALTER: Just a quick thing
13 about the vast majority of people who have
14 colon cancer are over 65 and, again, this was
15 not at all looked at in that population which
16 I think is a big problem.

17 CHAIR PENSON: Yes, I think that's
18 a very key point. That, you know, validity
19 goes with generalizability and can you
20 generalize and so I think that's a key point.
21 Steven?

22 DR. CHEN: Two things on validity.

1 One and then full disclosure. I do have
2 research contracts with some of the genomic
3 assaying companies, but they're very tests and
4 to the extent that they start getting you're
5 probably going to want to track that. Because
6 they're going to run about \$3/\$4,000 a pop.

7 The other thing though, I'm very
8 worried about validity in the terms of what's
9 a Simpson's paradox for people. Their case
10 mix is going to highly determine where these
11 patients fall in.

12 And so you could have someone
13 who's cheaper on both the chemo patients and
14 cheaper on the non-chemo patients and look
15 worse overall.

16 And you could also be incenting
17 poor care in the sense of you have someone who
18 really looks expensive, they're Stage II, if
19 you give them chemo you can kick them into the
20 higher expensive group because you're
21 stratifying based on chemo.

22 And so again it lends towards

1 promoting inappropriate care here.

2 CHAIR PENSON: So that's a problem
3 we're always going to end up with here. I
4 mean you've got to remember that it's, I think
5 it's NQF's belief that these should not be
6 used in isolation, that they need to be
7 coupled with a quality measure down the road.
8 You know because obviously sometimes cheaper
9 care is worse care.

10 So we have to go on the assumption
11 that there will be some sort of quality tied
12 to it. But I think the points you raise are
13 very valid and need to be considered. So
14 other comments with validity testing?

15 So what I'm hearing, you know, we
16 talked about some issues with 2b1 with the
17 evidence but I'm really hearing concerns about
18 validity.

19 I'm hearing concerns about
20 generalizability. Jay's comments about
21 whether or not we actually are capturing all
22 the costs are really in the sweet spot for

1 this criteria.

2 And the comment that you have such
3 a small number of players who are ultimately
4 in there makes you wonder if perhaps something
5 is being missed. I think Steven's comments
6 are well taken as well.

7 So I am hearing some concerns here
8 and I'm not sure they're completely
9 addressable. Rohit.

10 DR. BORKER: One question. And
11 this point of -- so this might apply generally
12 to all the specific measures is the
13 enrollment, the company's enrollment, that by
14 definition these people have to be in the data
15 system for a certain time.

16 So are we excluding patients who
17 are more severe or have a more aggressive
18 disease. They may not be metastatic when they
19 are seen but they could have, you know, severe
20 disease that they die and most likely to be
21 more expensive. Are we excluding them? And
22 it applies to this --

1 CHAIR PENSON: I think, you know,
2 when you look at a one year period, without
3 being able to control for stage, which I don't
4 want to give this away, but to me that's the
5 Achilles tendon here and it's not fixable in
6 my opinion.

7 You know, but the fact of the
8 matter is is that if you have a really
9 advanced patient who has a colectomy, turns
10 out they have a really advanced disease and
11 they die three months later your efficiency
12 measure is going to look great, because he
13 didn't run up any costs for nine months.

14 So you're going to penalize a
15 doctor either for his case mix or potentially
16 even for being, you know, not giving a
17 treatment when he should if you don't have a
18 quality measure to go with.

19 As far as the continuous, two
20 years continuous coverage, I think what we
21 discussed earlier applies here as well. So
22 I'm going to keep us moving because I am

1 getting hungry which is always a bad sign.

2 The next one was exclusions and
3 there are some patients excluded. We talked
4 a little bit about the colon versus colon and
5 rectal and I don't think we have to visit that
6 again.

7 For the most part I think people
8 were okay with the exclusions in the
9 preliminary. Although I think that may change
10 now that we've had this discussion about colon
11 tumors versus colon and rectal tumors. Do
12 other people want to discuss exclusion
13 criteria here?

14 I'm seeing no's. And Sally's
15 rolling over here to say something to me.

16 MS. TURBYVILLE: Not necessarily
17 great news. So we're still waiting for part
18 of the lunch and it should arrive at 1:00.

19 CHAIR PENSON: Okay. That's
20 perfect, we're going to tie it up perfectly.
21 They're going to time it perfectly.

22 MS. TURBYVILLE: We don't want you

1 starving.

2 CHAIR PENSON: It's all good.
3 It's all really good. As long as I keep
4 drinking coffee we're in great shape. It's
5 all right. I've done worse.

6 DR. WALTER: Actually I'll jump in
7 one other quick thing. Because they did
8 mention in their specifications that they
9 wished they could have looked back more than
10 a year to exclude people with colon cancer,
11 because obviously you're still going to
12 include people that had colon cancer two years
13 ago, three years ago and is that a big
14 problem.

15 CHAIR PENSON: I think that's a
16 very reasonable point. Steven?

17 DR. CHEN: I would also throw out
18 the possibility for them to consider excluding
19 people who by the nature of their treatment
20 appear to have metastatic disease.

21 For instance they get a liver
22 resection within the year. That's someone who

1 has metastatic disease.

2 CHAIR PENSON: But you know the
3 question with that becomes, you know, it's
4 almost it's post-hoc, so someone has a
5 colectomy and then have a liver resection
6 three months later. But you know, you're
7 looking backwards, it's hard to do that.

8 I mean I think in the end we're
9 going to get into the risk assessment
10 discussion and, simply put, it's hard to do
11 this unless you control for stage. And I
12 don't grade in colon cancer as well. But
13 certainly stage. You know, node stage, nodal
14 status and metastatic status is almost
15 meaningless to me without that.

16 So I think on that note I'm going
17 to keep us moving along because I think we
18 need to have that discussion now. We're up to
19 2b4, which is the risk adjustment piece.

20 And basically to remind everyone
21 here, do outcome measures have an evidence
22 based risk adjustment strategy? Is it based

1 on patient clinical factors that influence the
2 measured outcome?

3 Or they should have rationale for
4 not having risk adjustment. And I'll start
5 the discussion to repeat what I just said.

6 When I read this measure, without
7 being able to control for stage of
8 presentation, it's meaningless. It's just not
9 fair.

10 And one could argue that well
11 you're going to have, if you're going to
12 accountability then you're going to have, Dr.
13 Smith and Dr. Jones are going to have random
14 assignment of metastatic patients that it's
15 going to be the same across the board.

16 But John's shaking his head and I
17 don't buy that either. I mean there are docs
18 out there who attract the worst cases and you
19 could easily risk adjust that and say SEER-
20 Medicare.

21 But you can't do it in Market
22 Scan, you don't have stage information. And

1 to me I see it as a fatal flaw and I'll open
2 up to the floor.

3 DR. GILLIGAN: And the problem is
4 here, Medicare is just only part of the
5 country so that's not a national data.

6 CHAIR PENSON: I don't think
7 anyone has used SEER-Medicare in this setting
8 for public reporting. I'm not aware of that.

9 DR. WALTER: And from my reading
10 they didn't do any risk adjustment, right. So
11 I always laugh at measures that look at the
12 same kind of care for people 18 to 85. I mean
13 that seems a little --

14 CHAIR PENSON: So no, there is, I
15 think there was an error in the submitted form
16 as opposed to what's online. And Kevin and
17 Todd jump in here. They used the same risk
18 adjustment for this measure that they did for
19 the colonoscopy measure. That's correct isn't
20 it, Todd?

21 DR. LEE: The intent is to use the
22 same measure. But because, I think, as you as

1 you all have noted, we had such a small sample
2 size here our risk adjustment models would
3 have been very questionable simply because
4 we're only talking about just over 1,800
5 cases.

6 So our measure specifications are
7 developed so that we will do further risk
8 adjustment testing in additional populations.
9 We don't have any risk adjustment data that
10 was presented as part of this submission.

11 CHAIR PENSON: Okay. That helps.
12 Because when you go online you talk about that
13 HCC model again.

14 DR. LEE: Correct. And that was
15 just to illustrate the process through which
16 we will do risk adjustment for this episode.

17 We did not test it in the, or test
18 our risk adjustment methodology in the Market
19 Scan data because of the small sample size
20 that we were dealing with.

21 CHAIR PENSON: Okay. So that
22 clears things up, although it doesn't really

1 help. In that I think --

2 DR. WEISS: Kevin here real quick.

3 CHAIR PENSON: Go ahead, Kevin.

4 DR. WEISS: This is very helpful
5 to us and again I really appreciate your input
6 back to us as measure developers.

7 One of the things that kind of,
8 that I'm trying to understand, for the experts
9 in the room. To have a colectomy for colon
10 cancer and not treat with anything else, is
11 that the, because I heard that that concern
12 was that we may not be capturing people who
13 have nodes and other stuff.

14 Would that ever be not treated if
15 it was beyond, you know, would they ever take
16 someone with an advanced stage and not treat
17 them?

18 CHAIR PENSON: Steven's shaking
19 his head, I'll defer to him.

20 DR. CHEN: Yes, about a third of
21 people how have Stage III colon cancer, which
22 the consensus guideline is pretty clear that

1 they should all get chemo barring some sort
2 of, you know, some other comorbidity that
3 prevents them from doing so, about a third of
4 people don't.

5 And then when you get to Stage IV,
6 there are a fair number of people who may
7 chose something else because they have
8 overwhelming disease. They may chose hospice
9 or no further treatment.

10 CHAIR PENSON: You know my problem
11 with it is, just to jump in. I don't mean to
12 interrupt you, John, but the problem is it's
13 circular reasoning. Your outcome, which is
14 cost, is also your, you know, an independent
15 variable in a model which is controlling for
16 stage. So that's not how you do an analysis
17 in my mind.

18 You can't have your proxy for
19 stage also be an outcome measure, it doesn't
20 make any sense.

21 DR. GILLIGAN: Also it sets up a
22 scenario, like you said, where you reward

1 people for giving poor care.

2 CHAIR PENSON: Yes, I mean to me,
3 I'll say up front that I don't want to be too
4 heavy handed but I'm a voting member as well.

5 That on the one hand I would say
6 insufficient if I believed that the HCC model
7 that you've put together for, well I shouldn't
8 say you, I'm not speaking directly to you
9 Kevin or Todd.

10 I just, I would feel comfortable
11 if I felt that the HCC model ultimately could
12 risk adjust here then I say insufficient
13 evidence. But the fact of the matter is is
14 that without stage I just don't think it's
15 doable. So to me it's done before we even
16 start.

17 DR. WEISS: That's very helpful to
18 hear your reflections of that. The working
19 group, of course, went through the same
20 consideration of concern.

21 I mean I think they carried much
22 of the same concerns and felt that this was

1 way to manage this. But that's actually very
2 good to hear your reflections here.

3 CHAIR PENSON: I would defer to
4 John and Steven. I'm a urologic oncologist so
5 I'm probably talking out of school, but I
6 suspect I'm not wrong.

7 DR. SKIBBER: You know that's why
8 my first comment was that they need a
9 definition of localized. Because the
10 significant number of patients that present
11 with metastatic disease there's no individual
12 treatment for Stage IV disease. There are
13 guidelines but those patients tend to have a
14 variety of presentations.

15 Some of which require a colectomy,
16 many of which, frankly, and this is supported
17 in the literature, is that there's a
18 significant number of patients that go on to
19 have chemotherapy without colectomy.

20 And so until you get to the point
21 where at least say it's Stages I through III
22 versus a Stage IV patient you really have an

1 ill defined population.

2 DR. CHEN: Yes. So I think I
3 would have less concern if say this was 60 day
4 episode where I can say, you know, we'll have
5 you do the surgery, whatever.

6 But once you start to get into how
7 you treat them over the next 14/15 months it
8 becomes a huge problem.

9 And if they can't use their own
10 cancer registry or the NCDB or something like
11 that you've got issues that I think, as you
12 say, are basically unsolvable.

13 And the other thing is just to
14 commend to you the idea that if you were
15 looking at large regions you might be able to
16 say well it washes away because it's okay.

17 But your average surgeon in the
18 country does fewer than ten colon cancers a
19 year. And so there's no ability to get a
20 large enough sample unless you use their whole
21 career.

22 CHAIR PENSON: We'll get into that

1 region issue this afternoon, with the breast
2 measures. Tim.

3 DR. GILLIGAN: All right, I was
4 just thinking the breast measures that we're
5 going to talk about this afternoon, they
6 stratify people based on which chemotherapy
7 they got.

8 And that would be one, at least,
9 step in the direction of trying to balance
10 against this bias this talking about if we
11 don't control first.

12 CHAIR PENSON: Yes and they do
13 talk about seraphying by receipt of chem
14 versus not. Although they don't do by type.
15 And the question becomes do you think that's
16 a reasonable proxy.

17 Other comments on risk adjustment?
18 I've think we've beaten this one deep into the
19 ground. Carlos.

20 MR. ALZOLA: Yes, one comment that
21 I just didn't realize until today is that how
22 many resources they incur depends a lot on how

1 long they live. So all those patients who die
2 quickly, or soon, are, again, reflect a low
3 amount of resource use only because they die.

4 So I think that should whatever
5 risk adjustment approach they take in the end
6 they need to consider that. I mean you can
7 use some kind of sensoring method that are
8 kinds for sensoring or some kind of exclusions
9 but I think that's an important thing to
10 consider.

11 CHAIR PENSON: I think that's a
12 well taken point. It's really problematic,
13 and even if you had stage you'd still have
14 other issues as well. So again other issues
15 with risk adjustment?

16 So I think we're all hearing a lot
17 of concerns here. Why don't we do 2b1 through
18 2b4 now? Only because I think they tend to
19 fall together.

20 So the first one, 2b1, is
21 regarding, is validity and do the measures,
22 are they consistent with the evidence. And

1 just again to summarize, I think there was
2 some discussion here and some concerns about
3 whether or not this fell in line.

4 There we go and so this one split
5 with five people voting moderate, three people
6 voting low and one person voting insufficient.
7 And I think our comments certainly reflect
8 that.

9 Next is 2b2, which is validity
10 testing. That the testing demonstrates that
11 the elements are correct and they measure the
12 score correctly and they measure resource use
13 correctly.

14 And there were a number of
15 comments raised here as well. And here we had
16 one person who voted moderate and eight people
17 who voted low.

18 Next we'd go to 2b3 which were the
19 exclusions. Any exclusions are supported by
20 clinical evidence otherwise they're et cetera,
21 all that stuff. Are the exclusions
22 appropriate is basically the bottom line here.

1 CHAIR PENSON: Yes, it does
2 doesn't it. And here we had six people who
3 felt that the exclusions moderately met the
4 criteria and three felt low, it did not.

5 And let's, finally, to risk
6 adjustment. And obviously we had a long
7 discussion about this. There we go. And so
8 we had seven who said low and two who said
9 insufficient. And I, again, think that
10 reflects our discussion nicely.

11 Let's keep moving along, we're
12 actually picking up a little time now which is
13 good. We'll move on. We'll finish up the
14 scientific piece. We're on to 2b5 which is
15 the looking at differences.

16 So basically does the data
17 analysis demonstrate that the methods for
18 analysis and scoring allow for identification
19 of statistically significant or clinically
20 meaningful differences in performance or is
21 there evidence that overall less than optimal
22 performance.

1 And basically I actually wrote not
2 applicable and I'm not exactly sure why I did
3 that. I'll throw it open to the floor.

4 DR. WALTER: I mean I didn't think
5 they addressed this. So I voted insufficient.
6 But I never know whether it should be low or
7 insufficient, but.

8 CHAIR PENSON: Go ahead, Steven.

9 DR. CHEN: I voted low last time
10 for the same rationale I did for the previous
11 one, which is to say I don't think this is
12 fixable, as choosing that over insufficient.

13 CHAIR PENSON: Of the folks in the
14 room. I mean basically, obviously you can
15 generate statistically significant differences
16 in resource use, but how that get interpreted,
17 particularly in the absence of adequate risk
18 adjustment is problematic. I don't know why
19 I wrote not applicable.

20 DR. GILLIGAN: I think in the
21 report, they just said that they weren't
22 addressed. And I guess, I don't know, I put

1 not applicable too. I think that's probably
2 what I was --

3 CHAIR PENSON: So I guess the
4 question becomes probably not that it's not
5 applicable but it just would then be
6 insufficient. Or if you don't believe that
7 this is going to make for meaningful
8 differences you'd vote low.

9 Is there anyone who wants to speak
10 on a positive note? So I mean I think I was
11 in the same place with this. I don't think --

12 MS. TURBYVILLE: Let me see. Let
13 me just make sure.

14 CHAIR PENSON: So it'll be the
15 S12's. We're looking at 1584. It's a lot of
16 paperwork.

17 MS. TURBYVILLE: It is.

18 CHAIR PENSON: Sure it is.

19 MS. TURBYVILLE: So here,
20 presumably is a sample report.

21 CHAIR PENSON: That's the provider
22 report, so that's --

1 MS. TURBYVILLE: That's not
2 helpful. And then SA reliability and
3 validity. It's fine if you didn't find it, I
4 just want to make sure.

5 CHAIR PENSON: I know where I'll
6 find it.

7 MS. TURBYVILLE: So starting with
8 S11.6. I know, it's harder to think when
9 you're actually, at least for me, navigating.

10 CHAIR PENSON: Here we go. So
11 we're looking at S12's is basically it.

12 MS. TURBYVILLE: So if we had the
13 sample report. Let me see.

14 CHAIR PENSON: So type and score,
15 so here it is right here. It writes type of
16 score is a ratio. They have a sample report,
17 interpretation is an O to E.

18 And again if you're going to have
19 an E you have to have risk adjustment that
20 works. So at this point it remains to be seen
21 if that's the case.

22 There is a detailed score

1 estimation of how it's put together. But
2 again, the E depends on the risk adjustment
3 model. And so basically it's just O to E
4 ratios.

5 DR. WALTER: Isn't this also a
6 fatal flaw in that they're trying to do these
7 artificial windows of attributing costs to the
8 oncologists and surgeon. Like somehow they
9 hand off versus doing it at the same time. So
10 I think that would also be a problem with
11 this.

12 CHAIR PENSON: So basically what
13 I'm hearing from the group based on this is
14 that all we have is a sample report, an O to
15 E ratio with a risk adjustment that we don't
16 know anything about.

17 There are issues of accountability
18 which will come up again, I think, in criteria
19 3, but probably are worth mentioning here as
20 well.

21 That it may not be, it affects a
22 meaningful ability to interpret the scores.

1 Other comments where this is concerned? Okay.
2 We get now to multiple data sources. And just
3 for the sake of time we're not combining data
4 sources here.

