

THE NATIONAL QUALITY FORUM
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IMAGING EFFICIENCY STEERING COMMITTEE

MEETING

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TUESDAY
FEBRUARY 23, 2010

The Imaging Efficiency Steering Committee met in Suite 600 North of the Homer Building, 601 13th Street, N.W., Washington, D.C., at 9:45 a.m., Scott Gazelle and Eric Peterson, Co-Chairmen, presiding.

PRESENT:

G. SCOTT GAZELLE, MD, MPH, PhD, Co-Chairman
ERIC D. PETERSON, MD, MPH, Co-Chairman
MICHAEL BACKUS, Member
JACQUELINE A. BELLO, MD, FACR, Member
STEPHEN V. CANTRILL, MD, FACEP, Member
CARL D'ORSI, MD, Member

TROY FIESINGER, MD, FAAFP, Member
HOWARD FORMAN, MD, MBA, Member
MARY GEMIGNANI, MD, Member
RAYMOND GIBBONS, MD, Member
RICHARD GRIFFEY, MD, MPH, Member
LASZLO MECHTLER, MD, Member
PATTI RAKSIN, MD, Member

DONALD W. RUCKER, MBA, MD, Member
GAVIN SETZEN, MD, FACS, FAAOA, Member
REBECCA SMITH-BINDMAN, MD, Member
ROGER L. SNOW, MD, MPH, Member
KIRK T. SPENCER, MD, Member
ARTHUR STILLMAN, MD, PhD, Member
JUDY ZERZAN, MD, MPH, Member

HELEN BURSTIN, NQF
IAN CORBRIDGE, NQF
SARAH FANTA, NQF

T-A-B-L-E O-F C-O-N-T-E-N-T-S

Welcome, Introductions.3

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ED Head CT

Public Comment. None

Adjourn419

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

9:39 a.m.

CO-CHAIR GAZELLE: Good morning, everyone. It is five minutes early, but everyone is here. So we are going to go ahead and get started, and maybe that means we can finish on time at least.

My name is Scott Gazelle.

CO-CHAIR PETERSON: And Eric Peterson.

CO-CHAIR GAZELLE: And we are the two Co-Chairs of the meeting. So on behalf of the NQF and us, thank you for agreeing to participate and for all the work you have done before coming to the meeting.

Helen, do you or Ian want to say some comments about format?

DR. BURSTIN: Sure. Happy to. We will talk a little bit further about the actual contents in a little bit. I just want to at least add my welcome.

Helen Burstin. I am the Senior

1 Vice President of Performance Measures at NQF.

2 In case you can't tell, we
3 literally just opened up this conference room
4 on Friday. They unpacked the table. There is
5 still duct tape on the floor. We really
6 wanted to try to have in-house meetings rather
7 than always having to rely on hotels, and
8 again get you some wireless to be able to get
9 your materials in real time.

10 I apologize for our measure
11 developer friends for being a little cramped.
12 We will work on that next time. It has
13 literally just been since Friday. So let us
14 know if you need anything.

15 Again, I just want to add my
16 welcome to the Chairs. This is, obviously, a
17 very interesting project, very diverse, lots
18 of expertise required, which is why, actually,
19 the Steering Committee is a bit larger than
20 some of our prior ones. We aim for 15 to 18,
21 but just really felt, given the diversity of
22 measures, we wanted to be sure we had the

1 right expertise at the table.

2 So thank you all for coming, and
3 we will get into more details to follow, but
4 in terms of just logistics, there is food,
5 coffee right there at the side over here. Let
6 Ian or myself know, or Sarah, if there is
7 anything you need, and bathrooms are right out
8 to the --

9 MR. CORBRIDGE: Women's are right
10 out to the right, gentleman's to the left.
11 You need a key. If the key is not there, you
12 might have to do a handout as you go in there.

13 Just kind of some other
14 housekeeping stuff: There is a coat closet in
15 the back, if you want, and just wanted --
16 Before we move forward, I wanted to make sure
17 that everyone was aware that all of NQF's
18 workings are open to the public and recorded.
19 So everything that is said within this room
20 and discussed is actually being recorded.
21 Donald over there who takes care of all our AV
22 technical stuff is recording all the

1 information.

2 So individuals on the phone can
3 hear as well as later on, if individuals from
4 the public or the Steering Committee want to
5 listen to the actual recording, and there is
6 also a transcript available as well. So that
7 is just one housekeeping thing to keep in
8 mind, that what you do say today is recorded
9 and will be available to the public.

10 Another housekeeping that I want
11 to just bring to individuals' attention -- I
12 just was aware of it. Across on the south
13 side there is Toyota, and I think the hearings
14 are happening. So if you see reporters and
15 cameras in here, it is not because of this
16 meeting right now. So we are okay at this
17 time. I just want to bring that to people's
18 attention now, that there may be film crews
19 here today. Hopefully, I think they are going
20 to be on that side.

21 One other thing, I guess, for
22 individuals who want to access the Internet,

1 if you haven't already, it is the Homer
2 Building. There shouldn't be any lock to it.
3 So it should be free to get on line.

4 We would like to start off with
5 introductions. I know not everyone was able
6 to attend. There an introductory phone
7 conference.

8 CO-CHAIR GAZELLE: So we should go
9 around the room and introduce ourselves. I
10 will start. My name is Scott Gazelle. I am
11 an abdominal radiologist by training. My PhD
12 is in health policy, and most of my research
13 is new technology evaluation.

14 I was on the prior committee.
15 This is my second time on the metrics effort.

16 CO-CHAIR PETERSON: Eric Peterson.
17 I am a cardiologist by training, but have no
18 imaging background whatsoever. I am the
19 random assortment here. I also do outcomes
20 research and I'm associate director at Duke
21 Clinical Research Institute.

22 DR. SPENCER: I am Kirk Spencer.

1 I am a clinical cardiologist with expertise in
2 echocardiography, and I do work on advocacy
3 for the American Society of Echo.

4 DR. ZERZAN: Judy Zerzan. I am
5 Colorado Medicaid Medical Director. I also do
6 a little research on Medicaid prescription
7 policy at the University.

8 DR. MECHTLER: Hi. I am Laszlo
9 Mechtler. I am a trained neurologist with
10 subspecialties in neuroimaging and headache
11 and neuro-oncology, and I have been running a
12 fellowship program in imaging for 20 years at
13 the Headache Center.

14 DR. RAKSIN: Hi. Patti Raksin. I
15 am a neurosurgeon with Critical Care at Cook
16 County Hospital in Chicago. I am here as a
17 representative of the American Association of
18 Neurologic Surgeons Joint Guidelines
19 Committee.

20 DR. BELLO: I am Jacqueline
21 Bellow. I direct the Division of
22 Neuroradiology at Albert Einstein and

1 Montefiore Medical Center, and I run a
2 fellowship training program there, and I am on
3 the ACR guidelines Committee.

4 DR. FORMAN: I am Howie Forman. I
5 am a diagnostic radiologist practicing
6 primarily in emergency room, trauma imaging,
7 and I teach health policy and health economics
8 at Yale.

9 DR. RUCKER: Don Rucker, Chief
10 Medical Officer for Siemens. We, as I
11 mentioned in our disclosure sheet,
12 manufacture, I believe, all the devices under
13 consideration here, and so I am, in some
14 perverse sense, neutral, and I am also on the
15 clinical faculty at the University of
16 Pennsylvania, Emergency Medicine.

17 DR. FIESINGER: I am Troy
18 Fiesinger, a family physician in Houston. I
19 am on residency faculty at the program there,
20 and I am here on behalf of the American
21 Academy of Family Physicians. I have been on
22 their Commission on Quality for the last four

1 years.

2 DR. SMITH-BINDMAN: My name is
3 Rebecca Smith-Bindman. I am a radiologist at
4 UCSF. My research focuses on outcomes and the
5 benefits and benefits of a range of tests.

6 DR. D'ORSI: Carl D'Orsi. I am a
7 diagnostic radiologist. I have been doing
8 breast imaging for 20 years, and my research
9 interests are basically in technology
10 assessment, comparing various technologies for
11 detection of early breast cancer.

12 DR. GIBBONS: Ray Gibbons, staff
13 cardiologist at the Mayo Clinic, standard
14 experience in national cardiovascular disease
15 guidelines and cardiac imager, primarily in
16 nuclear cardiology.

17 DR. SNOW: I am Roger Snow. I am
18 internist and the Deputy Medical director for
19 Mass. Health, which is Massachusetts' Medicaid
20 program.

21 DR. STILLMAN: I am Arthur
22 Stillman. I direct the cardio-thoracic

1 imaging at Emory, here representing -- at the
2 request of American College of Radiology.

3 DR. CANTRILL: Steve Cantrill,
4 emergency physician from Denver. I have been
5 involved in clinical guideline development and
6 also quality performance measure development,
7 representative from American Academy of
8 Emergency Physicians.

9 DR. SETZEN: My name is Gavin
10 Setzen. I am a practicing otolaryngologist in
11 Albany, New York, and am here as Chair of the
12 Board of Governors of the American Academy of
13 Otolaryngology -- Head and Neck Surgery. I am
14 also involved in guideline development and on
15 the Board of the Intersocietal Commission for
16 the Accreditation of CT Laboratories, ICACTL.

17 DR. GRIFFEY: I am Richard
18 Griffey. I am an emergency physician at
19 Washington University in St. Louis. I did my
20 MPH in clinical effectiveness, and do work in
21 quality and safety.

22 MR. BACKUS: My name is Mike

1 Backus. I am with American Imaging
2 Management, which is a subsidiary of
3 Wellpoint. We manage radiology and cardiology
4 preop for about 35 million Americans. I am in
5 charge of analytics and medical economics.

6 DR. GEMIGNANI: I am Mary
7 Gemignani. I am a breast surgeon at Memorial
8 Sloan Kettering Cancer Center. My primary
9 research interest is in screening for high
10 risk women. I was on the previous NQF
11 meeting.

12 CO-CHAIR PETERSON: Great. I
13 think what we have heard as you go around the
14 table, there is a lot of varying interests,
15 and to the credit of NQF, they've got a
16 diverse group of people who might, outside of
17 here, be on opposite sides of various
18 arguments, or most any argument. We could
19 find some diversity of opinions around the
20 table.

21 What I would like you all to
22 consider, though, is why you might have got on

1 this committee, because you represented a
2 certain group or a certain field or even have
3 your own self-interest, unfortunately, in
4 these fields.

5 Today you are here as a physician
6 or a policy person who is trying to do the
7 right thing for medical care, and I would like
8 you guys to really keep that in mind as you
9 think about the deliberations over the next
10 two days.

11 We all have -- these have major
12 implications in theory or in reality for
13 American medicine. They can be remarkably
14 positive effects in terms of creating a system
15 of care that will improve major outcomes and
16 make it affordable to do in a right manner.

17 We all realize there are certain
18 things wrong and broken in the current system.
19 It is our responsibility, and those for the
20 next generation who will have to deal with
21 these, to make wise decisions.

22 Sometimes you may have to make

1 compromises in things that would be near and
2 important to your field or your profession or
3 even sometimes your belief system, but today
4 the main thing is come up with the answer
5 that you believe is ultimately the right one
6 when you leave the meeting.

7 DR. BURSTIN: We have some folks
8 in the back.

9 CO-CHAIR PETERSON: Sure. Go
10 ahead.

11 MS. STEPHENS: I am Sharman
12 Stephens, and I am with the Lewin Group, and
13 we are serving as a contractor for the Centers
14 for Medicare and Medicaid Services.

15 MS. PETERSON: I am Laura
16 Peterson. I am also with the Lewin Group.

17 MS. DaVANZO: I am Joan DaVanzo
18 with Dobson, DaVanzo Associates.

19 MS. ARDAY: I am Susan Arday. I
20 am with the Centers for Medicare and Medicaid
21 Services.

22 DR. DEHN: Hi. I am Tom Dehn, a

1 radiologist, Chief Medical Officer of National
2 Imaging and a consultant with CMS.

3 DR. BRUETMAN: I am Dr. Bruetman.
4 I also work for the Lewin Group.

5 MR. PENTACOST: I am Michael
6 Pentacost. I am one of the medical officers
7 of National Imaging, subcontractor for CMS.

8 MR. BASSETT: I am Larry Bassett,
9 director of Imaging at UCLA. I am here to
10 represent for the American College of
11 Radiology.

12 MS. WOUTERS: I am Ann Marie
13 Wouters.

14 MS. COOMBS: I am Laura Coombs, I
15 am the director of data registries of
16 mammography at the American College of
17 Radiology.

18 MS. BURLESON: I am Judy Burleson,
19 Director of Metrics at American College of
20 Radiology.

21 MS. GROMAN: Rachel Groman, the
22 Senior Manager of Quality Improvement and

1 Research at the American Association of
2 Neurological Surgeons.

3 MS. DUNLEY-GALLIGHER: Rita
4 Dunley-Galligher, Senior Policy Fellow at the
5 National Center for Nursing Quality at the
6 American Nurses Association.

7 MS. FANTA: Hi. Sarah Fanta,
8 Research Analyst at the national Quality
9 Forum.

10 MR. CORBRIDGE: All right, thank
11 you. I guess I would just like to just bring
12 your attention, two individuals who were
13 initially on the Steering Committee were
14 unable to attend today. So that is Dr.
15 Patricia Kunz Howard as well as Marilyn
16 Kramer. So they were unable to attend today,
17 just to let you know that.

18 In terms of just moving forward, I
19 want to make sure that everyone has the actual
20 paper copy of NQF's Measure Evaluation
21 Criteria. I know I tried to pass that out as
22 individuals came in the door, but if you are

1 missing it, we have copies here. I will just
2 pass some. Do you know how many we need down
3 there?

4 This is just a paper copy of the
5 digital PDF that you were provided. It is
6 just NQF's measure evaluation criteria.
7 Hopefully, it will be helpful in terms of
8 reviewing and reviewing the measures to be
9 able to look at NQF's criteria.

10 It seems like we are way ahead of
11 schedule. I know I was here at 8:00 o'clock,
12 and people started showing up. So I was quite
13 surprised. It is quite an eager group.

14 So we are ahead of schedule. I
15 think at this point, we would really like to
16 just touch on some of the points that we
17 looked at in the introductory conference call,
18 go over that just quickly, some of the key
19 highlights of the project, and then we will
20 move forward from there.

21 DR. BURSTIN: We are going to skip
22 over a lot of the stuff we did on the call.

1 MR. CORBRIDGE: Okay. So as we
2 mentioned, this is some of the information
3 that we discussed as well as had on the
4 webinar for our introductory call, just going
5 over some background of the project.

6 It is part of a sub-task of the
7 larger HHS Resource Use Project. This project
8 is specifically with imaging efficiency, which
9 makes it different from the other projects
10 that are primarily within resource use across
11 episodes of care.

12 Really, one of the main focuses of
13 this project is to expand NQF's current
14 portfolio of imaging efficiency measures. I
15 indicated at the last project, which Dr.
16 Gazelle participated with, I believe there was
17 eight endorsed measures that came from that.

18 We are really looking to expand
19 NQF's measurement domain in terms of imaging
20 efficiency, as well as to identify gaps within
21 the field which the Steering Committee
22 identifies are key areas that we need in terms

1 of measurement moving forward, and helping to
2 support health reform.

3 So just some goals of the project:

4 As identified earlier, to identify and
5 evaluate and endorse additional measures
6 suitable for public reporting and quality
7 improvement which specifically address imaging
8 efficiency.

9 I just want to bring to your
10 attention, as we discussed earlier key parts
11 of NQF's process is the public reporting and
12 quality improvement. So that is a lens that
13 each member of the Steering Committee will
14 need to look through in terms of evaluating
15 the measures. Are they available for public
16 reporting, and is the measure really intended
17 to improve quality within a specific study or
18 in cross-settings; and then as touched upon
19 earlier, really to identify gaps within
20 imaging efficiency domains.

21 So just the scope: These are
22 kinds of specific domains. When we put out

1 the call for measures, these are some areas
2 that we touched upon, trying to elicit some
3 measures. We didn't get everything that --
4 All the responses didn't touch on these areas,
5 but we got a very robust set of measures, I
6 think, that came to us.

7 So some areas we focused on were
8 overlap screening, patient safety. You can
9 see here. So looking at past projects, as I
10 talked about, we had an imaging efficiency
11 project in 2008. At the end of that, we
12 walked away with eight NQF endorsed imaging
13 efficiency measures, and they went across
14 different focus areas.

15 For the current projects, the
16 measures that came to NQF for the call for
17 measures, we kind of looked at them in
18 different buckets. The review group kind of
19 based on those buckets, and we tried to sit
20 you with fellow reviewers within the specific
21 group that you were looking at.

22 We had measures touching on

1 cardiac imaging, mammography, measures focused
2 on the emergency departments, fine CT as well
3 as the coordination of care.

4 So this next couple of slides will
5 just go over the process of what the actual
6 Steering Committees expect to do and
7 participate with NQF, and then what NQF's role
8 is within the projects.

9 At this point, you can look at the
10 top kind of bar. In the center, the projects
11 have really already been specified. We are
12 moving forward. At this point, we are now
13 really at the Steering Committee review of
14 measures submitted to NQF.

15 Some Steering Committees -- there
16 is a Technical Advisory Panel that supports
17 them. Just due to the smaller set of measures
18 that we received, we decided to just really
19 have a Steering Committee.

20 Really, in some groups we have
21 broken out into different review groups, and
22 they have come back and reported, but for the

1 flow of proceedings with this Steering
2 Committee, we are hoping just to be able to
3 take everything at the table.

4 We will have the primary review
5 group really lead and elicit the discussion
6 for a specific measure to which they are
7 assigned, and then have the rest of the
8 Steering Committee really add to that process.

9 The next step would be we are
10 looking at drafting recommendations throughout
11 this whole process at NQF. We are taking
12 notes. Everything will be recorded. We will
13 have transcripts. We will go back and record
14 the conversations. We will have a meeting
15 summary that will be provided online, and the
16 Steering Committee's input will really be key
17 in coming up with that meeting summary.

18 From that, we will move forward
19 into actually drafting recommendations. They
20 are put online for review and comment from the
21 public, and then moving forward we will come
22 up with actual recommendations for then voting

1 and CSAC and Board approval, and then we will
2 come up with an NQF endorsed set of imaging
3 efficiency standards. At the end of that,
4 there is an appeal process.

5 So NQF has moved toward really
6 trying to have complete transparency through
7 our -- really, at each step everything is open
8 to the public, as well as there are
9 opportunities when information is put online
10 for the public to respond.

11 So any type of public comment that
12 we get, that will be forwarded on to the
13 Steering Committee. So we hope that you guys
14 will be able to help us respond to those
15 comments.

16 So just going over a little bit
17 further, I know we talked on some of these.
18 Obviously, you are representing a diverse set
19 of stakeholders, and really, I guess the main
20 goal today is really to evaluate the measures
21 that came forward to NQF, based on NQF's
22 criteria, and make recommendations to move

1 forward.

2 Then the Co-Chairs are actually --
3 time permitting, will be there to represent
4 the measures that are potentially endorsed for
5 CSAC.

6 Then the role of NQF staff here:
7 Really, the staff are here to support the
8 Steering Committee and providing
9 documentation, providing kind of a conduit to
10 the measure developers, and providing access
11 to information the Steering Committee needs to
12 really make the rational and best decision
13 that they need.

14 Then really, another function is
15 to help along the process of drafting reports
16 and posting that onto the web so individuals
17 from the public can respond to it, and another
18 key part is to just maintain the documentation
19 in the documentation as it moves through this
20 process, making sure that we have sufficient
21 notes and documentation to capture what the
22 Steering Committee recommended to move

1 forward.

2 Here is a brief project timeline
3 that we are looking at. Obviously, December
4 and January dates already took place. We've
5 had the measures. We have formed the Steering
6 Committee. We had introductory call, and then
7 coming up in April and May, we are looking to
8 move toward a comment period, then moving
9 toward member voting, and then those measures
10 which we may determine to move forward then
11 would go to CSAC in July, and then NQF Board
12 endorsements on July 28th, after which there
13 is a 30-day appeals process.

14 So that is just a brief rundown of
15 the project's timeline, as well as the project
16 as a whole. Any questions from the Steering
17 Committee about the process, timeline? Yes?

18 DR. D'ORSI: I don't know if it is
19 particularly -- excuse me, Carl D'Orsi.

20 These metrics are meant to
21 evaluate efficiency and quality for
22 individuals, facilities, or both?

1 DR. BURSTIN: It actually depends
2 on the measure itself. I think the majority
3 of these measures are facility level measures.
4 There is a specific part of all the mission
5 forms that specifically ask the developer to
6 note the appropriate level of analysis. That
7 is a really important question, Carl.

8 So as you review those measures,
9 please keep an eye on whether that is a
10 measure that would be very appropriate for
11 public reporting with QI at the facility
12 level, and then consider whether rolling that
13 up or down makes sense. It is a really
14 important point.

15 DR. SMITH-BINDMAN: If there some
16 back and forth period with the developers of
17 the measures where we could provide some
18 impact on how to improve them?

19 DR. BURSTIN: I'm sorry. I was
20 just going to go through a couple of
21 additional things, just to emphasize your role
22 today.

1 So part of what -- again, really
2 emphasizing the point Eric made at the outset,
3 although you bring a very diverse stakeholder
4 perspective, you are here because you bring
5 expertise to the table. We want you to really
6 help us evaluate the measures, see if they are
7 the right set of measures to move forward.

8 The criteria that you were given
9 in this handout -- we have tried very hard
10 over the last few years to increasingly make
11 them more objective, make them things that you
12 could truly be able to rate overall and,
13 again, because we are so transparent, give
14 more information to the end users who are
15 going to be able to look at this, evaluate it,
16 see if they agree or not.

17 You should know that on all these
18 projects, we are probably averaging, oh, over
19 300 comments that we will receive from the
20 public and members. So there is a very alive
21 -- which is a wonderful part of the process,
22 but it means there will be a lot of back and

1 forth, even post this meeting, once we get
2 through your initial process.

3 As much as possible, your
4 evaluations are completely brought into these
5 evaluation criteria, and I am happy to answer
6 any questions as we move forward through
7 those.

8 Your options after each discussion
9 -- I want to spend a moment or two on that,
10 because I think it is an important piece of
11 this, and thank you for bringing that up. You
12 have the option of, at the end of the
13 discussion, if the reviewers who reviewed the
14 measure, after the discussion of the Steering
15 Committee, you can say we recommend this
16 measure move forward. That is the role of the
17 Steering Committee.

18 What that means is it will move
19 forward through the rest of the process. Now
20 all measures go out for public comment, not
21 just those that are recommended. We made that
22 change about a year ago. So we will get

1 public comments on even the measures you say
2 shouldn't go forward, and you will be able to
3 reflect on those.

4 Every once in a while, the
5 Steering Committee sees the comments and says,
6 oh, that is an aspect of this that we hadn't
7 really thought about, and may make some
8 changes, but in general, you will overall
9 recommend the measure.

10 You have the option of
11 recommending the measure with conditions, and
12 this is really the point, I think, that you
13 are trying to make. There may very well be
14 clear opportunities to improve the measure,
15 based on your expertise.

16 You can't rewrite the measure.
17 That is not appropriate, obviously. You can't
18 create a new measure. That is not appropriate
19 either. But you can very much make
20 recommendations to the measure developers.

21 They oftentimes can't on a dime
22 say, yes, we can do that, but we give them an

1 opportunity. After the meeting we will write
2 up all the details of what your recommendation
3 with conditions are. They will then have a
4 chance to respond to you. We will share that
5 with you, and then you can make a decision as
6 to whether you would continue to recommend the
7 measure, if the conditions have been met.

8 If the conditions weren't met, you
9 then have the opportunity to say, okay, we
10 will accept it as is, or you could, in fact,
11 make the decision to not recommend the
12 measure.

13 The other opportunity I want to
14 mention is that there are a fair number of
15 measures, I think, within this dataset as
16 well, within the set of measures that have not
17 yet been tested. So NQF does have a time
18 limited endorsement policy, which specifically
19 allows measures that have otherwise passed all
20 of the other evaluation criteria. This isn't
21 endorsement lite.

22 This is really, you have done

1 every other aspect of this with the exception
2 of the fact that you don't have adequate
3 reliability and validity testing yet. Since
4 the measure is brand new, hasn't been in the
5 field perhaps, there hasn't an opportunity to
6 do that yet, you also have the opportunity to
7 recommend the measure go forward as time
8 limited.

9 We, up front as staff, have
10 actually gone through it and at least
11 indicated is there testing here or not. It is
12 not as if you can recommend a measure that
13 could go forward fully if it, in fact, has no
14 testing.

15 So those are your options, and we
16 will work with you to be spelling out those
17 conditions, but again we can't just say
18 recommend with conditions and be vague. If it
19 is really recommend with conditions, there has
20 got to be two or three things: This
21 definition isn't quite right; the denominator
22 needs tweaking, you know, things that are very

1 discrete that we can hand back to the measure
2 developer based on the guidance of the
3 Committee.

4 CO-CHAIR GAZELLE: Helen, I just
5 wanted to comment. One issue that came up, I
6 know, in the past is where is the line
7 between, sort of, recommending changes and
8 rewriting? So a number of the measures that
9 we reviewed had internal instances -- for this
10 one, had internal instances where, for
11 example, the title, the definition in that one
12 sentence title was inconsistent with the
13 numerator and denominator, where to clear up
14 that, that doesn't count as rewriting the
15 measure. That just counts as with conditions.

16 DR. BURSTIN: Absolutely.

17 DR. SETZEN: One question. Gavin
18 Setzen. With respect to the handling of the
19 comment period when we have the comments, what
20 are the mechanics and logistics in terms of
21 how those are dealt with, with respect to
22 staff and the Steering Committee itself?

1 DR. BURSTIN: So what we will do,
2 what Ian and Sarah will do is take all those.
3 We will put them into a big spreadsheet for
4 you. We will go through the recommendations
5 initially. We will make some recommendations.
6 Most of them are "thank you for your comments"
7 or we will specifically highlight ones that
8 say Steering Committee needs to review it and
9 make a decision.

10 So we will highlight that. We
11 will have a conference call with you where we
12 will go over the entire comment table,
13 highlighting the ones where there is clearly
14 an issue where there is an expectation the
15 Steering Committee would need to reflect on
16 it, as opposed to more mechanical things that
17 we can do back and forth for you with the
18 developers.

19 So as much as possible, we will
20 try to reserve your time for the areas where
21 we think we need your expertise, and we will
22 make more of the mechanics the work of NQF

1 staff.

2 DR. SPENCER: So the steward of
3 the measure, if we think it needs some minor
4 changes, can change it and still save it for
5 this site.

6 DR. BURSTIN: Exactly.

7 DR. SPENCER: It is not like we
8 say no, and then --

9 DR. BURSTIN: Right. No. So that
10 actually part of the logic. You may have
11 wondered why we are meeting in February, but
12 it is not going out for comment until mid-
13 April. That is to allow the back and forth
14 with the developers. That will also be for us
15 to draft the draft report that goes out with
16 the measures.

17 So what goes out in our draft
18 report will, in fact, be after the back and
19 forth with the developers. You have seen it.
20 You have agreed it met conditions, and that is
21 what goes out. So that is why there is a
22 little bit of a cushion in there for us to get

1 that work done.

2 MR. CORBRIDGE: And today there
3 are opportunities, because many of the measure
4 developers are here today and tomorrow, to
5 actually discuss with them, kind of work out
6 some of these issues up front, and then move
7 forward, and we can have that back and forth
8 comment period later on, if needed.

9 DR. BURSTIN: But again, we can't
10 rewrite measures. We can't completely say
11 this doesn't work, but if we did it this way.
12 Now the one thing you will have the
13 opportunity to do as well, which is actually
14 becoming, I think, increasingly important, is
15 that at the end of the discussion -- all
16 through the discussion we will be kind of
17 culling from your comments what are the
18 measurement gaps? What are the measures that,
19 boy, we really wish they had come to the
20 table.

21 Then part of this draft report and
22 final report that we will put out will

1 actually be a set of what we call research
2 recommendations or measure recommendations.
3 They may not have been in this set, or maybe
4 if you had completely rewritten measure A, you
5 would have really gotten this measure, and
6 that would be in those research
7 recommendations.

8 So keep in mind as you are going
9 through it, as you can see, for those --
10 several of you who were on the first part that
11 we did on this, you know, this is a fairly
12 new area. Oftentimes, it takes a few cycles
13 to really put out to the measure development
14 field. There is really -- we are part of a
15 supply chain.