5 This goes the same as before and I
6 think we said not applicable before. So let's
7 just sort of avoid that discussion.

8 The last discussion here would be
9 in disparities in care. If disparities in
10 care have been identified measure
11 specifications, scoring analysis allow for
12 identification of disparities through
13 stratification of results.

14 This is by race, ethnicity, SES or
15 gender. Or alternatively they justify why
16 it's not there. The stratification we're
17 seeing here is by receipt of chemotherapy.

18 And I think this does get back to
19 were we were before. You can obviously
20 stratify it by gender in the Market Scan data,
21 but you can't stratify by race or SES.

22 And I think the question is is

1 this important? I would argue it's got some
2 meaning and some importance. So certainly you
3 can't do it, so other comments?

4 MS. TURBYVILLE: I think how we
5 scored it last time.

6 DR. KLOTH: Just to repeat an
7 earlier comment that KRAS testing is critical
8 and if that's not well described.

9 CHAIR PENSON: Well yes. That's
10 going to be, I don't know when they talk
11 about disparities I don't think they're
12 talking about stratification by KRAS testing
13 but more population characteristics, like
14 race, stage.

15 So I think we can probably go
16 through 2b, finish up 2. Let's do differences
17 in performance.

18 This is again, just to go through
19 this, this is basically looking at are these
20 differences measurable, statistically
21 significant and clinically meaningful.

22 So let's go ahead and vote on

1 that.

2 Yes, I think everyone's getting
3 hungry. Three more. So the majority of the
4 people voted low, three people voted moderate,
5 six people voted low. I think the comments
6 reflect this. Specifically what I think
7 Louise said.

8 Next is multiple data sources,
9 this is not applicable so we can switch over
10 this one. We have to do overall validity and
11 then we'll do disparities.

12 So what is your overall gestalt
13 for the validity testing, this includes risk
14 adjustment, it includes the ability to catch
15 what we're measuring, et cetera.

16 And I guess it does include
17 stratification for disparities. That
18 shouldn't be there, okay. So let's go ahead
19 and vote on what we talked about.

20 So it's actually we have
21 consensus. The panel feels low, everyone
22 voted low validity. And unfortunately I think

1 that will be reflected by the steering
2 committee with this measure.

3 Let's do disparities next. So we
4 talked a little bit about disparities of care
5 and stratifying by various groups.

6 So we actually have a spread here.
7 One person voted high, two people voted
8 moderate, three people voted low and three
9 voted insufficient.

10 I'm wondering again, I don't mean
11 to call people out, but for the person who
12 voted high do you mind just saying why?

13 DR. BORKER: Sure this is one
14 thing, the reason why I voted high is because
15 even the fact that the database lacks race
16 information or socioeconomic status, it's a
17 limitation of the database.

18 But to me if that data is
19 available there's nothing preventing this
20 measure from using that data to stratify.
21 That's the reason I --

22 CHAIR PENSON: Okay. So I think

1 that the message there is, if I can interpret
2 that a little bit just for the comment, that
3 basically much of what is there is acceptable
4 to you and the pieces that are missing that is
5 a flaw that should be addressed in future work
6 but you can live with it as is?

7 DR. BORKER: Right. And this only
8 applies to the stratification, not necessarily
9 the validity part of it, so absolutely.

10 CHAIR PENSON: Okay. Terrific.
11 Let's keep plowing along. I think we can do
12 this part relatively quickly. I think we can
13 be done by ten after one if I'm lucky today.
14 So next we're going to talk about usability.

15 And I'm the primary reviewer here
16 and I think many of the issues that we dealt
17 with with the colonoscopy are going to be the
18 same issues here.

19 Frankly what we end up here, the
20 first one, 3a, is this reportable to public at
21 large in the community reporting programs.

22 And at this point I felt it was

1 indeterminate. This is being tested through
2 the RWJ contract and this is changing in NQF
3 and I think, just like before, it's probably
4 the same issues and you should vote more or
5 less the same way you did for the breast
6 biopsy. I think it's insufficient. But defer
7 to others.

8 Okay. This is where it does get a
9 little bit more interesting with 3b which is
10 the performance results are meaningful,
11 understandable and useful to intended
12 audiences both for public reporting and
13 quality improvement.

14 And here initially I thought it
15 was sort of indeterminate, that there wasn't
16 a lot of evidence there.

17 But now as I start to get a better
18 understanding of what's going on with the risk
19 adjustment and these O to E ratios I'm
20 somewhat between low and indeterminate.

21 Because I have no evidence that
22 the risk adjustment works. So in some

1 respects I should just leave it as if you gave
2 me evidence I'd feel better. But then I know
3 full well that the risk adjustment method is
4 not going to control for stage and I think
5 that'll kill it.

6 So in the end I don't know how we
7 can interpret this because of those
8 limitations. Comments?

9 And then 3c which is the clinical
10 and construction logic. You know, this is
11 where you have transparency and understanding
12 and this is where I sort of got hung up on the
13 accountability piece.

14 That how can you accrue costs in
15 the first 42 days after surgery to the surgeon
16 and everything after that to the medical
17 oncologist?

18 As a surgeon if I get a parastomal
19 hernia it's going to show up six months later
20 and woe be my poor medical oncologist who's
21 now going to pay for my poor technical skills.
22 Not that she would ever blame me in a million

1 years because she loves me so much.

2 But the point is to me that's
3 where the construction falls apart.
4 Everything else I could live with. But that
5 is where the accountability piece came in.
6 Comments?

7 DR. SKIBBER: One small part of
8 that is the other side of the coin, which is
9 that their period for the accountability for
10 the surgeon is 30 days before the colectomy.

11 And frankly a large part of the
12 staging work up on a diagnosed patient may
13 occur during that time, which really may or
14 may not actually be under the control of the
15 surgeon.

16 Those things are often patient
17 comes with all their X-rays and whatever tests
18 anybody else thinks they ought to have before
19 they show up in the office. And I just think
20 that speaks to the same issue you've brought
21 up.

22 CHAIR PENSON: Other comments?

1 Steven.

2 DR. CHEN: I think going on
3 further with that that also as we get back to
4 rectal cancer there's a lot of neoadjuvant
5 chemoradiation is happening.

6 CHAIR PENSON: So I think there
7 are issues there. Other comments? So why
8 don't we vote on the usability piece.
9 Obviously harmonization is not applicable
10 here. So let's start with useful to the
11 public.

12 Are these results reported to the
13 public at large, is there evidence that these
14 are available. And again this is what we
15 talked about before, they're with RWJ and NQF
16 is still sort of all over the place here.
17 Should I not say that for the public record?
18 I apologize, I'm hungry, I'm punchy.

19 MS. TURBYVILLE: It's your
20 interpretation.

21 CHAIR PENSON: The steering
22 committee is on part of that, I just threw

1 myself under the bus. So we had one vote for
2 moderate, one vote for low and seven for
3 insufficient.

4 And now we'll move on to
5 usability, 3b, did the information demonstrate
6 that the results produced by the measure are
7 meaningful, understandable and useful for
8 information for QI and public reporting. Or
9 if not was a credible rationale presented?

10 Let's go ahead and vote on that.
11 And this one we have eight votes for low and
12 one for insufficient. Next is for the
13 clinical and construction logic.

14 The data and result detail are
15 maintained such that resource use measure,
16 including the clinical constructional logic
17 for the defined unit of measure, are
18 transparent and facilitate understanding. And
19 here we have eight votes for low and one for
20 insufficient.

21 And obviously we're passing on the
22 harmonizing one. So let's quickly go through

1 feasibility and then we'll break for lunch.

2 I'm hypoglycemic at this point, let's put it
3 that way.

4 So basically with feasibility with
5 4a and 4b, just to refresh everyone's memory,
6 this is more about administrative data claims
7 and I would actually see if I can't push us
8 through for acclimation for A and B.

9 So for A this uses administrative
10 aid and the required data elements are
11 routinely generated and used during care
12 delivery. So blood pressure, lab tests,
13 diagnosis and medication order.

14 So for things like genetic testing
15 and KRAS testing, I think it would be captured
16 in the administrative data set, is that a fair
17 statement? Steven? Dwight?

18 If it gets paid for it would be
19 captured, right?

20 DR. CHEN: Sorry. The genomic
21 information almost certainly would be because
22 it's a significant bill. I don't know if KRAS

1 would show as specifically KRAS or just some
2 sort of extra staining, depending whether they
3 do it by dish or not.

4 DR. KLOTH: I think that's an
5 appropriate concern. Or if it was done gratis
6 for some reason by a lab and not billed.

7 CHAIR PENSON: Well I think
8 anything that's done gratis that doesn't get
9 billed we miss. I mean that's a limitation in
10 administrative data. But it will get captured
11 if they want to get paid, correct?

12 DR. KLOTH: I would tend to think
13 so. And I'm sorry for continuing to harp on
14 this. But KRAS is such a critical issue.
15 When cetuximab first came out and then
16 panitumumab.

17 Initially it was that EGFR testing
18 was critical. And then we realized, and it
19 was presented ASCO 2008, that what really,
20 really makes a difference is KRAS testing.
21 And that is just so fundamental.

22 CHAIR PENSON: Well, but we're

1 capturing, I understand your concerns and I
2 think we've discussed it in the risk
3 adjustment piece. But the question here is do
4 we capture if it's billed as a resource use.
5 And I think the answer is yes from what you're
6 telling me.

7 DR. KLOTH: Well if their database
8 capture technique is all encompassing of
9 everything that would ever be billing for that
10 patient from time point A to time point B then
11 presumably the answer would be yes.

12 CHAIR PENSON: And I think we have
13 to go on that assumption. Because it's all
14 about the Benjamins here. So is it fair,
15 would everyone agree that this is probably
16 high?

17 DR. KLOTH: Sorry, me again.
18 There is one other thing to consider. They
19 may or may not capture variable drug costs if
20 they're primarily at J codes. Because J codes
21 is a function of a CMS billing unit.

22 It's not a function of what the

1 hospital or health care provider paid for
2 Leucovorin, generic, versus levoleucovorin or
3 if they had to switch because of shortages
4 from one brand of a drug to another brand, et
5 cetera.

6 CHAIR PENSON: And I think we've
7 sort of captured that in the validity
8 discussion. The question is if they got some
9 sort of agent, whether it was generic or brand
10 name, is that captured in the administrative
11 data? For commercial --

12 DR. KLOTH: Well it wouldn't be
13 reflected in the J code. Because J code is
14 what Medicare is willing to pay.

15 CHAIR PENSON: Okay, so why don't
16 we vote on it then. I think that's probably
17 the best way to do this. Let's vote on 4a,
18 are the required data elements routinely
19 generated and used during care delivery. So
20 we had six people who voted high and three
21 people who voted moderate.

22 Okay. On to 4b, which is the

1 required data elements are available in the
2 electronic health records. And if they're not
3 in the electronic health records there's a
4 credible near-term path. So I think our
5 earlier discussion applies here as well.

6 We can just vote on this as well.
7 And here we have eight for high and one for
8 moderate. Now let's just have a relatively
9 quick discussion about 4c and 4d and then we
10 can all eat.

11 So 4c is about errors and
12 inaccuracies. Susceptibility to inaccuracies
13 and errors and unintended consequences related
14 to measurement are judged to be
15 inconsequential or can be minimized.

16 And I think this is an area where
17 potentially you could factor in these issues
18 with J codes and different medications.
19 Discussion before we vote?

20 All right, I think we can have a
21 vote then. Hunger is an incredible motivator
22 isn't it. So here we had four people who

1 voted moderate and five people who voted low.

2 And I think that the low votes
3 here, for the folks on the phone, reflect
4 people's concerns as Dwight raised and Jay
5 raised and Steven raised about J codes and
6 whether or not that there can be errors in
7 there that'll lead to incorrect values.

8 So the last one is 4d. The data
9 collection and measurement strategy can be
10 implemented as demonstrated or testing did not
11 identify barriers to operational use.

12 And basically in looking at this I
13 think that if nothing else their certainly
14 demonstrating they can collect the data and
15 that they can measure things fairly well.

16 Other comments? Okay. Not
17 hearing any let's vote on this. So here we
18 had four people who said high, four people who
19 said moderate and one person who said low.

20 I will ask the person who said low
21 just if they can provide some rationale for
22 the NQF team to feedback to the measure

1 developers. All right, now who voted low?
2 Did someone vote low by accident? You want to
3 try that again?

4 Let's try that again. Keep voting
5 now. It's like Chicago, vote early, vote
6 often. There we go. All right, so four voted
7 high, five voted moderate. I think we have
8 the summary of feasibility one and then we can
9 take a break.

10 That's it? Okay. So why don't we
11 do this. Let's take ten minutes to get our
12 food, get ourselves comfy and then we'll start
13 working again. Before we do that we have to
14 ask if there's anyone from the public on the
15 phone.

16 MS. TURBYVILLE: Operator, if you
17 could open the line and see if anyone from the
18 public line has questions or input for the
19 technical advisory panel.

20 OPERATOR: And that is star, one
21 for any public comment at this time. We have
22 no public comment at this time.

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MS. TURBYVILLE: Does anyone in the audience have questions or input for the panel at this time?

CHAIR PENSON: Okay. So let's go get some lunch and start again about 1:20, 1:25. And we'll work while we eat.

(Whereupon, the meeting went off the record for lunch at 1:14 p.m. and resumed the meeting at 1:40 p.m.)

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A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:40 p.m.

CHAIR PENSON: Probably get started. But my hope is that we are running about a half hour behind. But my hope is that the breast cancer issues will be a little bit easier.

The reason I think that they may be somewhat easier is that basically with these measures that one of the major differences between these measures and the morning's measures is that there is no risk adjustment whatsoever.

And so that may or may not be acceptable to you as individual panel member. Because remember that these are not going to be accountable by provider.

They're going to be reported out by region and so in this setting the rationale is that because we're doing this by region and not individual provider it will wash out.

And you may or may not think

1 that's true. So before we start on the
2 measures I'm going to invite the folks from
3 the ABMS Foundation to say a couple words
4 about the two breast cancer measures.

5 We're going to start with the
6 episode of care for the newly diagnosed cases.
7 And then we'll get into the biopsies. So
8 Kevin or Todd if you want to say a word or two
9 about these measures that would be great.

10 DR. LEE: Sure, this is Todd. If
11 it's okay I'll start with the biopsy one first
12 just because it makes for me in talking about
13 them sequentially. So the focus of the biopsy
14 measure is to look at resource use in the 60
15 day period preceding a breast biopsy.

16 The Work Group felt that there was
17 going to be substantial variability in the
18 diagnostic work-up of a woman who had screened
19 positive leading up to the biopsy for
20 determining whether or not the person has
21 breast cancer, and wanted to capture the
22 resource use in this 60 day period preceding

1 the advent.

2 I should not that we also then go
3 seven days beyond the biopsy event to capture
4 the resource use that might happen because of
5 claims lag and so forth.

6 But essentially the workgroup felt
7 that there was going to be enough variability
8 regionally in the actual biopsy procedures
9 that were done and the diagnostic testing
10 leading up to the diagnosis that would provide
11 enough variability and resource use to look at
12 amongst this episode. If that's okay I'll
13 move to our breast cancer treatment measure?

14 CHAIR PENSON: Go ahead.

15 DR. LEE: Okay. So our breast
16 cancer treatment measure looks at newly
17 diagnosed cases of breast cancer over a 15
18 month period, that's following their
19 diagnosis.

20 I should say in the title we say
21 it's a 15 month period but it's actually a
22 year and a half because we go backward in time

1 for three months to look at resource use
2 leading up to the diagnosis and then 15 months
3 following the initial diagnosis.

4 We use an algorithm that's been
5 validated in the SEER-Medicare data to
6 identify new diagnosis for finding our breast
7 cancer cases.

8 We then use these patients and
9 follow them forward, again, for 15 months
10 capturing breast cancer related resource use,
11 stratify the population into four groups,
12 those that receive chemotherapy with
13 trastuzumab.

14 Those that receive but
15 chemotherapy but don't use trastuzumab. No
16 chemo and then a neoadjuvant chemo group and
17 look at what our workgroup defined as breast
18 cancer related resource use during that
19 period.

20 I'll make the final note that all
21 of this, as you noted, is reported at the
22 regional level. Our workgroups felt that it

1 was not necessary to use risk adjustment
2 following, because of the regional measure and
3 we weren't trying to attribute this at the
4 physician level.

5 Largely because of the concerns
6 about not being able to measure stage that you
7 all talked about for our colon cancer
8 measures. And I'll stop there and listen to
9 you guys and answer any questions that you may
10 have.

11 CHAIR PENSON: Thanks, Todd. So
12 we're going to dive into it here. The order
13 is the newly diagnosed breast cancer episodic
14 care for a case of newly diagnosed breast
15 cancer.

16 Do people want to do that one
17 first? Or would people feel better starting
18 with the biopsies first? Or if no one cares
19 we can just keep to the agenda.

20 I don't see anyone really caring.
21 So that's good, that's a good sign. Sally I
22 think we've broken them.

1 MS. TURBYVILLE: You weren't
2 supposed to say that out loud.

3 CHAIR PENSON: It's okay, it's so
4 darn obvious at this point. Okay. So let's
5 start with the episodes of care for treatment
6 as, then that's 1579.

7 And so basically let's sort of go
8 through the importance first and then we'll
9 get into number two. And so I'll sort of lead
10 the discussion here.

11 And I think that these are, I
12 think, for the most part looking at this there
13 was fairly high agreement here with regard to
14 importance. Although not 100 percent by any
15 stretch.

16 With 1a, almost across the board
17 looking at whether or not this addresses a
18 health goal priority by DHHS or the National
19 Priorities Partners.

20 I think everyone sort of felt this
21 was a high impact condition. Breast cancer is
22 really common. There are a lot of costs

1 associated with it. Anyone want to add to
2 that?

3 DR. WALTER: I only voted for
4 moderate because I actually wasn't sure how
5 important it was to look at regional levels.
6 Especially when I wasn't really sure what
7 regions they were looking at.

8 CHAIR PENSON: And I think that's
9 a good point. I don't know where exactly that
10 sort of comes in here. Whether it's the
11 impact level or the opportunity for
12 improvement or maybe it's usability and
13 usefulness to the public. I mean what does
14 public, even for accountability reporting
15 issues.

16 How do you interpret what goes on
17 at a regional level. And so I think that's a
18 reasonable issue. I think we can certainly,
19 I think we will visit that again later. But
20 I think beyond that I'm hearing consensus that
21 this is probably high impact.