16 So as much as we can help support
17 the supply chain and say the experts say what
18 we really need is a measure on why, we are
19 happy to put that out there, give them time to
20 let that work come through a process, which
21 can take up to a year, especially for measures
22 that are tested, and to then have another

1 opportunity in the future to bring back those
2 measures.

3 So the other thing you should know
4 is we didn't really talk about it very much,
5 but we also are always trying to refresh the
6 overall portfolio. So even if you endorse a
7 measure at the end of this process, it is only
8 endorsed for three years, and it is endorsed
9 only for three years because the expectation
10 is that evidence base changes.

11 Things happen such that, if you
12 look at most guidelines, the recommendation is
13 about three years is the general right amount
14 of time when there is a -- you know, you are
15 going to look at guidelines, and generally you
16 would probably want to revisit them.

17 So even if that measure goes
18 through, it is still going to get another
19 look. Secondly, we also have an ad hoc review
20 process. Again, just keep in mind the
21 evidence, particularly for some of these areas
22 and some of these guidelines change so quickly

1 that we also have the capacity that, if any
2 member or any public or anybody out there
3 says, you know, this measure no longer works,
4 this guideline has changed -- the study
5 indicates the evidence would suggest this
6 actually leads to unintended consequences of
7 measurement -- we have the chance to go back
8 and re-review the measure off-cycle.

9 So one notable example was that a
10 measure that had patients getting antibiotics
11 within four hours of hitting the ED for
12 pneumonia -- lots of unintended consequences
13 with that measure, lots of little old ladies
14 with PHF getting a good slug of antibiotics --

15 DR. FIESINGER: Antibiotic
16 resistance.

17 DR. BURSTIN: Yes, antibiotic
18 resistance, and we -- you know, as soon as a
19 lot of those articles began, that evidence
20 began coming out that there was a problem
21 there, we quickly worked with the measure
22 developer. We did an ad hoc review. A

1 revised measure was put forward that had a
2 provisional diagnosis of pneumonia required as
3 well as a six-hour window.

4 Again, so we can make those
5 changes. We try to make it such that the
6 portfolio really has currency and that we are
7 trying to get it best in class.

8 Also, if a better measure comes
9 forward within that period of time as well at
10 the time of maintenance, we have the
11 opportunity to refresh the portfolio as well,
12 and say, okay, that measure may have worked
13 for now, but it is all we got; there is a
14 better measure down the road, and we will try
15 to refresh the portfolio going forward. Long
16 answer, sorry.

17 DR. SMITH-BINDMAN: I know I am
18 going to ask this later. So I might ask it in
19 a general sense.

20 If we feel the need for risk
21 adjustment -- you used to have them. Is that
22 a minor -- Is that a rewrite or is that as

1 long as they can accommodate the writer to
2 change?

3 DR. BURSTIN: No, it really
4 depends on what we are talking about. If you
5 are asking, I think, somebody to add a risk
6 model that doesn't exist, that seems like a
7 pretty significant rewrite.

8 If, on the other hand, the data is
9 already stratified and you are saying, you
10 know, you should really add age and gender or
11 something like that, that might be something
12 they would be able to accomplish and put that.
13 But you couldn't add a risk adjustment.

14 DR. SMITH-BINDMAN: I am having a
15 hard time understanding what rewriting the
16 measure means versus adjusting -- not to put
17 work in our hands, but why can't we rewrite
18 the measure a little bit? Is that not in our
19 --

20 DR. BURSTIN: Well, first of all,
21 you know, you need to respect the fact that
22 the measure developers have often spent up to

1 a year coming up with this measure. They have
2 had advisory committees. They have had lots
3 of logic for the reason they put the measure
4 together. So you want to give them an
5 opportunity to go back to their advisory
6 committees and say, okay, this is what the
7 committee said.

8 And secondly, you know, if it is
9 really a different measure, that is one of the
10 sort of clear lines in the sand for NQF is,
11 because we are part of the supply chain, we
12 don't do measure development. I think we try
13 really hard to stay on the side of saying,
14 okay, the measure is before us. You know, it
15 either works or it doesn't. Maybe there are
16 some fairly minor changes, and again it all
17 depends on the measure developer as well.

18 We have seen some measure
19 developers being somewhat saying, okay, fine,
20 we will take the changes; we just want to make
21 it done. And if they can do it in the time
22 frame, and even if they are sort of bordering

1 onto being more significant changes, that is
2 fine. But again, it is a back and forth. We
3 can't force the developers to make changes.
4 They still have the opportunity to come back
5 and say, no, and you have to make a decision
6 at the end of the day.

7 Any thoughts from anybody who has
8 been through this process want to comment?

9 DR. RUCKER: This is helpful. I
10 think it is not well known that NQF doesn't
11 actually primarily generate the measures, just
12 as an out there in the world kind of comment.

13 CO-CHAIR GAZELLE: I think my
14 experience on the last one was that there were
15 a portion where we came to very clear
16 consensus of what needed to happen to make the
17 measure better, and on some of those the
18 measure developers agreed and were able to
19 respond, and those measures went forward.

20 In others, either the measure
21 developers didn't agree or the changes were so
22 large that they couldn't be accomplished, and

1 I think in that latter group we have seen some
2 of them come back this time.

3 DR. BURSTIN: Yes.

4 CO-CHAIR GAZELLE: I think we will
5 see that with the mammo measures where we have
6 made specific suggestions that couldn't be
7 accommodated in the review cycle, and so we
8 are now seeing them in the next cycle.

9 So I would say that is indication
10 that the process is working in all of the
11 different ways that it is intended for.

12 DR. CANTRILL: Steve Cantrill. As
13 was talked about before, I think you
14 potentially get better measures if there is a
15 larger lag time between the call for measures
16 and when you start looking at them. Some
17 folks may have been working these for a year,
18 as you say. Many of us only found out about
19 it in December, which is a very, very tough
20 window to produce a quality product.

21 DR. BURSTIN: Right, and one of
22 the things we are doing, which is a broader

1 sort of NQF approach, is we are actually
2 trying to move toward more of an expectation
3 of a slight goal of when measures will come up
4 for both new measures as well as maintenance,
5 and have come up with -- it scares me a bit,
6 but there's about 28 committees that would
7 need to meet over a three-year period of time.

8 The idea would be -- I mean, in
9 some ways it may replace some of these sort of
10 quick ad hoc, get these things in quickly, but
11 if you knew, for example, that cardiovascular
12 was happening in 2010 and is happening again
13 in 2013, it gives a better window to say when
14 you can prepare for the next cycle.

15 So that is definitely our emphasis
16 as well. It also then allows us to have the
17 same cycle to look at what is currently
18 endorsed and what is submitted.

19 One of the difficulties we get at
20 times is a measure may already be part of the
21 portfolio. It is not up yet for maintenance.
22 It has only been in the portfolio a year and

1 a half or two years, and yet a better measure
2 came in.

3 So to really say at the end of the
4 day we have best in class measures, we have to
5 have that capacity to do those head to head
6 comparisons with all measures being at equal
7 footing, both new and currently endorsed.
8 That is what that -- so the change in mindset
9 is moving toward us. We are getting there.

10 CO-CHAIR GAZELLE: I know we are
11 ahead of schedule. Is there any reason not to
12 move on to the mammo measures?

13 MR. CORBRIDGE: No, there is not,
14 actually.

15 CO-CHAIR PETERSON: Since I am on
16 the mammo group -- one thing we learned last
17 time was it takes us a lot longer to do the
18 first ones than the others, because we are all
19 orienting ourselves to the process, to each
20 other, and what-not. So I will try to do that
21 with benefit of how this worked last time.

22 The other thing I will say is that

1 we are all here because of our particular
2 expertise and background, but we are all here
3 also to participate in the whole process.

4 So even though you may be a
5 cardiologist or a neurosurgeon or have
6 expertise in an area other than mammo, now is
7 the time to become a mammo expert and to be
8 engaged in the discussion about the mammo
9 measures, because that is the idea of the
10 process.

11 All right. So we have five mammo
12 measures to consider today. Four of them are
13 proposed by the American College of Radiology.
14 One of them is proposed by CMS.

15 At the prior meeting of the
16 Steering Committee, one measure we considered
17 was the recall rate, and the short story from
18 that meeting was that we felt the recall rate
19 was not a good measure in isolation.

20 The specific discussion was
21 lengthy, but we felt that, for recall rate to
22 be a useful measure, it needed to be paired

1 probably with cancer detection rate and a
2 PPV2, which we will get to. So the measure
3 developers have -- because they really
4 couldn't do that in the time frame -- have
5 come back with a suite of measures that we are
6 here to discuss.

7 Because they all relate to each
8 other, I think how we should proceed is we
9 will have a brief discussion from the primary
10 reviewer of each metric, what it is, what its
11 strengths are, what issues might either relate
12 to its definition or its applicability, some
13 comments.

14 Then we will move on to the next
15 measure, if we could, because my suspicion is
16 what we will end up recommending is that we
17 can't approve one without some combination of
18 others, but that we probably don't want all of
19 them.

20 DR. BURSTIN: Yes. Just one
21 qualifier. It would be very helpful for us, as
22 the primary reviewer goes forward, to actually

1 give their ratings of the criteria. Again,
2 you want to keep it very grounded and make
3 that very transparent.

4 CO-CHAIR GAZELLE: But I think
5 for each primary reviewer, as you go through,
6 even though I know all of us who reviewed the
7 mammo measures have comments about the others,
8 we should try and focus just on a run-through,
9 knowing that we will come back and go through
10 them all as a suite.

11 So the five we have are Number 1,
12 2, 3, 4 and 9. In brief, Number 1 is the
13 cancer detection rate. Number 2 is called the
14 PPV2 for Screening, which I think some of us
15 would say might have been defined differently
16 as a PPV1. Number 3 is the PPV2. Number 4 is
17 the recall rate, and number 9 is the follow-up
18 rate.

19 So with that introduction, Carl,
20 do you want to go first, measure Number 1?

21 DR. D'ORSI: Do I want to or do I
22 have to?

1 The way I looked at this metric
2 was to be used in isolation, and that is very
3 important to what I am going to say. I think
4 it is a good measure, but not in isolation.
5 So my comments will be based on the what I was
6 told to evaluate it for, which was a metric.

7
8 This, basically, is a metric that
9 is asking, for all the agony you produce by
10 recalls and biopsies and evaluations, what do
11 you get back? So it is saying, for every
12 positive mammogram you do, which includes
13 Category Zero from a screening and includes 4
14 and 5s after the evaluation of the zero from
15 a screening, and that woman goes to some kind
16 of tissue diagnosis, i.e., needle core biopsy
17 or, much less frequently, surgical biopsy, how
18 much cancer is produced?

19 So that is what it is saying, and
20 the way it is written, it is written as a
21 percentage. We usually consider it as a rate,
22 X number per thousand. So the way it is

1 written, if you multiply that metric by 1,000,
2 you will get what the standard measures are.

3 It is very important to realize
4 that this metric varies -- can vary widely,
5 depending on the population you are testing,
6 i.e., age is very important, whether it is a
7 prevalent screen or not is very important, and
8 these numbers can vary.

9 There is a wide range, if you
10 include all of them, that will kind of include
11 all these variables. Anywhere from two to
12 eight or 10 per thousand is the range, but
13 again within that range there is a big
14 variability, depending on --

15 CO-CHAIR GAZELLE: Could I
16 interrupt for a second? I think, in terms of
17 procedure, it would probably be helpful for
18 everyone else if we start by defining the
19 numerator and denominator --

20 DR. D'ORSI: Oh, I'm sorry.

21 CO-CHAIR GAZELLE: -- as proposed
22 for the measure, because not everyone may --

1 DR. D'ORSI: All right. Let me
2 read right from the statement: The number of
3 screening mammograms -- this is the numerator
4 now. The number of screening mammograms where
5 the BIRAD assessment of 4 or 5 plus the number
6 of screening mammograms with a zero that
7 result in a tissue diagnosis of cancer.

8 So, basically, it is the positive
9 mammograms, including screening and
10 diagnostic, positive being defined on a
11 screening as zero, 4 and 5, positive being
12 defined on a diagnostic exam as 4 or 5. That
13 combination is the numerator.

14 The amount of screening exams you
15 have read is the denominator. That multiplied
16 by 1,000 is the cancer detection rate. So
17 that is the metric, and it is a very good
18 metric when used with others. In isolation,
19 it doesn't tell you too much, other than you
20 are in a huge range.

21 It is sort of like accuracy. I
22 can -- if I define accuracy for screening

1 mammograms, which sounds like a great metric -
2 - right? Accuracy is true positive, true
3 negative over everything you do. Well, if
4 they read everything as negative, I will have
5 an accuracy of 99.8 percent.

6 DR. SMITH-BINDMAN: Could we put
7 this into context, just so people have a
8 ballpark of what this means? If you read
9 1,000 screening mammograms, there should be in
10 the ballpark of six or seven or eight cancers
11 in that group of 1,000 women, and the cancer
12 detection rate is usually around five.

13 So you are expected to find about
14 five cancers per 1,000. As Carl said, it
15 varies by age. So if you are looking at 20-
16 year-old women, there aren't that many cancers
17 to find. If you are looking at 80-year-old
18 women, there are a lot of cancers to find. If
19 you are looking at women with palpable breast
20 lumps, there are a lot of cancers to find.

21 So those things matter, but
22 basically you are looking at about five or six

1 cancers that you usually find out of 1,000
2 mammograms. If you are really doing a lousy
3 job, you might not find that many. If you are
4 doing a great job, you might find more of
5 them. So that is what this is trying to get
6 at.

7 CO-CHAIR PETERSON: Just another
8 thing, just a little perspective thing.
9 Radiologists' view of the world is, the
10 patients I do, how did I do on them? From a
11 more societal perspective or a hospital
12 perspective, you might say, well, are you
13 screening the right people, as you sort of
14 indicted here.

15 If you, obviously, are screening a
16 remarkably low risk group, 20-year-olds, you
17 are going to have a low score on this, but it
18 is not reflecting anything the, quote/unquote,
19 radiologist did right or wrong. It is a
20 reflection of who is going to the test.

21 DR. SMITH-BINDMAN: So just taking
22 it one step further, a measure that

1 radiologists like to think doesn't matter so
2 much about the prevalence of the group is a
3 measure called sensitivity.

4 What that means, among the people
5 who had cancer -- I said there would be about
6 seven or eight cancers -- if you find five of
7 those, the sensitivity gives you a sense of
8 how you are doing proportionately that is not
9 influenced by the prevalence of disease.

10 It is really hard to get at
11 sensitivity. You have to learn about your
12 misses. Cancer detection rate, you don't have
13 to find out your misses. You know that you
14 found five cancers. I don't know how many
15 there is supposed to be. So cancer detection
16 rate has a measurability tool that sensitivity
17 does not.

18 CO-CHAIR GAZELLE: Yes. I guess
19 my sense is -- I am just trying to ground and
20 make sure I am correct on this. This is not
21 a measure of anything to do with how good the
22 reading was. It is a reflection of how we use

1 the technology itself. Did we screen a
2 population who was at reasonable risk?

3 DR. SMITH-BINDMAN: It turns out
4 that cancer detection rate is highly
5 correlated with cancer prevalence. So even
6 though it is imperfect, because it strongly
7 depends on the prevalence, and even though my
8 major problem is that it is not risk adjusted
9 to the population -- so I don't know how
10 useful it is without that, but in general it
11 is highly correlated.

12 So if you are doing a terrible job
13 in terms of finding cancer at a low
14 sensitivity, you will also have a low cancer
15 detection rate. They go hand in hand. So it
16 is used as a measure of gross quality. So in
17 facilities that provide care to underserved,
18 turns out the cancer detection rates are
19 lower.

20 DR. SNOW: One point of
21 clarification. The word screening I take to
22 mean an asymptomatic individual. So someone

1 who is there for a breast lump is not being
2 screened. There is something there or
3 believed to be there. So that is a different
4 bucket.

5 CO-CHAIR GAZELLE: The denominator
6 here is the number of screening mammograms.

7 DR. SNOW: Okay, so specifically
8 asymptomatic subjects.

9 DR. SMITH-BINDMAN: But the age is
10 hugely important.

11 CO-CHAIR GAZELLE: Yes. yes.
12 They are asymptomatic, but there is still a
13 difference in prevalence as a function of age.
14 Yes. So I think, let's try and get back to
15 Carl's review of the measure in terms of
16 giving your evaluation of it, remembering that
17 it is likely that we would recommend this be
18 paired with other measures or combined with
19 other measures.

20 DR. BURSTIN: Just one more point
21 of clarification. The measure developer did
22 put the measure forward to be looked at as a

1 group. So there was not an expectation on the
2 part of the measure developer that this
3 measure would get looked at in isolation. It
4 was supposed to be paired with, on the first
5 page there, the positive predictive value and
6 the abnormal interpretation of the recall
7 rate, just to put that in context.

8 DR. D'ORSI: Okay. Well, I called
9 specifically about this, just to bring up a
10 point, and I said should I evaluate this in
11 isolation or with the others, and I was
12 clearly told to measure it in isolation.

13 DR. BURSTIN: Clearly, evaluate
14 the measure as it stands on its own, but keep
15 in mind at the end of the day, the developer
16 is recommending they get looked at together.
17 So at the end we can put them together.

18 DR. D'ORSI: Okay, that is very
19 difficult to do. It is a great measure not in
20 isolation. That is all I can say. The way I
21 evaluated it, I gave it an N only because I
22 was told to consider it in isolation, and in

1 isolation it is relatively useless unless you
2 have something else to define how the leader
3 is obtaining these numbers.

4 CO-CHAIR GAZELLE: Could we go
5 through the specific points, though, the
6 specific areas in terms of its validity and
7 reliability?

8 DR. D'ORSI: Sure.

9 CO-CHAIR PETERSON: But, again, I
10 am just going to question right off the bat
11 here. Are we talking about a measure -- you
12 gave it an N because, as a radiologist, do I
13 think this reflects my quality.

14 DR. D'ORSI: Alone.

15 CO-CHAIR PETERSON: If the goal
16 isn't to reflect your quality as a
17 radiologist, the goal is to reflect how is the
18 ordering hospital screening patients. Then it
19 may need a different criteria.

20 DR. SMITH-BINDMAN: I think it
21 needs to be assessed within the strata of risk
22 groups, just like we assess risk of other

1 ones. So now we state what you are saying:
2 If the strata are 40 to 50-year-old women, or
3 50 to 60-year-old women, that will be our
4 measure of the radiology quality.

5 CO-CHAIR PETERSON: Right. You
6 are getting back to the radiologist again. I
7 don't really care about the radiologist --
8 just for a second. Let's imagine we want to
9 do this -- the analogy would be --

10 DR. SMITH-BINDMAN: At the
11 hospital level.

12 CO-CHAIR PETERSON: -- in cardiac
13 disease where you wanted to see, you know, did
14 you order testing the right patients, is what
15 it basically comes back to. I am just curious
16 if the measure itself couldn't be seen under
17 that light. You know that the radiologist
18 has a quality measure, but --

19 CO-CHAIR GAZELLE: But it is not
20 intended as an individual physician measure.
21 It is intended as a facility level measure.

22 CO-CHAIR PETERSON: Right.

1 DR. SMITH-BINDMAN: That is a
2 different -- we've got those in HEDIS already.

3 MR. BACKUS: To what degree does
4 this facility really define who their
5 screening, though? I mean, essentially, in a
6 straight screening mammography -- right --
7 asymptomatic patients, and this is much more
8 patient directed than the facility having a
9 substantial amount of influence over the
10 asymptomatic people that they get to show up
11 in the door.

12 CO-CHAIR PETERSON: Now, see, this
13 is where the world also -- the degree to which
14 the center who gets the test -- people I will
15 refer to you, you have the responsibility of
16 being a screener of, are the tests coming into
17 me the right ones. Are we getting the right
18 patients in to do this test?

19 CO-CHAIR GAZELLE: But, I mean,
20 screening mammography is at least something
21 that is fairly -- the eligibility requirements
22 are fairly clearly defined, notwithstanding

1 the November --

2 DR. SMITH-BINDMAN: But this is
3 completely separate from that. This is once
4 whomever comes in comes in, is the quality
5 that those patients are receiving at some
6 minimum level?

7 DR. D'ORSI: The problem, I think,
8 that you are actually touching on there is a
9 problem of, are we dealing with something like
10 a blood test where it doesn't take any
11 cognitive input, and then you can say, oh, the
12 facility or, you know, the testing of this
13 metric is good. Their method is very good,
14 and it works.

15 There is a cognitive input to
16 screening. So you can't separate it as
17 opposed to, okay, the facility is doing it.
18 Well, the facility is also the people who are
19 leading it.

20 So, indirectly, it is a measure of
21 the people working at that facility. So if
22 you have people who are -- again, my apologies

1 to any surgeons who read mammograms -- who are
2 all surgeons, they might have a cancer
3 detection rate of 3 sitting in the group, but
4 they should have had one a day, if we take
5 into account the age and if we take into
6 account all these other things.

7 The problem is it is very
8 difficult to stratify by age, very difficult
9 to stratify by prevalence. They can do this
10 in service screening countries where they have
11 that data right off the bat. You can't do it
12 here. So you have to get a range.

13 CO-CHAIR GAZELLE: So when that --
14 I think it might be mentioned in the next
15 measure, but what if they are rated 16, and --

16 DR. D'ORSI: Great.

17 CO-CHAIR GAZELLE: Well, but are
18 they really cancers or are they not, and is
19 there a lot of --

20 DR. SMITH-BINDMAN: Are there a
21 lot of cascades of tests to then, say, those
22 extra three maybe not being cascades?

1 CO-CHAIR GAZELLE: I still like to
2 let Carl get through his ratings of this, and
3 let's get through the discussion and ratings
4 of the measures, and then have a discussion,
5 if we could, because I think we need to at
6 least get to that point.

7 DR. D'ORSI: So, basically, as I
8 said, I ran through them in isolation, and I
9 said a No for the reasons that a lot of
10 everyone brought up.

11 CO-CHAIR PETERSON: Which did you
12 give a No?

13 DR. D'ORSI: The first one, the
14 first evaluation, that it shouldn't go
15 further. We are not supposed to evaluate it
16 as a pool.

17 CO-CHAIR GAZELLE: Let's go
18 through all of them, and then we will have a
19 discussion.

20 DR. D'ORSI: All right. As not a
21 pool. I don't know how to say this anymore
22 clearly. As not a pool, in isolation as one

1 metric, it is a No for me.

2 CO-CHAIR GAZELLE: For which one?

3 DR. D'ORSI: For each one, for
4 importance, yes.

5 CO-CHAIR GAZELLE: All right.

6 DR. D'ORSI: The reasons are what I
7 discussed already, that it varies so much on
8 factors that it is difficult to assess. It
9 doesn't tell you anything about what you are
10 getting. So that is --

11 CO-CHAIR GAZELLE: So that is
12 fine. So for discussion, how about the other
13 metrics?

14 DR. D'ORSI: The other metrics --

15 CO-CHAIR GAZELLE: In terms of
16 reliability, evidence to support, those
17 scientific --

18 DR. D'ORSI: The reliability is
19 excellent. There is a lot of evidence to
20 support its use, and there is the article by
21 Rosenberg that everybody is familiar with from
22 the BCSC that has a huge number of mammogram

1 screenings, and it is a very solid individual
2 metric. Its calculation is good. Its
3 definition is good, and what it gives you is
4 good alone.

5 CO-CHAIR GAZELLE: I think Helen
6 is pushing us. We would like to get for each
7 of those, if we could -- we need to record it.

8 DR. D'ORSI: All right. Let's go
9 back to process.

10 CO-CHAIR GAZELLE: We are going to
11 need to do that for every measure.

12 DR. D'ORSI: All right. So 2 is
13 the definition of the detailed measure
14 specifications, can they be attained? Yes,
15 they can be attained. It is much easier to
16 attain these electronically.

17 CO-CHAIR GAZELLE: Would you give
18 it a C then?

19 DR. D'ORSI: I would give that a
20 C. All right, the next is 3, which is --

21 CO-CHAIR GAZELLE: Helen, you want
22 us to do 2(a), 2(b)? You want us to do each

1 one? Yes. We would like to have each one, if
2 we could.

3 Just for process, let's see if we
4 can get through the primary reviewer's
5 comments, because I think from the NQF
6 standpoint, we need to get the specific
7 evaluation.

8 DR. BURSTIN: And, certainly, if
9 there's any ratings that would differ from
10 Carl's.

11 DR. SMITH-BINDER: I didn't know I
12 was the secondary reviewer.

13 MR. CORBRIDGE: There was not a
14 primary and secondary, really. It was review
15 group, just in terms of dividing up, because
16 we really didn't have enough to -- in terms of
17 efficiency. So there is a review group. So,
18 really, it should be in tandem, if individuals
19 can really work together.

20 CO-CHAIR GAZELLE: 2(a) is a C.

21 DR. D'ORSI: 2(a) is a C, and for
22 the reasons I gave. Let's go to 2(b), which

1 is reliability. I gave that a C as well,
2 because it has been reliably tested in this
3 large group.

4 Let's go to (c), validity testing.
5 I gave this a P, only because the analytic
6 method that's used to establish the validity
7 requires a little more description. The
8 current domain, I gave as a C. So it is a
9 combination. I gave this a Partially
10 Described.

11 Let's go to 2(d), exclusion is
12 justified. That is not applicable. The next
13 one, 2(e) wasn't applicable. The next one
14 2(f) wasn't applicable. The comparability of
15 multiple data sources method: I gave that a
16 C, because they clearly in this portion stated
17 that they included PPV2, and the cancer
18 detection rate, and the recall rate, which I
19 think is a beautiful set of metrics. They are
20 what you want to get at.

21 2(h), which is disparities in
22 care, I gave an NA, Not Applicable. So, let's

1 see, Steering Committee -- again, I only gave
2 it an M, because I was thinking of individual
3 use.

4 Why don't we go to 3? Okay, 3 is
5 in use. Couplet reporting of this initiative:
6 Alone, I gave an N. No one would know what
7 this means in isolation, especially for public
8 reporting. Look at us here discussing this,
9 and we fighting back and forth, and we are
10 going to put this on public information. So
11 I gave that an N. That is 3(a)(2).

12 3(a)(3), used in other programs
13 and initiatives: That I gave an N because of
14 the isolation.

15 3(b), which is -- what is 3(d)?
16 Harmonization. I gave that an Not Applicable.
17 I gave 3(c) an Not Applicable, and the
18 Steering Committee overall, to what extent
19 was a criteria of usability met? I gave that
20 an M. As a sole indicator, it really isn't
21 significant for the above reasons, but the M
22 came from the fact that it was well

1 constructed as an individual metric. So
2 instead of giving it an N, I popped it up to
3 a M, because its definition was very clear and
4 precise, and it is in use, not in isolation.

5 4 (a): Data generated as a by-
6 product of the care process. I gave that a C.

7 4(d): Electronic sources. I gave
8 that an A, because I don't have a -- in order
9 to get this metric, the easiest way is if you
10 have what is called a mammography module where
11 you prospectively, as you read each exam, you
12 put in the data, and it generates a clinical
13 report and saves the data. If you don't have
14 this, the usability is much, much, much more
15 difficult to do this by hand. So that is why
16 I gave it an A.

17 I don't know how many facilities
18 have a mammo module. I don't know if the ACR
19 knows this, but it is very difficult to get
20 without a mammo module. So that is my reason
21 for it there.

22 Exclusions were, for (c) were Not

1 Applicable, to me. Susceptibility to
2 inaccuracies, errors or unintended
3 consequences, I gave a C. I believe there
4 could be unintended consequences with that.

5 Data collection strategy, 4(e), I
6 gave as a C. I think the points that were
7 brought up are very good.

8 To what extent was the criteria of
9 feasibility met? I gave that a C.

10 I think that is it.

11 CO-CHAIR GAZELLE: Thank you. So
12 you can see what a challenge we have in front
13 of us. These measures are hard to evaluate.
14 One of the things that -- and then I am going
15 to ask Rebecca, since you also are with the
16 group, to comment on the measure, even if not
17 item by item.

18 One of the challenges: This has
19 been proposed as a suite of measures, if you
20 will, with two other measures, but we have
21 been given no specific instructions on how
22 they might be interpreted as a suite. So even

1 if all three were approved, the question is
2 what happens if you are high on one and low on
3 another. So there is no guidance yet there.