22 Opportunity for improvement.

1 Again this is where there is demonstration of
2 problems with resource use or cost and an
3 opportunity for improvement. Specifically
4 variation, delivery of care, cross providers
5 and population groups.

6 I think for the most part again
7 people thought this was a fairly high,
8 obviously people know about geographic
9 variation from the Dartmouth Atlas and other
10 places.

11 Although one or two people voted
12 it moderate to low, so I'll open it up to the
13 floor and see if people still feel that way
14 and if so why.

15 DR. GILLIGAN: I just, are we on
16 1b, am I --

17 CHAIR PENSON: Yes, we're on 1b.

18 DR. GILLIGAN: I just think the
19 whole concept behind these measure that we can
20 improve spending by looking at variations in
21 spending, to me it's a hypothesis. I haven't
22 seen a lot of evidence, honestly, to support

1 that. So I think that's why I put moderate
2 down.

3 That I think it'd be nice to see
4 more evidence supporting that. Because it's
5 not, I mean in some way you could argue that
6 the huge problem in cancer right now is that
7 we have all these really, really expensive
8 drugs and expensive imaging technologies. And
9 they're approved for use and they're in the
10 guidelines.

11 And if you practice the guidelines
12 it's extraordinarily expensive if you provide
13 standard of care. And that that's where the
14 crisis is then variations in care are less
15 important than the fact that we have these
16 hugely expensive treatments and no one's
17 controlling the costs of them.

18 CHAIR PENSON: Yes. Tim, I don't
19 disagree with you but that's a bigger issue.
20 I mean I think in the end that whether or not
21 you agree with this or not remains to be seen
22 but, you know, people will look and say we

1 probably shouldn't have huge variations
2 between say California and Tennessee and
3 Indiana, et cetera, that it should more or
4 less be the same.

5 So I think that that's what the
6 criteria sort of drives that, at least when
7 you think about geography. Now you may be
8 right that in fact the real problem is overuse
9 or just expensive costs overall. But I think
10 the question becomes is, you know, is there
11 room for improvement.

12 Could it be that this measure
13 could look at that and say for expensive
14 things across the board it can be used to
15 lower cost.

16 Can it be used to look at
17 variation? So I think what you're saying is
18 true but I think the measure addresses that.
19 Other comments?

20 DR. CHEN: The only other thing,
21 and I had marked this high initially but the
22 more I think about it the more I think it's

1 more of a moderate because the issue in
2 opportunity is well, once you report it
3 someone has to try to act on hey, there's
4 difference.

5 And the question is who's supposed
6 to act on it if you report a really big
7 region. I have no independent ability to fix
8 it.

9 CHAIR PENSON: See and that to me
10 is a key point. I agree with that.

11 DR. WALTER: Yes because, I mean,
12 there's like cancer centers are in certain
13 regions and you'd think they were going to
14 have higher costs that maybe someplace in, I
15 don't know, Wyoming, which doesn't have a --
16 It doesn't mean they're doing worse care.

17 CHAIR PENSON: Okay. So I'm
18 hearing some concerns but I'm also hearing to
19 some degree that they're moderate concerns on
20 something to consider. Other comments with
21 regard to that, if any?

22 So I'll move on to 1c, which is

1 the purpose and objective of the resource use
2 measure, including its components. And the
3 construct are clearly described.

4 And again I think here most people
5 felt that this was relatively straight
6 forward, that the constructs were there and
7 the purpose was there.

8 There were one or two people who
9 went moderate and even one person who went
10 low. And anyone want to comment on that?

11 DR. WALTER: Again, I guess this
12 is my, there just wasn't a lot of hypothesis
13 about what they were expecting that was going
14 to be driving some of this. And I guess I
15 would have loved a little bit more of that.

16 DR. GILLIGAN: Yes, I had the
17 concern. It seemed like a fishing expedition
18 to me.

19 CHAIR PENSON: Well, we're
20 sounding more like an NIH study section than
21 a NQF TAP. I mean I think in the end what you
22 have to look at is not, I don't think it's,

1 this is my opinion. But I don't think it's
2 incumbent on the measure developers, see we
3 can't think of them as researchers, as measure
4 developers, to give us their sort of research
5 questions.

6 But I think that it's helpful for
7 us to see how the measure would be used. That
8 gives it purpose. So the question becomes, is
9 clearly they haven't give that to us.

10 That's all right, we can either
11 ask them on the phone or we could say, given
12 what I see here I could see a purpose if I was
13 a researcher myself.

14 So the question is are you okay
15 with that, Louise and Tim, or should we ask
16 Kevin and Todd?

17 DR. WALTER: I guess I'd like to
18 hear from them, because I'm still rating it
19 moderate.

20 CHAIR PENSON: All right, so Kevin
21 and Todd, I know you guys are listening to the
22 discussion with regard to purpose here. And

1 I think people want to know given that you're
2 going to measure resource use on a regional
3 level for breast cancer care.

4 What are some of your thoughts on
5 what it's going to show and what are some of
6 the actionable items when it's done on a
7 regional level?

8 DR. LEE: Yes, I think the
9 actionable information may be a bit more
10 difficult for at least -- This is Todd, sorry,
11 for me to respond to. I'm not sure if we
12 measure this. And I'll sort of give some
13 foreshadowing to how we operationalize a
14 region.

15 We've done it in four geographical
16 regions in the U.S. as well as by state. And
17 so if one state is higher cost than another
18 state, what impetus or what actionable
19 information did that provide and who makes it
20 happen?

21 I think that's a little unclear
22 from how we've designed the specifications on

1 how that would actually happen and potentially
2 there's no entity that would exist right now
3 to use this information.

4 However, we do feel, and our
5 workgroup felt, that there was important
6 opportunities to evaluate variability in care
7 within these regions.

8 Because if we can identify
9 differences that do exist, this may actually
10 lead to some important hypotheses rather than
11 us knowing why there might be variability.

12 For example, some of our workgroup
13 felt that maybe there are differences in
14 number of follow-up visits and intensity of
15 follow-up visits for patients across different
16 regions. Or the types of services that were
17 used.

18 And I think all of this underlies
19 what we are trying to do is better understand
20 this variability. Whether or not it exists
21 regionally. And then hopefully eventually act
22 upon it. So I don't know if we have a lot of

1 A priority hypotheses going.

2 And we were trying to develop this
3 to understand whether or not variability
4 exists and then how to subsequently change
5 that.

6 And I guess what I'm hearing from
7 you all is that there may be issues on how
8 that happens if we measure this at the
9 regional level rather than doing it within a
10 health plan or within a cancer center or some
11 other entity.

12 CHAIR PENSON: Well let me add to
13 that and maybe sort of help you a little bit
14 here as I think about this. You know I think
15 when you're looking at big regions, cutting
16 the country into four corners, may not be that
17 helpful.

18 But as you get a little more
19 granular, I think there's some there there,
20 because when you start to break it down by
21 category of use, whether it's imaging,
22 inpatient, outpatient, there may be something

1 there. There's no doubt there's going to be
2 variation, I think, in resource utilization.

3 I just have to open up the
4 Dartmouth Atlas and chose any condition you
5 want and we can go from there.

6 But I think that there's, to me
7 when I look at these measures, I was a little
8 skeptical but I started to think well what
9 it's going to tell me is that maybe the far
10 west does more imaging whereas the south does
11 more procedures.

12 And that has some value. And that
13 may even be actionable. Because it may be
14 that the care in the west coast imaging use is
15 appropriate or may be overuse that's
16 inappropriate. So I think there's something
17 there, is my impression.

18 DR. WALTER: But how will you know
19 what's appropriate or not appropriate
20 variation?

21 CHAIR PENSON: That's a well taken
22 point. But how do we ever know? I mean how

1 do we know it's appropriate in Dartmouth
2 Atlas? We want to minimize variation between
3 areas but we just don't know.

4 DR. LEE: I would also argue
5 that's why these eventually need to be
6 partnered with quality measures so that we can
7 look at efficiency.

8 CHAIR PENSON: Yes, I agree with
9 you, Todd. Other comments from the panel
10 members regarding purpose and objective? So
11 what I'll do before, Louis is getting his
12 vote.

13 Don't vote yet, don't vote yet.
14 We have to do the discussion about resource
15 use service categories.

16 So this one has something like ten
17 or 11 categories. And the question is are
18 these consistent with and representative of
19 the conceptual construct, are they
20 appropriate? And certainly my impression was
21 they were, they are fairly comprehensive.

22 And I think everyone in the room

1 agreed, preliminary of them voted high. Any
2 comments, any changes to your thoughts on
3 that? Okay. So now you can vote, Dr.
4 Potters. So let's go through these each.

5 We'll start with 1a, which is high
6 impact. Does the measure focus address a
7 specific health national health goal priority
8 or was data submitted to demonstrate a high
9 impact aspect of health care. We have all
10 nine. And this one eight people said high,
11 one person said moderate.

12 Next is 1b, which is demonstration
13 of resource use or cost problems and
14 opportunity for improvement. So are there
15 data to support this or at least in your
16 clinical intuition does it support that?

17 DR. LEE: We can use our spidey
18 sense?

19 CHAIR PENSON: Use your spidey
20 sense, it's okay. It's a new field, so I keep
21 telling myself. So one person said high,
22 everyone else, all eight, said moderate.

1 1c, speaks to the purpose and the
2 objective of the resource use measure. Is it
3 clearly described? And we have consensus
4 there, everyone in the room voted moderate.

5 And then last one, 1d, resource
6 use service categories. Are the service
7 categories included consistent with and
8 representative of the conceptual construct
9 represented by the measure? And here we have
10 seven people said high and two people said
11 moderate.

12 And we have a summary on this one.
13 All right. So now let's move on to the
14 scientific piece of this on acceptability. So
15 for 2a, which for 1579, the primary reviewer
16 was Steven.

17 (Off microphone discussion.)

18 CHAIR PENSON: Okay, well.

19 Whichever one you want, go ahead.

20 (Off microphone discussion.)

21 DR. CHEN: I think in general
22 these were reasonably well defined. I did

1 have some minor issues but it's the one on
2 algorithm. I think the one thing that I have
3 concern is that when you do look at
4 administrative data in this circumstance
5 sometimes people will continue to use the same
6 ICD-9 for this as breast cancer.

7 Even though they had the breast
8 cancer treated and they're in the surveillance
9 mode and then they get a biopsy and it might
10 come back as not cancer but that code in that
11 association might cause unnecessary inclusion.
12 So that's one.

13 The other thing was that somewhere
14 in the exclusions it said that they wanted to
15 exclude people who had lymph node disease, but
16 on the other hand the measure doesn't actually
17 say that they want to exclude lymph node
18 disease.

19 I think they were looking go
20 exclude lymphomas, but sometimes people will
21 use that code to indicate that there's lymph
22 node disease. And that's on page, I don't

1 know what page that is, I forgot to write it
2 down.

3 MS. WILBON: I'm sorry I just need
4 to interrupt really quickly. Are we talking
5 about 1578, the breast biopsy, or 1579?

6 CHAIR PENSON: 1579.

7 MS. WILBON: Okay. Thank you.

8 DR. CHEN: But as far as 2a is
9 concerned I think in general it's pretty
10 precisely specified with those minor caveats.

11 CHAIR PENSON: Okay.

12 DR. GILLIGAN: There's one thing
13 that I wanted to clarify and some people have
14 brought up in their comments as well. In
15 terms of the definition they have these high-
16 risk and non-high-risk, definitions of what
17 qualifies as breast cancer.

18 And at one point having a cancer
19 other than breast cancer qualifies you in the
20 non-high-risk breast cancer group, but that's
21 also an exclusion criteria.

22 And so we have a criteria that is

1 both an inclusion and an exclusion criteria.
2 And I was wondering if maybe the authors can
3 clarify how to interpret this non-high-risk
4 group?

5 CHAIR PENSON: Todd or Kevin, any
6 thoughts on that?

7 DR. LEE: So if you look through
8 the non-high likelihood cases, under the
9 algorithm from Natinger, those patients, in
10 most cases, do not get included as incident
11 cases of breast cancer.

12 They immediately lump to this
13 group that's not likely to get in as you work
14 through the algorithm. And they do explicitly
15 become excluded as part of our exclusion
16 criteria.

17 DR. GILLIGAN: So on page 15 where
18 we have those three categories, why is other
19 cancer included there?

20 DR. LEE: So that is a part of the
21 algorithm for identifying incident cases. It
22 actually ends up being part of the algorithm

1 where if they have a diagnosis for another
2 cancer it may not be that they are a high
3 likelihood for an incident case of breast
4 cancer.

5 So if you continue to work through
6 he algorithm, those patients are not likely to
7 get into the cohort.

8 DR. GILLIGAN: All right, but
9 since that's an exclusion criteria it should
10 be guaranteed that they don't, shouldn't it?

11 DR. LEE: It absolutely is. So
12 that happens in the next step of our coding.
13 So they, if one of those persons would slip
14 through this algorithm they would be excluded
15 explicitly because of the exclusion criteria
16 that you see in the next step section down.

17 DR. BORKER: I had the same
18 actually, the same comment. It's like if you
19 plan to exclude them why even have them with
20 inclusion criteria?

21 DR. LEE: Well this is part of us
22 trying to apply a validated algorithm for

1 identification of incident cases.

2 DR. BORKER: Right, I understand
3 that but then the validity data is presented
4 on the original algorithm, then in that
5 algorithm any other cancer is part of the non
6 high likelihood cases.

7 So by having the additional
8 exclusion criteria in your measure aren't you
9 fiddling with that validity measure?

10 DR. LEE: I got you, I see what
11 you're saying. Why have the other non-cancers
12 if we're already getting rid of them as a non-
13 high likelihood case. I can't answer the
14 question to the extent that we actually ended
15 up excluding additional people.

16 DR. BORKER: Okay.

17 CHAIR PENSON: So let me just pile
18 on here. But it's hard for me. So how do you
19 actually identify the data diagnosis when you
20 get the high likelihood case? Are you able to
21 do that, do you think?

22 DR. LEE: Well, yes. Sure we can

1 do it. But how accurate is it? I don't have
2 a sense of how accurate the actual date of
3 diagnosis then becomes.

4 We identify the date based on the
5 information in the claims data so I'm not
6 sure, I don't have a good sense of the
7 accuracy of that date.

8 Nor do I know if there's been, or
9 am I aware of any validation efforts to find
10 whether or not that date is the date of
11 diagnosis.

12 CHAIR PENSON: Okay. Other
13 comments about this first criteria, 2a1, the
14 measure being well defined and precisely
15 specified? What I'm hearing from the group is
16 for the most part people sound relatively
17 comfortable with it.

18 But people are raising some
19 concerns about who is included and who isn't
20 and some of the reasoning behind the algorithm
21 and the date of diagnosis.

22 And while the algorithm had been

1 tested in other settings it's sort of new here
2 so I think that's what I'm hearing. Okay.
3 With that then let's move on to -- and thanks
4 again, Todd, that's actually really helpful to
5 us here.

6 Let's talk about 2b1, pardon me,
7 did I skip one. It must be getting late in
8 the day. Yes, sorry. 2a2, which is
9 reliability testing.

10 And we go through this a fair
11 amount. Testing demonstrates that the results
12 are repeatable and produce the same results
13 with a high proportion of the time. And the
14 reviewer for this was Rohit.

15 DR. BORKER: So I'll just kind of,
16 I looked at, obviously, my comments and the
17 comments from other reviewers here. So in
18 terms of strength obviously it is a process
19 that definitely adds value to the reliability
20 of the measure.

21 In terms of some of the
22 limitations there was a concern that without

1 controlling for the stage of the disease or
2 the disease characteristics it's kind of
3 difficult to interpret outcomes.

4 Then in terms of the data elements
5 there's no attempt to formally look for the
6 liability statistics, such as interrelated
7 reliability because a lot of these diagnosis
8 and outcomes are based on ICD-9 and DRG codes
9 so there's no formal analysis on that.

10 Again, this has been brought in
11 other measures as well as the reproducibility
12 of this measure hasn't yet been demonstrated
13 in another database, another commercial
14 database to be more specific.

15 Complex programming has been kind
16 of highlighted as one of the issues that could
17 cause some reliability issues when you're
18 trying to, you know, reproduce the same
19 analysis in another database. So that's the
20 general highlight of the comments on 2a2.

21 CHAIR PENSON: But accepting
22 Sally's comment before that it would only be

1 endorsed for use in a commercial payer
2 database, like the ones here.

3 Do you feel that the algorithm,
4 which it strikes me as somewhat complex
5 programming as well, is going to be able to
6 produce the same results in subgroups of that
7 Market Scan data set, or whichever?

8 DR. BORKER: Sure so let me answer
9 your first question first, which is even
10 within commercial the Market Scan database,
11 and again, based on what the steward has
12 submitted, is a little bit different than a
13 lot of other commercial database in the sense
14 that it has a longer duration of follow-up.

15 It's got an employer base so even
16 if the patient changes insurance they'll still
17 track. In other databases if you change your
18 insurance you'll lose that data.

19 So the 15 month guidelines and 15
20 month follow-up, this could have a little bit
21 different implications on other databases. So
22 that's that concern. The second was, I'm

1 forgetting the question now.

2 CHAIR PENSON: The question really
3 was regarding the programming and the
4 consistency of the results.

5 DR. BORKER: Right. So as I think
6 another panel member mentioned earlier, you
7 know, on paper it looks fine but when actually
8 somebody is going to go and start programming
9 it that's when the rubber is going to meet the
10 road.

11 CHAIR PENSON: So looking at
12 Carlos' comment with the reducibility he had
13 some concerns. I don't think he raised the
14 concerns you raised, Rohit, which is
15 reasonable, the question I have for you is do
16 you feel that it's a major limitation that
17 you're not convinced, that it's just missing
18 data, or it's a minor limitation?

19 DR. BORKER: I would say it's not
20 a major limitation by any means. It's a
21 minor, it's a remedial issue, but nothing that
22 cannot be handled by modifications. Yes.

1 CHAIR PENSON: Okay. Other
2 comments from the panel? Okay. So I think at
3 that point why don't we -- I'm sorry, go
4 ahead.

5 MS. TURBYVILLE: And this might be
6 something that gets reexamined at the time of
7 maintenance. So once it's implemented amongst
8 other commercial pairs are they encountering
9 issues with the specifications being able to
10 be followed, et cetera.

11 And NQF does ask for additional
12 information at that time. So hopefully in the
13 future we'll have more information.

14 CHAIR PENSON: Okay. So why don't
15 we, any other comments about 2a2? So what I'm
16 hearing, any other comments before? So what
17 I'm hearing, just to reiterate here is that it
18 does seem to be relatively reducible and
19 reliable in this data set.