4 DR. BURSTIN: Just as one comment.
5 Again, this notion of pairing it -- we don't
6 actually know exactly what that means. We do
7 have clear guidance on composite measures
8 where multi-measures come together with the
9 idea of getting a single score at the end of
10 the day.

11 CO-CHAIR GAZELLE: Right.

12 DR. BURSTIN: And at least from
13 that perspective, because I think that might
14 aid Carl's thinking of, again, they didn't
15 present it as a composite, is that we
16 individually evaluate each of the measures and
17 then make a determination of whether that
18 measure could stand alone or should really
19 only be used as part of a composite.

20 So I think, at the end of this
21 discussion, that would probably be the right
22 piece. I still think it will be helpful -- we

1 are not going to go through the whole measure
2 again, each of them separately, and then make
3 the decision overall, but we probably do need
4 guidance from the developer as well as this
5 group about what does it mean that they would
6 be reported together exactly.

7 CO-CHAIR GAZELLE: Yes. And in
8 fact, there is some ambiguity as well, because
9 they say they should be paired with cancer
10 detection rate, recall rate, and PPV2, but
11 then this measure has proposed two measures
12 that are both called PPV2. So we will need
13 to, as a group, come to clarity on that.

14 Rebecca, do you want to give a --

15 DR. SMITH-BINDMAN: Thank you,
16 because I think I have a very different take
17 than Carl.

18 I would just start out by saying
19 it is -- There are programs that use these
20 measures together. So the best example would
21 be the National Screening Program in the UK,
22 which uses cancer detection rates, PPV, and

1 recall rate together.

2 Basically, you have to have a
3 minimum cancer detection rate and, if you
4 don't -- you are not doing well -- then they
5 try to balance that cancer detection rate with
6 a recall rate that is acceptable.

7 It is not that easy, the way they
8 do it, but they combine them together. They
9 don't use it as a composite. They basically
10 plot each facility and each radiologist in
11 this space that includes both PPV and cancer
12 detection rates. I think it is a very nice
13 model that you guys could adopt.

14 I actually like this measure a
15 lot. I think the measure -- If you had to ask
16 women what the single most important thing
17 about a mammogram was, they would say to find
18 cancer, and this tells you about finding
19 cancer.

20 So I think that this measure, if I
21 could pick one, it wouldn't be an inefficiency
22 file. That is not efficient, but you would

1 want to find cancer. So I care about this
2 measure more than any others, and I would be
3 happy with this measure by itself. So I
4 really like cancer detection. So I rate it as
5 a C in terms of the importance of this
6 measure. I think it is extremely important.

7 Going through the numbers --
8 Helen, do you want me to just give you my
9 results or do you want me to say them out
10 loud?

11 DR. BURSTIN: If you just want to
12 probably just say them out loud, especially
13 the discrepancies with what --

14 DR. SMITH-BINDMAN: Okay. I
15 highlighted those columns. So for: Was it
16 important for the measure to report? I would
17 say yes, which is number 1.

18 Going down to number 2 in terms of
19 the specification of the measure, I think it
20 is very good. In terms of -- and so C. In
21 terms of harmonization, I am not sure about
22 other measures that you guys have. I don't

1 think there are any others.

2 DR. BURSTIN: No.

3 DR. SMITH-BINDMAN: So that was
4 kind of easy. Going into: Was the extent
5 usability met? I gave it a C.

6 Going to 4(b) Electronic Sources,
7 I think all these data are available
8 electronically. So I gave it a C.

9 I am actually looking for the
10 width. I keep going past that. So --

11 CO-CHAIR GAZELLE: I think it was
12 not listed.

13 DR. SMITH-BINDMAN: Right. I'm
14 sorry. So I am going back up to 2. So 2(a)
15 12-13, the people who submitted this measure
16 said no risk adjustment was needed, and then
17 gave an explanation of breast cancer risk from
18 Gil Barlow's paper, which is not relevant.
19 Risk adjustment is for this measure, and I
20 think risk adjustment is absolutely needed for
21 this measure.

22 So I think it is a fabulous

1 measure. I think risk adjustment absolutely
2 needed to make it a useful measure, and it
3 doesn't need to be risk adjustment. It needs
4 to be risk stratification, which is easier to
5 do. So there isn't a model to do risk
6 adjustment, but there are models to do the
7 stratification.

8 CO-CHAIR GAZELLE: And you propose
9 stratifying it by age?

10 DR. SMITH-BINDMAN: It needs to be
11 stratified by two factors. It needs to be
12 stratified by age, and whether exams are first
13 or subsequent.

14 The relevance of that, I can't
15 really emphasize enough. There is a two to
16 threefold to fourfold difference in these
17 variables based on age and first and
18 subsequent, and you can imagine that
19 facilities have a very different distribution,
20 whether they see younger patients or older
21 patients or they see patients who come in
22 every year at Kaiser for a mammogram and they

1 are subsequent screenings versus a population
2 that is an underserved population, and they
3 are trying really hard to get everyone to come
4 in once. Those variables are different.

5 So I think it is a great measure,
6 but I think it needs stratification.

7 DR. D'ORSI: By risk
8 stratification, you are not referring to
9 breast cancer risk, are you?

10 DR. SMITH-BINDMAN: That is
11 correct. Thank you.

12 DR. D'ORSI: They did. Okay,
13 that's the problem.

14 DR. SMITH-BINDMAN: Well, they are
15 talking about a breast cancer risk model, not
16 a model of a measure. They both have risk in
17 the name, but otherwise they have nothing to
18 do with each other.

19 DR. D'ORSI: Correct.

20 CO-CHAIR GAZELLE: And I think
21 what you are saying, if I could paraphrase, is
22 that if you have a facility that is actually

1 doing a really good job of getting everybody
2 in at their recommended intervals, they are
3 going to have a lower cancer detection rate.

4 DR. SMITH-BINDMAN: They are going
5 to have a lower cancer detection rate.

6 CO-CHAIR GAZELLE: And that
7 facility that is doing the right thing would
8 be --

9 DR. SMITH-BINDMAN: I would say
10 that the range of allowable values to this
11 cancer detection rate include tolerable care
12 and off-the-chart good care. So that range
13 needs a little more narrowing. The reason
14 they gave this range is because they haven't
15 done the stratification. It is in a useless
16 category at the moment. The range is too
17 wide.

18 DR. D'ORSI: The fine tuning on
19 that range, which is more difficult to obtain
20 but is really important, is minimal versus
21 non-minimal cancer. You can be in that range
22 and be finding Stage IV. You know, that is

1 useless for a mammography range, but -- and as
2 you alluded to -- you may be at the lower end
3 and be finding early cancer. But minimal
4 cancer versus non-minimal is a very difficult
5 metric to get.

6 DR. SNOW: There is another
7 element to this. A feature of this is that
8 the numerator requires a biopsy diagnosis of
9 cancer. Now what happens -- one, that is a
10 whole separate step, and there are other
11 cracks to fall through, but probably not a
12 large crack.

13 The one that is larger is what do
14 you do if it is -- in a place like the Sloan-
15 Kettering, everything gets done in the same
16 shop, but what do you do if the initial four
17 or five is done in a little community
18 hospital, and immediately the patient is
19 referred to the Sloan-Kettering for the
20 biopsy? There is a big gap.

21 I know for sure that our record
22 keeping isn't 100 percent in that area. That

1 is why we are spending billions of dollars to
2 get there. That contaminates the result. I
3 just don't know how much.

4 DR. SMITH-BINDMAN: It is also a
5 very relevant point when you are talking -- I
6 was going to get to it when I got to 2(h) --
7 disparity, in fact. So facilities that are
8 underserved are much less likely to either
9 find the cancer or to know about the cancers
10 that they have found.

11 DR. SNOW: Should there be
12 stratification for ethnicity, too, was the
13 question. I don't know.

14 DR. SMITH-BINDMAN: Cancer
15 detection rates vary a lot by underlying race
16 and ethnicity, but not in the way that you
17 would necessarily think that they varied. So
18 to do what you are saying, there aren't data
19 out there to create metrics, but in terms of
20 this measure biasing against facilities that
21 have less resources, which is what you were
22 raising, is a -- to get at the racial and

1 ethnicity one.

2 DR. GEMIGNANI: But is it not the
3 responsibility of the primary place that
4 orders are issued to follow up on those
5 results, even if that biopsy is not done at
6 that -- I mean, that is part of reporting
7 what your --

8 DR. D'ORSI: Right. The way that
9 verbiage is stated is a reasonable effort. If
10 you have -- if you are a small facility and
11 you are sending a lot of your things out, that
12 becomes a big problem to get -- order biopsies
13 done somewhere else. This was a good example.
14 That is not an issue in countries that have
15 service -- because they are all attached. So,
16 easy. We don't have that.

17 DR. GEMIGNANI: So that facility
18 would get a lesser rate, having used a measure
19 like this, because they are --

20 DR. D'ORSI: Correct, because they
21 don't know, or they don't know, if they can't
22 find it.

1 DR. GEMIGNANI: But isn't that
2 something that you want to know about that
3 facility, that they are not able to track?

4 DR. D'ORSI: Yes, but that may be
5 an unintended consequence. They may be doing
6 something very correct in defining a four or
7 five, but they may not have the resources to
8 search.

9 DR. GEMIGNANI: So they can't
10 detect those cancer rates.

11 DR. D'ORSI: Well, that is a
12 problem.

13 CO-CHAIR GAZELLE: So let me take
14 a stab, then, at summarizing the discussion on
15 this measure to this point, because I think it
16 will be important to go through all of the
17 mammo measures and then come back to a global
18 discussion -- is that the general sense I am
19 getting is that there is some value in
20 measuring cancer detection rate, probably in
21 combination with other measures.

22 There's issues about

1 stratification by first screening or
2 subsequent screening and by age. There's
3 issues about how the data would actually be
4 collected, registry data, claims data,
5 etcetera. But I think, as a group at least,
6 we have -- is it fair to say we have a sense
7 of what this measure is trying to accomplish
8 and what some of the issues are, and it would
9 be all right to move on to the next measure?

10 CO-CHAIR PETERSON: I just have a
11 few clarifying questions. Question number
12 one: since you like the measure, I will
13 direct it your way, but anybody can click in.

14 I am getting a relative magnitude.
15 It appears that this rate would vary much more
16 depending on the strata that you are talking
17 about, age of patients, ethnicity, first
18 versus follow-up screening, than anything to
19 do with the quality of the reader, meaning
20 that, in fact, the degree to miss -- if your
21 concern is that this is a reflection of missed
22 cancers that were there that were missed, that

1 rate would be, we would imagine, relatively
2 low relative to the magnitude of two, three or
3 fivefold variation, depending on if you are
4 first or second, or very young versus very old
5 population.

6 So if this is to reflect quality
7 in terms of the reader, I would argue that
8 this probably is to work without this
9 stratification by the underlying population.
10 That is one clarifying question, and as it is
11 written, it doesn't stratify.

12 CO-CHAIR GAZELLE: But we could
13 propose that.

14 CO-CHAIR PETERSON: I am not so
15 sure that that isn't a remarkable rewrite of
16 this.

17 DR. D'ORSI: How is that not a
18 remarkable rewrite when there is a fourfold
19 difference?

20 CO-CHAIR PETERSON: We don't need
21 the answer right now.

22 CO-CHAIR GAZELLE: Well, we don't

1 need to answer it. But, for example, we could
2 say the measure would be acceptable if it was
3 reported by decade-age strata, and first or
4 repeat screening. We don't need to have a
5 model.

6 DR. SMITH-BINDER: It turns out
7 that those variables that would be needed in
8 this case are available for everyone. We know
9 the age of the woman, and you know if it is
10 first or subsequent, pretty much. You know,
11 that is pretty good. So it is not a fancy
12 model.

13 CO-CHAIR PETERSON: We can maybe
14 take up some discussion about whether it gets
15 rewrite or not.

16 DR. D'ORSI: One other point on
17 the stratification. You need number of hits
18 for it to be valid. When you start teasing
19 decades of age out, you are going to need a
20 lot more in that age group to make a
21 meaningful data analysis. That is why it is
22 done as a group, and may not be as stratified

1 and useful for a single facility.

2 CO-CHAIR PETERSON: Great. Just
3 one more clarifying question, and then I will
4 stop.

5 CO-CHAIR GAZELLE: Before we leave
6 stratification, the argument against
7 stratifying, which is probably not valid, but
8 if you assume that everyone has the same
9 general mix, if you aggregate up against large
10 enough -- some people have argued that, and we
11 could reject that. I would reject it, but
12 that has been proposed as, well, you know, if
13 you look at facilities, everyone has got about
14 the same mixture across a large enough group.

15 So just for perspective, that
16 argument has been proposed by some people.

17 DR. BURSTIN: I just need to point
18 out that Dr. D'Orsi and anybody else may still
19 have a chance to respond.

20 CO-CHAIR PETERSON: And then the
21 other is an unintended consequence question,
22 because actually, you are ranking that, which

1 is going to include -- I thought, if I heard
2 you right, you said it had potential
3 unintended consequences, but you gave it a C.
4 So that is just a positive-negative thing, I
5 guess. I would have said it the opposite. If
6 it does have unintended consequences, then it
7 should be ranked as not scoring.

8 DR. D'ORSI: Let me look again. I
9 may have been wrong.

10 CO-CHAIR GAZELLE: I am going to
11 propose that we take a break. We are
12 scheduled for a break. We will take about a
13 10-minute break. We can come back to conclude
14 -- do you have one other?

15 CO-CHAIR PETERSON: So the
16 unintended consequences portion of this that
17 you were concerned about are that, in fact, if
18 you do mark -- let's take it to the extreme.
19 Every one of your tests are positive, and you
20 send every woman on to a biopsy.

21 Your score here would be good,
22 because you would, hopefully, find every

1 cancer, assuming the system worked, at the
2 downside of every woman having now the
3 negative effects that we have heard in the
4 news so much.

5 So that, in fact, this measure has
6 the very strong potential of encouraging over-
7 reading as opposed to -- you know.

8 DR. SMITH-BINDMAN: When people
9 use this measure -- just to sort of put it
10 into context, there is a very nice breast
11 cancer program going on in Chicago to figure
12 out -- it is a unified effort across the city
13 for everyone who provides breast cancer care.

14 They found that their cancer
15 detection rates at their hospitals were
16 really, really low. They were missing all the
17 cancers. So it is more of something that we
18 think about at the extreme of they are
19 providing services, but they are not finding
20 cancer. Is there a major quality problem at
21 the low end, rather than at the high end,
22 pushing so many recalls that you will find

1 more cancer?

2 At some point, recalling more
3 women, you don't tend to find that much more
4 cancer. It becomes a random.

5 DR. ZERZAN: But do you think
6 that, in trying to figure out what the
7 inefficiency is, it's both under- and overuse
8 that we are trying to get a better -- what is
9 that middle measure, and then --

10 DR. SMITH-BINDMAN: This
11 particular measure doesn't show much push-
12 through overuse. The other ones, the other
13 four measures --

14 DR. SNOW: I don't think this
15 would cause over-reading, because you have to
16 have a confirmed diagnosis. If you screen
17 everybody and send them all to the
18 pathologist, that doesn't mean that they are
19 all going to come back positive. If you over-
20 read, you are going to have a lower rate,
21 because your numerator will go down, because
22 you won't be able to get sufficient diagnoses.

1 CO-CHAIR GAZELLE: I think,
2 really, this is a balancing measure against
3 recall rate; whereas, if we want, say, to
4 achieve recall rates below 10 percent, for
5 example, one way to do that is to miss a lot
6 of cancers. So if you --

7 DR. SMITH-BINDMAN: This is a fail
8 safe on the low end.

9 DR. D'ORSI: If you look at an ROC
10 curve, it is very clear. As your false
11 positives go up, what happens to your false
12 negatives? It goes down, and that is exactly
13 what is being said here. As you get close on
14 an ROC asymptotically to the top, the price
15 you pay to get one or two more cancers is
16 massive.

17 So most people operate in the
18 middle of an ROC curve, because they realize
19 that, if I operate here, I am going to miss;
20 if I operate up here, it doesn't pay for what
21 I am doing to get the cancers.

22 CO-CHAIR GAZELLE: And, in fact,

1 from the last meeting when we did consider
2 recall rates, the feedback that came from the
3 Steering Committee as well as the mammography
4 community at large was you can't possibly have
5 recall rate unless you also have cancer
6 detection rate.

7 That is why it is hard to discuss
8 these alone, because they really do need to be
9 considered together.

10 DR. FIESINGER: I just wanted to
11 throw out a vignette. I think the measure is
12 important. The unintended consequences, I
13 think, are really significant. On one hand,
14 you could just throw the measure out there and
15 see what develops, but I was Medical Records
16 at MQHC, we had a breast cancer graft.

17 Texas Medicaid doesn't cover
18 undocumented women for cancer treatment or
19 biopsy. So if you get the mammo, detect it,
20 we would have low cancer detection rates, a
21 barrier to citizenship status, and then you
22 add financial resources on top of that.

1 Grant funding depends on measures
2 for compliance standards; whereas, like 95
3 percent want us to track every patient.
4 Therefore, health care which funds that case
5 sees this big push for tracking quality
6 metrics, has no time for funding yet, maybe
7 down the road.

8 So how it is interpreted can
9 really impact the safety net system quite
10 severely in the wrong way.

11 DR. SMITH-BINDMAN: Because your
12 patients couldn't find out about cancers,
13 because they were not documented?

14 DR. FIESINGER: Because we
15 couldn't get funding to get a biopsy. You can
16 get the mammograms through a charitable
17 organization, but getting emergency -- you
18 have to get a biopsy and, if they have cancer,
19 get a emergency Medicaid to have cancer
20 treatment. But if they are not documented,
21 meaning not citizens, they can't get Medicaid.
22 So how do you get the biopsy?

1 DR. SMITH-BINDMAN: So they really
2 don't need a mammogram.

3 CO-CHAIR GAZELLE: Yes. If they
4 are not going to get care anyhow.

5 I think we could go on, on this
6 measure, forever, as a base. I know you said
7 the most -- you know, the thing that a woman
8 wants when she goes to get a mammo is that
9 cancer is found -- cancer detection. My
10 question would be is it that cancer -- you
11 know, it is a place that has a high cancer
12 incidence or is it a place that is better on
13 PPV2, so that she has faith in the
14 radiologist's judgment? Right? You are
15 balancing the concern of a negative.

16 It seems to me that what I really
17 want to know is that, when they say I have
18 cancer or say I have an issue or say I don't
19 have an issue, they are right; as compared to
20 this wild population here.

21 MR. BACKUS: That gets into our
22 next couple of measures.

1 DR. SMITH-BINDMAN: I agree with
2 you. Women don't, for better or worse.

3 CO-CHAIR GAZELLE: Let's go ahead
4 and take a 10-minute break, if we could,
5 because I think otherwise we will just spend
6 the rest of two days on this first measure.

7 (Whereupon, the foregoing matter
8 went off the record at 10:58 a.m. and resumed
9 at 11:14 a.m.)

10 CO-CHAIR GAZELLE: Okay, could we
11 get started again, please. Because the other
12 measure in review group 1, which was Number 9,
13 Rebecca's, is proposed by CMS and not the ACR,
14 we are going to go on to the other three that
15 were proposed by the ACR.

16 We will discuss the four total
17 from the ACR as a group after we go through
18 each one individually. Then we will allow
19 Larry Bassett from the ACR to comment after we
20 have all commented, and then we can talk about
21 our feeling of those four as a group.

22 DR. SMITH-BINDMAN: Do you think

1 the ACR might be able to say a word or two
2 about this measure before we go on?

3 CO-CHAIR GAZELLE: No, they just
4 want to go through all of the four first, and
5 we talked during the break about that.

6 All right. So the next one, which
7 is number 002-10, titled Screening Mammography
8 Positive Predictive Value 2, and it is
9 described as being the percentage of screening
10 mammograms with abnormal interpretation that
11 result in a diagnosis of cancer within 12
12 months.

13 It is actually defined in terms of
14 the numerator and denominator slightly
15 different from that. So the numerator is the
16 number of screening mammograms with the BIRADS
17 4 or 5 or BIRAD zero associated with a 4 or 5
18 on a diagnostic mammogram, so basically a
19 positive screening mammogram that results in
20 cancer within 12 months.

21 The denominator is defined as the
22 number of screening mammograms with a 4 or 5

1 or zero, and the zero has to be associated
2 with a 4 or 5 on a diagnostic.

3 So it is basically the positive
4 screening mammograms denominator. Numerator
5 is the subset of those that have cancer.

6 So the first thing I will say is
7 that in the literature this might be called
8 the PPV1, and so there is going to be some
9 confusion about that for those of you who are
10 familiar with the literature on those
11 measures.

12 So, in terms of my evaluation, I
13 thought for 1(a), Importance to Measure and
14 Report -- let me make an overall comment
15 first. There are two very similar measures,
16 this one and the next one. They are both
17 called PPV2. I think this is really PPV1, and
18 the next one is PPV2.

19 I am going to score this in
20 isolation, but as a preface I am going to say
21 that, if I had to choose between the two, my
22 choice would be for the next one. But I am

1 going to score this in isolation.

2 So I thought for 1(a) I gave it a
3 C in terms of importance to measure and
4 report. For 1b I gave it a C, and for 1(c),
5 the relationship to outcomes, I gave it a P
6 for partial, because I think -- for all the
7 reasons that we have discussed before. 3 is
8 only partially collected outcomes.

9 In the text of the proposal, the
10 measure developer suggests that it should be
11 combined with other measures, and we have
12 already talked about that, though there is no
13 clear guidance on what that would mean. I
14 don't think we are envisioning a composite
15 measure so much as reporting of the three
16 individually, but that hasn't been addressed.

17 Then for the global one,
18 importance to measure and report, I said yes.

19 Then for measure specifications:
20 2(a), Precisely Specified, I said yes. 2(b),
21 reliability testing, I said partially, because
22 it was my impression that the text in the

1 measure was talking about, really, the
2 reliability of BIRADS and not the reliability
3 of the proportional measurement. So I would
4 give that a P.

5 For validity, I gave it -- I'm
6 sorry, for 2(c), the validity meaning the
7 relationship of this measure to outcomes, I
8 gave it an M for minimal, because I didn't see
9 that there was a connection between this
10 measure and outcomes of concern.

11 Then for exclusions, NA, and data
12 sample, NA.

13 Identification of meaningful
14 difference in performance, 2(f), I gave that
15 as M. They do cite ranges from the
16 literature, although I think there is a typo.
17 They cite a range for PPV2, notwithstanding
18 the comments I made about the confusion
19 between the two measures labeled PPV2 of five
20 to 10 percent, and from the article that was
21 cited, it is 25 to 40 percent. So I believe
22 that is a typo in this one and some of the

1 other measures.

2 DR. SMITH-BINDMAN: This is a
3 screening measure?

4 CO-CHAIR GAZELLE: Yes.

5 DR. SMITH-BINDMAN: Then it should
6 be the lower number.

7 CO-CHAIR GAZELLE: Right, but the
8 screening measure would be PPV1. So that is
9 the confusion.

10 DR. SMITH-BINDMAN: But we are
11 assuming that this measure is PPV1.

12 CO-CHAIR GAZELLE: Right. I think
13 we have to.

14 For 2(g), multiple data sources, I
15 am not sure how to evaluate that. So I gave
16 that an N, but it could have been an NA, and
17 for disparities I gave that an NA.

18 So for the overall: To what
19 extent was the criterion scientific ability of
20 measure properties met? I gave it a P for the
21 reasons I just stated.

22 Then for 3: 3(a), the current use

1 one, I gave it a C, although there was some
2 question I had as to whether or not this could
3 actually be done everywhere as opposed to at
4 the sites participating in the ACR net for
5 mammography database and the BCSC.

6 For harmonization, hard to
7 evaluate, because I think the proposed -- so
8 the way I interpreted that question 3(a) was
9 that it could be used in a public reporting
10 initiative, and there is a lot of text there
11 about BCSC and the National Mammo Database,
12 but there is no text to indicate what
13 percentage or what proportion of sites in the
14 country participate in one of those two. So
15 it wasn't clear to me that this is usable --

16 DR. SMITH-BINDMAN: But I think it
17 could be. They don't cite the right
18 literature.

19 CO-CHAIR GAZELLE: Right.

20 DR. SMITH-BINDMAN: But I think it
21 could be.

22 CO-CHAIR GAZELLE: I gave it a C.

1 I did give it a C. It is just that I raise
2 that question based on the text.

3 Now let's see. For 3(b),
4 harmonization, I gave it a P, and it was hard
5 for me, because it is really not harmonized
6 with the existing measures so much as
7 harmonized with others that are proposed, but
8 I think it is harmonized with the intent of --
9 or there is the intent of harmonization.

10 For added value, I gave it a C. I
11 thought that it was clear that it did.

12 Dataset, data generated -- so my
13 overall for 3 -- what extent was the criterion
14 usability met? -- was a P, again for the
15 reasons I said. In my view, you got to get a
16 C on everything to get a C for the overall.

17 Okay, and then for 4, Data
18 Generated as a Byproduct, I thought it was:
19 4(a), clearer, that the data elements could be
20 generated as a byproduct of the care process,
21 but it may not entirely be now, based on the
22 issue of the cancer rates. So I gave that a

1 P -- cancer detection.

2 Electronic sources, I gave that,
3 again, a P, because I think the feasibility of
4 using those existing electronic data sources
5 is there, but I don't think everybody is using
6 them yet.

7 Exclusions, NA. Strategy --

8 DR. D'ORSI: You mean C, right,
9 not A?

10 CO-CHAIR GAZELLE: NA.

11 DR. D'ORSI: Oh, NA, I'm sorry.

12 CO-CHAIR GAZELLE: There weren't
13 any. So then I think there were a lot of --
14 To what extent were the criteria on
15 feasibility met? I gave that a C as well. I
16 gave it a P leaning towards a C, to be honest
17 with you, because I think that it may be close
18 to feasible. I am just concerned about some
19 sites that may not have access to the full
20 panoply of electronic data registries and
21 sources.

22 Then for my overall -- do you

1 recommend it for endorsement? -- I gave it a
2 Yes with the proviso -- I know we are not
3 allowed to give this proviso on an individual
4 measure, but with the proviso that either this
5 or the real PPV2 -- my preference would be
6 that real PPV2, the next measure -- should be
7 paired with recall rate and cancer detection
8 rate. A quick run-through.

9 Now leaving all these boxes and
10 scores, here is my gestalt on it. It is a
11 valuable measure, not in isolation. If it is
12 being paired with other measures, I think it
13 does add value; but if it is being paired with
14 other measures, I would rather see us use the
15 next measure, the PPV2, and not this one.

16 So let's see. Mary, comments?

17 DR. GEMIGNANI: Yes. So I am
18 going to be the primary reviewer for --

19 CO-CHAIR GAZELLE: First, any
20 other comments on this measure before the next
21 one?

22 DR. GEMIGNANI: I have no

1 comments.

2 MR. BACKUS: My only thing is how
3 much are we looking at one being a measure of
4 screening mammography and one being a measure
5 of diagnostic mammography, and those are, to
6 me, really two different target audiences
7 amongst -- if we operate within the context of
8 this is information for the public, then they
9 may be thinking much more about going and
10 getting a screening mammogram; whereas, as
11 health care professionals are thinking much
12 more about PPV2, which is how good are you at
13 picking it, once you get it.

14 So to me, it is just two
15 completely different populations that you are
16 looking at. In one, you should be hitting one
17 out of four, so to speak, and in the other you
18 are hitting one out of 20.

19 DR. GEMIGNANI: I think that the
20 previous -- the measure we just discussed with
21 the PPV1 sort of leads into the PPV2, because
22 it takes all comers of the pie; whereas, once

1 you move all the true diagnostic
2 mammographies, it is a purer measure.

3 MR. BACKUS: Right.

4 DR. GEMIGNANI: So I am not so
5 sure whether excluding the other one, if we
6 were able to tweak it a little bit, is
7 necessary, because they are actually targeting
8 two different things.

9 CO-CHAIR GAZELLE: Are there any
10 other comments from the group on this measure?
11 I forgot to mention, please give your name
12 when you are commenting, if you could, for the
13 recording.

14 DR. SMITH-BINDMAN: Just a
15 question. You skipped by -- instructions are
16 hard. This is Rebecca Smith-Bindman.

17 Just a comment on whether or not,
18 to the degree that cancer detection rate needs
19 to be stratified by age, should I just comment
20 on whether that needs to be the case for PPV1.
21 I think it varies by age.

22 So the PPV1 of mammography in

1 women who are in their forties is about two to
2 three percent. The PPV1 for women in their
3 seventies is about eight to nine percent. So
4 there is a pretty big range in that. It is
5 not as important as for cancer detection rate
6 or for recall rate, because they go a little
7 bit in tandem. So they both go up together.

8 So when you are dividing them,
9 there may be a little bit less error, but --

10 CO-CHAIR GAZELLE: So that wasn't
11 addressed in the measure.

12 DR. SMITH-BINDMAN: No, it wasn't.

13 CO-CHAIR GAZELLE: And the only
14 thing I would say -- I am not sure that I
15 could comment on it from a sufficiently
16 educated viewpoint, except to say that, if we
17 are proposing these as a group, three or two
18 or four or whatever, and if we are saying at
19 least one of them needs to be reported by, for
20 example, strata, that they all probably ought
21 to be. It would seem reasonable to me.

22 DR. GIBBONS: Ray Gibbons. Just

1 to follow up on that point, I am having a hard
2 time understanding when you are describing
3 what seems to be a known narrow range, how
4 this will spur quality improvement.

5 If you now start talking about
6 risk stratification, how many patients do you
7 have to have to have a reasonable precision to
8 every use that it is required?

9 CO-CHAIR GAZELLE: So those data
10 were not presented. So I am not sure we can
11 answer that question based on data. However,
12 an average site would do what number of
13 mammograms?

14 DR. SMITH-BINDMAN: I can address
15 that based on the data. Your point is very
16 well taken. So the average facility size in
17 the U.S. is between 1,000 and 2,000. It is a
18 medium size.

19 So in the -- and there are a fair
20 number, 25 percent of facilities who are very
21 small, and the very small facilities won't
22 possibly have enough cancers to get at cancer

1 detection rate, let alone cancer detection
2 rates of five.

3 So I think this has to be limited
4 to facilities of a certain size, and that
5 will, by definition, throw out at least a
6 quarter of the sites.

7 DR. GIBBONS: So out of the one or
8 two thousand, how many are positive, because
9 that is the denominator in this study?

10 CO-CHAIR GAZELLE: Right.

11 DR. SMITH-BINDMAN: No. The
12 denominator is easy, because out of the 2,000
13 mammograms there will be 300-400 that are
14 positive. It is the numerator, the number of
15 cancers, that is the trick in this.

16 CO-CHAIR GAZELLE: The denominator
17 is positive screening mammograms.

18 DR. SMITH-BINDMAN: That is easy.

19 DR. GIBBONS: So 300-400, you are
20 saying, is --

21 DR. SMITH-BINDMAN: Will be
22 positive. The denominator will get a 10-15

1 percent positive rate, the denominator. There
2 will be about 150 per thousand to 300 in the
3 2,000 example. So that will be about 2,000.
4 The numerator would be something like 10.

5 DR. GIBBONS: Well, I am just
6 trying to work through the math. We are down
7 into single digits.

8 CO-CHAIR GAZELLE: Yes.

9 DR. GEMIGNANI: I think this
10 measure is -- this is Mary Gemignani. I think
11 this measure is also getting at how often are
12 you calling it an abnormal mammogram just on
13 any facility that comes in, and how often are
14 you really having a cancer out of you calling
15 a BIRADS 4 or 5.

16 So if you use it in isolation
17 probably to the point that has been discussed,
18 probably not such an effective number. But if
19 you are using it in conjunction with your
20 cancer detection rate, then you are getting
21 more at how many abnormal tests are you really
22 -- false positives are you really doing?

1 DR. SMITH-BINDMAN: But it is a
2 question about how applicable this is for
3 small facilities and how many facilities are
4 small. It is quite a lot.

5 CO-CHAIR PETERSON: But I guess I
6 am just missing why is it not a reasonable
7 measure in extent here, by itself, because
8 this is a meaningful number to patients. I
9 want to know how many times -- if you call me
10 again and tell me I have a positive study, how
11 many of those will really end up being
12 cancers?

13 DR. SMITH-BINDMAN: If your target
14 is four percent -- that is the target, or five
15 percent -- you need to have a large enough
16 sample size that my estimate of your four or
17 five percent is valid.

18 CO-CHAIR PETERSON: And the target
19 is four or five percent, because?

20 DR. SMITH-BINDMAN: That's because
21 that is as good as it gets. That is the
22 number. That is the average PPV across

1 mammography.

2 CO-CHAIR GAZELLE: So if you think
3 of an ROC curve, one way to get a really high
4 PPV is to operate toward the specificity side
5 of your ROC curve, which is to have too high
6 a positivity threshold. So, basically, if it
7 takes an awful lot to get you to call it
8 positive, everything you call positive is
9 going to truly be positive.

10 So in isolation, you might have a
11 high positive predictive value, but you have
12 a really low cancer detection rate.

13 DR. D'ORSI: When you are looking
14 for something that is potentially lethal with
15 a very small client probability, almost by
16 definition, when you are screening for that,
17 you are next going to have to pull in a lot of
18 things that are not related to that.

19 If you had -- if the prior
20 probability of cancer was 50 percent, you can
21 have a very wide net, and you would have a
22 pretty good pickup rate. When you go down to

1 three or four prior probability of malignancy
2 per thousand, your net has to be very, very
3 large to catch a reasonable sample of those
4 malignancies. So there is no way you are
5 going to drop false positives and do that.

6 CO-CHAIR PETERSON: So I'm just
7 trying to get this again. So a good score
8 here is 96 percent wrong. A bad score is
9 what?

10 DR. SMITH-BINDMAN: Say it is 92
11 percent wrong, if you are going to say really
12 good. I mean, the best of the best. The best
13 of the best.

14 DR. D'ORSI: But it is not wrong,
15 Eric. It is not wrong. It is not wrong.

16 CO-CHAIR PETERSON: Yes, it is.
17 It is a miss. It is a miss.

18 DR. D'ORSI: It is a miss by
19 statistics, but it is not a miss for what you
20 are doing.

21 CO-CHAIR PETERSON: I am just
22 asking. So this is the range -- so we're

1 talking about 92 percent to 100 percent wrong.
2 That is the range we are talking about
3 measuring. Let me get this down.

4 CO-CHAIR GAZELLE: Basically, low
5 prevalence.

6 DR. D'ORSI: So if you went to a
7 facility and your wife went in and said, hey,
8 Eric, this place is wrong 90 percent of the
9 time, so the other place is wrong only 98
10 percent of the time, I would say go to the
11 place that is wrong more often. That is what
12 I would say to my wife.

13 DR. GIBBONS: The probability of
14 detecting the cancer is higher.

15 DR. D'ORSI: Correct.

16 CO-CHAIR GAZELLE: Depending on
17 whether on whether or not they are moving on
18 the same ROC curve.

19 DR. D'ORSI: I am assuming that
20 they also -- all the same line.

21 DR. GIBBONS: Ray Gibbons. I am
22 sorry just to keep harping on this point, but

1 if the numbers are going to exclude 25 percent
2 of centers, facilities, in the country, do we
3 have any data as to where there are quality
4 problems with respect to facility size;
5 because much of what else we have in medicine
6 suggests that volume helps drive quality, and
7 low volumes helps lead to low quality.

8 So I am concerned about a measure
9 that might exclude 25 percent of facilities in
10 the country.

11 CO-CHAIR GAZELLE: What is the
12 volume that is required for certification?

13 DR. SMITH-BINDMAN: The volume is
14 only at the radiologist level, not the
15 facility level. So the radiologist level is
16 just about 500 mammograms per year, and it
17 turns out the facility averages are about 27.
18 So your question about whether or not there is
19 an association of volume and facility, there
20 hasn't been strong data to look at that.

21 I have two large papers on my desk
22 that are looking at that, and the answer is it

1 is not clear. But your concern that those
2 facilities, where there could be a problem, we
3 don't have a tool to measure the quality, is
4 inherently more in the statistical sample
5 size.

6 DR. D'ORSI: But you bring up a
7 very good point. There are several articles
8 that are trying to relate experience with
9 performance metrics, and what they found
10 overall is that there is not that close a
11 relationship. But it appears that, if you are
12 reading about -- this is data from Linda
13 Warren Burhenne in British Columbia who has a
14 large screening population there.

15 If you reading about -- each
16 individual is reading about 2,000-2,500, they
17 are doing better in that group than the ones
18 who are reading less.

19 The UK requires 5,000, and there
20 is no real solid data of a linear orientation
21 with number of performance other than that
22 British Columbia reported about 2,000-2,500.

1 But that is another country. It is another --
2 whole set of circumstances. So it is not a
3 linear relationship.

4 CO-CHAIR GAZELLE: Are there other
5 comments on this measure, number 2, before we
6 go on to measure number 3, which is a very
7 similar measure? Hearing none, Mary?

8 DR. GEMIGNANI: This is Mary
9 Gemignani. I am going to review measure
10 number 3-10, and I think a lot of the points
11 that we brought up for the previous measure
12 are definitely applicable to this measure, and
13 this measure is actually probably the easiest
14 one of all, because we are working off of
15 diagnostic mammography as opposed to the
16 screening in general.

17 So it is the subset of patients
18 that already have an abnormal mammogram, and
19 you really want to determine biopsy proven
20 cancers within this subset.

21 So the numerator is cancer, and
22 the denominator is anyone who has a BIRADS

1 score of 4 or 5 mammography.

2 So having said that, I will move
3 on through some of the reviews. Looking at
4 number one: So as far as eliminate overuse or
5 ensuring delivery of appropriate care -- So
6 that is 1(a).1 through 3. So 1(a) is
7 Completely Agree.

8 For the opportunities for
9 improvement, I think that this one also gets
10 a C.

11 Outcomes for evidence to support
12 measure focus: The writers of this do mention
13 that sometimes we use recall rates in
14 comparison with this, and how using a recall
15 rate individually can cause controversies for
16 the evaluation of mammography in centers.

17 So they do bring this up, and I
18 think that that was a good thing to sort of
19 bring up in the measure. So I put it as a C.

20 So was a threshold criterion,
21 importance to measure overall for measure,
22 quality measure number 1 is Yes.

1 So scientific acceptability of
2 measure and properties, which is number 2, I
3 put C for 2(a), which is basically looking at,
4 again, the target population in the
5 denominator. Then 2(b) was a C for the
6 testing and analysis that they used, and for
7 validity testing I put C.

8 Exclusions justified: There were
9 really no exclusions for this. So we put it
10 as NA. Then there was really no true
11 discussion of risk adjustment on this here.
12 So I put it as an NA, and it sort of comes
13 back to what our discussion was. It should be
14 looking at some stratification in this.

15 So for 2(f), it is C, and then
16 comparability of multiple data sources and
17 methods -- that was NA, and there was no
18 disparities in care statement with this. So
19 that was an NA. So overall for the scientific
20 acceptability, I put it as a C.

21 Usability: Most centers do have
22 data on this, on how many that they actually

1 have biopsy tissue on. So I think that being
2 able to obtain this data should not be
3 unfeasible. So I gave it a C.

4 Then for harmonization, I didn't
5 see any harmonizations that I could sort of
6 find. So I gave it as an NA, and then again
7 we have had a lot of discussion so far about
8 whether we should be using these in relation
9 to each other. So as far as its individual
10 value, I think out of all of them, this is
11 probably the one that could most likely stand
12 on its own, but would be best in conjunction
13 with the other measures we talked about. So
14 overall for usability, I gave it a C for
15 feasibility.

16 For 4(a), I gave it a C. Then I
17 had some questions, and it came up in
18 discussion for 4(b). I gave it a Partial, a
19 P, because if we came up with this discussion
20 a few minutes ago about whether we would be
21 able to track patients who went elsewhere. If
22 you gave them a BIRADS 4 and 5 and then they

1 went to another place and they had their
2 biopsy and we had a reasonable attempt at
3 getting their pathology but we couldn't, how
4 is that going to really affect this measure?
5 So I put it as a Partial.

6 Exclusions were NA, and that is
7 4(c). Then unintended consequences: I gave
8 this a Partial, because I think that, without
9 knowing the volume of the center, without
10 being able to incorporate the detection rate
11 and the other rates, it may be difficult to
12 interpret this value by itself.

13 Also, if it is a small center and
14 you don't have access to get the additional
15 pathology results from the biopsies, you might
16 not have complete data collection. So I gave
17 the data collection aspect support a P, too.

18 So overall, even though I kind of
19 dinged it a little bit for the data collection
20 and being able to get that pathology, I think
21 this is a good measure, and so for feasibility
22 and endorsement: feasibility, Complete, and

1 then recommendation would be Yes.

2 That is the primary.

3 CO-CHAIR GAZELLE: Okay. Thank
4 you, Mary. Carl?

5 DR. D'ORSI: Carl D'Orsi. Can I
6 make one comment? This is PPV2, which is a
7 recommendation for biopsy, not the actual
8 performance of biopsy. So if we do PPV2, that
9 is an added difficulty for a facility to go
10 find their 4s and 5s who actually haven't
11 gotten anything in their own facility, and it
12 is over and above those who have a biopsy
13 somewhere else.

14 So it is a little more difficult.
15 They are probably pretty close in this
16 country, but it is a difference.

17 CO-CHAIR GAZELLE: Can I ask for a
18 clarification on that, because that is not how
19 it is defined here, I think. The denominator
20 is a BIRADS score of 5.

21 DR. D'ORSI: It should be
22 recommendation -- the BIRADS is a

1 recommendation, by and large. It does not
2 mean that they are going to have the biopsy.
3 That is PPV3.

4 CO-CHAIR GAZELLE: That is right.

5 DR. D'ORSI: And that is a
6 difference, though.

7 CO-CHAIR GAZELLE: But the
8 denominator is defined here as the number of
9 diagnostic mammos that are 4 or 5, and the
10 numerator is the cancer. So --

11 DR. D'ORSI: Right, but 4 or 5 is
12 a recommendation. It doesn't mean that they
13 have the biopsy. The denominator of PPV3 is
14 biopsy obtained.

15 CO-CHAIR GAZELLE: Right. No,
16 this is PPV2, though.

17 DR. D'ORSI: Right. I am just
18 making that slight difference, that it is
19 going to be a little bit harder. People have
20 to follow up their 4s and 5s in their own
21 facility who decided not to have it.

22 DR. GEMIGNANI: Yes.

1 DR. ZERZAN: This is Judy. I
2 would say that the outcome, whether the labs
3 actually have been done is more important than
4 whether it's recommended, because that's
5 what's really going to change patient health.
6 You can recommend things, but that doesn't get
7 you to better health.

8 DR. D'ORSI: Carl D'Orsi. That
9 could be important to see how follow-up is,
10 but you are right. As far as this is
11 concerned -- that is mandated for the FDA that
12 we present, not two but three.

13 DR. GEMIGNANI: But this is also
14 getting at the BIRADS. So all BIRADS are
15 recommendations for physicians. So I think
16 the way it is written, it is still getting at
17 the recommendation, not the --

18 DR. D'ORSI: I just wanted to make
19 sure that everybody understood the three
20 levels of definitions, that's all. They are
21 very close, if not identical.

22 DR. BURSTIN: We are not talking

1 about -- but one of the other measures is
2 trying to get at what we have actually done
3 versus what was recommended.

4 DR. D'ORSI: Right.

5 DR. SNOW: This is Snow. It is
6 worth making the point that, for that small
7 facility, being able to document
8 electronically the recommendation as opposed
9 to the completion is much, much easier. So
10 from the standpoint of feasibility, taking a
11 PPV2 and saying, well, they are going to get
12 it, right, I would have a little hope for that
13 last bit. This makes it easier to do. I am
14 not saying that you should stop there, but --

15 DR. D'ORSI: Well -- Carl D'Orsi
16 -- you have two layers now. You still have to
17 find out who's got cancer in the 4s and 5s
18 that you recommend. So not only do you have
19 to find out who goes somewhere else; you also
20 have to find, out of your own group, who
21 didn't do it. So it is a little more work.

22 MR. BACKUS: This is Mike Backus.

1 Do we have any sense for what proportion of
2 people that are a 0, 4 or 5 don't come back
3 for follow-up? What group of people drop off,
4 five percent, eight percent, one percent?

5 DR. D'ORSI: It varies by area.
6 It varies by the population you are looking
7 at. Most people, when you recommend a biopsy,
8 will get it done. I don't know what "most"
9 means.

10 DR. BASSETT: In our practice,
11 every one you recommend basically gets done.
12 There are some other practices where you might
13 recommend it, but the surgeon won't do it.

14 DR. SMITH-BINDMAN: It is an
15 extremely hard question to answer. What you
16 have to do is ascertain it. So the CDC
17 National Breast and Cervical Cancer Early
18 Detection Program first published Mays' paper,
19 and they have in their underserved population
20 25 percent lack of follow-up to recommend it.

21 So that number was huge, and most
22 of that has to do with assessment and

1 ascertainment problems that they got down to
2 about 10 percent. So it is a really hard
3 question to look at, and the way they deal
4 with this issue on two papers that are going
5 through the Breast Cancer Surveillance Center,
6 a big dataset, is they cut off the time period
7 at six months and say, if we can't find you by
8 six months, you kind of didn't have it done;
9 and they are getting about a 90 percent, 92
10 percent, but that mostly is a data issue.

11 So you are looking at the
12 underlying rates, and there is no way to do
13 it. It hasn't been done.

14 MR. BACKUS: Well, we know it -- I
15 mean, it is not half.

16 DR. SMITH-BINDMAN: Less than 10
17 percent.

18 CO-CHAIR GAZELLE: All right. Are
19 there any other comments on this particular
20 measure? See, we are getting better at this.

21 Okay. So the next one -- I think
22 we have time to do this one. Let's do IPE-

1 004-10, which is the recall rate.

2 MR. BACKUS: I am Mike Backus. I
3 was assigned primary review for this. I don't
4 have the benefit of what appears to have been
5 substantial discussion about this measure the
6 last time the NQF met, but I will go through,
7 once again, a little bit in isolation, and my
8 comments are obviously tinged with it coming
9 in a set.

10 So the measure is recall rate,
11 which is, you know, how often you are calling
12 it for a unknown. And rate is strictly the
13 percentage interpretive is 4s or 5s, and it
14 does look at screening mammograms here, not
15 diagnostic.

16 CO-CHAIR GAZELLE: Zero, 4 or 5.

17 MR. BACKUS: Zero, 4 or 5, right -
18 - and not diagnostic mammograms.

19 If you come down, you know, from
20 an importance, I gave that a C. Obviously,
21 the impact is pretty well understood. It has
22 been discussed before for 1(a).

1 1b, the opportunity for
2 improvement: The same thing. It is a pretty
3 straightforward measure and a way that
4 compares centers.

5 1(c), outcome or evidence to
6 support the measure focus: Once again, I
7 think it is fairly important, although on its
8 own, I would say it might be a Partial. In
9 conjunction with everything else, I would give
10 it a C.

11 So overall, I think it does meet
12 the importance criteria. The scientific
13 acceptability of the measure, 2, that I give
14 a C. It has obviously been around the block.

15 Reliability, I think, is C; and
16 the same for validity. The exclusions: I
17 gave that a P, only because there might be
18 some issue about stratification of the
19 population, if you are working in a different
20 demographic. So if you could stratify it,
21 that would be a little bit better.

22 The analytic method is 2(e). I

1 gave that a C.

2 Meaningful difference in
3 performance: I went back and forth here
4 between a C and a P, and I ended up on a C,
5 once again just because of the stratification
6 issue. You will get differences in the
7 centers, I thought.

8 2(g), the comparability of
9 multiple data sources: I put this as an NA.
10 One thing I did think about using the multiple
11 data sources is -- and the reason I asked the
12 question about dropoff before is you say a
13 BIRADS 0, 4 or 5.

14 Assuming that it almost always
15 goes to follow-up, taking the perspective of
16 a health plan instead of the perspective of
17 the imaging center, if you have continuously
18 enrolled members, it is pretty straightforward
19 to look at who had a screening mammo. You
20 paid a claim on it. Then who came back and
21 had either a diagnostic mammo to follow it up
22 or a biopsy, and actually out of the

1 pathology, you would see a cancer diagnosis
2 coded on the pathology.

3 So I do think that from the plan
4 perspective there is a pretty good way to get
5 at alternate data as compared to from the
6 imaging center where you are kind of going to
7 chase down that path. That might have
8 happened in a different place.

9 Disparities of care: I put that
10 as an NA.

11 So overall, I like the measure,
12 and even within the realm of the patient
13 population, once again, from a health plan
14 perspective you've got a much narrower band of
15 membership or a demographic. You might have
16 like a full Medicaid plan, a full Medicare
17 plan or a commercial plan. So I thought that
18 that might help take out some of the
19 stratification problem.

20 It is meaningful. I gave that a
21 C, and then harmonization gets between a C and
22 a P. Obviously, I think it should go with the

1 other measures, and I think it has some
2 additional value, and the feasibility for 4:
3 I thought it was -- given that there is a low
4 dropoff rate, I think the data is generated.

5 I think the electronic sources are
6 there from the plan perspective. I don't
7 think electronic sources are there from the
8 center perspective, because as soon as it is
9 outside your center, you have to go get it.
10 But if we have -- you know, the EMR eventually
11 comes to be, there are electronic sources
12 available.

13 Then for exclusions, I put NA.

14 4(d), susceptibility to unintended
15 consequences: I gave that a Partial, just
16 because of the things that we have talked
17 about where you could bias your sample set.

18 Then data collection and
19 strategies: I gave that a P. From the health
20 plan, it is pretty good. From the center, it
21 is not as good. There is possibly a manual
22 component there.

1 Overall, I do think that it is
2 feasible, and overall I like it as a measure
3 even on its own basis, and I think it is a
4 little bit better if you put the other stuff
5 with it.

6 CO-CHAIR GAZELLE: Thank you. Are
7 there other comments, first from the group
8 that reviewed the mammo measures, and then
9 from the group as a whole?

10 DR. GEMIGNANI: This is Mary
11 Gemignani. The only other additional comment
12 is I wouldn't endorse it on its own, this one,
13 because I think that it has the unintended
14 consequence of being able to provide a rate
15 that is really meaningless.

16 So the question becomes, if you
17 have a high recall rate, is that a good thing
18 or a bad thing; but if you don't really know
19 what your cancer is within that population
20 risk, if you are just having -- you know, an
21 individual woman wouldn't know whether to go
22 to Center A or Center B, if you gave her two

1 recall rates. They are going to say, well,
2 maybe I don't want the extra radiation from
3 mammography. So I am going to go to Center A
4 that has a 12 percent recall rate. But she
5 should really be going to Center B that has a
6 higher cancer detection rate, and they may
7 have an 18 percent recall rate.

8 So that is the only caution I have
9 when I reviewed this one about this measure.

10 CO-CHAIR PETERSON: I am still at
11 a loss. I can't quite get how -- it seems
12 like there is such a uniformity of views, if
13 this measure has meaning. There is a good
14 high number or a low number here?

15 DR. SMITH-BINDMAN: This is
16 Rebecca Smith-Bindman. Just to put it into
17 context, if you look at how individual
18 physicians perform, the variation in the
19 recall is two percent to 27 percent.

20 So the example that you gave of
21 going to a facility that has an 18 percent
22 recall rate, I would strongly disagree that

1 that is a place to go. There is no overall
2 benefit above a certain level, but you don't
3 find those cancers if you have a low recall
4 rate. So at the extremes of recall rate, I
5 think it is clear that you are spending a lot
6 of money. You are doing a lot of tests, and
7 you are not getting much bang for your buck.

8 So at 26 percent, it is easy to
9 say that out of 1,000 mammograms, we are
10 looking for five cancers, but you are calling
11 back 250 women to find them. That is a lot of
12 recalls.

13 So at the extremes of recall, it
14 is very expensive, and you are not getting
15 much.

16 CO-CHAIR PETERSON: Let me just
17 try it this way. Two centers; both have rates
18 of 10 percent recall. One of them is sending
19 the right 10 percent on recall. The other one
20 is sending the wrong 10 percent. Do you know
21 which 10 percent is good or bad?

22 DR. D'ORSI: That is why everybody

1 is saying this is no good as a standard.

2 DR. SMITH-BINDMAN: That is the
3 other measure. That gives you the bang for
4 your buck. I think the example you gave of 18
5 percent -- that is a pretty high number. That
6 wouldn't be acceptable to me.

7 CO-CHAIR GAZELLE: Rebecca, two
8 comments that I think you probably know a lot
9 about, but my reading of the literature
10 suggests that, one, there is variation between
11 initial mammogram and subsequent mammograms at
12 the recall rate.

13 Two is -- and we got hung up on
14 this at the last cycle of this committee,
15 setting the threshold at 10, which is the
16 least stated here, when the average is 9.8 or
17 11, depending on which study you are
18 believing, and sort of the range from the --
19 whoever published this study -- the range from
20 the big Rosenberg study was something like 6-
21 14 percent for the middle 50 percent. So --

22 DR. SMITH-BINDMAN: But, I mean,

1 Rob focuses on the interquartile range. So
2 the standard that are set for the ACR don't
3 really make sense. The purpose of this
4 guideline is not to identify half a facility
5 is just not doing a good job.

6 So I think, separate from is the
7 measurement good, what threshold are we going
8 to define quality. I would sort of question
9 this because it's the only thing I keep
10 raising, whether or not you need
11 stratification of the recall rate. The recall
12 rate goes up two or threefold with age, and
13 even within a HMO well defined screening
14 population, that range will go from 40 to 80,
15 and that is where the recall rate goes up
16 substantially. Well, I actually take it back.
17 It is higher, and then it goes down, some
18 factors, but what's the big difference?

19 MR. BACKUS: If I look at the
20 population of 40-65, how much does that recall
21 rate move?

22 DR. SMITH-BINDMAN: A factor of

1 two.

2 CO-CHAIR GAZELLE: Everybody has a
3 blend. This is Scott Gazelle. The real
4 question is not that. The real question is
5 what is the extreme of variation due to
6 different age make-ups in different practices?

7 DR. SMITH-BINDMAN: And in this
8 one, to argue -- this is Rebecca Smith-Bindman
9 -- about what is said, the recall rate, I
10 think that will be driven by the quality of
11 the mammography rather than the patient mix,
12 because now we are twofold to threefold
13 difference.

14 CO-CHAIR GAZELLE: Carl?

15 DR. D'ORSI: Carl D'Orsi. Let me
16 bring something else up that clinical
17 mammographers know. About 25 percent of
18 recalls are due to what is called fake
19 densities. You look at a 2(d) image, and you
20 don't know whether it is real or not -- 25 to
21 30 percent.

22 Those are drastically diminished

1 when you have a prior exam to study. So if
2 you have a facility that doesn't have a closed
3 population, that tends to get people from
4 various sources, they are not going to have as
5 many prior exams, and their recall rate is
6 going to be up much, much more than the age
7 stratification.

8 So that is just something you
9 don't realize until you do this.

10 CO-CHAIR GAZELLE: This is Scott
11 Gazelle. That is the value of stratifying --
12 at least considering stratifying both by age
13 and by first versus --

14 DR. D'ORSI: It is very high if
15 you don't have prior exams.

16 CO-CHAIR GAZELLE: So other
17 comments on this measure, in particular? Ray?

18 DR. GIBBONS: I am like Eric. I
19 am baffled by the mathematics. So if my
20 recall rate is slightly higher but within the
21 acceptable range, but my earlier measure of
22 PPV2 is slightly lower, is that good or bad?

1 CO-CHAIR GAZELLE: I would say
2 that is what you expected.

3 DR. SMITH-BINDMAN: By definition.

4 DR. GIBBONS: Okay. But what are
5 the magnitudes that you would expect, or do we
6 know that? In other words, from a quality
7 improvement standpoint, if those are my
8 measures year one, and then year two, is that
9 good or bad? Am I getting better or am I
10 getting worse?

11 CO-CHAIR GAZELLE: So could I ask
12 for clarification? Our role is not to define
13 the threshold or the standard so much as to
14 define the measure that would be used for
15 reporting. Is that correct?

16 DR. BURSTIN: It actually varies
17 very much by the measure. I am still struck
18 by -- the question is how useful is a
19 continuous measure if it is uninterpretable?
20 So I guess the question would be acceptable --
21 I am being hyperbolic intentionally, just not
22 about this measure specifically, but just at

1 times that is when measures get -- you have
2 been trying to identify -- you guys keep
3 repeatedly talking about that tale where there
4 is potential for quality.