20 But there are some minor concerns
21 and certainly it's something that could be the
22 focus of further testing. So having

1 summarized that let's do 2a1, which is, is the
2 measure precisely specified so it can be
3 implemented consistently. And the results are
4 four for high and five for moderate.

5 And we'll do 2a2 next, which is
6 the reliability piece. Does the reliability
7 testing demonstrate the results are
8 repeatable, produce the same results a high
9 proportion of the time when assessed in the
10 same population, the same time period and that
11 the score is precise. And here we have
12 consensus, everyone in the room felt moderate.
13 Excellent.

14 Okay. You see I always, you see
15 you got to throw something at me. Don't let
16 that computer restart now, whatever you do.

17 So let's get the overall gestalt
18 here, what is the level of overall reliability
19 testing. And here we have one person voted
20 high and everyone else, the remaining eight,
21 voted moderate.

22 Okay. So now we'll move on to 2b

1 and do these basically four pieces together
2 and vote. So 2b1 is the item regarding the
3 evidence.

4 Basically, the measure
5 specifications are consistent with the
6 evidence presented to support the focus of
7 measurement, and it is specified to capture
8 the most inclusive target population, both
9 Steven and Tim got to do this, so gentlemen.

10 DR. CHEN: So for me this was a
11 moderate. Again, the precision is basically
12 there I have big concerns, and this bleeds
13 into the validity issue, of despite the fact
14 that it's population based that there's still
15 no risk adjustment at all.

16 And we know that regional
17 comorbidity burden is different. And that's
18 going to play a part in lengths of stay,
19 response to chemo, these are toxic agents that
20 we're giving people and what their
21 comorbidities are.

22 On top of that I think stages is

1 important, less important so at the population
2 level, but still important because we do see
3 regional variation in just stage of diagnosis.
4 And then finally, they stratify based on
5 chemo, no chemo, new adjuvant and with chemo
6 trastuzumab or not.

7 But what that eliminates is one of
8 the key elements in variation in cost, which
9 is the decision making to give chemo or not.

10 And that is, I understand why they
11 did it because they don't have stage data, but
12 again, at least that's circular thinking. Of,
13 you know, you're cheap because you don't do
14 this, so.

15 DR. GILLIGAN: So actually I
16 thought in some ways it was the opposite.
17 Because if you're only comparing people who
18 give trastuzumab to other people who give
19 trastuzumab, I think you're then better able
20 to pick up variations in practice, other than
21 the decision to give trastuzumab.

22 Because that's such a huge

1 proportion of the costs, if you measure the
2 difference between just trastuzumab or not
3 then a lot of the other differences get washed
4 out.

5 CHAIR PENSON: So I think we're
6 now getting into what I suspected we would get
7 into here. Which is we're going to break up
8 into Protestants and Catholics in a minute,
9 says the Jewish kid from New York.

10 But the fact of the matter is
11 you're either going to buy that it's okay to
12 have minimal or no risk adjustment and look at
13 it on a regional level or not.

14 And it's, you know, I'm not sure
15 if this is going to be discussed in the
16 validity piece in 2b2 and the risk adjustment
17 piece in 2b4 or if it's appropriate to discuss
18 it here.

19 I would maybe say that we kind of
20 wait, kind of put it all into 2b2 and 2b4. I
21 mean basically what you're saying is do the
22 specifications capture the patients in such a

1 way that it lets them get at looking at the
2 resource use around treatment? And if you say
3 no, I'm okay, but I'm just trying to sort of
4 focus it a little bit.

5 DR. CHEN: And I think my answer
6 to that is generally yes with the caveats I
7 gave before. I think you are including some
8 people who don't actually have cancer and you
9 are excluding some people who have known
10 positive cancer because you're treating them
11 as metastatic. And those aren't metastatic.

12 CHAIR PENSON: Okay. Other
13 comments? Okay. So we'll move on to 2b2 and
14 I think that this is probably going to be the
15 time that we need to think about this, the way
16 this measure is structured.

17 And basically this is, validity
18 testing demonstrates that the data elements
19 are correct and they correctly reflect the
20 cost of care or resources provided, adequately
21 distinguishing higher and lower cost and
22 resource use.

1 So I think that last line is where
2 you really start to say, you know, does it
3 adequately distinguish things if you're using
4 a regional level?

5 And again, this is, actually it's
6 not. Who is the primary reviewer for this?
7 Rohit, you are.

8 DR. BORKER: So I give moderate to
9 this. Because I think a lot of things that
10 I'm going to say can be resolved to
11 appropriate statistical techniques.

12 But again, in terms of strength, I
13 think they have done a reasonable good job
14 with that iterative process which inherently
15 kind of increases the face validity of the
16 measure.

17 But then there are a lot of
18 concerns and some of these concerns have been
19 raised before. Again, there has not been a
20 formal analysis of like a known groups testing
21 or convergent discriminate validity in terms
22 of whether certain groups which are expected

1 to cost higher, are they really costing
2 higher.

3 So no formal analysis has been
4 presented so it's kind of difficult to know
5 whether the measure is really valid. Then the
6 implications of that 15 month requirement
7 hasn't been discussed. Again this is the same
8 issue that we had raised earlier.

9 Are excluding more severe cases?
10 It could be in that time frame be very
11 expensive but overall may reduce the cost
12 because they don't cost anything, once the
13 patient dies.

14 Again there's this issue with high
15 likelihood and not high likelihood cases. And
16 although the algorithm has been validated the
17 implications of these two groups hasn't been
18 studied so it would be nice to see cost and
19 resource use among patients who fell under the
20 high likelihood cases versus the non-high
21 likelihood cases.

22 In terms of other threats to

1 validity hasn't been, again, tested in another
2 database. This was raised for reliability,
3 the same thing applies for validity as well.

4 So I think another issue that was
5 raised was the differences that we are likely
6 to see in cost and resource use we are not
7 sure whether it is because differences in the
8 patient mix or is because of difference in
9 quality of care that is provided to the
10 patients? So that's just the summary.

11 CHAIR PENSON: And that's a good
12 summary, thank you. I mean I'm sort of, and
13 I should add that Carlos isn't here, but he
14 had some minor to moderate points with regard
15 to validity testing that he raised that I
16 think are worth at least reviewing and
17 considering. Other thoughts in the room?

18 DR. WALTER: Just again that
19 breast cancer is most common in older people,
20 so again I think that's another validity
21 issue.

22 CHAIR PENSON: You know on the one

1 hand looking at this it sort of, you know, it
2 had face validity, it passed the smell test.

3 But when you start to get sort of
4 under the cover and look into it you see a lot
5 of these other smaller problems. For me I'm
6 able to, I'm okay with it.

7 I'll say up-front, I'm okay with
8 this regionalization business and I think when
9 you regionalize to some degree it does take
10 care of some of the risk adjustment.

11 But I don't think it takes care of
12 all of it. But at least from a face validity
13 standpoint I'm okay with this.

14 It's not generalizable to older
15 women, there are other issues with regard to
16 the algorithm, but I saw them as minor
17 problems when I was reviewing it. I'm not
18 sure about the risk adjustment thing. So we
19 can come to that in a minute.

20 DR. CHEN: I will mention as far
21 as regionalization I'm kind of more okay with
22 the four corners thing than I am the state by

1 state thing. Because there are a lot of
2 border cities where their MSA is much more
3 relevant than what state they actually live
4 in.

5 CHAIR PENSON: That's a very good
6 point. So other comments specifically about
7 2b2?

8 DR. GILLIGAN: Does anyone ever do
9 chart review as validity testing for database?
10 Or is that just impossible to do?

11 CHAIR PENSON: It's not impossible
12 to do and if you think that would be helpful
13 I'm sure that Kevin and Todd on the phone are
14 listening and will take that into account. I
15 mean it's expensive, it's not easy, but I
16 think that it is, it's often lost.

17 I mean without going into it I
18 think a lot of the, throughout the quality
19 improvement movement we've often failed to do
20 many of the validation studies we need to do.
21 Either because they're hard to do, they're
22 expensive, there is political expediency to

1 getting things done.

2 And I think it's a very well taken
3 point, Tim, that while these are all
4 reasonable things, if not now certainly at the
5 renewal point, one would hope that there will
6 be some real validity testing.

7 DR. SKIBBER: Interesting that you
8 mention that. I think there's been the
9 development of a number of extracted databases
10 that are coming out now that may be very
11 helpful in doing that sort of thing.

12 I think one is maybe not
13 specifically for this issue, but the NSQIP
14 database by the College of Surgeons as well as
15 the NCCN for specific disease entities.

16 And their breast database is
17 immense and that's pretty granular data that's
18 reasonably reliable. At least in certain
19 disease entities. And the NSQIP is also
20 abstracted data, so that may be helpful at
21 some point.

22 CHAIR PENSON: Yes, I mean you

1 really could do some studies going with NSQIP
2 and NCvB, you know STS has their data set
3 there are ways to do this and it just hasn't
4 been done.

5 DR. POTTERS: The problem is you
6 can't crosswalk those to the claims data.

7 CHAIR PENSON: Not necessarily.
8 You could if you had identifiers and everyone
9 signed on the bottom line. Those are big ifs
10 though for sure.

11 DR. CHEN: To that point I mean I
12 did write an abstract and the paper did
13 eventually generate where we actually linked
14 cost accounting data to our NSQIP data. And
15 so it can be done.

16 It's not as onerous as you might
17 think. It was onerous the first 1,000 charts
18 when I hand checked them. But after that I
19 had made an algorithm that is sort of done
20 with a 98/99 percent accuracy.

21 CHAIR PENSON: I'll focus us
22 again. Because as much as I enjoy this

1 discussion there's another comment that I have
2 which I'm squashing, stop, just for the sake
3 of time. Yes, yes. I think that that's
4 actually something that's is worth discussing
5 at a higher level on NQF side. Steven.

6 DR. CHEN: I did want to respond
7 to your question as far as risk adjustment.
8 So while we're sitting here I apologize I
9 haven't been able to collate them, but I just
10 took 2007 SEER at the 17 SEER registries to
11 look at their stage variation and you can have
12 up to 2X variation, or 3X in the various
13 stages between SEER regions.

14 CHAIR PENSON: And that to me,
15 thank you for doing that because that's an
16 important point. When I looked at this on the
17 one hand I was okay with the regionalization.
18 On the other hand there's a part of me that
19 keeps saying even when you have big regions
20 there can be differences.

21 And so I think that we need to
22 discuss that, it may be a little more involved

1 even than just saying I buy it or not. But
2 I'll ask you to table that for just a few more
3 minutes. Other comments with regard to
4 validity testing?

5 All right, so let's move on to
6 exclusions. And we did have a discussion
7 about the algorithm and about excluding other
8 cancers. So we probably don't need to revisit
9 that. So, Louis, you were the person looking
10 at exclusions, any other comments?

11 DR. POTTERS: Yes, there's really
12 not that much, right. There are really no
13 exclusions in that it's a population based
14 measure.

15 The exclusions that are there, you
16 know, we talked about are either the insurance
17 based and clinical. That gets you down to
18 about 24 percent of the total population but
19 they certainly seem reasonable.

20 Except for that oxymoron on the
21 second cancer word sort of included and
22 excluded but we talked about that. So it just

1 sort of is, it's really no opinion about it
2 either way.

3 CHAIR PENSON: So what I'm hearing
4 is that from what you're saying, there's some
5 issues there that either are very minor or at
6 most moderate. Is that a fair statement?
7 Other things to add? Okay.

8 So now let's have the discussion
9 that I think all these other measures get
10 bogged down in. Well, that's appropriate
11 though. Which is looking at the risk
12 adjustment piece.

13 The question is, is an evidence
14 based risk adjustment strategy specified, are
15 patient clinical factors included, or if
16 there's no risk adjustment, which is the case
17 here, does the rationale or data support that.

18 So the question at hand is, and
19 remember the stratification is not risk
20 adjustment, is it okay not to have risk
21 adjustment here? And I heard Steven's comment
22 that really, I think, gives pause. I don't

1 know.

2 DR. WALTER: I guess I'm wavering
3 between low and insufficient evidence. I
4 think it depends on what the region is,
5 because I haven't heard exactly what the
6 region is.

7 Or, you know, it'd be nice to have
8 the data that Steven provided about the
9 variation and stage or other things across
10 whatever region they're thinking about doing.

11 MS. TURBYVILLE: And that's a
12 challenge because when we asked for unit or
13 level of analysis from the developers we just
14 had population, region and national. We
15 didn't ask them to specify.

16 So I don't know how we would, I
17 guess it would have to be if they have
18 guidance on that it would it have to be part
19 of the written text? Or does that even make
20 sense, Ashlie?

21 (Off microphone discussion.)

22 CHAIR PENSON: So let me throw

1 something out there that may make this a
2 little easier. Because I'm with you, Louise,
3 I'm having a hard time with this. And it
4 would certainly be helpful, and I know Kevin
5 and Todd are listening, and I'll ask you guys
6 to comment in a minute.

7 It would be helpful to know
8 exactly how you're breaking down your regions.
9 I know you mentioned the four corners versus
10 individual states.

11 But if you're going to use both
12 methods or one or the other, but then what
13 would make me feel a lot better is someone
14 reviewing this measure.

15 Some just basic descriptive
16 information based on your regional breakdown
17 to provide me with some reassurance that there
18 is no major differences between the northwest
19 and the southeast, or for that matter Iowa
20 versus Arizona, as an example.

21 Steven's comment about differences
22 in stage by SEER registry is concerning. So

1 I'll ask other people in the room and then
2 I'll give Kevin and Todd a chance to comment.

3 DR. GILLIGAN: I'm just wondering,
4 and I don't know the answer to this, but since
5 we're breaking these patients up into all
6 these different groups.

7 And most of those differences in
8 treatment are going to be based on stage, does
9 the different chemotherapy categories act as
10 a reasonable surrogate for some of these
11 regional differences or not.

12 Because we're only comparing
13 neoadjuvant to neoadjuvant and trastuzumab to
14 trastuzumab and no chem to no chemo.

15 CHAIR PENSON: I don't know if
16 stratification is adequate here. I mean,
17 because the fact of the matter is also, A,
18 it's circular again, because your
19 stratification variable is also your outcome.

20 DR. GILLIGAN: I don't think it's
21 circular here. I think it was the other time,
22 I don't think it is here. Because you're

1 doing a stratification --

2 CHAIR PENSON: Yes, you're right
3 in that you're not going to be comparing those
4 who did versus those who don't. You're right
5 about that, that's correct. But it's still,
6 I don't know.

7 DR. CHEN: To the extent you're
8 trying to predict stage, the problem with
9 breast cancer, not so much problem, but the
10 facts are that we start giving chemo somewhere
11 in the middle of Stage I, and if you're at MD
12 Anderson somewhere towards the lower end of
13 Stage I you start getting chemo.

14 And so there's that decision
15 making, particularly in that upper part of
16 Stage I, is very discriminating as to how you
17 use resources. And again, there's the point
18 to disclose that I do do work with the genomic
19 assay companies that try to predict which part
20 that falls in.

21 But that decision plays a huge
22 part in your resource utilization for

1 identical size and otherwise stage diseases.

2 CHAIR PENSON: So I'm --

3 DR. GILLIGAN: I'm still puzzled
4 though. Because the difference in cost is
5 going to be the difference in whether or not
6 you give the chemo. But you're only comparing
7 people who got chemo to people who got chemo.

8 DR. CHEN: Yes, and so I think
9 that's my point is that one of the biggest
10 issues in at least resource utilization when
11 you look at provider to provider, is whether
12 you're choosing to use chemo for identical
13 disease.

14 DR. GILLIGAN: Right.

15 CHAIR PENSON: You know, and yes
16 I'm hearing a lot of issues here is what I'm
17 hearing. And think I'm kind of in the same
18 boat that Louise is in, which is, is this a
19 fixable problem or do I just need data to make
20 me feel better about it?

21 I think if you showed me data, you
22 know, and this wouldn't be hard to do, to some

1 degree to look by population and it doesn't
2 even have to be in the necessarily the same
3 data set.

4 It just would make me feel a
5 little bit better that, you know, over these
6 three states versus those three states on
7 opposite side of the country, stage is more or
8 less the same and the age distribution is in
9 the same ballpark, I'd feel better.

10 Is that a fair statement? Well at
11 least that's me. I'm wondering if others
12 agree with me, or -

13 DR. GILLIGAN: Well I think in
14 some ways the appeal of the way this measure
15 is done to me is that I think in some ways
16 it's unfair to the provider to guess from such
17 abstract data whether or not giving chemo was
18 the right decision or not. Without stage
19 information and all that stuff it's very hard
20 to look over their shoulder.

21 But to look at someone who's
22 giving chemo and they have twice as many

1 complications and hospitalizations as someone
2 else who's giving chemo maybe that tell me
3 something about quality of care that's
4 actually worth knowing. So I mean I'm sort of
5 playing devil's advocate a little bit.

6 But I think there's strengths and
7 weaknesses either way. Of course it'd be nice
8 to have stage data but you just can't, that's
9 not an option.

10 CHAIR PENSON: And the question
11 becomes again because you don't have that
12 level of granularity, because you're not
13 looking by the provider you're looking by
14 large region. Here I get more comfort with
15 the concept that maybe the regions are
16 comparable.

17 I mean I sure would feel better if
18 I had some evidence. Why don't we let the
19 measure developers say a few words on this
20 because we're having a lot of discussion here.
21 Kevin or Todd, any thoughts on this?

22 DR. WEISS: Perhaps I'll start.

1 And then, Todd, it'd be great if you wanted to
2 add anything. The discussion I had is very
3 close tied to that of our workgroup. I didn't
4 mention it at the very beginning of today but
5 it may be obvious but it may be not.

6 But the intent of our project to
7 try, where possible, to work on attribution to
8 the most granular place that we thought was
9 reasonable. And so on this one everyone
10 recognized that without clinical staging you
11 really can't drill down very far.

12 On the other hand when you get up
13 to a certain population you should have a
14 certain randomness of effect that you would
15 avoid miss-classification based on stages.
16 Now having state based information on stages
17 would help us a lot.

18 However we also realized in that
19 discussion how the practice of treatment
20 really is developing more and more network.
21 And that these networks are pretty complex,
22 that often go across state boundaries.

1 They really work across health
2 systems and patient, because of the way that
3 the centers are being set up and such, that it
4 really does begin to feel like you need to
5 start with a very high aggregate to look at
6 this.

7 And then probably the only people
8 who could be beneath that would be individuals
9 who would be individual systems who had large
10 enough population that they could actually do
11 some benchmarking but that was beyond our
12 scope.

13 In that context we said that we
14 can in this case go without formal staging but
15 rather look at these different stratum of the
16 types of care.

17 Recognizing that they would have
18 to be matched to quality indicators to make
19 any sense of any of the other resources these
20 measures would be.

21 So I hope that addresses, kind of
22 reflection, partly it's just a reflection of

1 you doing the same hammering that the
2 workgroup did, how we got there and the fact
3 that without that clinical enhancement of the
4 stage this may be as good as we can get. But,
5 Todd, your thoughts here?

6 DR. LEE: I don't have anything to
7 add, Kevin, I think you've touched on a lot of
8 the issues that, again, our workgroup
9 struggled with and that is sounds like this
10 technical advisory panel is struggling with.

11 DR. WEISS: I might add that they
12 felt that it was important to shed light on
13 possible variations and research use, I mean
14 they were not forced to make this measure.

15 They said this is an important
16 issue from their perspective. So this is
17 something that we have reached a high level of
18 concurrence in terms of a topic of interest.

19 CHAIR PENSON: So there's, I mean,
20 I don't think anyone's arguing with the
21 importance of it. I think that sort of, we
22 are all in agreement there.

1 It's interesting so Steven just
2 showed me these data from SEER and you really
3 do see between Stage I, Stage II and Stage III
4 these ten percent or so variations by registry
5 and registry.

6 Now there are some differences in
7 timing and other things, but the question
8 really becomes is, it would be comforting, I
9 think that's the best word to use here, if
10 there was more data here to sort of make the
11 group feel better about the risk adjustment.
12 Is that a fair statement as I look around the
13 room?

14 I think what I'm seeing in the
15 room is sort of just some concerns that, yes
16 it's important. Yes, we appreciate why the
17 workgroup did it, we're coming up with the
18 same, running into the same walls they did but
19 it may not be quite ready for prime time
20 without some additional data. Is what I think
21 I'm hearing from the group.

22 DR. WEISS: Well one question that

1 might be helpful to me and the rest of our
2 team. Is SEER data is not fully population
3 based, it is dependent upon, it's a very nice
4 sampling frame.

5 But I'm not sure is it
6 representative of something that would be
7 equated as a state sample? And I'm not, I
8 just don't know SEER well enough --

9 CHAIR PENSON: Well that I can
10 speak to. So the answer is it's not fully
11 population based for the United States, so it
12 doesn't represent all 50 states.

13 But within the state itself,
14 whether say it's Iowa versus Connecticut, it
15 is completely population based for that
16 particular state over that particular time
17 period.

18 It's not a random sample. Every
19 patient in the state of Iowa who is diagnosed
20 with cancer is included in the tumor registry.
21 Same story with Connecticut. Now when you get
22 into the metropolitan areas, you know, Los

1 Angeles, Atlanta, that's a different animal.
2 But when you look at state registries they are
3 population based by law.

4 DR. GILLIGAN: So one thing that
5 someone could do is take a SEER area and run
6 this measure with and without the staging
7 information and compare the results and see
8 what it adds.

9 CHAIR PENSON: I don't think you
10 need to have particularly extensive data here.
11 I think you need to give people a gestalt.
12 You can look, SEER has been broken down into
13 region, as an example.

14 Or you could break it down by
15 state and just sort of look and say when I go
16 to region those stage differences over the
17 same time period seem to dissipate.

18 And I think it would make people
19 feel better. Because I think there is some
20 concern in this room that even with the sort
21 of regional comping and even without
22 individual provider accountability you may

1 have confounding by differences in population
2 by geography. Steven.

3 DR. CHEN: And then just beyond
4 the cancer staging, I still am somewhat
5 concerned about not using comorbidity at all.
6 Because we do know that things like cardiac
7 disease is very widely across different
8 states. And particularly smoking rates vary
9 widely and they have huge comorbidity effects.

10 CHAIR PENSON: Other comments? So
11 like we've done before I think this is the
12 right time for us to stop and vote on these
13 four criteria.

14 So why don't we start with number
15 1 which is a validity measure, are the measure
16 specifications consistent with the evidence.
17 For measure 2b1 we have one vote for high and
18 eight for moderate.

19 Now we're on to 2b2, which is the
20 validity testing. Validity demonstrates that
21 they measured data elements are correct or
22 that the measure correctly reflects the cost

1 of care resources provided adequately
2 distinguishing higher or lower cost of
3 resource use. And here we had seven who said
4 moderate, one who said low and one who said
5 insufficient.

6 Next we'll move on to the
7 exclusions, 2b3, are the exclusions supported
8 by clinical evidence or analysis of frequency,
9 is the information about exclusions
10 transparent. And here we had one vote for
11 high and eight for moderate.

12 And last but certainly not least
13 in section. Basically what we're asking here
14 is the rationale and data support no risk
15 adjustment of stratification.

16 And here we had two voted for
17 moderate, five who were low and two felt it
18 was insufficient. And I think certainly our
19 discussion reflects that spread. I don't
20 think we had much to add there.

21 So we'll keep moving along. We're
22 actually doing fairly well I think. Let's

1 talk about 2b5, this is differences in
2 performance.

3 And basically do the methods for
4 scoring and analysis specified allow for
5 identification of statistically significant
6 and clinically meaningful differences in
7 performance.

8 Or there's evidence of overall
9 less than optimal performance. Lewis, you
10 were the primary reviewer on this.

11 DR. POTTERS: Yes, I thought all
12 of these 2b4, 5 and 6 sort of bleed into each
13 other. I think we've had this discussion, to
14 some degree in terms of, you know,
15 understanding the stratification relative to
16 a risk adjustment type of analysis.

17 And, you know, the pros and cons,
18 as per the voting, I think there's a fair
19 amount of moderate to this criteria.

20 CHAIR PENSON: I hear what you're
21 saying. Other comments? When I first looked
22 at this I actually wrote not applicable

1 because I kind of couldn't figure out what
2 does it mean if the west coast is less or more
3 than the east coast.

4 I'm not sure if that means it's
5 not applicable or whether or not it's just
6 difficult to interpret. So in certain
7 respects it could be not applicable, it could
8 be low. I don't know. You know, again, it
9 goes back to do you think it's meaningful to
10 look at regional differences.

11 The more I think about it I think
12 in some respects it is, but in some respects
13 it isn't. Again, I don't know the answer
14 here.

15 MS. TURBYVILLE: I think you did a
16 N/A for this one.

17 CHAIR PENSON: You do or you
18 don't?

19 MS. TURBYVILLE: Yes, you have to
20 have these, high, low, moderate or
21 insufficient. So they didn't give us enough
22 information.

1 CHAIR PENSON: Yes, so I think I
2 can't vote N/A, I was hoping I could. I guess
3 not. So I guess in the end I'm soliciting
4 help. Other thoughts?

5 DR. CHEN: I tended toward
6 moderate because I do think you are finding
7 differences here. They are real. Whether
8 they're useful or not I guess I mentally
9 thought I would deal with that over in
10 usability. But I think there are differences
11 are they're real.

12 DR. WALTER: I guess I won't help
13 you because I'm leaning towards insufficient
14 waiting for some of this other data to be
15 presented to me to understand how meaningful
16 it would be.

17 DR. BORKER: I would rate this
18 insufficient as well. I guess -- Oh, I'm
19 sorry you had a comment? Because to me that
20 is again leading back to the validity issue.
21 It's the sealed analysis that was recommended
22 here might be really helpful there.

1 CHAIR PENSON: Yes, it's
2 difficult. I mean a part of me is with Steven
3 where I think that there is some use to this
4 assuming it could be collected in a valid
5 manner. I'm sure it's sitting there, don't
6 want to heap on because we really did heap on
7 before with the risk adjustment piece.

8 But the fact of the matter is on
9 the other hand if the risk adjust doesn't work
10 then it's not going to fly, so I'd like more
11 information there.

12 So I think in some respects maybe
13 it's insufficient. Although I think Louis'
14 comment, I mean on the surface it's okay.
15 It's back to whether or not you buy it's okay
16 not to have risk adjustment it sounds like.

17 DR. POTTERS: It really depends
18 what they're going to do with it. I mean if
19 they're going to put it on the front page of
20 the New York Times it's not sufficient. If
21 they're going to use the data and perhaps
22 crosswalk it to other databases then it is.

1 MS. TURBYVILLE: That's a very
2 important question. So in general you should
3 be thinking that it's not just them that would
4 be using it, it'd be any user and we don't
5 control.

6 So when you endorse a measure it's
7 for those accountability and public reporting
8 models that you had for use in those and
9 feeling that they've provided enough
10 information to meet that kind of use. So we
11 don't really oversee the use of the measures.

12 CHAIR PENSON: I'm sure starting
13 to think that it's insufficient because the
14 fact of the matter we do have these issues
15 with risk adjustment.

16 And the fact of the matter is that
17 even if it is perfectly risk adjusted and you
18 see this sort of ten percent increase in
19 region A versus region B I don't know what
20 that means.

21 Now it may mean something but
22 you've got to give me more data to interpret

1 it. And I don't have that information at this
2 point.

3 Other comments? So next is 2b6,
4 which is multiple data sources, methods are
5 specified, there's demonstration they produce
6 comparable results. And, Lou, this was you as
7 well.

8 DR. POTTERS: I mean this would be
9 an N/A if there was an N/A.

10 CHAIR PENSON: Yes, okay. And so
11 let's finish up with the 2b and then we can do
12 -- actually.

13 (Off microphone discussion.)

14 CHAIR PENSON: Yes. Yes, let's do
15 it that way, that way we get the one gestalt
16 measure.

17 MS. TURBYVILLE: It's starting
18 with 2b1.

19 CHAIR PENSON: Well we did 2b1
20 already. We're at 2b5 so don't make us go
21 back there. Never go backwards, Sally.

22 MS. TURBYVILLE: Sorry.

1 CHAIR PENSON: It's okay. So in
2 2b5, this is the differences or results
3 reported, did they identify differences in
4 performance or overall less than optimal
5 performance.

6 Okay. And so here we had two
7 people who felt it was moderate and seven
8 people felt it was insufficient. And I think
9 our discussion reflects that vote.

10 And then as we've said before
11 multiple data sources was not applicable so we
12 can step right over that. So this is the
13 overall gestalt.

14 What is the overall level of
15 validity testing, taking into account the
16 discussion we had about risk adjustment, about
17 the differences, et cetera. And go ahead and
18 vote.

19 Okay. Well interesting. We had
20 three people, I told you this was going to be
21 a religious discussion. We had three people
22 that felt that the overall validity was

1 moderate, three people who felt it was low and
2 three people who said it was insufficient.

3 And I think the way to interpret
4 that for when we're writing the report, and I
5 know Kevin and Todd is listening, is I think
6 as one of the people who voted insufficient
7 and the others can agree or disagree, I just
8 think that there's a need for more
9 information.

10 It's not necessarily and
11 indictment that it's no good but it really,
12 truly I just don't know. Is that a fair
13 statement for the folks who?

14 (Off microphone discussion.)

15 CHAIR PENSON: Well for low I
16 think people basically looking at it and
17 they're not buying. Yes, they're not buying
18 that the risk adjustment, you know, people
19 felt you needed risk adjustment. I mean there
20 really is, sort of three people said it was
21 okay, not perfect.

22 Three people said it's never going

1 to fly and three people said I don't know,
2 give me more information to make me vote one
3 way or the other.

4 And I think that the discussion
5 really reflects that, frankly. And it'll
6 probably be the same on the next measure too.

7 (Off microphone discussion.)

8 CHAIR PENSON: Yes, we're getting
9 there, we'll be done on time. No phone calls,
10 I swear. So we'll do 2c now. Disparities in
11 Care. If disparities in care have been
12 identified measured specifications, scoring,
13 and analysis allow for identification through
14 stratification that is by race, ethnicity,
15 socioeconomic status or gender.

16 Or alternatively there's a
17 rationale on data which justifies why
18 stratification isn't feasible. And for this
19 one, Rohit, you were the reviewer.

20 DR. BORKER: So as you can see the
21 validations are all over the place. But I
22 gave it a high just because of the same reason

1 that I mentioned last time as that's the
2 limitation of the database.

3 But if the database has those data
4 elements there is nothing preventing this
5 measure from stratifying the data on those
6 disparity measures.

7 CHAIR PENSON: See I kind of, and
8 Sally, correct me if I was wrong, but I had an
9 N/A and the reason I said N/A was because
10 you're doing this sort of by region. So it's
11 hard to stratify a region by gender or by
12 race. I mean you could look at --

13 MS. TURBYVILLE: Proportions.

14 CHAIR PENSON: -- proportions
15 potentially, but it's still hard to do.

16 MS. TURBYVILLE: I think that's an
17 appropriate question. And it could be that,
18 it's fine for committee to feel that the
19 stratification of disparities isn't warranted.
20 It's an important signal to send to
21 developers, even in commercial databases where
22 we know it's very difficult to do, that it is

1 warranted if not now in the future.

2 So I think especially for these
3 commercial administrative derived pieces it is
4 kind of important to kind of provide that
5 feedback for the measure.

6 CHAIR PENSON: So allow me to
7 summarize that as I think through this. Which
8 is if you believe that stratification, by
9 gender, so all the women in the west versus --
10 well this breast biopsy.

11 So all the older women in the west
12 versus all the older women in the east, if you
13 think that's value there that you either have
14 to think about it as insufficient or it wasn't
15 addressed.

16 If on the other hand you sort of
17 look and say well stratification isn't that
18 important for a population based, or for a
19 measure which is based on region, the
20 population may be --

21 MS. TURBYVILLE: Well in
22 particular this measure.

1 CHAIR PENSON: This measure, so
2 then you say high because the rationale to
3 justify why stratification isn't necessary.
4 Thoughts?

5 DR. BORKER: I have a quick
6 question on what you're saying. So in this
7 particular case, using that database, one can
8 stratify older versus younger women across
9 states.

10 But doesn't mean the developers
11 have done it. How do we rate that, when we
12 know that they can do it, it just that it
13 hasn't been reported?

14 CHAIR PENSON: Well, so the
15 question becomes, and I do think it's
16 important, if you think that it's not
17 important then you say, I would assume, you
18 say high and you let it go. Because in your
19 mind there's rationale for why stratification
20 isn't there, by age as an example.

21 If on the other hand you think
22 that's an important piece, you know it can be

1 done so you would put it as insufficient. Or
2 you could even say -- Go ahead.

3 MS. TURBYVILLE: Right, so I
4 wouldn't use insufficient in that case. I
5 think insufficient would be you don't have
6 enough information to determine whether or not
7 disparities, socioeconomic, race, ethnicity,
8 should be addressed for this measure.

9 I think you might put moderate,
10 for example. For commercial testing, because
11 you know they can't test it but perhaps they
12 could have recommended that users, if they
13 have the data stratified, because the
14 literature supports that there are some racial
15 disparities that you would want to exposed.

16 You might say low if they don't
17 address it all, but the literature does or you
18 know it does. So --

19 CHAIR PENSON: And you raised a
20 point with the slip of the tongue, because
21 there's no race information here. Okay. So
22 if you feel that race is an important

1 stratifier and that you can't do this without
2 stratifying for race, then you would vote low.
3 And so it's just because of matter of clinical
4 opinion.

5 DR. CHEN: And to that point I
6 would say that race is actually fairly
7 important in breast cancer.

8 From molecular studies we know
9 that African-Americans have a much higher rate
10 of triple-negative breast cancer which is much
11 deadlier and requires much more aggressive
12 therapy.

13 CHAIR PENSON: Okay. Other
14 comments? All right, so why don't I call the
15 question on this and I suspect we'll be all
16 over the map here.

17 So with regard to Disparities in
18 Care, do the measures allow for identification
19 through stratification results or do you buy
20 that the rationale justifies that
21 stratification is not necessary or feasible.

22 There you go. So three put it as

1 moderate, five put it as low and one put it as
2 insufficient. All right, we're moving right
3 along.

4 We're actually I think doing fine,
5 Sally. So next we're going to talk about
6 usability for this. And this I think will
7 also be a somewhat interesting discussion.
8 The primary reviewer for this was Louise.

9 And basically we'll start with 3a,
10 which basically looks at whether or not the
11 results are reported to the public or at large
12 in national or community reporting programs by
13 the time of endorsement maintenance review.

14 And again we go back to the
15 discussion we had before. Which is this is a
16 work in progress both with regard to NQF and
17 this also has not been tested by RWJ, it's
18 currently being tested.

19 DR. WALTER: Right so there were
20 four highs and two insufficients and I rated
21 it as insufficient because it's not in use.
22 And I think that's what we've been

1 consistently voting for the other things if
2 they haven't been publicly reported, and it
3 hasn't been.

4 CHAIR PENSON: So I will say one
5 thing here, because I'm with you on that. And
6 I was the other insufficient. And I think
7 that for the people who voted high, you know,
8 people have been changing their votes here.

9 But the one thing I will say here
10 is that there is something to consider, the
11 useful to the public when you report at a
12 regional level. And for those other pieces on
13 the slide if, and I'm not suggesting you do
14 this by the way.

15 But if you look at this and you
16 say just the way it's designed, these regional
17 reporting measures, it's just not useful for
18 benchmarking accountability, whatever, then
19 you would vote low here. I don't feel that
20 way, but there may be some in the room who do.

21 DR. WALTER: Okay. So that was
22 3a. And 3b, most people thought it was

1 insufficient as well. There's not really
2 enough information presented to understand
3 whether it would actually be meaningful and
4 understandable to the public.

5 And then 3c, all over the map.
6 Two highs, two mediums and two lows. Yes, I
7 just didn't think this would necessarily
8 facilitate transparency and understanding at
9 this regional level without significant
10 clinical detail.

11 So I actually rated it low. But
12 one of the reviewers said it was high because
13 at least the data elements were clear.

14 CHAIR PENSON: So I'm with you on
15 this, ironically. But I'm curious to know,
16 for the people who felt this was high, again
17 I don't want to call people out, but with
18 regard to the construction logic and how it
19 worked and whether or not it was transparent,
20 does someone want to speak to what they
21 thought were the strengths here?

22 DR. BORKER: I think I voted high

1 here. But then based on the clinical
2 arguments that have been made I'm going to
3 revise that rating definitely.

4 DR. POTTERS: Yes, I mean I voted
5 high too and then that was in the context of
6 what I thought was, in my narrow way of
7 thinking before this discussion, an
8 interesting way for the developers to try and
9 make up a stratification that I think we've
10 had a discussion on that. Perhaps it's not as
11 valid as I had originally thought.