5 The question would be, if you put
6 all these -- and I agree, my head is spinning
7 from the math as well in terms of the small
8 numbers here. But is there a tale of poor
9 quality here that you are really trying to
10 identify, in which case a threshold might be
11 something to consider. Again, it might be
12 something we would like to hear from the
13 developer.

14 CO-CHAIR GAZELLE: So I could
15 imagine that we would say -- we could come to
16 the point, perhaps not today, where there
17 would be three measures, and they would be
18 taken as a suite of mammo measures, for
19 example, and to obtain a passing grade, you
20 had to be within range from all three, for
21 example. Conceptually, I could imagine that.

22 I think the data exists for us to

1 get to that point, but it is the discussion of
2 individual measures versus combining them that
3 may be a challenge. I'm sorry, Judy. Go
4 ahead.

5 DR. ZERZAN: This is Judy. But
6 what happens when two of those measures, as
7 the example that you just gave -- when you get
8 better at one, you also get better at the
9 other one -- what is the utility of having two
10 measures that you expect will change in the
11 right direction together? What you really
12 want is something that is going to get at a
13 different piece of that to try and get at both
14 accuracy and reliability.

15 CO-CHAIR GAZELLE: And that is why
16 you need all three.

17 DR. ZERZAN: If one going up
18 always means the other one is going to go
19 down, assuming that those are the good
20 directions, then why do you need both?

21 DR. SMITH-BINDMAN: They don't
22 necessarily go in that direction.

1 DR. D'ORSI: Yes, they do. The
2 false positives and false negatives vary
3 indirectly. So what you have to do is get a
4 balance. Obviously, if you call everyone
5 back, you are going to have a little higher
6 cancer detection rate, but if you are working
7 where normal people work, in the middle, in
8 order to get that little extra cancer
9 detection, you are going to have to call a
10 hell of a lot back.

11 So you cut it off there. Okay,
12 you are now, yes, doing better for cancer
13 detection but, boy, you are calling back 800
14 women to see two cancers. So it is a balance,
15 and so the edges are important.

16 CO-CHAIR GAZELLE: Scott Gazelle.
17 Carl, that is only correct if you assume
18 everybody is operating on the same ROC curve.

19 DR. D'ORSI: Correct. That is
20 true.

21 CO-CHAIR GAZELLE: And they are
22 not. We know that they are not. That is why

1 we have multiple measures to get at the people
2 who are not on the same ROC curve.

3 DR. D'ORSI: But that is an
4 indication of education, not metrics, to get
5 people on the same --

6 CO-CHAIR GAZELLE: Not
7 necessarily.

8 DR. D'ORSI: Sure it is.

9 CO-CHAIR GAZELLE: It's an
10 indication of people's ability to perform.

11 DR. SMITH-BINDMAN: This is
12 Rebecca Smith-Bindman. We studied several
13 hundred doctors who read several million
14 mammograms, and we plotted them all in this
15 ROC space, and there were a few doctors who
16 recalled everybody and found most cancers, a
17 few doctors who recalled nobody and found no
18 cancers. The vast majority of doctors were in
19 the middle. There was no threshold
20 association. Some were good, and some were
21 bad.

22 So we want to identify the doctors

1 who were bad, and I would argue the main way
2 I want to find them is they are not finding
3 any cancer.

4 MR. BACKUS: And that is why you -
5 - Mike Backus. That is why you want cancer
6 detection rate on the bottom?

7 DR. SMITH-BINDMAN: Right. Then I
8 get past cancer detection rate, and I say,
9 okay, you've met the threshold, but you are
10 doing two times or three times as many tests
11 for the cause; let's see if we can move you.
12 But I think Helen's idea about the extremes
13 are very clear. There are people who are just
14 not operating at a safe level, and that is
15 what it would be great if these metrics could
16 identify. Either they are finding no cancer
17 or they are doing too many tests.

18 DR. D'ORSI: That does relate
19 exactly to what I said. If the false
20 positives and false negatives vary internally.
21 If you are not finding a lot of cancers, you
22 got a lot of false negatives; and if you have

1 a high false positive rate and a low false
2 negative rate --

3 DR. SMITH-BINDMAN: Those are 10
4 doctors out of the 270.

5 DR. D'ORSI: Well, that is who you
6 want to cut out.

7 DR. SMITH-BINDMAN: No. You want
8 to get rid of them, too, but you also want to
9 do a better job of figuring out who is not
10 coming up with a minimum standard.

11 DR. D'ORSI: That is an education
12 thing. That is moving along a curve. That is
13 not moving the curve up or back. That is
14 moving along a curve.

15 CO-CHAIR GAZELLE: So, Helen and
16 Ian, we are at noon. Should we take a lunch
17 break now and then come back to the developer
18 comments? Is that a logical break point?

19 DR. BURSTIN: Do people feel like
20 they are ready for that yet? Or do you want
21 to just -- food's here. It's right there. Be
22 easy enough to grab a plate and come back.

1 CO-CHAIR PETERSON: Work through
2 lunch?

3 CO-CHAIR GAZELLE: We are
4 scheduled for an hour for lunch. Why don't we
5 take 20 minutes or half an hour to get lunch,
6 do whatever anybody needs to do in terms of
7 catching up, and then try and continue the
8 discussion as we are eating lunch.

9 (Whereupon, the foregoing matter
10 went off the record at 12:03 p.m. and resumed
11 at 12:45 p.m.)

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A F T E R N O O N S E S S I O N

(12:45 p.m.)

1
2
3 CO-CHAIR GAZELLE: All right. We
4 got an extra 15 minutes for lunch. We are
5 ready to go again. To bring us all back to
6 focus on the mammo measures, we have reviewed
7 four of the mammo measures, number 1, 2, 3 and
8 4. We are going to leave off number 9 for a
9 moment to consider the four that were proposed
10 by the ACR.

11 I think what I would like to do is
12 take about a minute to summarize what I think
13 I heard, which was that we had positive things
14 to say about each of those four measures. We
15 felt that there is probably greater value in
16 some combination of them, not necessarily all
17 four but possibly three, than any of them
18 alone.

19 We had some concerns about exactly
20 how to interpret the four measures, either
21 alone or in combination. So I think what we
22 should do now is take comments from the

1 measure developer.

2 Larry Bassett is here from the ACR
3 to respond, I think, to the discussion we had
4 this morning, make any other comments about
5 the measures or how you would like to see them
6 taken together. Then we can have some more
7 discussion about those four measures, and then
8 we can go on to discuss the CMS measure, which
9 was number 9.

10 DR. BASSETT: Okay. This won't be
11 a long time, but I wanted to just review some
12 of the things we put forward and what you all
13 said, and then maybe add something else to
14 that.

15 So I just am not sure you are
16 aware, but in 2005 the Institute of Medicine
17 published a recommendation for a more
18 comprehensive medical standard than required
19 by the mammography quality standard.

20 Currently, the MQSA now only
21 requires a report on the positive predictive
22 value for biopsies, and so this is really very

1 minimal. So they recommended to revise and
2 standardize the requirement by the QSA.

3 Now the question has been why not
4 just the recall rate. The developmental
5 studies have shown the recall rate alone is
6 not a reliable standard. While very high
7 recall rates can reach more cancers, as we
8 talked about, there are negative effects such
9 as the quality of unnecessary biopsies, and
10 this has been in the public attention,
11 particularly when it was published in the
12 Preventive Health Service report.

13 It is also important to know if a
14 facility's very low recall rate is associated
15 with too many missed cancers. So this again
16 is a balance. We will talk about what that
17 balance should be in just a second.

18 So what else do we need to know
19 except just the recall rate? We probably want
20 the cancer detection rate, as was discussed
21 here, percent of cancers detected for the
22 number of biopsies recommended in PPV2. That

1 can be based on screening exams or diagnostic
2 exams, and I don't want to get into this,
3 because this is something that was brought up
4 by Dr. Rosenberg, and it is really
5 complicated.

6 I could just say briefly that it
7 turns out most of your high end facilities, at
8 least the ones that are recognized nationally
9 and so on, do not get a 4 or 5 on the
10 screening exams.

11 DR. SMITH-BINDMAN: The way it is
12 used by most people is not the way it is used
13 by what you are calling your high end
14 something.

15 DR. BASSETT: Yes. But we don't
16 know for sure how many -- I think that the
17 BCSC had problems with this, too. A lot of
18 places recommend biopsies on the screening
19 exam.

20 We don't do it, have never done
21 it, for a lot of reasons. One is we want to
22 work it out carefully. We may want to do an

1 ultrasound, and we don't like to inform the
2 patients by telephone. We want to talk to
3 them one on one and show them what we are
4 looking at. But it is not standardized.

5 Other information that we are not
6 recommending but in the long run is probably
7 reasonable is what is the size of the cancers
8 detected. If you are detecting a lot of
9 cancers in your population but they are all
10 large, then that is not really a good sign.

11 Also, for example, most of them
12 today should be a centimeter or less, if it is
13 a screening exam, and that is why the whole
14 staging system was changed only a few years
15 ago, because most cancers now have moved from
16 the larger sizes to those that are in the
17 centimeter or less range, which is Stage 1.
18 So they had to restage Stage 1 into A, B, C
19 and D, including carcinoma in situ.

20 That is a good sign this is
21 working, but it also means that we have to
22 look at that as well when we are evaluating.

1 Are they detecting little cancers, like we are
2 hoping, ones that are curable, or are they
3 just finding big ones?

4 The stage will also determine how
5 the treatment is. Since we now have mostly
6 at Stage 1, we can subdivide that and then
7 determine do all these really need the full
8 treatments we have been giving for the
9 advanced things? That allows us to do some
10 research in that area, too.

11 Also, these particular metrics
12 that we talked about, the cancer detection
13 rates, positive predictive value of 2, and the
14 recall rates -- they are in the literature.
15 They are recommended, I think, in the
16 literature, including the Agency for Health
17 Care Policy Research Guidelines for
18 Mammography, which was published almost 15
19 years ago now, had some ideas for what those
20 numbers should be as a consensus of the people
21 on the panel.

22 Subsequent studies by the Breast

1 Cancer Screening Surveillance Consortium, and
2 a new publication that is going to come out in
3 Radiology from the Breast Cancer Surveillance
4 Consortium are going to give some guidelines,
5 again, on what those metrics should be.

6 So we do have stuff in the
7 literature to look at that say what it should
8 be. We don't have to develop those. They are
9 there.

10 Then in addition, I should
11 mention, because I think I have been hearing
12 at this table something over and over again;
13 that is that not everyone is collecting their
14 data, that how do these certain facilities
15 collect the data if they don't have the data
16 systems or the mammography modules that are
17 currently made by private companies.

18 In addition, I told you that we
19 don't have patients who don't get their
20 biopsies done. Why? Because we have a
21 special person, a quality assurance person,
22 who tracks them down, finds out where they

1 are, why they haven't done it, did you forget
2 it? We talk to their referring physicians.
3 We have very few that don't get done.
4 However, you said, I think, earlier that there
5 is a large number that don't get done in large
6 practices. So there's lots of issues that
7 affect these patients' metrics.

8 The other thing that the IOM said
9 just based on what I just mentioned and what
10 we have all been talking about is that they
11 suggested a proposal for a voluntary advanced
12 medical audit on a national level.

13 What they want to do is make it
14 accessible to people to find out, okay, well,
15 what about a community like mine? What are
16 the rates in that community, in those
17 communities, and to be able to find out how
18 they are doing compared to other people.

19 That is not acceptable to all of
20 them, as you all mentioned, because they can't
21 always find out if the biopsy was done
22 somewhere else. If we did have a national

1 mammography database, we would be able to find
2 out if that patient on follow-up did have a
3 breast cancer or not.

4 So this is something we are
5 lacking in this country that we have in other
6 countries that we think would be a better
7 solution in terms of giving an incentive to a
8 facility in terms of their payment, if they
9 belonged to a National Mammography Database.

10 I think that would be an incentive that would
11 really help create an improvement in the
12 overall managing of these patients.

13 So that is basically just my
14 summary, but how we look at this, and just to
15 tell you, the ACR National Mammography
16 Database metrics are the same ones that we
17 recommended here and the same used by the BCSC
18 databases.

19 They could provide access to
20 national and regional aggregate data for the
21 participants. They are a quality improvement
22 tool for physicians and practices, and some

1 facilities may not understand when you ask
2 them for metrics, and they need to be provided
3 guidance from some kind of a group that they
4 are working with, whether it be the National
5 Mammography Database or another organization,
6 so they could get the right information in,
7 because sometimes they are sending the wrong
8 stuff.

9 We all have problems even
10 understanding the recommendations in the
11 centers, but think about these people who are
12 not physicians or the quality assurance person
13 in that practice. Many radiologists do not
14 collect data, cannot evaluate the outcomes
15 relative to the BCSC or other benchmarks. So
16 it is essential in order for them understand
17 how well they are doing.

18 Again, I think I would recommend
19 the work group joining the National
20 Mammography Database with the goal of
21 improving overall quality of mammography, as
22 much as any other incentive.

1 Lastly, but not least, this is not
2 mine. Carl has been mentioning this over and
3 over again, and that is that there is a
4 relationship between sensitivity and
5 specificity and recall rates and low recall
6 rates. It is very complicated, but it has
7 been mentioned. Carl, did you want to comment
8 on that?

9 DR. D'ORSI: Just that you don't
10 get something for nothing. That is the no
11 free lunch curve.

12 DR. BASSETT: And that is it.
13 Thank you very much.

14 CO-CHAIR GAZELLE: Thanks very
15 much. I think this would be a good time for
16 anyone to ask questions of Larry, representing
17 the measure developer, if there are specific
18 questions about these measures that are still
19 unanswered that we like. Don, then Rebecca.

20 DR. RUCKER: I think you mentioned
21 the IOM report at the very beginning, but I am
22 trying to understand the overall magnitude of

1 the problem here.

2 I am a little puzzled, because as
3 far as I can tell, mammography is the most
4 heavily audited activity, just about, in all
5 of medicine, and maybe cardiac surgery and
6 some of the CAD stuff being runner-ups. So in
7 that environment where there is already a ton
8 of oversight as opposed to almost everything
9 else, I am just puzzled, or not clear, that
10 this would add on top of all of that.

11 DR. BASSETT: It is very highly
12 regulated, but the regulations in terms of a
13 medical audit are pretty simple. You just put
14 your positive predictive values for the
15 biopsies you did and, as we all know, one of
16 those metrics alone doesn't work usually. It
17 can depend on -- I mean, I could get what
18 sounds like one of the numbers, but my
19 community may provide that because the patient
20 population is so high and the fact that they
21 are very good about coming for their exams and
22 at a higher level socioeconomically.

1 Lacking that, somebody who is in
2 the countryside doesn't have a place to look
3 and see what the metrics are for their kind of
4 population.

5 CO-CHAIR GAZELLE: Rebecca and
6 then Howard.

7 DR. SMITH-BINDMAN: I participated
8 a little bit in the IOM report, and I think
9 what the brunt of it was, is there is this
10 test that is being used a lot. There is
11 pretty high quality for the technical aspect
12 of this test, but there is much less
13 consistency in the quality of the
14 interpretation. There are still gaps in terms
15 of under represented groups not having access
16 to it. So it really focused on how to improve
17 the quality of that.

18 So if you looked at some of the
19 other points, it was on how to we improve the
20 quality.

21 DR. BASSETT: Yes, and the
22 technical part, as you just mentioned, the

1 referred ledgers have to be reviewed by an on-
2 site entity, and they have to be pretty
3 perfect in order to be accepted for
4 presentation. They've got to have the medical
5 tests done on a regular basis. There are all
6 kinds of other reasons. But the medical audit
7 request is very minimal, basically one metric.

8 DR. FORMAN: I was on the
9 committee that did the MQSA reauthorization
10 report, whatever you want to call it at the
11 time -- I think it was the Committee on
12 Improving Mammography Quality Standards.

13 Our charge at the time -- We were
14 doing this because MQSA was coming up for
15 reauthorization. It actually got
16 reauthorized, and then this report came out.
17 Subsequently, some of it has been put into
18 place in a regulatory way.

19 The concern that was raised in the
20 committee, and a big part of the committee
21 report that is not necessarily reflected in
22 these standards, was the access issues as

1 well, and the fact that the higher the
2 regulatory hurdle in probably on the most low
3 reimbursed parts of imaging was actually --
4 could adversely impact access to care, while
5 not necessarily connecting to improvement in
6 imaging outcomes, because one of the things
7 that we observed and we really were able to
8 slice whatever available data there was at the
9 time, and find that, despite what we might
10 anecdotally or even in small empirical fashion
11 identify as being quality improvements with
12 certain high quality mammographers and
13 mammography sensors, it wasn't linear at all.

14 I mean it wasn't linear at any
15 point in the curve, that if you had higher
16 volume, you are necessarily going to be
17 better. These were great concerns to be able
18 to try to regulate or mandate the use of
19 measures or mandate a mandatory audit at a
20 higher level as opposed to a voluntary audit,
21 that it would actually drive out access to
22 mammography at that time.

1 That is why, I think, the ultimate
2 report was a lot softer than a lot of us
3 thought it should be going into it. I think
4 sitting here and listening to us talk about
5 these measures, I feel like I am at the exact
6 same meeting just seven years later or six and
7 a half years later, because it is -- you know,
8 I think what we felt back then and what a lot
9 of you are implying right now is it would be
10 great to get this data.

11 We are not sure we know what to do
12 with it, once we get it. We are not really
13 certain that any of these metrics on its own
14 or even if you could come up with a scoring
15 system would allow you to know who really is
16 a better performer or not, because you can't
17 plot out their entire ROC curve. All you know
18 about is a couple of points.

19 I just wanted to give a little
20 back-story for that. Having sat through this
21 for, I think, 18 months in 2003 and 2004, I
22 feel like it is deja vu.

1 DR. BASSETT: IOM actually has
2 been involved here.

3 DR. FORMAN: That is right.

4 CO-CHAIR GAZELLE: Arthur and then
5 Rebecca.

6 DR. STILLMAN: A sort of similar
7 sort of comment. I am sort of struck in the
8 conversation this morning that we have had
9 several reasonable metrics for quality, but
10 none of them are useful in isolation, and that
11 there needs to be some sort of combination.

12 Yet I have not heard any
13 articulated concept of how they could be
14 combined to develop a true quality metric. I
15 am concerned about making a recommendation
16 without that piece.

17 CO-CHAIR GAZELLE: Okay. Thank
18 you. Rebecca.

19 DR. SMITH-BINDMAN: Rebecca Smith-
20 Bindman. My question is not dissimilar to
21 yours. It's two-part. I am wondering, and I
22 think I know the answer, if the ACR would be

1 interested and willing to come up with some
2 simple stratification schemes that might make
3 some of these measures a little more reliable
4 in terms of being age or possible first and
5 subsequent mammograms. That would be the
6 first part.

7 The second part: Helen sort of
8 raised the possibility of thresholds. I
9 think, in some ways, it would be much easier
10 to apply a crude threshold where, not so much
11 getting people in the range but identifying
12 people who are far outside what would be
13 acceptable, if that might be allowed and if
14 that might get at what Dr. Forman is
15 suggesting, the need to improve this, but
16 maybe -- we can't do it in subtle ways, but
17 maybe we can put a sledgehammer to this and
18 say above this, you can't assess it.

19 DR. BASSETT: And that is why it
20 is important to get as much data as possible
21 and, like you say, stratify it.

22 CO-CHAIR GAZELLE: A number of us

1 talked over the lunch break. One possible way
2 to think about combining -- so let's say we
3 have three, and we were able to establish
4 threshold or ranges that you had to be within
5 for all three of those, and we actually got,
6 say, a passing score if you were in range on
7 all three.

8 So if it would be possible to,
9 say, have an upper threshold for recall rates,
10 a threshold for PPV2, and a threshold for
11 cancer detection rate, and you had to be
12 within the range on all three, at least
13 conceptually that could be a way to combine
14 the measures.

15 DR. BASSETT: Measures and
16 guidelines are out there. One of the problems
17 we talked about was, if you are in an unusual
18 population, that probably would be an issue.
19 But those guideline numbers are there. They
20 are in the original AHC policy and research
21 guidelines for mammography.

22 DR. SMITH-BINDMAN: None of these

1 guidelines reflect any of the Breast Cancer
2 Surveillance Consortium 30 publications. So
3 I think those standards need to reflect the
4 literature --

5 DR. BASSETT: Yes. We have just
6 finished -- I served on a committee, and we
7 came out with a method to try to come up with
8 some recommendations. It is kind of a
9 consensus type of method. It's considered
10 scientific but it's mainly a bunch of experts.
11 That is going to be published in the journal
12 Radiology in the next couple of months. But
13 the metrics are out there. The guidelines are
14 there.

15 CO-CHAIR GAZELLE: Well, they are.
16 The question is they aren't proposed within --
17 They are not proposed within these metrics.
18 They are cited, but they are not proposed. So
19 the procedural question is would we -- could
20 we ask the measure developers to come back
21 with thresholds, and then would that count as
22 something that could still be approved within

1 this cycle or would the approach be to say
2 let's approve these as reporting metrics and
3 then anticipate down the line setting
4 thresholds? I don't know the answer to that.

5 DR. BURSTIN: Some of it depends
6 on how complex that task is. I am still left
7 at the end of the day wondering -- I mean just
8 to remind us what we said early on. The
9 intent of NQF endorsed measures is that they
10 are only for public reporting.

11 I guess the question would be: In
12 this current form, are these measures in
13 isolation or in some combined way appropriate
14 for reporting. If the answer is, well, maybe
15 if they are combined, then, obviously, that is
16 a pretty big if. I don't know how a big a
17 reach that is without knowing how easy it is.

18 There is a fair methodology in
19 coming up with composites, all or none,
20 however the case may be. So I don't know how
21 -- not being an expert in this field, I guess
22 my feeling would be I can't answer that

1 question without knowing how big a list that
2 is in terms of coming up with something.

3 CO-CHAIR GAZELLE: But, for
4 example, the easiest way to consider it is to
5 say -- I don't want to throw out numbers,
6 because we will get caught up in the numbers -
7 - but we have a threshold for cancer detection
8 rate, recall rate, and PPV2. So you have got
9 to check all three -- You have to report all
10 three, and to get a passing grade you have to
11 be within range for all three.

12 That is not, for me at least, too
13 big of a stretch, if we had the data to set
14 those thresholds, and I would think the
15 strategy would be to set them fairly broad, to
16 start with, and then consider through this
17 process of public reporting, collecting more
18 data and relooking at it in three years. But
19 at least it is conceptually something I can
20 grasp without needing to have a composite
21 score that somehow weighs each of the
22 measures, and we would calculate the lineal

1 number. Eric.

2 CO-CHAIR PETERSON: I think the
3 concept thing is going to be a little -- just
4 a little challenge. It may be doable, but I
5 would have to think through it, because these
6 are measures that are partially quality,
7 partially efficiency, and how you -- I mean
8 where you sit is complex.

9 Think about how that might play
10 out and the degree to which there would be
11 validation of how many -- do they have enough
12 data and enough time to do this in a short
13 window to both develop the measures and
14 provide me back data to say that this would
15 identify X number is good centers and these
16 many bad.

17 CO-CHAIR GAZELLE: Don, Carl, then
18 Ray.

19 DR. RUCKER: Maybe the question is
20 for Carl and Rebecca. If we did a composite,
21 are all of these sort of essentially
22 gatherable from the same stream of information

1 or is it really sort of, you know, you need to
2 go to one bucket for one set of the composite
3 and another bucket for another? Because I
4 think there is just an economic issue here.
5 It is a very poorly paid, litigious prone
6 activity. As far as I can tell, most
7 radiologists run away from mammography faster
8 than summer lightning. I mean, as a non-
9 radiologist -- if we are going to do that, we
10 ought to have something that meets some sort
11 of simplicity test as well.

12 DR. D'ORSI: I can incorporate my
13 comments with that question. I think the ACR
14 and Larry are absolutely correct. We have to
15 start collecting data. When we collect any
16 kind of data to compare, we need a gold
17 standard.

18 The gold standard is going to be
19 what you are finding pathologically, not only
20 cancer but what kind of cancer you are
21 finding. Once you get that, then you can
22 start setting gross metrics against that gold

1 standard. A recall rate 2 does not relate to
2 50 percent or minimal cancer, but this does.

3 Once you get that, then you are
4 able to make some sense out of a composite
5 metric, but until you do that, you are only
6 estimating, which is okay. What I hope does
7 not come out of this is some rushed measure to
8 come across, just to get something across and
9 it has no validity even on a composite level.

10 I think the big thing is to start
11 collecting data and working on this, getting
12 what a composite metric means with an X
13 recall, and it doesn't necessarily -- it is
14 not necessarily as simple as you think, Scott,
15 because if you are here, your cutoff may be
16 good here or here or in the middle somewhere
17 on another metric. It may not be in a range.
18 It may be good in the middle, and you may be
19 at an outlier here, but you may be in the
20 middle here. So what do you do with that?

21 You have to compare all these
22 metrics to some gold standard, which is what

1 you are finding, stage-wise and curability-
2 wise. That is the bottom line.

3 To do that, you need tons of data,
4 and I hope these metrics are not going to be
5 yearly evaluated. They should be evaluated
6 over a longer period of time so you have
7 enough hits in each facility to do a valid
8 comparison.

9 I don't know if that answers.

10 CO-CHAIR GAZELLE: Ray?

11 DR. GIBBONS: Ray Gibbons. I
12 think I can understand the concepts of setting
13 acceptable ranges, but I would just offer the
14 caution that, as part of the process of
15 deciding on what those are, you need to look
16 at the precision of the estimates for smaller
17 volume facilities, because working in an area
18 of the country where there is a lot of rural
19 health care, the unintended consequence here
20 would be very severe if you penalize centers
21 out in western North Dakota, who are the only
22 option for women in that area, because of the

1 statistical noise in their small numbers.

2 This would be a very bad
3 consequence. So that has got to be part and
4 parcel of this effort.

5 The second thing is I would
6 amplify the point that Eric made, which is I
7 think this process should be developing
8 measures that facilitate quality improvement
9 for everyone.

10 Having listened to this
11 discussion, once you have met the acceptable
12 threshold, it sure isn't clear to me what you
13 are going to aspire for the next year with
14 respect to those numbers, from the discussion.
15 It would seem to me that has got to be part of
16 the context as well.

17 DR. SMITH-BINDMAN: You want a
18 continuous quality improvement?

19 DR. GIBBONS: Well, something to
20 aim for. In other words, once I am acceptable
21 in those three numbers, does that mean I am
22 good, I'm done, or is there something I should

1 be aiming for the following year?

2 CO-CHAIR GAZELLE: You need to do
3 it again next year.

4 DR. GIBBONS: Well, but aside from
5 just being it again, am I going to be better?
6 Can I be better, and can I facilitate quality
7 improvement in the country in some way, which
8 seems to me ought to be a goal for any
9 measure.

10 CO-CHAIR GAZELLE: Okay. Others?

11 DR. BASSETT: Just relating to
12 that, I think it is also important to remember
13 also the facility. So it also helps the
14 facility evaluate their own persons as well as
15 that person evaluate himself.

16 CO-CHAIR GAZELLE: In response to
17 your comment, Ray, the existing NQF measures -
18 - I don't think any of them have that sort of
19 continuous quality improvement component,
20 which is to say that they have -- As far as I
21 can think of, they have -- They don't have a
22 sort of, if you made it this year, it gets

1 harder next year component to them.

2 DR. GIBBONS: Rate of aspirin use
3 post-myocardial infarction is an NQF --

4 CO-CHAIR GAZELLE: I am talking
5 only about the imaging ones.

6 DR. GIBBONS: I know, but --

7 CO-CHAIR GAZELLE: I am just
8 speaking of so far the eight approved imaging
9 ones.

10 DR. GIBBONS: Right.

11 CO-CHAIR GAZELLE: There are
12 reporting percentages, but there is not a --
13 What you are suggesting needs to be there is
14 not there in any of the eight that already are
15 approved. So I don't know that that is the
16 bar we need to pass here today, or else, if we
17 did, we would have to throw out all the
18 others, too. Right? I mean, none of them
19 have that kind of context.

20 DR. BURSTIN: There certainly are
21 with continual variables oftentimes or your
22 readmission rate may be X or your time to

1 license may be Y.

2 CO-CHAIR GAZELLE: But I am
3 talking about the imaging ones.

4 DR. BURSTIN: Not within the
5 imaging. This is a fairly new area. That is
6 part of what we are seeing here, is it is not
7 tons of measures and years of experience. I
8 think this is a newer area, and the question
9 is still are these measures really at this
10 point appropriate for QI, but are they not yet
11 ready for public reporting, I think, is my
12 major question.

13 I think even the fact that NQF
14 endorsed measures is the ultimate intent, that
15 they are okay for the use of public reporting,
16 I think that is the question I want the
17 committee to think about, either alone or in
18 combination; and if in combination, I don't
19 think we still have a -- I don't feel like I
20 have a comfort level on what that means, if
21 they are paired and how they would be
22 interpolated.

1 DR. SMITH-BINDMAN: This is
2 Rebecca Smith-Bindman. For other measures,
3 not imaging, what proportion of the U.S.
4 population should they be applicable to, for
5 your other measures? So aspirin use -- you
6 know, everyone who is admitted with an MI
7 should be in the denominator. How big a chunk
8 do you need to consider it?

9 DR. BURSTIN: It doesn't need to
10 be a particular size denominator. I think it
11 is just a question of do you feel like at the
12 end of the day you have a reliable and valid
13 estimate that will reflect the quality.

14 DR. SMITH-BINDMAN: But if you are
15 looking at mammography quality, you need a
16 large enough mammography facility. You know,
17 Larry sort of slipped in there that this
18 should be used to evaluate the physician
19 level, which is not how we are using it. Then
20 you are even talking more noise, but if only
21 half of facilities in the U.S. would have
22 sufficient volume to use this quality measure,

1 would that be okay or would that be a measure
2 that is not okay, because it just doesn't find
3 enough? You will have to come up with other
4 measures.

5 DR. D'ORSI: Or can you grade them
6 by size versus how often you are going to look
7 at these numbers, so you have enough hits?

8 DR. BURSTIN: Sometimes a measure
9 will be stratified. So, for example, there
10 would be a facility that could only do
11 procedure Y that is getting looked at. I
12 think that is part of the issue here, is you
13 may have a fairly specialized procedure that
14 would be only be happening in a small
15 proportion of facilities.

16 DR. SMITH-BINDMAN: No. This is
17 happening everywhere. It is happening
18 everywhere.

19 DR. D'ORSI: You have to reach a
20 certain denominator count before the measure
21 would have value.

22 DR. SMITH-BINDMAN: And if only

1 half the facilities could get to that count,
2 would that --

3 DR. BURSTIN: I don't know. Small
4 sample sizes -- you just can't get a sample
5 size to make it something that is meaningful.

6 DR. CANTRILL: Steve Cantrill.
7 Just a brief comment about CQI concept.
8 Remember, those of us who work in training
9 institutions, no matter if you have a static
10 endpoint, that is always CQI, because we did
11 the training, and then we graduated them. So
12 we start over with a whole new dumb set.

13 DR. BURSTIN: That is --

14 CO-CHAIR GAZELLE: And in fact,
15 even if it is not a new set of physicians, the
16 same physicians having to achieve that
17 performance on a new set of patients is still
18 not entirely static. It is not like you have
19 achieved it once, and then you automatically
20 have it forever.

21 All right. Now would you like us
22 to do the last mammo measure before we vote on

1 them?

2 DR. BURSTIN: I think that makes
3 sense.

4 CO-CHAIR GAZELLE: So let's shift
5 gears a little now to the one which is IEP-
6 009-10, which is mammography follow-up rate
7 among Medicare beneficiaries. Rebecca, you
8 are the primary reviewer.

9 DR. SMITH-BINDMAN: I will be
10 honest. When I read this measure, I was a
11 little bit confused exactly what was trying to
12 be measured. So the two possibilities are
13 either it is looking at mammography recall
14 rates, which is very similar to the measure
15 that we discussed just before lunch, meaning
16 of women who are sent for mammography, how
17 many then are sent for additional tests, so
18 recall rate; or if this is trying to measure,
19 of women who are being sent for abnormal
20 mammograms, how many actually come back.

21 So it is sort of -- it is the
22 former? It is a little bit unclear, but okay.

1 So if it is the recall rate, then
2 it is very similar to the discussion we had
3 before lunch. I will go through it very
4 quickly. That is sort of how I thought it
5 was, but some of the text was a little bit
6 confusing.

7 So in terms of how good and how
8 important it is, I think it is a good measure
9 and an important measure, the same as the
10 discussion before lunch.

11 Opportunities for improvement is
12 also a C.

13 If I move to 1(c), outcome, given
14 the outcome for this consideration, is
15 sufficiency. This is absolutely important for
16 sufficiency, so it is a C.

17 If I move to 2, for the numerator
18 versus defined, there are some questions I
19 have with how it is defined, but in terms of
20 in general defining it, I think it is very
21 good. So 2(a) is a C.

22 In terms of 2(b), reliability

1 question, this metric is specifically made for
2 use in Medicare data. So looking at the
3 number of women who are insured by Medicare
4 who have follow-up mammograms that our
5 diagnostic defined by billing codes for
6 diagnostic, I am not sure that the data are
7 presented to let me know that the Medicare
8 billing data is accurate for differentiating
9 screening from diagnostic mammograms. So I
10 think that is a significant problem.

11 The problem is twofold, whether
12 things are captured and, in general, the
13 follow-up rates are low in the Medicare data,
14 and whether you can tell screening from
15 diagnostic. So for 2(b), I gave it an M.

16 For 2(c), for the same reason, I
17 gave it an M.

18 MS. STEPHENS: Excuse me. What
19 did you say? I'm sorry.

20 DR. SMITH-BINDMAN: I am saying I
21 don't have data to know whether the Medicare
22 data are valid for assessing screening versus

1 diagnostic mammography in a relatively
2 straightforward way.

3 There are new codes for it, CPT
4 codes. I know a lot about the old codes, and
5 they are not reliable, and the new codes I
6 don't know very much about and I haven't seen
7 the data to support that they are actually
8 accurate.

9 So just to give people background,
10 in the older codes most mammograms were billed
11 as diagnostic, even though most mammograms
12 were screening, for billing purposes they got
13 higher reimbursement for diagnostic. So they
14 were screened that way. Well, no, I take it
15 back. I don't know why they were billed that
16 way, in fact.

17 I have actually published on
18 differentiating screening from diagnostic
19 mammograms using the Medicaid data, and you
20 can do it, and I argued you could do it. It
21 just took a lot of work. It wouldn't be a
22 reasonable thing to do. So again, it might be

1 okay.

2 For 2(d), there are no exclusions.
3 For 2(e), risk adjustment, I think very
4 strongly it does need to be stratified, but in
5 the Medicare data it should be easy to do it.

6 Meaningful difference in
7 performance is C. I think there are
8 differences that could be improved upon.

9 2(g) is a C. There is great data
10 on this from lots of different data sources.

11 Disparities in care, I gave it a
12 C. There are some differences, not enough to
13 waylay this measure.

14 3(a), I gave it a C.
15 Harmonization, I gave it a Not Applicable.
16 3(c) also Not Applicable.

17 Feasibility, 4(a), is a C,
18 assuming we can assure that the data are valid
19 and reliable. My guess is we can, but then it
20 would be an easy data to use electronic
21 sources. C, exclusions, NA; 4(d), N.

22 Feasibility, I think, is a C; and

1 recommendation: I think the issue of validity
2 needs to be established, but if they are, I
3 guess it is risk adjusted or risk stratified,
4 and I think it is a good measure overall.

5 CO-CHAIR GAZELLE: All right.
6 Thank you. Other comments from the mammo
7 review group before we throw it open to the
8 whole group? Carl?

9 DR. D'ORSI: Let me just go down
10 these, if that is okay with you, go down the
11 numbers again, just on the ones that I had
12 questions on.

13 CO-CHAIR GAZELLE: Sure. I'm
14 sorry. Can you try and speak up a little?

15 DR. D'ORSI: I'm sorry. I am just
16 going to go through some of these that I
17 wanted to make some comments on, on this
18 metric. I'm sorry. I will speak louder.
19 Usually, I don't have that trouble, being from
20 Brooklyn.

21 One of the things that Rebecca
22 mentioned, which to me is problematic, is the

1 method that was developed to measure this
2 recall rate. Remember, this is a recall rate
3 attached to an event that happened previously,
4 not an individual event.

5 So let's take this scenario, which
6 is not uncommon. A woman comes in, has a
7 screening mammogram. She has no symptoms.
8 She hasn't seen her doctor for a year. She
9 has her mammogram, and correctly is read as a
10 1. She goes away, and she says, oh, boy, I
11 had better go have my exam now. She goes in,
12 but two weeks later says, gee, I feel some
13 thickening here: Go back and have your
14 mammogram and an ultrasound.

15 Within 45 days, that gets tagged
16 onto the normal mammogram as a recall, which
17 it is not, and that is not an uncommon
18 scenario. So I think that data is going to be
19 corrupted by not a small amount. So I have a
20 problem with measuring so called recall rate
21 using that type of metric.

22 The other data that was used in

1 lb.2 to support the metric as a single event,
2 one of the studies that was quoted was a 2005
3 study that says you should be within 4.9 to
4 5.5 percent as a good tradeoff between
5 sensitive and positive predictive value.

6 If you look at that article, that
7 was not the thrust of the article. Their
8 basic conclusion was, when you compare
9 performance metrics with other order programs,
10 the time frame for a screen is important.

11 So those metrics can vary whether
12 that woman comes in for a screen at 12 months,
13 18 months or 24 months. So that is an unfair
14 statement to make regarding that article.

15 Another article, a retrospective
16 study that was quoted -- this is also in lb.2
17 -- was the lack of integrating what we
18 discussed before the benchmarks, and I think
19 we had enough discussion on that.

20 Let's see, what else do I have?
21 The other thing is ethnicity. I think there
22 is data coming out that not only is the breast

1 cancer different in African American women,
2 but is more prevalent. You might want to
3 consider that. No?

4 DR. SMITH-BINDMAN: No.

5 DR. D'ORSI: How no?

6 DR. SMITH-BINDMAN: Overall breast
7 cancer rates are lower in African American
8 women. The distribution of higher grade and
9 higher stage tumors are higher. So they end
10 up having worse outcomes, because the tumors
11 tend to be in a higher grade, but in terms of
12 the prevalence of disease, it is overall a
13 little bit lower, which probably is just a
14 reflection of screening.

15 So the true prevalence of disease
16 is probably the same. Hispanics and Asians
17 tend to have slightly lower breast cancer
18 rates. Asians also have lower stage, but in
19 terms of the pool of breast cancer in the
20 U.S., it is remarkably stable by race and
21 ethnicity.

22 DR. D'ORSI: That is all I really

1 had.

2 CO-CHAIR GAZELLE: Thank you,
3 Carl. I have two -- yes, please?

4 DR. SMITH-BINDMAN: Can I say just
5 one thing to agree with Carl. I think the
6 measures, though -- the range of acceptables
7 that is presented in that is not nearly
8 specified enough, and I would expect -- you
9 know, because I think it needs to be age
10 stratified and screening cycle stratified, the
11 numbers don't make a lot of sense, but those
12 numbers that are cited, again, need to reflect
13 more time limited.

14 CO-CHAIR GAZELLE: Thank you. I
15 have two issues with this. The first is the
16 general question, I suppose, of the -- I
17 understand why it is valuable to CMS to have
18 a measure that applies only to Medicare
19 beneficiaries. I am not sure I understand why
20 it is valuable to us or to NQF to have a
21 measure that only applies to Medicare
22 beneficiaries when the condition and procedure

1 of concern spans that.

2 It would be one thing if we were
3 talking about a procedure that is only done in
4 people over 65, but here we are talking about
5 something from, say, 40 to 75.

6 DR. SMITH-BINDMAN: I'm sorry.

7 Isn't this the same as measure 4?

8 CO-CHAIR GAZELLE: Except it only
9 applies to Medicare beneficiaries, as
10 specified. So my question is, you know, since
11 they are similar, why would we choose this as
12 opposed to one that applies to everybody?

13 DR. SPENCER: It makes the
14 feasibility higher, doesn't it?

15 DR. ZERZAN: It is a huge payer,
16 huge payer, in this category especially.

17 CO-CHAIR GAZELLE: I understand
18 why it is important to measure, but I wouldn't
19 support it personally as an NQF measure,
20 because it is only 10 years of the, say, 35
21 years of mammo screening that is covered by
22 this. So in my own opinion, I would rather

1 see measures that apply to the full spectrum
2 of the condition.

3 The second issue is -- and I may
4 be missing something here -- that it only
5 applies to hospital claims, so hospital and it
6 specifically excludes screening done in non-
7 hospital facilities, and a lot of screening is
8 done in non-hospital facilities.

9 So it is further narrowed in terms
10 of its broad applicability. It does allow for
11 the numerator hospital and non-hospital
12 facilities to fully capture all of the events
13 from the denominator patients, but the only
14 way for someone to make it into the
15 denominator is for the index screening exam to
16 be done at a hospital facility, at least as
17 worded. So I think that is a problem with the
18 measure as well.

19 MR. BACKUS: This is Mike Backus.
20 I agree with you that the hospital is too
21 narrow. I think Medicare gives you two huge
22 advantages, though.

1 One is the feasibility, because
2 what you have taken out is the insurance
3 question. So the ability to have the exam or
4 the follow-on care paid for comes out of the
5 equation. So I think you are probably more
6 likely to have true follow-up or -- I mean, we
7 talked before about the FQACs and how you
8 could get a mammo, but then you can't get the
9 biopsy paid for. That piece has been removed.

10 You know, the Medicare dataset --
11 it gives you the ability then actually to --
12 you know, if you are going to work in that
13 dataset, you can head down the biopsy road as
14 well, because you are going to get a path
15 report, and it is all coming through one
16 payer.

17 CO-CHAIR GAZELLE: But this is
18 only about the follow-up. This is not about
19 the biopsy.

20 MR. BACKUS: I understand. I am
21 just saying that, as you -- if you think about
22 where that measure might go over time, the

1 ability to have that dataset becomes --

2 CO-CHAIR GAZELLE: I see what you
3 are saying with respect to biopsy, but I can't
4 imagine a situation where the screening was
5 covered, but the follow-up diagnostic was not
6 covered.

7 MR. BACKUS: Right, in Medicare it
8 is. In FQAC wasn't the exam --

9 CO-CHAIR GAZELLE: Only the biopsy
10 was not covered. To the degree that you get -
11 - you take out the insurance coverage
12 question.

13 DR. ZERZAN: In Medicaid you fall
14 off, and then maybe you have to reapply, and
15 then it is another whatever period of time.
16 So I think from that perspective, it does take
17 out that insurance piece of the question, the
18 access piece. You know it is covered. So it
19 should be there, and this should be able to be
20 sort of the best case scenario, because the
21 extraneous factor has been taken out.

22 DR. SMITH-BINDMAN: This is

1 Rebecca Smith-Bindman. You are saying why
2 start with Medicare. The answer might be
3 this is the only place you can start, and
4 maybe if you have this measure that is
5 endorsed and you can see how it does, it might
6 give you more insight into other data systems.
7 Currently, with small groups, you don't have
8 enough data, but maybe -- I don't know, but as
9 a place to try it, it might be interesting.

10 MR. BACKUS: You would also
11 address some of the stratification question,
12 because now you are doing the 10 over the
13 year, so to speak, instead of 30. So you have
14 narrowed your stratification piece down.

15 CO-CHAIR GAZELLE: Clearly, you
16 do. My issue is that, if we said for the
17 other measure that recall rate wasn't valuable
18 freestanding, by itself, and now we are saying
19 this is essentially a recall rate. This is a
20 slightly differently phrase recall rate
21 measure, but the same problems exist. This is
22 valuable as a stand-alone.

1 DR. SMITH-BINDMAN: But we could
2 help them by suggesting that they could get at
3 cancer detection rates, that they could
4 identify breast cancers pretty accurately,
5 about 80 percent in the dataset, maybe close
6 to 90. So I agree --

7 CO-CHAIR GAZELLE: It doesn't
8 exist.

9 DR. SMITH-BINDMAN: It doesn't
10 work as it is.

11 CO-CHAIR GAZELLE: It is not a
12 proposed measure.

13 DR. SMITH-BINDMAN: It is not
14 stratified now. It is not adjusted now, but
15 your concerns are completely valid, but as a
16 measure they could also care.

17 CO-CHAIR GAZELLE: So the other
18 question, though, that we haven't addressed is
19 the why hospital only for the denominator
20 event. I think it ought to -- and I am
21 assuming it is because of some data
22 feasibility problem.

1 MS. DaVANZO: No, no, not at all.

2 CO-CHAIR GAZELLE: Then what is
3 it?

4 DR. BURSTIN: What is the logic?

5 MS. DaVANZO: -- hospital
6 outpatient quality data reporting. We have to
7 start with where our data is. We can look at
8 it for IBPFs. We can look at it --

9 DR. SMITH-BINDMAN: This is Part B
10 data we are talking about?

11 MS. DaVANZO: Part B. I can look
12 at it for anything.

13 DR. SMITH-BINDMAN: How is it
14 written? Is it written Part A or Part B?

15 DR. BURSTIN: Just a point of
16 clarification. It is really important to --
17 obviously, we want to get at the best quality
18 measure we can here. I think the Medicare-
19 only issue, obviously, is we do routinely
20 endorse measures for Medicare-only, because
21 the data -- for example, the readmission
22 rates, for example, for CHF pneumonia. But

1 the issue there is they are sometimes an older
2 population, to start with.

3 I guess the real question would be
4 I would like to find out what proportion of
5 mammograms, in fact, that could have been at
6 this rate are excluded because it is only
7 Medicare.

8 The second question is what
9 proportion of mammograms are excluded, because
10 it is only hospital outpatient departments.

11 I think my preference would be that, if
12 possible, you would actually want to have the
13 measure be broadest as possible, allow CMS to
14 stratify it for their own payment rule issues.
15 That is not our concern. NQF doesn't do
16 payment. We do the quality measures.

17 So I think one recommendation of
18 that might be, if the data is doable, why not
19 do it for the entire population at facilities.
20 You guys can stratify it for whoever you need
21 to, for whatever payment rules you have, but
22 the bottom line -- Scott is right. I'd like

1 to know what proportion of mammograms are done
2 in hospital outpatient facilities versus not.

3 Is that a known answer?

4 MS. DaVANZO: Sure --

5 DR. BURSTIN: It's got to be
6 pretty small.

7 MS. DaVANZO: But the follow-up is
8 in --

9 DR. BURSTIN: Exactly.

10 MS. DaVANZO: -- you can easily go
11 through the initial screening mammography
12 facilities --

13 DR. BURSTIN: I see.

14 MS. DaVANZO: -- as well.

15 CO-CHAIR GAZELLE: My point is
16 that we have to separate what is important for
17 NQF versus what is important for CMS, and it
18 may be valuable for CMS to look at only
19 hospital denominator events, but I don't think
20 it is valuable for us. And as someone said,
21 they could look at that on their own, if they
22 wanted, but this is not a CMS committee. This

1 is an NQF committee.

2 DR. BURSTIN: But again, I think
3 for Medicare only data issues are really quite
4 reasonable.

5 CO-CHAIR GAZELLE: Right.

6 DR. BURSTIN: I do think the
7 issue, though, of facility only versus
8 hospital outpatient is one that I am not sure
9 is justifiable.

10 CO-CHAIR GAZELLE: The only issue
11 I have with Medicare only is if we are also
12 proposing and supporting essentially the same
13 event that is not limited to Medicare only --

14 DR. BURSTIN: Right, and this has
15 come up repeatedly before as well.

16 CO-CHAIR GAZELLE: -- having two
17 sort of competing same measures may be a
18 problem.

19 DR. BURSTIN: This has come up
20 repeatedly before as well. So at times NQF
21 will endorse two measures when there are
22 different data sources for the measures or

1 distinctly different populations.

2 So the question may be if there is
3 -- this is logical on the Medicare side, given
4 the data source. The key issue from our
5 perspective is those measures have to be
6 harmonized. They can't be different. You've
7 got to be able to have apples and apples at
8 the end of the day, accounting for the --
9 Obviously, there may be significant
10 differences based on data source, but at least
11 in terms of the way you are coming up with the
12 recall rate, it has got to be defined here.

13 CO-CHAIR PETERSON: To clarify two
14 things: One, we probably have an idea of the
15 age breakdown of mammograms. Right? What is
16 the percent 65-plus of all mammograms?

17 DR. SNOW: Percentage of all
18 mammograms on people older than 65? I don't
19 know.

20 MS. DaVANZO: We did a study at
21 MCDS so we could combine the claims in the
22 clinical and survey data that was in the

1 Medicare current issue survey, and we used the
2 2005 data, because that was the last one that
3 had the claims in full over the period. We
4 found that 22.7 percent of women, though it
5 can be men as well -- but we found 22.7
6 actually got their screening mammogram in
7 2005, and then --

8 CO-CHAIR GAZELLE: Right. The
9 question was what percentage of all screening
10 mammograms are done in the Medicare
11 population.

12 DR. BURSTIN: Right. So the MCDS
13 is only Medicare. We are asking the broader
14 question. So we are asking what proportion of
15 screening mammograms are done for the Medicare
16 versus the non-Medicare population.

17 CO-CHAIR PETERSON: Okay. So we
18 are hearing somewhere in the 30 to 40 percent
19 are, so a substantial minority.

20 Anyway, the second question is
21 inpatient versus outpatient -- do we know that
22 breakdown?

1 CO-CHAIR GAZELLE: No, it is not
2 inpatient/outpatient. it is outpatient
3 hospital versus outpatient other sites.

4 CO-CHAIR PETERSON: You have no
5 idea? Do you guys have an idea?

6 DR. DEHN: Of all diagnostic
7 imaging, 15 percent is now done individually.
8 I would think that it would be far less than
9 that for --

10 CO-CHAIR GAZELLE: No, that is not
11 the question. The question is: Of all the
12 mammos which are done as outpatients, what
13 percentage of them are done in hospital
14 associated outpatient facilities versus IVP or
15 that are nonhospital facilities?

16 DR. DEHN: Well, it is apparent,
17 obviously, on --

18 CO-CHAIR GAZELLE: The only
19 question is average across the country, what
20 the answer is.

21 DR. DEHN: Twenty percent, 25
22 percent at hospitals, and it is increasing,

1 because hospitals are buying practices. So
2 those practices in which diagnostic imaging is
3 performed is considered hospital.

4 CO-CHAIR GAZELLE: I understand
5 that, but what we are trying to get at is
6 mammography, not all diagnostic imaging.

7 CO-CHAIR PETERSON: So am I right
8 in saying on the low end of -- the lowest
9 extreme, this measure would account for 30
10 percent and then 20 percent of the 30 percent.
11 So that would be six percent. That would be
12 the low end.

13 MS. DaVANZO: No. The thing is,
14 about 40 percent of women get mammograms in
15 general.

16 CO-CHAIR GAZELLE: That is not the
17 question.

18 MS. DaVANZO: In the Medicare
19 surveys, we got a slice in time. So it was
20 the people in Code 5 that got it, and there is
21 a two-year -- you get it every two years.

22 CO-CHAIR PETERSON: All I am

1 saying is of the tests ordered, not of the
2 people -- of the tests ordered, what percent
3 are you capturing in this measure. You don't
4 capture under 65. So that is 60 percent of
5 the mammograms, approximately, or 70 percent.

6 Of the mammograms in 65-plus, you
7 don't capture the outpatient nonhospital right
8 now, and that was said to be 80 percent of the
9 study. So if you took that --

10 DR. DEHN: I think there is a
11 question before. If you choose that we
12 include that, though that wasn't our mandate.

13 CO-CHAIR GAZELLE: So if we chose
14 to approve it, we could choose to put the
15 condition that it has to include in the
16 denominator all mammography screening exams.
17 That is what is in our purview.

18 MS. DaVANZO: Yes.

19 CO-CHAIR GAZELLE: And you could
20 do that?

21 CO-CHAIR PETERSON: Okay. Then we
22 are back to the question of what the measure

1 means by itself, which is where we are.

2 CO-CHAIR GAZELLE: Yes, which is
3 where we are. So I think we have already --
4 before we turn it to formal comments from the
5 measure developer, let us ask if there are any
6 more questions from the committee or comments
7 from the committee, either on the measure
8 itself or on the merits of the measure -- a
9 measure such as this in the absence of the
10 other sort of balancing measures.

11 DR. FIESINGER: You are saying it
12 is all the same recall rate. Do we need a
13 similar measure, really, or can they be merged
14 together, have one measure for everyone;
15 because there a number of measure exploding
16 every year to this group. We have measures on
17 measures, and when I am practicing and seeing
18 patients, it is very intimidating and costs a
19 lot for practices to measure all this stuff.

20 So there if is a way to save a
21 measure and achieve the goal, I would be in
22 favor of that.

1 MR. BACKUS: This is Mike Backus.

2 With this measure, we are suggesting, gets
3 measured out of CMS data. Right? So
4 essentially, there is no additional cost to
5 the practice.

6 My question on the measure is: do
7 we think that, because Medicare has a more
8 stratified population -- right? You are only
9 working 65 and over, excluding the disabled --
10 that you have taken out enough of the
11 population bias that recall rate by itself is
12 now substantially more meaningful and can
13 stand on its own, or do you still need PPV2 to
14 go behind it?

15 DR. SMITH-BINDMAN: Are you saying
16 one measure is good enough in this population?

17 MR. BACKUS: I am always brought
18 up, because I work in it -- it is like crawl,
19 walk, run. Yes, there is a gold standard. I
20 mean, there is a gold standard -- right? --
21 where you want to know the tumor size and --
22 but we will wait for the electronic health

1 record and being here in 20 years, but from
2 CMS' perspective, if they are trying to get
3 close, does this narrow it enough to be
4 worthwhile? And I don't have a view.

5 DR. SMITH-BINDMAN: This is
6 Rebecca Smith-Bindman. I was going to say a
7 very similar point. I still think it needs to
8 be stratified by age, but if extremes of poor
9 quality were set in this measure, then I think
10 you could identify those extremes with just
11 this measure standing alone.

12 CO-CHAIR GAZELLE: Scott Gazelle.
13 I assume this is a facility-level measure. Is
14 that the intent? So basically, we are judging
15 the facility and how it manages its Medicare
16 patients. Okay. Right? If it is a facility-
17 level in a Medicare setting -- so is that
18 valuable?

19 DR. D'ORSI: Carl D'Orsi. This is
20 a facility-based metric. You tie it to the
21 woman. What happens if she goes to another
22 facility for that diagnostic exam, the

1 screening?

2 DR. SMITH-BINDMAN: It should be
3 in the range. She is billed.

4 CO-CHAIR GAZELLE: So it is the
5 facility of the denominator, I would assume.

6 DR. D'ORSI: Got you. Okay.

7 CO-CHAIR GAZELLE: Eric?

8 CO-CHAIR PETERSON: Eric Peterson.
9 Sorry, one more time. Clarification of what
10 is good quality or bad quality? You said you
11 could use it for that. How?

12 DR. SMITH-BINDMAN: This is
13 Rebecca Smith-Bindman. If a facility recalls
14 more than 20 percent of their patients for
15 additional mammography, that is a measure of
16 poor quality and large cost. After a recall
17 rate of about 10 percent, you are not getting
18 much in the way of cancer detection. So we
19 will give them from 10 to 20 to waste those
20 resources, but above 20, whatever that cutoff
21 is, that is poor quality.

22 CO-CHAIR PETERSON: And you would

1 argue for then some sort of binary?

2 DR. SMITH-BINDMAN: Think of it as
3 a bubble in the window of a level, too much
4 above, too much below.

5 CO-CHAIR PETERSON: Do we have or
6 were we provided data that said what percent
7 of institutions fall in that greater than 20?

8 DR. SMITH-BINDMAN: It turns out
9 the way the data were presented were not age-
10 stratified, were not first and subsequent,
11 ended up being very misleading.

12 CO-CHAIR GAZELLE: They do present
13 first and subsequent.

14 So let's finish comments from the
15 committee, because I can't find it this
16 moment, but there were data on first and
17 subsequent.

18 DR. SMITH-BINDMAN: They come up
19 with about -- recall rates of about 10 percent
20 with a very narrow distribution. It was very
21 low.