12 CHAIR PENSON: Other comments? I
13 definitely see us losing energy here, so
14 let's, stay with it, stay with it folks.
15 We're almost done, another hour I promise you.

16 All right so I guess at that
17 point, any other comments about usability? So
18 I actually feel like we're actually reaching
19 a consensus here on this, so let's go through
20 these together.

21 MS. TURBYVILLE: Before you rate,
22 just keeping in mind we know that these

1 measures haven't yet been implemented and we
2 understand that, for in particular these
3 measures, so you also want to put the mental
4 twist as they're presented, would they be
5 suitable as well. So kind of broadening that
6 context.

7 CHAIR PENSON: Okay. So let's
8 start with 3a, to the measure results are
9 reported to the public, are they going to
10 reported to the public at large, community
11 reporting standards.

12 In the past we've been voting
13 insufficient, I'm going to actually move by
14 acclimation, is there anyone who is going to
15 vote differently for insufficient here?

16 So everyone votes insufficient,
17 that's everyone gives it a nine, which is
18 consistent with what we've done with other
19 things.

20 So for usability, 3b, which is the
21 public reporting, the performance results are
22 meaningful, understandable and useful to the

1 intended audiences both for public reporting
2 and quality improvement. And we can actually
3 vote on that. All right, we're good. So here
4 we had one moderate, two low and six
5 insufficient.

6 And now we'll move on to 3c, which
7 is the clinical and construction logic.
8 Basically this is are the data and the results
9 maintained such that the measure including the
10 clinical and construction logic for defined
11 unit of measurement can be decomposed to
12 facilitate transparency and understanding.

13 Go ahead and vote here. All right
14 that's interesting. Okay, so we had five
15 folks who said it was moderate, three who said
16 it was low and one said it was insufficient.

17 Do you think that the discussion
18 we had reflects that? I mean I sort of
19 thought we were going to be all over the map
20 on this one.

21 MS. TURBYVILLE: The moderate
22 would be interesting. So the conversation at

1 least that I picked up I heard the issue with
2 it being at the regional level and how would
3 that work and how it would be actionable, so
4 I'd be very interested for those who supported
5 it at the moderate level to, for our notes,
6 provide a little bit of rationale would be
7 helpful to us.

8 CHAIR PENSON: Don't get shy now,
9 we're all friends.

10 DR. CHEN: I voted moderate. I
11 guess my feeling on it is in the narrow
12 context of can this be deconstructed and made
13 transparent I think the answer to that is yes.

14 I don't necessarily think that the
15 things that make up the elements are the most
16 useful things but the technical question is
17 yes.

18 CHAIR PENSON: That's great.
19 That's very helpful. And obviously the
20 harmonization piece is not applicable. So
21 we'll now finish up with the feasibility
22 items. Then we'll take a five minute break

1 and knock off the last one and call it a day.

2 MS. TURBYVILLE: Maybe we could
3 get out early.

4 CHAIR PENSON: I think you're
5 overly optimistic. If we do it's only because
6 we're all beat to heck. All right, so 4a, and
7 we've been through this numerous times today.
8 I don't know if have to have a lot of
9 discussion about it.

10 For the clinical measure here the
11 required data elements are routinely generated
12 and used during care delivery. So blood
13 pressure, so basically we're looking at
14 administrative data here.

15 I don't think that the comments
16 before about J codes and genomic testing are
17 quite as relevant here, although I could be
18 wrong. Thoughts?

19 DR. CHEN: I think they're still
20 relevant here in the sense that we're giving
21 chemo and there are the genomic assays, but
22 having said that.

1 CHAIR PENSON: Okay. But you'd
2 probably call out something more along the
3 moderate way than anything else, that would be
4 my guess. Okay. Let's move on to 4b, the
5 required data elements are available in the
6 EHR. And I think everyone can agree that
7 that's probably the case. You're probably not
8 going to miss much here.

9 We may have the same issue as
10 before with the types of chemotherapy and how
11 things get priced out. But I think they're
12 still going to there. Are there other
13 comments?

14 Okay. Susceptibility to
15 inaccuracies, errors and unintended
16 consequences. Fairly, looked like it was
17 middle of the road looking at scores. And I
18 think we've been here before with this. I
19 mean it's still administrative data, it's not
20 perfect. Other comments?

21 And finally, barriers to use
22 collection and measurement strategy can be

1 implemented as demonstrated by operational use
2 and external reporting programs. Or testing
3 did not identify barriers to the operational
4 use. In my mind this becomes a matter of
5 whether or not you buy the algorithm. And if
6 you buy the algorithm I think it's applicable.
7 Other comments?

8 (Off microphone discussion.)

9 CHAIR PENSON: Well right, in your
10 opinion does it, I mean my gut feeling is it's
11 just SAS code, you know, so it's doable and
12 implementable at other places. Whether or not
13 it's valid we talked about already.

14 All right, let's vote on this and
15 take a short break. So on 4a, are the
16 required data elements routinely generated and
17 used during delivery of care. And here we had
18 six votes for high and three for moderate.

19 For 4b, the required data elements
20 are all available in the electronic health
21 records and if not there's a plan to get them.
22 And here we had eight people vote for high and

1 one person vote for moderate.

2 4c, susceptibility to inaccuracy,
3 errors or unintended consequences taken into
4 account, et cetera. So here we had two highs,
5 six moderates and one low.

6 At the risk of, I just wonder did
7 whoever voted low mean to vote low? Okay.
8 And did you vote low on all the other ones as
9 well or? No? Do you just mind sharing
10 comment why so the NQF folks can report that
11 back?

12 DR. CHEN: I think my concern with
13 this one goes back again to the ability to
14 adjust for things. I think it is susceptible
15 to inaccuracy, that's why.

16 CHAIR PENSON: Okay. That's
17 reasonable. All right. And then 4d, can the
18 data collection strategy be implemented. That
19 is is the measure already in use or is there
20 testing that shows that it can be put into
21 use. So we have four high, four moderate and
22 one low. Again I'll ask whoever voted low

1 just to share their comment for the record.

2 DR. GILLIGAN: That was me and my
3 mistake, I meant to vote moderate.

4 CHAIR PENSON: Okay. Can you
5 change that yourself? Okay. Good so it's
6 four high and five moderate. So that takes
7 care of the treatment one. We have the breast
8 biopsy one left.

9 Why don't we take a five to ten
10 minute break. Let's start again at 3:15 with
11 an eye towards getting it done in about an
12 hour. Okay? Thank you guys for hanging in
13 there, I appreciate it.

14 (Whereupon, the meeting went off
15 the record for a break at 3:06 p.m. and went
16 back on the record at 3:18 p.m.)

17 CHAIR PENSON: Guys, I don't mean
18 to be rude, but I know a lot of folks are
19 going out to the west coast, or a few of you
20 are and I don't want you to miss your flights.
21 I don't want you to miss your flights and I
22 don't want you to have to get on the phone

1 with me for an hour in two weeks, okay? So
2 with that note let us continue.

3 So we're on to the last of the
4 four measures, which is the episode of care
5 for a 60-day period prior to breast biopsy.
6 And in many respects, this is like the other
7 one, the one regarding treatment of care,
8 pardon me, costs around care.

9 So let's start with the importance
10 issues and we can go off from there. So 1a,
11 just to refresh your memory if you haven't
12 gotten tired of this already.

13 This focuses on a national health
14 goal/Priority Identified by DHHS, or National
15 Priorities Partnership, and I don't think
16 anyone is going to argue again, breast cancer
17 is a big ticket item, and so it's high impact.

18 And I think most of everyone's
19 scores reflect that, their H's and M's.
20 Anyone who voted for an M and wants to add, be
21 my guest.

22 DR. WALTER: Well I guess I wasn't

1 sure what the, I mean it seems to me that the
2 big disparities are in getting follow-up of
3 your abnormal mammogram, or abnormal lump or
4 something like that, this measure is not going
5 to get at that.

6 It truncates it at 60 days. It's
7 not going to measure, a lot of the delays are
8 because you don't get follow-up in 60 days.
9 So I didn't think this was really, again it
10 would've been helpful to have more conceptual
11 clarity about why, you know, what they're
12 doing is important, but it wasn't really
13 stated in their introduction.

14 DR. CHEN: I think what they're
15 trying to get at and I'm, you know, trying to
16 do the psychic thing here it's like a friends
17 network for them, but is that there has been
18 a push more recently towards trying to get
19 people to do needle biopsies instead of open
20 biopsies.

21 And yet despite consensus
22 statement saying needle biopsy is the way to

1 go, only like 40 percent of breast cancer is
2 diagnosed by needle biopsy. And so that's I
3 think where they're going.

4 DR. GILLIGAN: Although, I just
5 have to weigh in. I actually voted
6 insufficient, but I didn't get my survey in on
7 time. But they have nothing in the section on
8 any impact from breast biopsy whatsoever.

9 So I mean, yes I agree it is a
10 high impact, but it would've been nice if
11 they'd said something about breast biopsy as
12 opposed to about breast cancer.

13 CHAIR PENSON: Yes, we go back to
14 this where, you know, even though we all feel
15 that it is, did they by not putting it down,
16 should we penalize them. They're on the phone
17 sort of shaking their heads.

18 But I just don't feel, Kevin and
19 Todd you can yell at me any time, but the fact
20 of the matter is I just, you know, you're
21 right it's not breast cancer, but look you
22 don't get to breast cancer without a breast

1 biopsy. And I think Steven's comment about
2 what sort of biopsies are done is valuable.

3 But I'm not hearing anyone say low
4 or insufficient, I'm hearing high or moderate,
5 so.

6 DR. WEISS: Would it be okay for
7 me to step in here here -

8 CHAIR PENSON: Oh yes, yes,
9 absolutely, come on in now.

10 DR. WEISS: Yes, so I think that
11 you're right to help us notice that we didn't
12 give you that level of detail. The two things
13 that the workgroups were very clear on was the
14 type of procedure, and that is the open biopsy
15 or not.

16 And the second is that there's a
17 proliferation of different types of
18 pathological assays that can be used here.
19 Some very simple, some pretty complex and very
20 expensive.

21 And that there's a real belief
22 that on both those issues there's a lot of

1 variability, and that means that there's
2 research issues and quality issues probably.
3 So that's why that's there.

4 CHAIR PENSON: That's helpful
5 Kevin, I appreciate that. Any other comments
6 about 1a? So 1b is that demonstration of
7 resource use and cost problems represent an
8 opportunity for improvement. Excuse me. The
9 data demonstrated that there's a variation in
10 the delivery of care.

11 It's interesting because when I
12 looked at this originally I scored it as an M.
13 And that's because I'm not a clinician that
14 treats breast cancer, and it never occurred to
15 me, you know, this issue about the biopsies,
16 that that is actually what's most important.

17 I mean it strikes me though, that
18 in the document that the issue is always about
19 imaging, and the imaging is going to drive it.
20 But what I think I'm hearing here is that type
21 of biopsy is important as well.

22 I mean are we comparing apples to

1 apples? When you look at open versus say,
2 needle biopsies, I don't know the answer to
3 that and so I'll defer to the breast cancer
4 docs in the room.

5 DR. CHEN: Yes and no. There are
6 some people who can get needle biopsies, who
7 are getting open biopsies. I mean we give
8 grand rounds to the community and have
9 arguments with other physicians who say no,
10 they don't like needle biopsies when they
11 clearly could do them.

12 On the other hand, there is some
13 element of people who have to get an open
14 biopsy for various technical reasons.

15 And there's a kind of a level that
16 you can't go below, and that's going to vary
17 from place to place. Often also dependent on
18 what kind of resources they have available to
19 them. Not every place has stereotactic biopsy
20 available to them.

21 CHAIR PENSON: Other comments? I
22 mean I'm not hearing any deal breakers here by

1 a long shot. I'm getting the impression that
2 everyone thinks this is either high or
3 moderate, and I think that's good.

4 So next, onto purpose then. The
5 purpose or objective of the resource use
6 measure, and the construct for resource use
7 and cause is clearly described.

8 And pretty much everyone in the
9 room voted that as high or moderate. I don't
10 think there were a lot of questions here. I
11 think the purpose is pretty straight forward.
12 Any comments?

13 All right. And then we'll do 1d,
14 which is the resource use categories. And
15 like the earlier measure, the categories are
16 very straight forward in my mind, and they
17 have validity for me so I didn't have any
18 problems with that. Other thoughts?

19 DR. GILLIGAN: I just wanted, one
20 very brief comment which is because this
21 happens so much these days. On page 6 it
22 says, "In 2009, the USPSTF issued guidelines

1 advising against any screening for women in
2 their 40s." And that's just factually
3 incorrect.

4 The USPSTF recommended against
5 routine screening. They recommended the
6 doctors counsel the women based on whether or
7 not they want to be screened.

8 And it constantly gets quoted this
9 way, as if they said, don't screen, and that's
10 specifically not what they said. They said,
11 don't do routine screening, talk to the woman
12 first. So I just wanted to clarify that.

13 CHAIR PENSON: Kevin, did you
14 catch that?

15 DR. WEISS: I did.

16 CHAIR PENSON: There's no comment,
17 just you noted it and change it, and next time
18 you submit it, it's all good. But I think, we
19 won't spend too much time on it because
20 everyone's really punchy.

21 But Tim's, but I'm not minimizing
22 Tim's comment, I mean I do prostate cancer,

1 which is, you know, the ultimate in that
2 world. And I think people make those mistakes
3 all the time.

4 And it's important because a lot
5 of times these documents get picked up in the
6 lay press, or by patients and other people.
7 And suddenly what was sort of a mental lapse
8 for lack of a better way to put it, becomes an
9 unhealthy policy.

10 So with that in mind, why don't we
11 go through the importance to measure
12 variables. So 1a, high impact, does this
13 measure focus on a specific national
14 health/goal priority, or is it a high impact
15 aspect of health care? So here we have five
16 people voting high, and four people voting
17 moderate.

18 1b, the performance gap issue,
19 demonstration of resource use or cost problems
20 and opportunity for improvement is there,
21 where overall there's less than optimal
22 performance across providers, population

1 groups. And here we had two people vote high,
2 and seven people vote moderate.

3 1c, Purpose/objective. The
4 purpose/objective of the resource use measure,
5 including it's components and the construct
6 are clearly described. And here we had five
7 people vote high, and four people vote
8 moderate.

9 And finally, 1d, the resource use
10 service categories are the categories
11 included, consistent with and representative
12 of the conceptual construct represented by the
13 measure. And here we had seven people vote
14 high, and two people vote moderate.

15 Does this one have a summary one,
16 no, okay good. All right. So you'd think by
17 the end of the day I'd have figured that one
18 out by now, wouldn't you? Appreciate that.

19 Okay so next, we're going to move
20 onto Scientific Acceptability. 2a, and 2a is
21 basically is the measure precisely specified
22 so it can be implemented consistently. And

1 the primary reviewer for this was Louise.

2 DR. WALTER: All right. So it
3 looks like we had three middle's, three high's
4 and one low. I actually voted this low
5 because while the measures and CPT codes are
6 clearly labeled in the table, they're actually
7 not specific for breast biopsy.

8 So there's two CPT codes, the
9 10021, 10022, that are basically biopsies of
10 any organ, they're final aspirations.
11 Normally they're paired with a breast cancer
12 diagnosis, and then you can use it as a
13 biopsy.

14 But if it's not paired with a
15 breast cancer diagnosis which in this case
16 it's not, then it is basically a F&A of some
17 organ, be it your thyroid.

18 So I didn't see that there was any
19 evidence that this was a validated algorithm
20 for identifying breast biopsy. And at least
21 in my work doing claims coding, I know that
22 that is not a specific code for breast biopsy.

1 CHAIR PENSON: Other comments in
2 the room? I'm going to take the prerogative
3 and ask the measure developers about Louise's
4 comment, because I didn't capture that, not
5 being someone whose focus is on breast cancer.
6 And that's a major concern, are you picking up
7 non-breast cancer or non-breast biopsies?

8 DR. WEISS: If Todd's here, if he
9 can maybe address that?

10 DR. LEE: Yes, so these were
11 through our workgroup, identified as an
12 iterative process, you know, I'm not aware
13 that, why they got through our workgroup if
14 they're not specific to breast biopsies. I
15 can't answer that right now.

16 DR. WALTER: And let me put, I was
17 going to put one other thing because I looked
18 at the evidence that you provided, the data,
19 and there was a statement about, they couldn't
20 understand why the cost was so much lower for
21 CPT code 10022, which is the non-specific
22 code, versus 19103, which is a specific breast

1 cancer biopsy code. So that actually would
2 track with that this is not a specific for
3 breast biopsy, based on your data.

4 CHAIR PENSON: Louise, is there
5 something you could suggest here, whether it's
6 either taking out those codes, or some sort of
7 evidence they could provide to make you feel
8 better?

9 DR. WALTER: Well I guess we're
10 getting back to chart review. But it's a
11 little concerning since one of the non-
12 specific was the second most commonly used CPT
13 code, so I don't know how often is that used
14 for breast biopsy versus other biopsies.

15 CHAIR PENSON: Steven?

16 DR. CHEN: Yes, I actually had a
17 concern about F&A too. In particular my
18 concern was that it excluded you if you had an
19 F&A followed by another breast biopsy.

20 Now in general outside of breast
21 cysts, we don't do F&A for anything besides
22 abscess and cysts, unless you don't have core

1 available to you, and that's where people stop
2 doing needle biopsies. Because they just get
3 so poor information, and so I would say that
4 in my mind, I would probably exclude that.

5 And then as a triggering event,
6 and put that into resource use, the same way
7 that you might use an MRI or something like
8 that. Someone is wasting their time putting
9 a fine needle into something that didn't need
10 a fine needle. It's just my, because the
11 other ones are not cancer directed questions,
12 they're abscesses and cysts.

13 CHAIR PENSON: So Sally, how best
14 to handle this because what I'm hearing from
15 the panel is, this is worrisome, probably the
16 best way to deal with this would be to exclude
17 these patients. But I also add as someone
18 pointed out, that if you exclude the patients
19 you lose half of the sample size, and I don't
20 know what to do with that.

21 MS. TURBYVILLE: I think there are
22 several possibilities. Throwing it back to

1 the developer to see if, for example pairing
2 it with a diagnosis or some other code would
3 increase it's reliability, and whether they
4 can do that in this project.

5 Or if the committee votes on the
6 measure as it's specified now, and I think it
7 might be an opportunity to ask the measure
8 developer if they think they can think about
9 this a little bit more and come back, if not
10 to this panel to the steering committee, as
11 having addressed a concern with this TAP.

12 CHAIR PENSON: So, what I would
13 then support here, or propose I should say, is
14 this is probably insufficient evidence. And
15 what I mean by that is that, it would be
16 accompanied by a comment basically saying
17 that, as currently defined this measure is
18 problematic because of these two CPT codes.
19 And that it would be preferable to have these
20 removed, so that that way the cohort is more
21 precisely defined.

22 However, that being the case, then

1 it would be useful to have the cohort rerun
2 and see what sort of sample sizes come up. So
3 does that seem like something that would be
4 reasonable?

5 DR. GILLIGAN: Just one question.
6 You said that if you pair the CPT with the
7 breast cancer diagnosis, then it becomes more
8 valid. Is that an option?

9 DR. WALKER: Well that's just,
10 yes, I mean because at least then you think,
11 gosh if it's paired with a diagnosis, they
12 must be biopsying the breast versus without
13 anything, yes.

14 CHAIR PENSON: Yes, but the
15 problem becomes is, what do you do with
16 negative biopsies? You don't want, I mean
17 what you could potentially do is pair it with
18 benign diagnoses from the breast too.

19 But what I'm hearing here is, is
20 that with the inclusion of these two CPT codes
21 it's causing real problems certainly. I'm
22 glad you're here, I didn't even think about

1 that. Other comments?

2 So I think what I would, and just
3 to repeat what I had said was, that I think
4 it's probably, the best way to handle it would
5 be to say that there is insufficient evidence
6 as it's currently written.

7 It's not acceptable because the
8 CPT code is capturing non-breast biopsies in
9 all likelihood and we would propose, or
10 suggest I should say, either excluding those
11 patients, or potentially tying it to a
12 diagnosis code that localizes it to breast,
13 whether it's breast cancer or benign breast
14 condition, and then --

15 (Off microphone discussion)

16 CHAIR PENSON: I guess in certain
17 respects I would, what's that? I would say
18 it's insufficient because the fact of the
19 matter is, is low implies that we don't think
20 it's going to work.

21 And it's not that I don't think
22 it's going to work, it won't work in it's

1 current format. It may work with the
2 modifications but we need to test that.

3 MS. TURBYVILLE: Right. I
4 completely understand with what your
5 struggling here with, I think we would like to
6 vote on how the measure is specified now.

7 CHAIR PENSON: Okay.

8 MS. TURBYVILLE: Whether the
9 measure developer can follow-up or chooses
10 then to remove the measure, or continue to
11 pursue it, you know, as it is written, we'll
12 explore.

13 I mean obviously there's time line
14 issues for those projects so we'll work with
15 the developer to see if they can come up with
16 an approach that would address your concerns,
17 and how you rate the precision of the specs.

18 CHAIR PENSON: So I think what, so
19 then that's what you prefer, so let me, before
20 we talk anymore in the room, I want to go to
21 the folks on the phone, Kevin and Todd, and
22 make sure you guys are hearing what we're

1 saying.

2 And if you have any questions
3 about this or disagree, let us know now so we
4 can discuss it, because obviously this will
5 affect things. Kevin, Todd?

6 DR. WEISS: Yes, so there's not a
7 process for us to easily say to you that if
8 it's a very clear concern of specificity of
9 the diagnosis that is affecting your ability
10 to go forward, that we would just take these
11 out and work with the more specific, the
12 smaller end.

13 So there's no way of us doing it
14 on the fly like this, but and I can't speak
15 for Todd and the rest of the group.

16 But I would suggest from my
17 understanding of how they work is that, they
18 would probably be very pleased to make sure
19 that the specificity increased in fact if this
20 was a big problem that would make us all feel
21 uncomfortable.

22 So I don't know if that did

1 anything more than just reflects the fact that
2 we're very much attuned to your feedback.

3 CHAIR PENSON: We sort of went in
4 and out for the last part of that, so if you
5 just repeat it again, I'm real sorry.

6 DR. WEISS: That's okay, I'm an
7 instructor of repeat. We are very, you know,
8 we are as concerned as you are if, in fact,
9 that these diagnosis would lack a lot of
10 population where there was nonspecificity and
11 created any sort of misclassification into the
12 population.

13 And so if we had a way to, a
14 mechanism on this call to just say change it
15 by deleting these two codes, we would. I just
16 don't think that the process is set up to
17 allow us to do it, either on NQF side or on
18 our side.

19 But we would be very responsive to
20 that concern if it was addressed to us. And
21 to the extent that you could look at the rest
22 of the measure and give us some feedback in

1 the context. It would be extremely helpful
2 because it seems like a very straight forward
3 issue to address.

4 CHAIR PENSON: So yes, I'm with
5 you on that and I think everyone in the room
6 is too. As Sally pointed out, we're sort of
7 obligated to vote on the measure as is.

8 But as Sally also pointed out,
9 it's entirely possible that you could turn
10 around, crunch this, get it back to us fairly
11 quickly, and either as a TAP or even as a
12 steering committee, address it that way.

13 So I think that what I'm hearing
14 from Sally is that NQF will find some sort of
15 mechanism, because it's a very discreet
16 request that your getting from the TAP, which
17 is easy to deal with. All right.

18 DR. WEISS: That's fine.

19 CHAIR PENSON: Great. Thank you.
20 Other comments in the room? Okay, so with
21 that, let's move on from 2a1 to 2a2, which is
22 reliability testing. And reliability testing

1 demonstrates the results are repeatable
2 producing the same results a high proportion
3 of the time when assessed in the same
4 population. Louise?

5 DR. WALKER: Oh sorry, I didn't
6 have this down for me.

7 CHAIR PENSON: Oh, I'm sorry,
8 sorry, I apologize. You're right, you don't.
9 This was Dwight, who the dog ate his homework
10 there, so I'm just teasing. It's that point
11 in the day. So basically I think that while
12 looking at this, I think I was the only one
13 who voted insufficient.

14 It's sort of all over the map,
15 most people voted moderate. Rohit, you said
16 low. So I think I'd ask Rohit just to comment
17 on the negatives, and while I figure out why
18 I put it insufficient again.

19 DR. BORKER: This is again 2a2,
20 correct?

21 CHAIR PENSON: This is 2a2, yes.

22 DR. BORKER: So this is kind of

1 reflecting the same concerns I had with other
2 measures is, we haven't really evaluated this
3 measure in another database, and that to me is
4 like the biggest evidence gap here.

5 Whatever processes that they have
6 done has been in the same database. Until we
7 have that data, I can not evaluate. And to
8 your earlier comment, I should put that as a
9 insufficient evidence rather than the low
10 evidence.

11 CHAIR PENSON: Right.

12 DR. GILLIGAN: I have actually the
13 same concern. I thought it was low or
14 insufficient as well.

15 CHAIR PENSON: I now have found my
16 notes. The reason I actually said it was
17 insufficient was because of a comment that
18 Carlos made in his, was data reproducibility
19 assessed and he specifically said there's no
20 evidence that the process was validated, or
21 there was any type of QA to insure accuracy.

22 So he raised some concerns that, I

1 mean my common sense says it's probably very
2 reproducible, but there's no, the data aren't
3 provided and they were requested.

4 Other comments? Okay, so why
5 don't we vote on 2a2 and 2, let's vote on
6 these, whatever numbers we're up to now. It's
7 been a long day.

8 2a1. So 2a1 is this is precisely
9 defined and implemented consistency, and this
10 was, there was a lot of discussion around
11 whether or not we're including breast
12 biopsies, biopsies which are not of the breast

13 So here we had two who said
14 moderate, four who said low, and three who
15 said insufficient. So I think we've had
16 enough of a discussion here that we don't have
17 to beat this over the horse.

18 And the next one is reliability.
19 Does the reliability testing demonstrate that
20 the results are repeatable, producing the same
21 results a high proportion of the time when
22 assessed in the same population.

1 And so here we had three who said
2 moderate, and six who said insufficient. And
3 I think that Carlos's comments sort of
4 addressed that, so. I'm sorry.

5 MS. TURBYVILLE: Overall.

6 CHAIR PENSON: Just looking at
7 what Carlos said, okay. Let's move onto 2b1.

8 (Off microphone discussion)

9 CHAIR PENSON: Oh summary, gosh
10 darn it, that's what you were saying, God I
11 was so lost today. All right, so this is the
12 summary for a liability. Just vote and shoot
13 me now, okay. And here we had one that was
14 moderate, two that were low, and six that were
15 insufficient.

16 Now we can move on, good. Yes,
17 this is the fun one, actually I think it may
18 go a little quicker now.

19 So, we're now onto 2b1, which is
20 related evidence. Evidence measure
21 specifications are consistent with the
22 evidence presented to support the focus of

1 measurement under criteria on 1b. And the
2 measure is specified to capture the most
3 inclusive target population indicated by the
4 evidence.

5 I think to some degree this is
6 going to get back to that issue of the breast
7 biopsies that aren't really breast biopsies.
8 So the reviewer for this one was Louise, so.

9 DR. WALKER: All right. Yes, I
10 was going to say this tracks very well with
11 2a1. So in addition to it not being specific
12 for breast biopsy, I think another question I
13 had was a lot of the measurement choices were
14 not necessarily justified. So why a 60-day
15 window before biopsy?

16 I had a question like, well many
17 women don't get follow-up breast biopsies
18 within 60 days of a lot of their imaging.

19 So therefore, a region with lower
20 costs in the 60 days before biopsy, maybe
21 that's due to long delays between getting all
22 their testing and then their biopsy. And how

1 would this be detected? So I guess I had some
2 questions about that.

3 Also, why stratify at age 30,
4 mammography. Generally the guidelines suggest
5 starting at age 40. So there wasn't really a
6 lot of rationale for that. So those were sort
7 of my comments on specification.

8 CHAIR PENSON: Other comments
9 regarding sub-criteria 2b1, whether or not the
10 measure is consistent with the evidence? I
11 think Louise kind of hit the nail on the head.

12 Now my question to you is, with
13 regard to this, I mean does this also come
14 back to low based on what we discussed before?
15 I mean I think that issue about not, if it
16 wasn't for the non-breast biopsies, I'd be a
17 lot more comfortable here, but I really think
18 that's a major problem here.

19 Okay, let's move onto 2b2, which
20 is validity testing demonstrates measure data
21 elements are correct, and that the score
22 correctly reflects the cost of care. This was

1 assigned, I'm looking here, to Dwight.

2 And I think in the end, we can
3 sort of use Carlos's review as a proxy. And
4 I think Carlos in reading the review picked up
5 some minor concerns, but nothing that was
6 overwhelmingly problematic.

7 I mean I think that, you know, if
8 you get, let's for lack of a better way to put
9 it, suspend disbelief for a minute, and say
10 that all the biopsies were done on the breast,
11 then you are validly measuring the resources
12 here within reason. And I think Carlos may
13 have raised some minor concerns, but that was
14 it. Steven?

15 DR. CHEN: I think the one thing
16 that for me is of major concern is, what
17 generated this biopsy to begin with. Is it
18 something that is a palpable mass? Is it
19 something that is of minor concern?

20 You know, because I think that
21 that does change the resource utilization,
22 because a palpable mass, you're much more

1 likely to go direct to biopsy, whereas
2 something that maybe was a little amorphous,
3 you may end up with an MRI somewhere along the
4 way.

5 And that has nothing to do with
6 practice variation, it has everything to do
7 with what's actually happened.

8 CHAIR PENSON: Well, I understand
9 what you're saying and it raises two points.
10 I don't think that that affects the validity
11 of the measure, I think that it is a risk
12 adjustment situation. So in other words, you
13 know, why was it done? We can risk adjust for
14 that.

15 And so I don't know if it's
16 appropriate to discuss it here. We can
17 discuss it later, but then we'll get into the
18 discussion later again like we had on the last
19 one is, do you need risk adjustment when
20 you're looking at a regional setting.

21 Shouldn't the number of women who
22 have palpable breast masses in Florida be the

1 same as in Arizona. And I'm not saying that's
2 true or not by the way, I don't know. But I
3 would think if it's okay with you, this
4 probably comes up in the risk adjustment
5 piece.

6 DR. WALKER: But if you don't
7 believe the codes, how can, I mean can you
8 vote anything other than low?

9 CHAIR PENSON: Well, here's what I
10 would say is that, I think we've already dealt
11 with that in all fairness. So I mean as,
12 let's now say that we're cool with, we've
13 gotten over the fact the inclusion criteria is
14 a problem, okay.

15 But now let's now say, looking at
16 the outcome measures, you know, which is
17 resource utilization, do they have face
18 validity? Does that fly with you?

19 Because otherwise what we're going
20 to end up doing is we're going to put low for
21 everything. It may bounce back and then it
22 may fix this problem, this problem.

1 If there's a problem with say the
2 validity of these measures, you know, going
3 with what we were getting at before with J
4 codes, and this and that, I don't want that to
5 get lost because we were so caught up in the
6 issue with the CPT code. So we've already
7 sort of voted on that.

8 Let's now pretend as if everything
9 else is okay, so we can give additional
10 information to the steering committee and to
11 the measure developers, so they can make
12 appropriate changes. So having said that,
13 what do you think?

14 DR. CHEN: I'm looking at this
15 again, and I think by and large I think
16 they've captured most of it. I think, the one
17 thing I'm looking for and I can't seem to find
18 it in here, is lymph node assessment and
19 things like that that sometimes comes after
20 biopsy, but it's a minor point that I don't
21 think prohibits it from going forward. And
22 it may be in here, I just lost it in the mess.

1 DR. WALKER: I guess the only
2 other thing I'd like to see for validity
3 testing is, different intervals. Again,
4 convince me of why 60 days is the interval
5 that we should be using.

6 CHAIR PENSON: I think that's a
7 reasonable point. Other comments? All right,
8 so now we're onto 2b3, and this is the
9 exclusions, did I miss one, I don't think I
10 did. No, 2b3, okay good, I'm not completely
11 losing my mind, only sort of at this point.

12 So the exclusions are supported by
13 clinical evidence, and the measure
14 specifications include computing exclusions so
15 it's transparent. And the reviewer for 2b3
16 was Rohit, and again I'll ask you before you
17 start, remember let's sort of, we've beat the
18 excluding the CPT codes at this point. Just
19 so we can give useful information.

20 DR. BORKER: So just to kind of
21 point out the strengths. One of the things
22 that you just mentioned was transparency in

1 terms of the exclusion criteria and it's
2 impact that got tested on the cohort size.

3 But that also serves as one of the
4 limitations as they lost pretty much 52
5 percent of their potential eligible patients.
6 So you're losing half of your patients, we
7 don't know what, you know, what impact that
8 has on the outcome measures. That's the major
9 point there so, and there are some minor
10 things that I don't want to bring it up.

11 CHAIR PENSON: Steven?

12 DR. CHEN: One exclusion I just
13 bring up for a discussion and I'm not sure how
14 I feel about it, is they excluded unpaid
15 claims and they zeroed those out.

16 But for things that have zero
17 cost, they gave them a one and gave them the
18 standardized price. Which would seem to imply
19 that if you have a crummy insurance company
20 covering your state that you might look really
21 good on resource utilization.

22 CHAIR PENSON: I think that's an

1 interesting point. I didn't catch that,
2 that's interesting. I was on Rohit's comment,
3 which is you throw out half your patients
4 because of your exclusion criteria, what does
5 that do to your generalizability? And could
6 that vary by region which would confound any
7 comparisons.

8 I looked at it not as a major
9 point, but a moderate point. In other words,
10 I didn't want to throw the baby out with the
11 bath water, but that was something there.

12 DR. WALKER: This is just a
13 question. Again, it would be nice to have
14 explanation, rather than excluding women with
15 a prior history of breast cancer, they
16 stratify by this, and I just didn't know why,
17 why stratify versus exclude, and what was the
18 hypothesis behind that?

19 CHAIR PENSON: That's a reasonable
20 point, I mean maybe they just wanted to
21 capture more interesting data. As long as
22 they stratify I think you're dealing with it,

1 but I think it's, other points on 2b3,
2 exclusions?

3 So what I'm hearing, just to
4 summarize, is some minor to moderate points
5 here. A lot of good information for a summary
6 report and I didn't hear anything that killed
7 it, but I definitely heard some interesting
8 thoughts there.

9 Let's move onto the criteria which
10 we always seem to spend the most time talking
11 about, which is appropriate too obviously, is
12 2b4, which is the risk adjustment issue.

13 And again, there is no risk
14 adjustment here, so that what you're voting on
15 with 2b4 will be whether or not the rationale
16 as you see it, for the lack of risk adjustment
17 is appropriate. There is some stratification,
18 but I don't know if I would say that's
19 adequate, and so I'll throw it open to the
20 floor.

21 DR. CHEN: I feel like I'm talking
22 less.

1 CHAIR PENSON: No, it's okay.

2 DR. CHEN: There's a couple of
3 things. One is, and I didn't issue this
4 objection before, is you have this, again it's
5 320 days of coverage on both sides for a 60-
6 day episode.

7 And that only makes sense if
8 you're going to do risk adjustment, which they
9 specifically said they don't want to do.

10 So I would say that I would leave
11 that in and get the risk adjustment in,
12 particularly because what kind of biopsy you
13 choose may be very related to what their
14 comorbidity is, in particular anti-coagulation
15 becomes a huge deal if you want to do a needle
16 biopsy.

17 CHAIR PENSON: And I'm with you on
18 that. I think that the exclusion by, you
19 know, two years continuous coverage is a fine
20 point, it's a good point, but it's also a fine
21 point. In other words, a minor point.

22 What I would ask, which I'm having

1 a hard time with, I personally am comfortable
2 in this particular measure not to have the
3 risk adjustment.

4 Only because the things we've
5 talked about, Steven, with regards to, for
6 example anti-coagulation, palpable breast
7 masses, that's going to the, I would assume
8 that the distribution is going to be random
9 between the west coast and the east coast.

10 I may be wrong about that, but
11 that's my gut feeling, that you're not going
12 to find more people on anti-coagulation,
13 significantly more in California than in New
14 York, but I could be wrong.

15 That's what it boils down to. If
16 you think that you're going to see this
17 variation by region, then risk adjustment is
18 necessary. If not, then it's not.

19 My gut is on this one, and I'm not
20 a breast cancer doc so, either the folks who
21 are say so, you know, I'm not feeling it, so.

22 DR. WALKER: Well I guess it just

1 comes down to again, trying to really
2 understand what region it is, if it's the
3 state, you know, maybe there are. But, you
4 know, if it's bigger, maybe not. So I guess
5 I wish there would've been more specification
6 on the region.

7 CHAIR PENSON: Other comments?
8 All right. Well, we are going to get done on
9 time the way we're going now. We beat them
10 right down. Okay, let's vote on these four
11 like we've done before.