22 CO-CHAIR GAZELLE: Let's see.

1 Roger, then Mary, then Carl.

2 DR. SNOW: I may have missed it,
3 but Carl earlier mentioned something that is
4 important here, particularly if you are going
5 to have an upset threshold for bad quality,
6 that these data are at risk of being
7 contaminated by independent events that send
8 someone back for a mammogram, a second
9 mammogram. I don't know the numbers. I have
10 no idea, but it is not zero.

11 DR. SMITH-BINDMAN: The recall
12 rate is driven by women who are normal. So of
13 a thousand women, the recall might be 150.
14 Those are normal. The concern that Carl
15 raised is driven by cancers. So that is
16 driven by a recall of one of those five women
17 out of 1000 who have cancer.

18 So the recall rate of 150 could be
19 contaminated by one of those a thousand with
20 breast cancer. So instead of being 150 out of
21 a thousand, it would be 151.

22 DR. SNOW: But she doesn't -- I

1 take the point, but she doesn't have breast
2 cancer. She has a lump.

3 DR. SMITH-BINDMAN: She has a
4 palpable lump.

5 DR. SNOW: She has got a lump.
6 She's got a piece of fat there.

7 DR. SMITH-BINDMAN: But it is not
8 -- it is an order of magnitude for prevalence.

9 DR. SNOW: So you are saying it --

10 DR. SMITH-BINDMAN: Not that it is
11 not an issue. Carl's issue is absolutely
12 real. It's just a small bit of noise.

13 DR. GEMIGNANI: This is Mary
14 Gemignani. I favor this recall type of
15 measure over the one previously, because it
16 has a couple of things that are uniform about
17 it. The population is more uniform. The
18 payer is more uniform, and it is a small
19 metric that we can start with.

20 The other one is much more
21 broader, and it has so many variables about
22 the institution, the population that you are

1 looking at. So if I were to pick one of
2 those, I think I would favor this one.

3 DR. D'ORSI: I am confused, as
4 usual. But let me ask this. What is the
5 basic difference about the discussion we had
6 with the other recall rate versus this as far
7 as equating this to quality? Is there any
8 difference in that discussion that I am
9 missing?

10 CO-CHAIR GAZELLE: This group is
11 age-stratified.

12 DR. D'ORSI: It is age-stratified
13 and it is easy to get. But does it still give
14 you a quality measure as a stand-alone?

15 DR. SMITH-BINDER: I am raising
16 that. I am raising it as an extreme, not as
17 a continuous metric where there is a lot of
18 subtlety, but as a threshold.

19 DR. D'ORSI: You could do that
20 with the regular recall rate, too, and as a
21 matter of fact, you are stating only one edge
22 of a group where you are saying above is not

1 good. What about one percent? Is that good?

2 DR. SMITH-BINDER: That is not
3 good either.

4 DR. D'ORSI: So then you shouldn't
5 say blank and above. If you are going to do
6 it at all, you need a range.

7 CO-CHAIR GAZELLE: What are the
8 ranges that is being proposed?

9 MS. DaVANZO: Ten to 14.

10 CO-CHAIR GAZELLE: Ten to 14?

11 DR. D'ORSI: So if you are under
12 ten, you are no good?

13 MS. DaVANZO: No. If you were
14 two, like you said, you would have to work --

15 DR. SMITH-BINDER: Ten percent
16 involved half of the facilities not being
17 good, because their recall rates are too low,
18 which is an interesting state of affairs.

19 MS. DaVANZO: Older people -- I
20 mean, the recount was eight and a half,
21 different studies that we have done over the
22 years.

1 DR. SMITH-BINDER: So you are
2 saying ten is not -- lower than ten is not
3 good.

4 DR. DEHN: I think we're in danger
5 of rewriting it. I mean, the fact is that, as
6 Rebecca said, there is a range, and we can
7 identify those ranges, and if support from
8 this group asks us to take a look again at
9 what is too low versus what is too high, we
10 can do that. I mean, it is not real
11 complicated.

12 DR. D'ORSI: What will you use as
13 -- this is Carl D'Orsi. What will you use as
14 a gold standard to set those ranges besides
15 just a recall rate? What would you say?
16 Where would you pick, two, three, four, nine,
17 ten, 11? Where would you pick it and why
18 would you pick it?

19 CO-CHAIR GAZELLE: So why don't we
20 finish our comments, and then we will ask for
21 formal comments from the developer, and then
22 we can have a back-and-forth.

1 DR. CANTRILL: If we are going to
2 be setting a range, where does that data come
3 from and has it been published? I mean, if
4 this is proprietary information --

5 CO-CHAIR GAZELLE: We will ask
6 them to address that in their comments.

7 DR. SPENCER: I mean, we have
8 talked about it a lot. So if your recall rate
9 is very low but your cancer detection rate is
10 excellent, not only are you not not bad, you
11 are excellent.

12 DR. D'ORSI: Supposing you are
13 finding Stage 3. Are you still excellent?

14 DR. SMITH-BINDMAN: I think those
15 cut-offs -- if the purpose is to identify
16 really low quality, they have to be set at
17 such extremes that that is unlikely to be the
18 case. I would argue they would have to be
19 very wide. The recall rate of two percent --
20 there are problems with it, but that is how
21 the entire Danish mammography program
22 operates.

1 DR. D'ORSI: In the UK, I think it
2 is about five percent.

3 DR. SMITH-BINDMAN: Five percent.
4 The recall rates in the UK are half what they
5 are --

6 DR. D'ORSI: And they recommend
7 below five. Five is the upper limit. The
8 Dutch are 1.8, but their stages of cancer are
9 much higher.

10 DR. SPENCER: Are Dutch women
11 dying of breast cancer? Is that what you are
12 saying?

13 DR. D'ORSI: Yes. That is exactly
14 what we are getting at, that you need to know
15 what you are finding.

16 CO-CHAIR GAZELLE: I am sensing
17 that this is a good time to ask the measure
18 developer to give their comments, and then we
19 can ask them questions afterward.

20 DR. DEHN: This is Tom Dehn
21 talking, and this is my second episode with
22 Carl.

1 I think, for those of you who are
2 not mammographers, I was somewhat, at least as
3 a general radiologist. I have probably heard
4 everything you could ever hear about
5 mammography, and it was really very, very well
6 done, in my estimation.

7 I want to thank the committee for
8 looking at this, and especially thank Rebecca
9 and Mary for your comments and support of it.

10 Let me just say that what we are
11 really looking at, I think, as a radiologist -
12 - what we are really looking at is
13 indeterminate rates. That is kind of what you
14 are looking at.

15 While we call them recall rates,
16 what we are really talking about is, a
17 radiologist has really three options when he
18 or she looks at a study. It is either
19 positive, negative, or I need more
20 information.

21 There are some radiologists that
22 always need a lot of information, and some

1 radiologists that don't need information and
2 they are good. It doesn't get a lot more
3 complicated than that, although it isn't
4 anywhere near that simple.

5 When we look at data, yes, there
6 is age stratification, but kind of the good
7 news for the proposal that we mention is that,
8 in and among the 65 and older age group, the
9 results -- and we can certainly provide those
10 for you -- the differences in those strata are
11 relatively low.

12 What we do find when we compare it
13 to private data -- and, certainly, Mike has
14 access to that and we have access to that --
15 is the recall rate is very high in relatively
16 young people for the reasons that you
17 mentioned. Their breasts are denser, and the
18 most important thing we have is the previous
19 study and they aren't around in many cases.

20 I have the feeling that in
21 transient populations that the same thing
22 happens as young people, that you get more

1 recalls, because you can't find the previous
2 studies that were done but we haven't really
3 looked at that.

4 So what we have that is different
5 than the earlier proposal that sounds kind of
6 similar is that we have a fairly homogeneous
7 group, and we are not dependent upon a
8 voluntary BIRADS sort of participation. That
9 is, that when we define an index study that is
10 followed by a given number of studies, we can
11 extrapolate that, that that was an
12 indeterminate study because they asked for
13 some more information or it was a positive,
14 and the positives are pretty well going to be
15 relatively stable.

16 So what did we find and what do we
17 find? We find huge variations. Rebecca was
18 very kind to our colleagues -- and I have
19 worked with people like this and I think some
20 of you have. They just can't -- they probably
21 should not be reading mammograms, although
22 they probably don't make a lot of mistakes.

1 It just takes them a long, long time to get
2 there, and we see rates as high as 80 percent
3 in some areas, and within communities that
4 have -- nearly everybody has a nine to ten
5 rate. I mean, I actually know some of your
6 practices around here, and you are all doing
7 just fine.

8 The thing is that -- but in that
9 community where you are seeing the same kind
10 of people in another radiology group or in
11 another facility, you will have double or more
12 the amount of additional information that is
13 necessary for those radiologists or diagnostic
14 imagers to reach their level of confidence.

15 So what we are really saying is
16 that there are some radiologists that have a
17 level of confidence that seems to be
18 appropriate for reading and interpreting
19 diagnostic imaging, and there are some that
20 probably shouldn't be.

21 Now is there an -- and when you
22 look at these high numbers, and we certainly

1 will look at the low numbers and report those
2 out as well -- when we look at the high
3 numbers, you begin to wonder whether asking to
4 get lower will drive people into a behavior
5 that they don't feel comfortable doing, and
6 that certainly is a concern, or that when you
7 start to see the data folks, you will find
8 that small institutions with relatively low
9 volumes have a very much higher additional
10 imaging rate.

11 So what would that do to the rural
12 areas that Roger talked about before, and
13 others? I think that, in terms of policy, if
14 we could make policy -- if it were my family,
15 I would probably identify centers of
16 excellence and with the digital imaging,
17 teleradiology, send them in.

18 Radiologists in the middle of
19 nowhere don't want to read mammograms anyway.
20 So the fear of driving mammography from Chico,
21 California to Sacramento is, at least in my
22 estimation, not a realistic concern. It is a

1 concern, but not a realistic concern.

2 What we will give you is insight
3 into the terrific variation between imaging
4 providers. Now you say, well, wait a minute.
5 That is kind of related, isn't it, to the
6 amount of tumor discovery; and the next thing
7 is we have the good Rebecca here who wrote the
8 article, along with others, and they are
9 really quite interesting.

10 MS. PETERSON: It is on Slide
11 Three.

12 DR. DEHN: On Slide Three? Well,
13 this is very interesting, because there is a
14 point at which you can continue to add
15 additional studies for call-backs or follow-
16 ups, however you want to describe it but you
17 really don't get anywhere, and this is
18 somewhere around 14 percent.

19 So if, in fact, this committee or
20 anyone on this committee would like to
21 contribute a suggestion to us on what level we
22 would like to set those thresholds, we can

1 certainly -- we can certainly do that. I
2 think, if I were to do that, it would probably
3 be back of the envelope. But when we know now
4 that, after a given rate, you don't find any
5 more cancers, they are in pretty good shape.

6 CO-CHAIR GAZELLE: Is this for the
7 CMS population or is this all?

8 DR. DEHN: This is all.

9 CO-CHAIR GAZELLE: I thought we
10 heard earlier that the numbers would be
11 different in the CMS population.

12 DR. DEHN: The call-back numbers
13 will be lower and, in fact, they are. The
14 call-back numbers we looked at are somewhere
15 in the seven to eight percent range. So we
16 are operating down here.

17 So if you set -- if we are
18 discussing where to set the threshold, I think
19 that might be a discussion for another time.
20 Should we set a threshold that experts suggest
21 is realistic? Yes, of course, we should.

22 DR. SPENCER: I misunderstood. I

1 thought you said you had data that you could
2 present from the Medicare population.

3 DR. DEHN: Now what we have here
4 is kind of a peculiar -- I didn't do this.
5 Radiologists don't do slides like this. But
6 what you see here is, of the 2,800-some
7 hospitals, there are some here, about half,
8 that are below 8 1/2 percent national average,
9 national average for Medicare, and there is
10 about 50 percent that are over, and there are
11 some that are really over -- really over.

12 DR. BASSETT: Please don't use
13 that word, follow-up, because that refers to
14 patients who are in a short term follow-up.
15 As we go into this era of IT and all the
16 electronic records, we don't want that
17 overlay. So I just wanted to --

18 DR. DEHN: I agree, and we have
19 all grappled with it. I noticed in yours it
20 is called recall rate, and essentially, if you
21 really looked at recall rate, that measures a
22 whole different thing. I mean, you are

1 compliant and your enrollees or your patients
2 that you take care of are relatively well
3 educated and are compliant and you have a
4 program.

5 That is a whole other issue is
6 that, when you find something abnormal, are
7 you able to get them back, and that is not
8 what we are looking at. We are really looking
9 at indeterminate rates. So when you look at
10 a case, you need more information, some need
11 a lot more than others, and that is what we
12 are looking at.

13 So we think it is clean. We would
14 like to take a look at it, get started on it,
15 report it back to you, and let it change as
16 time goes on. Please?

17 DR. SPENCER: This is Kirk
18 Spencer. Two quick questions. So how does a
19 Medicare database tell recalls from short term
20 follow-ups?

21 DR. SMITH-BINDMAN: Short term
22 follow-ups -- what exactly is that?

1 DR. SPENCER: Well, you are just
2 going to find something done in less than six
3 months.

4 DR. DEHN: That is correct.

5 MS. DaVANZO: The metric is 45
6 days.

7 DR. DEHN: And again, we are
8 seeing less and less short term follow-up, and
9 we are seeing more and more definitive imaging
10 studies. It is either MR or it is biopsy or--

11 DR. SPENCER: I know it says --
12 from someone who remotely reads echoes, having
13 anybody do the echo at the other end, and then
14 they will send it to me to read, and the echo
15 clearly doesn't work.

16 In mammography, is the technical
17 aspects of it substantially less than the
18 radiologist? I don't have a good sense for
19 that?

20 DR. DEHN: Yes, and the good news
21 is, as Dr. Forman indicated --

22 DR. SPENCER: And the reader is

1 the dominant variable?

2 CO-CHAIR GAZELLE: One other point
3 is that we are including follow-up for mammo,
4 diagnostic mammo or ultrasound, but not MRI in
5 this measure.

6 DR. DEHN: And we intentionally
7 left that out, because during the time of the
8 study that we collected and intend to collect
9 the data from, MRI is not real well defined,
10 and I am not so sure it is yet well defined on
11 one-use MRI in conjunction with an abnormal
12 mammogram.

13 DR. FIESINGER: You know, on this
14 curve -- it is a funny kind of curve, because
15 it sort of suggests -- and maybe this is the
16 fact in the real world, but it suggests there
17 is a group of people who are just utterly lost
18 in space.

19 I mean, you see a lot of
20 variability in the clinical world. We can
21 take their choice of that, but are there
22 really a group of people who are lost in space

1 who are just doing all the MQSA stuff and
2 figured out all of that, are getting paid,
3 have all these other things, but somehow are
4 just, as centers, congenitally unable to read
5 mammograms?

6 DR. DEHN: Yes.

7 DR. FIESINGER: Because that is
8 what is describing to me. That is what this
9 curve is describing to me, and it seems like -
10 - it just seems like who are these people?

11 DR. DEHN: What we will see, and
12 when we did this in the private sector in that
13 whole population that we were talking about --
14 that means the non-Medicare population -- I
15 was totally surprised.

16 To answer your question, I thought
17 you would have some variation, like you do.
18 But I can only conjecture that there are folks
19 out there that are either motivated by certain
20 things, and then there are others that are so
21 insecure that they always get additional
22 films.

1 Now many of you have worked in
2 radiology groups. I have. A couple of my
3 partners had double what my call-back rate
4 was.

5 DR. ZERZAN: Do you have any base
6 for, like, numbers, because I could imagine
7 the 100 percent one is somebody that reads
8 three a year, and they are going to call back
9 all three, because they don't know.

10 MS. STEPHENS: No. We have got
11 minimum case counts on it.

12 CO-CHAIR GAZELLE: What do you
13 mean by that?

14 MS. STEPHENS: It varies by the
15 ratio level. We asked for the -- the case
16 count asks them to count -- we had a lot of
17 people at the low end and a lot of people at
18 the high end. So the minimum case count
19 actually varied by -- in this data, varied by
20 ratio level, and we are working at a 90-
21 percent confidence level.

22 DR. RUCKER: It doesn't look like

1 normal distribution to me. I understand you
2 are doing some other funny graphing here, but
3 it doesn't look like a normal distribution.

4 DR. DEHN: But what we do see,
5 though, is you do see some outliers that are
6 way out there. Unexpected to me as it might
7 be to you -- I mean, how can you be that far
8 off?

9 DR. RUCKER: Is that just fraud?

10 DR. FORMAN: Why aren't these --
11 I am still not clear.

12 CO-CHAIR GAZELLE: Hold on.
13 Please give your name.

14 DR. FORMAN: Why aren't these
15 tiny, tiny practices that are seeing three
16 cases a week -- I mean, I am not trying to
17 defend them, but --

18 MS. STEPHENS: I want to clarify.
19 These do not include facilities who have a
20 small case count. They have to have had a --
21 at the tail there, they have to have done at
22 least 45.

1 DR. FORMAN: Forty-five what?

2 MS. STEPHENS: Screening

3 mammograms.

4 DR. FORMAN: During what period?

5 MS. STEPHENS: During a year.

6 DR. FORMAN: That is nothing. You
7 know, I once watched a resident in a practice
8 that had -- you know, they did screening
9 mammograms out of convenience, and you would
10 see a patient once a week. So you are
11 basically dealing with 140 practices at the
12 tail, all of whom may account for less than .1
13 percent of the population.

14 So they are out there, but I
15 wouldn't necessarily imply fraud. It is
16 probably more likely that they -- people are
17 saying that even pecuniary instincts are
18 causing this. I have a feeling that most of
19 the tail are probably radiologists who don't
20 want to be doing mammography, and are just
21 doing it because the set-up is in the office.

22 MS. STEPHENS: No, these are not

1 offices. These are hospital outpatient
2 departments.

3 CO-CHAIR GAZELLE: Can I ask for a
4 clarification. Is this a computer-generated
5 curve or is this an actual curve? And the
6 specific question I have is: are there really
7 sites that are recalling 100 percent and zero
8 percent or is this just --

9 MS. ARDAY: This is the real data.
10 The maximum is 100 percent. The maximum
11 between data where you know they started is 45
12 screening mammographs.

13 DR. DEHN: In the private sector,
14 high-volume facilities have 80 percent. I
15 have not seen any at 100 percent. There are
16 some that have 80 percent with high-volume
17 providers, and high-volume providers that have
18 close to zero percent, in fact, I would worry
19 about.

20 The deal is let's look. Now what
21 I have produced that graph for is a different
22 way, sure. But I think -- the radiologist put

1 a lot of work into this thing, but I am
2 passionate about this. There are radiologists
3 that have to have a lot more information than
4 other radiologists, and they are out there in
5 significant numbers, and we got to identify
6 them.

7 DR. D'ORSI: I agree with that.

8 DR. DEHN: Okay. Carl.

9 DR. D'ORSI: I agree with you,
10 John, but I am again confused. If the MQSA
11 says an individual has to read 500, this would
12 imply that somebody who is reading for 100
13 facilities to get that, do you know that or
14 not? Where does 45 reconcile with the FDA
15 minimum of 500?

16 DR. DEHN: You know, Carl, I had
17 the same question, and I suspect that there
18 are a fair number of radiologists that are not
19 -- they are not qualified.

20 DR. SMITH-BINDMAN: As part of the
21 Breast Cancer Surveillance Consortium, it
22 seemed that there were a lot of low-volume

1 doctors, and there are a lot of low-volume
2 doctors. But in fact, doctors read at many
3 facilities, and so on a practical level you
4 are only assessing the mammograms they are
5 reading in the elderly, and you have no idea
6 if they are making up their volume in other
7 places. So I kind of agree with --

8 CO-CHAIR GAZELLE: Or with non-
9 Medicare patients.

10 DR. SMITH-BINDMAN: Right. Those
11 are the elderly.

12 CO-CHAIR GAZELLE: But it could
13 have been in their same facility, just a lot
14 of non-Medicare patients.

15 DR. SMITH-BINDMAN: Exactly. So
16 it is very difficult to get.

17 DR. DEHN: From the back of the
18 envelope you feel that Medicare is probably 30
19 to 40 percent or 30 percent of your
20 mammography volume. That would be 90, you
21 know, and there isn't a radiologist that I
22 know that isn't terrified of someone coming

1 after you if you are reading two a week. I
2 mean, basically, that is two a week. So they
3 must be working at other facilities.

4 DR. SMITH-BINDMAN: But just
5 looking at the distribution of your data, the
6 99th percentile distribution and the recall
7 rate is 24.9 percent and I can give you six
8 separate references that have gotten exactly
9 that number: 25 percent.

10 So I think the one percent outlier
11 which we are looking at is either a data issue
12 or it is a -- I don't believe -- or represents
13 a couple of doctors that are doing something
14 odd. I think that is unlikely, and if your
15 quality metric is only measuring that one
16 doctor, it is not doing anything. It is doing
17 nothing.

18 DR. DEHN: I understand that, and
19 I would just say -- Offline I will share some
20 of the blinded private information that we
21 have and it really does happen.

22 DR. SMITH-BINDMAN: But that is

1 not the benefit of this measure. I mean, it
2 might be a benefit to you to identify those
3 few really, really extreme cases.

4 DR. DEHN: The thrust of this
5 measure is to find --

6 DR. SMITH-BINDMAN: You don't need
7 this measure to identify them. You can
8 identify them in a lot of other ways without
9 having an NQF measure.

10 CO-CHAIR GAZELLE: Do we have a
11 proposed range, though, for this measure? Are
12 we supposed to sign off on the measure or sign
13 off on the measure with a range? Is there a
14 range that is being proposed?

15 MS. DaVANZO: Yes. The literature
16 supports ten. That is one of the benchmarks
17 that you see a lot in the articles, and then
18 14 or 15.

19 DR. SMITH-BINDMAN: But you are
20 saying you are applying a standard that half
21 of your facilities would fail.

22 MS. ARDAY: No.

1 DR. SMITH-BINDMAN: Am I confused
2 about that?

3 MS. ARDAY: We are not marking any
4 of these as pass or fail. What we are really
5 looking for is a more extreme rate of
6 distribution --

7 DR. SMITH-BINDMAN: What was the
8 ten to 14 percent you just cited?

9 MS. ARDAY: -- hospital outpatient
10 departments establish a dialogue of what is
11 going on with our patients here? What is
12 going on with our clinicians?

13 CO-CHAIR GAZELLE: So that I
14 understand, but the question is what are those
15 numbers? Below what is not acceptable? Above
16 what is not -- or is not good?

17 MS. ARDAY: We haven't done that
18 piece. This is pay for reporting, not pay for
19 performance.

20 CO-CHAIR GAZELLE: For CMS, but
21 for NQF the question is whether or not we are
22 going to approve a measure that doesn't have

1 a threshold. Right?

2 DR. BURSTIN: Just to be clear,

3 not all measures need that threshold.

4 CO-CHAIR GAZELLE: No, I
5 understand.

6 DR. BURSTIN: We would endorse,
7 for example, an episiotomy rate. No one knows
8 what the exact rate perhaps is, but the
9 question is, is it useful for a bench purpose
10 in reporting to begin to see where the --

11 CO-CHAIR GAZELLE: I completely
12 understand that, but we have had a discussion
13 back and forth about a lot of different
14 ranges. What I am trying to get clarity on
15 is, is there a range being proposed with this
16 measure and, if so, what is it, or is there
17 not a range.

18 I understand that there could be.
19 That is not the question. The question is, is
20 there one being proposed with this measure?

21 DR. DEHN: Let me speak, please.

22 There is one that is proposed, and the

1 discussion today has prompted us to take
2 another look at it.

3 CO-CHAIR GAZELLE: What is the one
4 that has been proposed.

5 DR. DEHN: Ten percent and 14.

6 CO-CHAIR GAZELLE: Within 10 to 14
7 is the range that is being proposed?

8 CO-CHAIR GAZELLE: So eight and a
9 half and nine would be outside of that range?

10 MS. ARDAY: No. No, because there
11 is no cancer found. The 10 to 14 percent is
12 on the general population. This is
13 predominantly --

14 DR. SMITH-BINDMAN: So it has no
15 relevance for our discussion. Is that
16 correct? It has no relevance to the
17 discussion.

18 CO-CHAIR GAZELLE: So there is no
19 range.

20 DR. BRUETMAN: This is one of the
21 issues that was brought up, which is we are
22 talking about the stratification of data. I

1 mean, CMS stratifies their data into age: 65
2 and over and all that, but we have done that,
3 and it is not significantly changed.

4 What it does indicate is that at a
5 certain age, this sub-segment has at least a
6 lower reach than average, a little bit lower,
7 because of many clinical issues. So that is
8 why you see it comes a little bit lower than
9 expected, which the literature says ten to 14
10 percent is the expected recall rate that we
11 see here. But CMS has stratified data, so a
12 little bit lower level. Now we haven't
13 defined do we think it should look at the low
14 end and somewhere at the high end.

15 CO-CHAIR GAZELLE: So I think we
16 need to be clear on this. First of all, I
17 don't know what literature you are speaking of
18 that says ten to 14 percent. So that would be
19 the large study. The BCSC study was an
20 average of 9.8 percent. Well, that is not ten
21 to 14 percent. The European data is all
22 single digits, and I have seen one study that

1 has a median of about ten, and I think at 75th
2 percentile -- what was it, 16 percent?

3 So I don't know of a study, and it
4 isn't cited here. So I don't think we should
5 say the literature says ten to 14 percent
6 unless the literature does say ten to 14
7 percent, which would mean that someone can
8 cite that.

9 DR. SMITH-BINDMAN: AHRQ has old
10 numbers, and I don't know if that is the
11 number that you are citing.

12 MS. DaVANZO: I think the range
13 five to 15, and it is an average of 12.3.

14 CO-CHAIR GAZELLE: The
15 interquartile range was, I think, 6.4 to --
16 no, 4.6 to --

17 DR. D'ORSI: I have it right here.
18 It is 6.4 to 13.3 is the 50 percent. Fifty
19 percent of radiologists fall into that. If
20 you use your numbers, 25 percent would fall
21 into that.

22 DR. SMITH-BINDMAN: I think these

1 are for age-adjusted. Are these Ralph's data?

2 DR. D'ORSI: Yes.

3 DR. SMITH-BINDMAN: I think they
4 are age-adjusted.

5 CO-CHAIR GAZELLE: So is it fair
6 to say that the ten to 14 percent is not
7 relevant to this measure and not relevant to
8 this discussion? Right? So we can leave that
9 behind? All right.

10 Okay. Other questions of the
11 committee to the measure developer? Ray?

12 DR. GIBBONS: Ray Gibbons. Just
13 two broad comments. One point has already
14 been made, but in terms of the potential
15 impact of this, you would have to know the
16 volumes of these studies being performed and
17 the extremes to know how useful this measure
18 would be to CMS for overall quality.

19 The second observation I would
20 make is that using different kinds of datasets
21 in far larger populations -- if I look at
22 published data for cardiac procedures, these

1 extremes don't look bad at all.

2 DR. DEHN: Believe me, I know.

3 DR. SMITH-BINDMAN: From zero to
4 100?

5 (Laughter.)

6 DR. GIBBONS: For example, the
7 published data on cardiac procedures based on
8 Medicare markets -- so these are hundreds of
9 thousands of patients -- show customarily
10 five- to ten-fold differences in non-zero
11 rates, and a well known, published example of
12 one referral region that is three times higher
13 than a referral region 60 miles away.

14 So I am surprised. These look
15 pretty good.

16 DR. D'ORSI: So, John, these are
17 facility numbers; right?

18 DR. DEHN: Yes, and they can be
19 broken down into individuals, but were are
20 instructed not to do that. When you look at
21 it, however -- when we look at it in the
22 private sector --

1 DR. D'ORSI: But this metric you
2 are presenting is relatively unfair, because
3 there is no facility standard with a recall.
4 It is an individual metric. So it is a little
5 bit unfair to say those people are really --
6 those facilities are stupid, because they may
7 be going to somebody who is very good at
8 reading, but only doing 45 a year.

9 DR. DEHN: By extrapolation, we
10 simply say that there is a quality issue if
11 you know that your partners are not reading
12 or, in the aggregate, you are doing well. So
13 you can blame it on something systemic within
14 the facility.