12 So the first one is 2b1, which is
13 the evidence or the measure specification is
14 consistent with the evidence. And here we
15 have seven who say moderate, and two who say
16 low.

17 Then let's go onto 2b2, which is
18 validity testing. Does validity testing
19 demonstrate the measured data elements are
20 correct and that they correctly reflect the
21 cost of care resources provided.

22 There we go. And here again, we

1 have the same seven who said moderate, and two
2 who said low.

3 Okay. Let's move onto 2b3, which
4 is exclusions. Are the exclusions supported
5 by the clinical evidence or analysis of
6 frequency and distribution, and is it
7 transparent. And again it's seven moderate,
8 and two low. At least we're all consistent.

9 Now this one I'll bet you we'll
10 get different ones though. This is the risk
11 adjustment question for, and basically there
12 is no risk adjustment here. Do the data or
13 the rationale support no risk adjustment
14 stratification strategy.

15 And so here we had four moderate,
16 three low, and two insufficient. And I think
17 the discussion reflects the uncertainty in the
18 room regarding this and I think that's
19 appropriate.

20 All right, let's keep moving
21 along. We're doing great and everyone's going
22 to catch their planes, and the work's going to

1 get done.

2 So we're going to 2b5, this is
3 differences in performance. Data analysis
4 demonstrates that the methods for scoring an
5 analysis of the specified measure allow for
6 identification of statistically, and again
7 importantly clinically meaningful differences
8 in performance, or there is overall evidence
9 of less than optimal performance. And 2b5 was
10 reviewed by Rohit.

11 DR. BORKER: So for 2b5, one of
12 the points that was raised was it's not clear
13 how unwarranted variation would be determined.
14 So I guess the, one of the people who
15 commented was to see if, whether any changes
16 or variation in costs is because of difference
17 in the patient mix again, or is it because of
18 just a different quality of care that's being
19 offered to the patient.

20 And the second comment I had is
21 again around the statistical tests. Because
22 these are cost data of, more than likely

1 they're not going to be normally distributed.
2 So performing regular difference, like T tests
3 and all may not apply here, so those are two
4 of the concerns.

5 CHAIR PENSON: Other comments?
6 You know, when I looked at this, it's sort of
7 the same as the last one. The big problem I
8 have here is not the statistical piece
9 although, that's a well taken point that I
10 hadn't considered with regard to normal
11 distribution.

12 But really, what do I do with
13 information, you know, if the west coast is
14 different than the east coast. And I just
15 don' know. I don't know what we're going to
16 do with that bit of data.

17 It doesn't mean that it's flawed.
18 I just, you know, assume it's less when I'm
19 sort of between moderate versus insufficient.

20 On the one hand, the more I think
21 about it, the more I come to the conclusion
22 that we at least got to measure it, and look

1 at it, and go from there. So I don't know.
2 Other comments? All right, I can hear you
3 breathing people.

4 Yes, we're almost done, we're
5 almost done. It gets easier from here.

6 Okay, let's just do disparities
7 and then we'll be done with the scientific
8 inaccuracy piece. And again we've had this
9 discussion before as well, with the
10 disparities.

11 You know, when you look this, if
12 disparities in care have been identified, does
13 the measure allow scoring specifications and
14 stratification by race, ethnicity, other
15 issues. And the reviewer for 2c was Dwight.

16 And I think in the end, we're
17 right back where we were before with this. I
18 think a lot of people are confused by this,
19 and people are all over the map.

20 The question becomes is do you
21 think you can really only, you know, stratify
22 it by age, and if you think that you need to

1 stratify it by more than that in this, then
2 you would say low or insufficient. Where if
3 you think that's adequate, you would go from
4 there.

5 So let's vote on this, what's
6 left, and then we'll just go through the last
7 pieces of it. So go to 2b5 and to summarize,
8 this was the differences in performance and
9 like I said there, Rohit raised some issues of
10 statistics, and I think we are again at that
11 issue of the clinical meaningfulness of this,
12 and so it's, let's go ahead and vote. So we
13 had seven who said moderate, and two who said
14 insufficient.

15 MS. TURBYVILLE: We've got to do
16 validity overall.

17 CHAIR PENSON: All right, thank
18 you.

19 We've got to do, yes, validity
20 overall. So this is, you know, based on sort
21 of the whole nine yards, where you see with
22 risk adjustment, validity testing and the

1 specifications piece.

2 So I think in the end, this is
3 where you can take into account the business
4 with the CPT code. So we had three who said
5 moderate, five who said low, and one who said
6 insufficient. And I think again the comments
7 reflect that.

8 And disparities, we discussed this
9 already. Disparities in care, if they've been
10 identified, can you measure them or is it do
11 you need to measure them. One, two or three?
12 So five who said moderate, three who said low,
13 and one who said insufficient.

14 All right, we're in the home
15 stretch for real now. Let's talk about
16 usability and then we'll talk quickly about
17 feasibility because I think we've been through
18 those already.

19 Usability, 3a, which is basically
20 the results can be reported to the public at
21 large in national community reporting
22 programs. And for this Steven, you were the

1 primary reviewer.

2 DR. CHEN: For this I actually had
3 a little bit less problem with reporting to
4 the public, because it is at such an aggregate
5 level. Without the attribution, I'm a little
6 less concerned about how precisely accurate it
7 is.

8 And I do think that this is a
9 problem that people should be aware of, that
10 other regions do have more needle biopsies
11 than they do. That's just my personal
12 opinion.

13 CHAIR PENSON: Other comments? Go
14 ahead Louise, don't be shy.

15 DR. WALKER: I'm losing my ability
16 to think. Well I just, again I wasn't sure if
17 that was important to know. And also with all
18 the caveats of the problems, I especially was
19 wondering if it was something that I'd want to
20 report to the public at this current stage.

21 CHAIR PENSON: Let's remember that
22 with this particular item, that this was the

1 one that throughout the day this is being
2 tested by the RWJ contract, and NQF is sort of
3 redefining the way they look at this.

4 You know, the downside with all
5 these regional measures is, I don't know what
6 to do with the information myself. I don't
7 know if consumers, if programs will know what
8 to do with it, so I sort of, I've been voting
9 insufficient throughout the day on this, and
10 I'm kind of still there with it.

11 Steven, I'm with you on that, with
12 regard to the accountability is less
13 worrisome, but even so I don't know what to do
14 with it then, so.

15 Okay. Let's move onto 3b, the
16 measure results are considered meaningful,
17 understandable, and useful to the intended
18 audience, both for public reporting and
19 quality improvement. And this sort of gets to
20 what I was just saying which is, you know,
21 what do you do with this.

22 And I suspect looking at the

1 comments that everyone else was sort of in the
2 same place which is, what to you do with this.
3 I think Louise you were the primary reviewer
4 for this. Were you, maybe not, am I screwing
5 up again? Steven, I'm sorry, Steven.

6 DR. CHEN: And this is why I did
7 put insufficient here, because I don't see how
8 it's an actionable piece of information beyond
9 consumers saying, hey, I heard we don't do a
10 lot of needle biopsies, am I eligible? It's
11 the only thing that they can do.

12 CHAIR PENSON: Yes, but now the
13 question becomes is it's not actionable, but
14 insufficient supplies it with more evidence
15 that might be actionable?

16 DR. CHEN: Yes, I think if they
17 put together some sort of detail that says,
18 this is how one would expect to use it, I
19 might be convinced that it was useful. But
20 it's insufficient leaning towards low in this
21 sense.

22 CHAIR PENSON: All right, that's

1 good. Other comments? All right, let's move
2 onto 3c then, which is the one concerning
3 clinical and construction logic, that the data
4 and result detailed are maintained such that
5 the measure, including it's clinical
6 construction logic, can be decomposed to
7 facilitate transparency and understanding.
8 Steven?

9 DR. CHEN: This one I put low
10 mainly because it used the word construction
11 logic, and I'm not really pleased with their
12 construction logic. Do I think it's
13 decomposable, it is. I'm not particularly
14 sure I want them to decompose it because I
15 don't really like it.

16 CHAIR PENSON: So with regard to
17 the construction logic, and again I'm just
18 trying to generate thoughtful comments for the
19 reviewers on the steering committee.

20 I mean it's straight forward
21 having a biopsy although, maybe not straight
22 forward as to where the biopsy is performed.

1 So that part strikes me as easy, so what sort
2 of issues are you having with it?

3 DR. CHEN: I still have trouble
4 with F&A just in general, because it is not
5 typically used as something diagnosed heading
6 towards a cancer diagnosis.

7 And so including that logic, but
8 then excluding them from if they have had a
9 second biopsy which would presumably be the,
10 I got an F&A, it looks weird, now I want
11 another biopsy so I know what I actually was
12 supposed to have done the first time.

13 Or, you know, I thought it was
14 cyst, I aspirated it with the F&A, and it
15 turns out now there's a mass. So I think they
16 excluded the wrong thing.

17 CHAIR PENSON: So are you inclined
18 to say this is insufficient or low?

19 DR. CHEN: I could live with
20 either. It certainly could be fixable I
21 suppose, so insufficient would be fine.

22 CHAIR PENSON: Okay, good. Go

1 ahead.

2 DR. BORKER: Quick comment. I'm
3 not sure if they excluded the second biopsy.
4 I think they called the first one the entry
5 or incident biopsy, but then they just ignored
6 the second biopsy. And maybe the developers
7 can tell us more on that, if that's true.

8 CHAIR PENSON: So Todd and Kevin,
9 could you just talk a little bit about what
10 you did with patients on this measure that had
11 first versus second biopsies?

12 DR. LEE: It's only the first
13 biopsy that is identified in a measurement
14 period that is included. If the second biopsy
15 occurred within seven days of the event those
16 resources would be captured, but other than
17 that, we only identified a single biopsy per
18 individual.

19 DR. BORKER: Right. The question
20 is, so for an individual if you have the first
21 biopsy then entered into the database, but
22 then within seven days they had the second

1 biopsy, what happens to that data, post that
2 second biopsy? Is the data excluded from the
3 analysis, or is the patient excluded from the
4 analysis?

5 DR. LEE: After seven days the
6 data is not included as part of the resource
7 use associated with this episode.

8 DR. BORKER: Right, so for a case
9 where they enter the system, within three days
10 they had the second biopsy, what happens to
11 the remaining four days?

12 DR. LEE: They are included. The
13 remaining four days are included, but any
14 resource use after day seven is not included
15 as part of the episode.

16 CHAIR PENSON: Right. Okay, other
17 comments?

18 MS. TURBYVILLE: If it's included
19 as a resource, you still have the second
20 biopsy?

21 CHAIR PENSON: That's my
22 understanding, yes. Steven?

1 DR. CHEN: I think the other thing
2 I didn't really like about the logic part,
3 there are some thing's that are kind of
4 flexible as to when you might get them,
5 whether you get an MRI before, or after for an
6 obvious breast cancer.

7 And so the window seems arbitrary
8 enough and short enough, that things might
9 fall outside the window that should belong in
10 the window, just because at my institution
11 getting an MRI within seven days is actually
12 reasonably difficult, unless you personally
13 make a phone call.

14 CHAIR PENSON: Okay, but what I'm
15 hearing from you though is, while these are
16 major concerns, they are addressable concerns?

17 DR. CHEN: Yes.

18 CHAIR PENSON: Okay. So and
19 obviously, other comments about 3c? So 3d is
20 not applicable, so let's vote on the usability
21 and then we'll wrap up on feasibility, and go
22 from there.

1 So let's start with 3a, the
2 measure performance results were reported to
3 the public at large in reporting programs,
4 either at the time of endorsement and
5 maintenance review. And obviously we've
6 talked about the ongoing issues here with RWJ,
7 et cetera. Go ahead and vote.

8 (Off microphone discussion)

9 CHAIR PENSON: What's that?

10 (Off microphone discussion)

11 CHAIR PENSON: Okay, let's vote
12 again.

13 (Off microphone discussion)

14 CHAIR PENSON: Now we're going to
15 get done on time, I'm a machine. There we go.
16 Okay, we have five for moderate, and four for
17 insufficient. Okay.

18 Next is 3b, the results are
19 considered meaningful, understandable, and
20 useful to the intended audiences for public
21 reporting and quality improvement.

22 (Off microphone discussion)

1 CHAIR PENSON: And here we've got
2 one moderate, three low, and five
3 insufficient.

4 Next is the clinical and
5 construction logic that data results are
6 maintained such that the measure, including
7 the clinical and construction logic can be
8 decomposed to facilitate transparency and
9 understanding. Go ahead and vote on this.
10 And here we had four moderates, one low, and
11 four insufficients. And I do think that the
12 discussion reflects that, that some people
13 were more convinced than others.

14 Okay, so let's do the last three
15 measure pieces fairly quickly. I think these
16 actually will be quick, not just because we're
17 tired but because they're relatively straight
18 forward in this setting.

19 So 4a is the feasibility measures.
20 This is the one that the required data
21 elements are routinely generated and used
22 during care delivery and are going to be

1 captured.

2 And I think unlike the discussions
3 we had with colon cancer and the earlier
4 breast cancer treatment, because this is a
5 sort of diagnostic work-up, we're probably
6 going to catch most of this. We're not going
7 to have issues with J codes, et cetera. So my
8 inclination is that this is probably high.

9 4b, the required data elements are
10 available in the electronic health records.
11 Similarly I think that this is going to be
12 captured as well, and again high.

13 Why don't I just move for
14 acclimation here, does anyone feel that it's
15 not high, for 4a or 4b? So that we're good at.

16 4c and 4d are worth a little
17 discussion before we wrap up. So for 4c, this
18 is the element susceptibility to inaccuracies,
19 errors, and unintended consequences.

20 And again, this is administrative
21 data so we don't have to repeat that. Steven,
22 you're the reviewer here, were there any other

1 issues beyond it's administrative data?

2 DR. CHEN: I think the only other
3 thing is that a lot of these biopsies are
4 being done for unknown diagnoses by
5 definition, and so you're going to get a lot
6 of variation in ICD-9 codes.

7 And so that makes it a little more
8 susceptible to inaccuracy, but not fatally so,
9 probably. My biggest concern were the
10 original concerns that Louise had.

11 CHAIR PENSON: Okay. And 4d is
12 the data collection strategy can be
13 implemented as demonstrated by operational use
14 or the testing didn't identify barriers. And
15 my inclination was with this was fairly
16 straight forward, programming.

17 So let's vote on 4c and 4d, and
18 then we can wrap up. So let's do 4c, this is
19 inaccuracies, errors, and unintended
20 consequences.

21 MS. TURBYVILLE: One more.

22 CHAIR PENSON: Keep voting people.

1 MS. TURBYVILLE: Your thumbs will
2 be very strong after today. Running out of
3 time. No?

4 CHAIR PENSON: Oh.

5 MS. TURBYVILLE: Okay. It just
6 came unplugged.

7 CHAIR PENSON: Let's try it again.

8 (Off microphone discussion)

9 CHAIR PENSON: Yes. There we go.

10 MS. TURBYVILLE: Wow.

11 CHAIR PENSON: So for 4c, we had
12 seven who said moderate, and two who said low
13 with regard to inaccuracies and errors.

14 And 4d. There we go, nine. And
15 here we had five who said high, and four who
16 said moderate. So that takes care of that.

17 Before we go we have to do public
18 comment. So operator, could you open up the
19 lines to public comment?

20 OPERATOR: Certainly sir, I'd be
21 happy to. Ladies and gentlemen for public
22 comment, please press star, one. Again that

1 is star, one for public comment. There's no
2 public comment at this time.

3 CHAIR PENSON: Thank you. Anyone
4 in the room, audience in the room? Everyone's
5 afraid to say anything because everyone wants
6 to leave. Well before I turn it over to
7 Sally, well Kevin, Todd, do you guys have
8 anything you want to add?

9 DR. WEISS: For me it's just a
10 thank you from the committee. You've done
11 very thoughtful and respectful review of the
12 work that was done by this project, and the
13 workgroup, and the staff of the team. Really
14 appreciate your time taken out to deal with
15 these difficult and new types of measures.

16 CHAIR PENSON: I think I can speak
17 for everyone in the room, that we're really
18 grateful you were on the phone today, it
19 really made this easier. I'm getting a lot of
20 head shakes.

21 It really is good to be able to
22 talk to the measure developers, and work

1 together to sort of identify the strengths,
2 and identify the weaknesses which often can be
3 improved. So thank you guys for spending the
4 day. This is probably more painful for you
5 two, than any of us.

6 And I personally as the Chair want
7 to thank everyone else in the room. This is
8 a lot of work and I appreciate it.

9 DR. POTTERS: So I just want to
10 personally and have the minutes reflect, that
11 we thank you for running the meeting
12 officially.

13 CHAIR PENSON: I guess we're on
14 time.

15 (Off microphone discussion)

16 CHAIR PENSON: Thank you,
17 appreciate that. So Sally, I'll turn it over
18 to you now.

19 MS. TURBYVILLE: I just want to
20 echo what David said, as well as Kevin on the
21 phone. Thank you, all of you so much for all
22 your time in preparing for the meeting. And

1 then also, today in contributing your expert
2 input and opinion.

3 I think you were very clear with
4 your rationales. I think it certainly helped
5 the measure developers, and certainly will
6 help us at staff as we continue to move these
7 forward. Next steps, Ashlie if you want to
8 quickly?

9 MS. WILBON: So next steps,
10 everyone submitted their votes today on the
11 measures. We will be following up with the
12 developers on some of the questions that you
13 guys had, and we'll email that back to you.

14 What we've found with some of the
15 other TAPs is, it seems to be a little bit
16 more difficult over emails for people to re-
17 vote, but that we'll probably end up sending
18 out the information if you guys have any like,
19 verbal, you know, responses or statements you
20 want to pass forward in response to what
21 they've submitted.

22 And we'll move that forward to the

1 steering committee, rather than having you
2 guys re-vote, and we'll put your votes here
3 and get the context that you rated the measure
4 as is, and that the additional information
5 submitted by the developer, you know, here's
6 kind of what any other additional comments as
7 it moves on.

8 So no follow-up conference calls.
9 So just look forward to some follow-up emails
10 from us, and hopefully wrap things up.

11 So again, thank you David for
12 keeping us on track and keeping us entertained
13 and awake, so we appreciate it very much. And
14 he's actually going to be here two more days
15 for the steering committee meeting, so
16 appreciate that. Thank you.

17 CHAIR PENSON: I mean I get to be
18 like Lou Potters, and I get to sit there and
19 listen and sort of let other people talk.
20 Thank you again guys.

21 (Whereupon, the meeting went off
22 the record at 4:21 p.m.)

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