15 DR. D'ORSI: But it is a little
16 misleading.

17 CO-CHAIR GAZELLE: All right.

18 DR. GIBBONS: The thing I take
19 from these, and I saw another similar curve,
20 is that you can't draw final conclusions from
21 these data, but you can say, well, there is a
22 sector of interest out there at that far end,

1 whether it is because they are very
2 conscientious, whether it is because they are
3 this or that or the other.

4 So you know, the ones in the
5 middle maybe you don't have to worry so much
6 about, and use your resources the same way you
7 have used resources on the people at the end.
8 That is as far as you can go with those data,
9 I think.

10 CO-CHAIR GAZELLE: Okay. Other
11 comments on this specific measure?

12 DR. SMITH-BINDMAN: I raised
13 something when I reviewed it. Rebecca --
14 sorry. Are you guys -- do you have some
15 measure of the ability of these new CPT codes
16 to differentiate screening from diagnostic
17 exams?

18 MS. DaVANZO: They are separate
19 codes. They are separate CPT codes.

20 DR. SMITH-BINDMAN: Right. Do you
21 know the ability to differentiate screening
22 from diagnostic using those codes to get some

1 reference standard like data in the Breast
2 Cancer Surveillance Consortium data, in self-
3 reported mammography, that sort of thing?

4 We did a paper that was published
5 in Medicare a couple of years ago that looked
6 at the classifications of mammograms using CPT
7 codes, using CMS data compared to Breast
8 Cancer Surveillance Consortium. So,
9 certainly, it would be something that you guys
10 could repeat using your new codes.

11 MS. DaVANZO: Right. We have it
12 from the old codes.

13 DR. SMITH-BINDMAN: If we were
14 using the old codes.

15 MS. DaVANZO: If we used the old
16 codes.

17 DR. SMITH-BINDMAN: Then I would
18 say you don't have a measure here.

19 CO-CHAIR GAZELLE: Because you
20 don't believe in the validity of the reporting
21 of the total.

22 DR. SMITH-BINDMAN: The ability to

1 frame it from screening to diagnostic. So I
2 am assuming your new codes are going to be
3 better. I am asking you if you have looked at
4 that. I am suggesting it might be useful. It
5 requires some chart abstraction, or the
6 simplest thing to do -- the simple thing that
7 you could do is in states that have a SEER
8 tumor registry or Breast Cancer Surveillance
9 Consortium registries -- so you can do it in
10 New Mexico; you can do it San Francisco; you
11 can do it in Washington -- they currently have
12 done the linkage for you.

13 So the linkage is done between the
14 Breast Cancer Surveillance Consortium and the
15 Medicare data. So you just have to put in
16 this request, and if you speak to me after, I
17 will tell you how to do it, and then you can
18 find out the rest.

19 MS. DaVANZO: And it is very
20 possible that CMS is also researching
21 demonstrations for these, probably after
22 looking back at the SEER registry. So it

1 might be as simple as having a talk with Jerry
2 Riley or somebody and say, hey Jerry, have you
3 looked at this number lately.

4 DR. SMITH-BINDMAN: It's the
5 Breast Cancer Surveillance Consortium. So it
6 is Rachel Ballard Barbash. It is under her.
7 Diana is the Coordinating Center person in
8 Seattle.

9 CO-CHAIR GAZELLE: So that would
10 be an important point of clarification, if we
11 would decide to --

12 DR. SMITH-BINDMAN: If we would
13 decide they haven't shown us which measures
14 can be used.

15 CO-CHAIR GAZELLE: Okay. Carl?

16 DR. D'ORSI: Just one quick one,
17 John, and you can answer this yes, no, I don't
18 know. So you have information at that end of
19 readers who are MQSA-certified with these
20 recalls and if somebody is reading who is not
21 MQSA-certified with these readings.

22 DR. DEHN: That is correct.

1 DR. D'ORSI: Okay, thank you.

2 DR. SMITH-BINDMAN: Do you know
3 their personal individual MQSA?

4 DR. DEHN: That is correct.

5 CO-CHAIR GAZELLE: Mike?

6 MR. BACKUS: I just look at the
7 curve, and 2801 is there, and the total sample
8 size is 2957. So this tail that we are
9 spending all this time talking about -- this
10 is like 30 guys.

11 MS. DaVANZO: That curve there,
12 Mike, represents 2.7 million mammograms --

13 MR. BACKUS: Well, no. I am
14 talking about number of facilities. So you
15 look at that list of facilities -- I mean this
16 is what we do from the plan perspective all
17 the time.

18 You know, I have said just back of
19 the envelope -- you set that line at a
20 standard deviation or a standard deviation and
21 a half off, and you go, okay, I want to look
22 at the guys that are sub-three, and I want to

1 look at the guys that are over 20, and I am
2 going to end up with 200 facilities to look
3 at. That is what is going to
4 tell you, because CMS or any organization --
5 we can't be in the position Rebecca has talked
6 about where half of the facilities in America
7 don't meet the measure. That doesn't serve
8 anybody any good. Just look at the tails and
9 -- you know.

10 CO-CHAIR GAZELLE: I would like to
11 raise one issue for discussion that we talked
12 about this morning with the recall rate
13 measure. The question is, is there value, if
14 we were to approve this, in having essentially
15 a recall rate measure that doesn't include a
16 cancer detection rate or possible prediction
17 values in the measure?

18 Should we go back and ask CMS if
19 they wanted a Medicare population measure for
20 recall rate to also have a cancer detection
21 rate?

22 DR. CANTRILL: Steve Cantrill. I

1 was impressed this morning in the discussion
2 for each of the first four measures where we
3 were saying this alone is not good; you've got
4 to take it in conjunction with other measures,
5 and this alone is what we are talking about.

6 CO-CHAIR GAZELLE: Yes.

7 DR. CANTRILL: So I don't
8 understand how we can strive to have a, quote
9 combined measure or call it what you will,
10 firstly, and then say, oh, but in this case,
11 because the data is easy to get, we are just
12 going to do this alone.

13 So I would say we are obligated to
14 go back to the makers of this measure and say,
15 do you have the data. Can you do what we were
16 talking about in that set of first four
17 measures as well as this single measure?

18 CO-CHAIR GAZELLE: Thank you.

19 Other comments on that topic or other topics?

20 MR. BACKUS: Look, CMS doesn't
21 hold the BIRADS information, though. Right?

22 CO-CHAIR GAZELLE: No, it doesn't.

1 MR. BACKUS: So that becomes a
2 drop-off question. If you assume everybody
3 with Medicare that comes zero, four, five has
4 an insurance coverage -- or does not have an
5 insurance coverage issue, then you would
6 expect a dropoff of zero, four, fives that
7 don't get follow-on care, assuming they are
8 continuously enrolled or whatever, you know,
9 the drop-off should be trivial, you would
10 hope. So you would end up with cancer
11 detection down the stream, because you have
12 the path data.

13 CO-CHAIR GAZELLE: Don?

14 DR. RUCKER: Maybe for the measure
15 developers -- Don Rucker. I think some of our
16 requirements for the NQF process -- I think
17 the first one on importance -- did we have a
18 sense of the area under the tail here in terms
19 of the requirement for the importance?

20 We are asking a lot of people to
21 do a lot of reporting, as far as I can
22 understand here, that has a cost to it.

1 DR. SMITH-BINDMAN: No. It is all
2 paid for.

3 DR. RUCKER: So it is sort of,
4 quote/unquote, "free"?

5 DR. BURSTIN: Right.

6 DR. RUCKER: Then maybe just on
7 the importance question -- I don't have it; is
8 that 1(a)? It is pretty high here. -- just a
9 raw importance metric, if we could understand
10 that, because --

11 DR. BURSTIN: I think that was
12 referring to 1(b), which is the demonstration
13 of quality and opportunity for improvements.
14 If you are making the argument, the tail is
15 fairly small here. It is a facility level
16 measure. So the question is how many
17 facilities does that 1000 cases represent.

18 MR. BACKUS: Well, the 95th
19 percentile is 17-1. So you would have 200,
20 right? You would have five percent on top out
21 of 2000. It is 150 on the top, 150 on the
22 bottom. Right? If you went fifth percentile

1 and 95th percentile? So 300 facilities --
2 that is five percent of the hospitals in
3 America. That is pretty substantial.

4 CO-CHAIR GAZELLE: Correct.

5 DR. SMITH-BINDMAN: It is the
6 99thh percent.

7 MR. BACKUS: I'm sorry. Right.
8 That was at 25, right. At the 95th
9 percentile, if you cut it at 17. If you cut
10 it at 17 and 5, you are up to 300 hospitals,
11 fifth percentile and 95th percentile.

12 DR. SMITH-BINDMAN: I like that.

13 MR. BACKUS: Three hundred
14 hospitals to go look at.

15 CO-CHAIR GAZELLE: Troy, you look
16 like you are about to raise your hand. No?

17 DR. FIESINGER: No. I was just
18 pointing to the data. I am fine.

19 CO-CHAIR GAZELLE: All right. Now
20 we need to move toward decisions, voting, and
21 it is complicated. I am not sure how best to
22 approach it, because seems like we have the

1 four measures this morning that we want to
2 consider as a group, and then our decision on
3 that might affect our decision on this
4 afternoon's measure.

5 So what I propose is we have a
6 brief discussion, try and limit it to about 10
7 minutes or so, on which of the four we would -
8 - on the merits of approving them individually
9 this morning or of grouping them.

10 I will throw out a straw man
11 proposal based on what I thought we heard this
12 morning, is that the measure developer wants
13 to see them approved or presumably not
14 approved, but approved as a group, and I think
15 from our discussion, the consensus was from
16 the four this morning, the three that would
17 make sense to bring together or consider
18 together would be the recall rate, the cancer
19 detection rate, and PPV2.

20 DR. SNOW: The PPV2 on the
21 diagnostic?

22 CO-CHAIR GAZELLE: Yes. So I

1 think that was -- If I am off, speak up,
2 please, but I think that was kind of where we
3 were thinking based on the morning's
4 discussion.

5 So I don't know then how we go
6 about voting for that without voting for the
7 individual measures.

8 DR. BURSTIN: You still need to
9 look at each of the individual measures, make
10 recommendations, recommendations for
11 conditions, whatever the case may be.

12 CO-CHAIR GAZELLE: And the
13 condition could be only with the other two?

14 DR. BURSTIN: Yes, although I
15 think -- Again, it is really the question of
16 how the three at the end of the day get
17 presented together, but I still don't think we
18 have clarity since they are not a composite.

19 CO-CHAIR GAZELLE: Right.

20 DR. ZERZAN: This is Judy, I have
21 a quick question. The one thing that I do
22 like about the first PPV2 or 1 is that it is

1 based on tissue diagnosis. So it is a real
2 outcome rather than asking for follow-up. So
3 I don't know if there is a way to change or
4 recommend that the second one move to tissue
5 diagnosis or -- I guess I still don't know.

6 CO-CHAIR GAZELLE: Is diagnosis
7 recommended?

8 DR. ZERZAN: It says it is
9 recommended to get a tissue diagnosis rather
10 than the actual tissue itself, which to me is
11 a difference in terms of, I think, my
12 philosophy of quality measures in general is
13 that we should be pushing toward more outcome
14 based things and measuring more things that
15 really change health rather than the
16 indeterminate process-ey things that we
17 sometimes focus on.

18 So, to me, tissue sounds more
19 definitive than, oh, I recommend that you go
20 there by --

21 CO-CHAIR GAZELLE: You speaking
22 for what? You are speaking for the

1 denominator?

2 DR. ZERZAN: I like the second
3 one, but the part I don't like about it is
4 that it just recommends. It doesn't say get
5 the tissue.

6 DR. SMITH-BINDMAN: This is
7 Rebecca Smith-Bindman. Your point has been
8 raised by others, and the argument -- not that
9 I endorse it or not -- is that from the
10 quality point of view, all the radiologist can
11 do is recommend that something else happen,
12 and there are a lot of factors outside that
13 doctor's control in terms of whether the
14 person chooses to follow up at that facility
15 or any facility, and that it would be better
16 to separate -- Your point is that the doctor
17 can take responsibility. The doctor can't,
18 and that is why it is adopted as a
19 recommendation rather than what actually
20 happens.

21 CO-CHAIR GAZELLE: It is also the
22 issue of --

1 DR. SMITH-BINDMAN: Impractical.

2 CO-CHAIR GAZELLE: -- you know, in
3 terms of positive predictive value, it is the
4 positive predictive value of a positive
5 mammogram. Right? So that is why a positive
6 mammogram is a 4 or 5, which is the
7 recommendation for biopsy, and what percentage
8 of those positive mammograms are actually
9 positive.

10 I think we can't redefine a
11 commonly used measure.

12 DR. ZERZAN: But why not push for
13 -- I mean, I understand that the doctor
14 doesn't necessarily have control over that,
15 but that is also a reason why doctors say they
16 can't address obesity, you know. They are
17 still -- Did it help push the system, health
18 system, the payers, as well as the providers
19 to a higher standard than what is already
20 there? Maybe we are not there yet in terms of
21 data, but if we are close, I guess I would
22 argue for getting the tissue rather than just

1 the recommendation, to push that a little
2 further.

3 DR. SNOW: Roger Snow. I am very
4 sympathetic with what you say, but I think
5 that that is an argument for another table,
6 because what is being done here is a measure
7 that works on what radiologists do and can do.
8 The point has been made that they can't get
9 the biopsy. The interventional guys may, but
10 that aside, the actual thing, the step of
11 getting the outcome, would be a separate
12 measure. That would use PPV3, I think, and
13 maybe we all come back in a year and go after
14 the primary care guys.

15 I think it really is a measure of
16 quality at the care delivery level rather than
17 at the diagnostic level. It is a different
18 measure.

19 CO-CHAIR GAZELLE: So what I am
20 looking at --

21 CO-CHAIR PETERSON: Can I just ask
22 for a clarification? So let's take one

1 assumption. When could this come back to
2 this, if it were not passed today? When would
3 it be potentially re-eligible to come up
4 again?

5 DR. BURSTIN: It is not clear.
6 When we have another project with the right
7 expertise, we could review it. So I don't see
8 any --

9 CO-CHAIR PETERSON: But we don't
10 know when the next imaging efficiency group
11 will --

12 DR. BURSTIN: I suspect, given how
13 important this area is, it is probably within
14 the next two years, but I wouldn't say it is
15 less than that. Since this is a starting
16 point --

17 CO-CHAIR GAZELLE: Maybe what we
18 should do is vote on this measure in isolation
19 first, because if it passes in isolation, we
20 are done -- each of them.

21 DR. BURSTIN: Each of them.

22 CO-CHAIR GAZELLE: The first four.

1 Then if they don't pass in isolation, come
2 back and vote again with the grouping; and if
3 they don't pass there, then they haven't
4 passed. I don't think I can think of another
5 way to do it. Voting is endorse/not endorse.

6 CO-CHAIR PETERSON: We are looking
7 for simple majority here?

8 CO-CHAIR GAZELLE: Yes.

9 DR. BURSTIN: Although, again, if
10 it is a split vote, we will just present it to
11 the public as such.

12 CO-CHAIR GAZELLE: So let's --
13 Carl?

14 DR. D'ORSI: I just want to make
15 one quick statement. In this country, 2 and
16 3 are almost the same. So the vast majority
17 of PPV2s will have tissue, the vast majority.
18 So it is not like --

19 DR. ZERZAN: Well, then why not go
20 for tissue?

21 CO-CHAIR GAZELLE: Well, because
22 tissue hasn't been proposed. So we can't vote

1 on it.

2 DR. D'ORSI: What Rebecca said is
3 correct. The 2 is the cognitive part of the
4 radiologist and the surgeon to say, out of
5 here. So nobody is talking about it. Go away
6 from me. So she doesn't get it. No, but this
7 is -- I am hyperbolic, but this is a scenario.
8 So you are really judging the cognitive
9 thinker on doing the 4 or 5. After that, they
10 can't really control what happens, but it is
11 very close.

12 CO-CHAIR GAZELLE: But also we
13 don't have a PPV3 measure to discuss or vote
14 on.

15 DR. BURSTIN: And it may wind up
16 being that is a research recommendation. Just
17 to follow up on Judy's point, there is a
18 strong interest in measures that get at shared
19 accountability. It doesn't need to just
20 reflect the facility, if the end game really
21 is to zoom in with positive mammograms, get
22 the outcome we expected, and that is, I think,

1 a very reasonable expectation. I just don't
2 know that the measures in front of us today
3 offer us that option.

4 CO-CHAIR PETERSON: So to clarify
5 one more time, we are going to go and vote on
6 these individually. If they are voted up,
7 then they are in. If they are voted down,
8 then we will take them as a group.

9 CO-CHAIR GAZELLE: As a group,
10 with the condition that we would approve them
11 if they were a group. Then they may or may
12 not pass.

13 Okay. So do you want to call for
14 the voting or should I call for a vote?

15 MR. CORBRIDGE: I just want to
16 bring something to the screen. We do have an
17 NQF just kind of form to capture the process
18 that you are going through. Sarah has been
19 working on getting the Steering Committee
20 comments and recommendations, covering the
21 black discussion points, response of sponsor
22 measure developers or response from the

1 public, which at the end of discussing
2 mammography measures we will open it up to the
3 public to see if there is any responses.

4 On the lefthand side, we have
5 NQF's criteria for looking at measures. So
6 you have importance, scientific acceptability,
7 usability and feasibility. Our plan is, as we
8 are going through, I will collect the Steering
9 Committee's votes on that.

10 So we are looking at how many
11 people are voting on each.

12 CO-CHAIR GAZELLE: And an overall?

13 MR. CORBRIDGE: Well, taking -- I
14 guess taking -- For the four main criteria.

15 CO-CHAIR GAZELLE: Right. So
16 there's five votes on each one. Okay.

17 MR. CORBRIDGE: Then, I guess,
18 depending on how things lay out, if there are
19 comments that are needed to justify some of
20 the recommendations that the Steering
21 Committee puts forward, we will put those
22 comments in.

1 CO-CHAIR GAZELLE: And these are
2 binary votes on each of these five measures?

3 DR. BURSTIN: You mean yes/no?

4 CO-CHAIR GAZELLE: Yes/no.

5 DR. BURSTIN: I'm sorry. It is
6 recommendations specifically on a criteria are
7 high, medium, low.

8 CO-CHAIR GAZELLE: Okay. So do
9 you have a matrix to capture these four by
10 four, and then the one by two?

11 MR. CORBRIDGE: Yes. We are just
12 going to take this down.

13 CO-CHAIR GAZELLE: All right. So
14 now here we are. We are voting on measure
15 number 1, cancer detection rate. We have
16 discussed it this morning. We are voting on
17 it in isolation, and we need people to raise
18 their hands. This is Steering Committee only
19 members. We need you to raise your hands
20 under the importance.

21 So how many people want to rate
22 the importance as high? C? High up here? So

1 this is all of the different subparts of High
2 together.

3 DR. BURSTIN: Yes.

4 CO-CHAIR GAZELLE: The options are
5 High, Middle or Low?

6 DR. D'ORSI: Can you read the
7 evaluation criteria, the main ones, before you
8 ask for a vote?

9 CO-CHAIR GAZELLE: I will, once we
10 count. The importance, everybody knows. I
11 will read it again while we are counting.

12 "Importance: Extent to which the
13 specific measure" -- Hands down. It is,
14 "extent to which the specific measure focus is
15 important for making significant gains in
16 health care quality, defined by the six
17 dimensions of the IOM, and improving health
18 outcomes for a specific high impact aspect of
19 health care where there is variation in or
20 overall poor performance."

21 So that is the importance. Now
22 we've got -- How many people would like to

1 rate that M for Middle rating? Four?

2 How many people would like to rate
3 that Low for low? I figure we need to say it.

4 Okay. So next we are going on to
5 criterion number 2, scientific acceptability:
6 Extent to which the measure, as specified,
7 produces consistent (reliable) and credible
8 (valid) results about the quality of care when
9 implemented.

10 Remember, we are voting on this
11 measure now in isolation. How many people
12 want to give it a High rating? None.

13 How many people want to give it a
14 Middle rating? All right. And how many people
15 would like to give it a Low rating? We should
16 have an easy way to calculate that.

17 Now the next is -- I am not going
18 to read these definitions with every measure,
19 but there was a request to read them.

20 Next is usability, which is the
21 extent to which intended audiences can
22 understand the results of the measure and are

1 likely to find them useful for decision
2 making.

3 Again, we are voting on measure
4 number 1 in isolation at this point. High?
5 It looks like three. Middle? Looks like six.
6 And Low?

7 DR. SMITH-BINDMAN: Can I just
8 clarify. When you read the second one, you
9 said as written.

10 CO-CHAIR GAZELLE: As written.

11 DR. SMITH-BINDMAN: But you didn't
12 say for this usability as written.

13 CO-CHAIR GAZELLE: Oh, I thought I
14 did, but we are voting on this thing as
15 written.

16 DR. SMITH-BINDMAN: Only as
17 written?

18 CO-CHAIR GAZELLE: Only as written
19 now, because we agreed we would just vote on
20 them as written first, and then talk about the
21 modifications.

22 DR. SMITH-BINDMAN: I want to

1 change my vote.

2 CO-CHAIR GAZELLE: We can do that
3 just by counting. What do you want to shift
4 from what to what?

5 DR. SMITH-BINDMAN: High and
6 Middle.

7 CO-CHAIR GAZELLE: Okay. So that
8 would be two High and Seven middle then.

9 Okay, the last category is for
10 feasibility, extent to which the required data
11 are readily available, retrievable without
12 undue burden, and can be implemented for
13 performance measurement.

14 Again, this is measure number 1 in
15 isolation. How many votes for High? Five.
16 How many votes for Middle or
17 moderate?

18 MR. CORBRIDGE: Is it 15? Yes.

19 CO-CHAIR GAZELLE: Okay. And now
20 we have an overall -- Oh, Low, sorry. How
21 many Low? Who wants to vote Low? Should be
22 a couple. You could abstain. Okay.

1 The important thing is the NQF
2 will report the numbers of the votes. They
3 are not going to come to a binary decision.

4 So now we want to have an overall
5 recommendation, and that is either Yes or No.
6 So you vote either to approve to recommend
7 this for endorsement or not.

8 So who would like to recommend
9 this for endorsement as is, as written, in
10 isolation? Okay, who would vote not to
11 recommend this? Okay. So that is this
12 measure.

13 So we will go through. We are
14 going to do the same process now for measures
15 2, 3 and 4, and then we can come back and talk
16 about a proposed either conditional approval
17 and what the condition might be as a group.

18 Let's go to measure 2, which is
19 screening mammography, positive predictive
20 values, PPV2, which as a footnote should
21 really be PPV1, but as long as we are voting
22 on it as it is written and defined in the

1 measure. Okay.

2 We are on the first category,
3 which again is the importance. Who wants to
4 give it a High? Is it eight?

5 Who would like to give it a Middle
6 or Moderate? Eleven. And who would like to
7 give it a Low? None? Okay.

8 So now we are going to move on to
9 the second category, which is scientific
10 acceptability of the measure property. Who
11 would like to give it a High? Zero. Who would
12 like to give it a Middle? Seventeen.

13 Who would like to give it a Low?
14 MR. CORBRIDGE: Is it Four? Five,
15 sorry.

16 CO-CHAIR GAZELLE: We keep getting
17 different totals. Are there 22 people? How
18 many people are there?

19 MR. CORBRIDGE: Are individuals
20 abstaining?

21 CO-CHAIR GAZELLE: There are 22
22 people.

1 DR. SNOW: Vote early, vote often.

2 MR. CORBRIDGE: The problem with
3 the 17, I can't see -- I don't know if you
4 would like to be in the middle?

5 CO-CHAIR GAZELLE: So raise your
6 hand if you want to give this a Middle.

7 DR. D'ORSI: This is a lesson in
8 statistics.

9 CO-CHAIR GAZELLE: I got 14. Who
10 would give it a Low?

11 MR. CORBRIDGE: I saw 14, yes.

12 CO-CHAIR GAZELLE: Who would give
13 it a Low?

14 MR. CORBRIDGE: One, two, three,
15 four, five. So that gives the right number.

16 CO-CHAIR GAZELLE: Thank you.

17 Okay. So the next category is category 3,
18 which is usability. Who would like to give it
19 a High? High for usability? No? One high.

20 Who would like to give it a
21 Middle?

22 MR. CORBRIDGE: I count 15.

1 CO-CHAIR GAZELLE: I got 14. Who
2 would like to give it a Low? Three?

3 MR. CORBRIDGE: Three, yes.

4 CO-CHAIR GAZELLE: I think we need
5 to ask everybody to vote. You have to make a
6 decision. You can't really abstain.

7 DR. BURSTIN: You can abstain.
8 You just have to let us know you are
9 abstaining.

10 CO-CHAIR GAZELLE: I can
11 understand how you could abstain on the for or
12 against it, but how can you abstain on the
13 high, medium or low?

14 The next one -- The last one is
15 feasibility. How many people would like to
16 give this a High on feasibility. Raise your
17 hands high.

18 MR. CORBRIDGE: Looks like we have
19 three.

20 CO-CHAIR GAZELLE: How many people
21 would like to give it a Middle for
22 feasibility?

1 MR. CORBRIDGE: Seventeen.

2 CO-CHAIR GAZELLE: So that should
3 be zero Lows. Okay, good.

4 So now you have the option of
5 either voting to recommend for endorsement or
6 not to recommend for endorsement. How many
7 people would like to vote to recommend for
8 endorsement, again single measure in
9 isolation? All right.

10 How many people would not
11 recommend for endorsement? Looks like
12 everybody. All right, we are making -- Oh,
13 that is not progress.

14 Okay. So now we have measure
15 number 3, which is diagnostic mammography
16 PPV2, which is the percentage of positive
17 mammograms that lead to a diagnosis of cancer.

18 Again, we are voting for
19 importance. How many people would like to
20 give it a High?

21 MR. CORBRIDGE: Eighteen.

22 CO-CHAIR GAZELLE: How many people

2 is completely out of
the running

1 would give it a Middle? Two?

2 How many a Low? Zero.

3 Next is for scientific
4 acceptability. How many people would give it
5 a High?

6 MR. CORBRIDGE: Seven.

7 CO-CHAIR GAZELLE: Middle?

8 MR. CORBRIDGE: Thirteen.

9 CO-CHAIR GAZELLE: And a Low?

10 MR. CORBRIDGE: It would be zero.

11 CO-CHAIR GAZELLE: And next is for
12 usability. How many people would like to give
13 it a High?

14 MR. CORBRIDGE: Four.

15 CO-CHAIR GAZELLE: Middle?

16 MR. CORBRIDGE: Sixteen.

17 CO-CHAIR GAZELLE: And Low? It
18 should be zero. Okay. I am not trying to
19 influence your vote.

20 And for feasibility, how many
21 people would like to give it a High?

22 MR. CORBRIDGE: Six.

1 CO-CHAIR GAZELLE: Middle?

2 MR. CORBRIDGE: Thirteen.

3 CO-CHAIR GAZELLE: And Low? It
4 would be one -- No? One abstention. So
5 should we ask for abstentions, just to check
6 our math, Helen?

7 DR. BURSTIN: Did somebody
8 abstain?

9 CO-CHAIR GAZELLE: Did somebody
10 abstain on that one? It was six, 13 and zero,
11 but no one is claiming an abstention. So we
12 must have counted wrong. Could we count
13 again, please? Highs? How many Highs?

14 MR. CORBRIDGE: It looks like
15 there is six. Should be 14 middle.

16 CO-CHAIR GAZELLE: All right. Who
17 would like to vote to recommend endorsement of
18 this measure? One. One for.

Final voting outcome is
only one for recommended

19 Who would vote against
20 endorsement? That looks like 19 to me. Any
21 abstentions? That is 19.

22 Okay. Now let's go on to measure

1 4, which is recall rate, and we are back to
2 importance. How many people will give this a
3 High importance?

4 MR. CORBRIDGE: Thirteen.

5 CO-CHAIR GAZELLE: Okay. How many
6 people will give it a Middle?

7 MR. CORBRIDGE: Seven.

8 CO-CHAIR GAZELLE: Should be no
9 Lows. Any Lows? All right.

10 Now we are on to the next measure,
11 which is scientific acceptability. How many
12 people will give it a High?

13 MR. CORBRIDGE: Five.

14 CO-CHAIR GAZELLE: How many people
15 would like to give it a Middle?

16 MR. CORBRIDGE: Fifteen.

17 CO-CHAIR GAZELLE: How many Lows?
18 We must have counted wrong.

19 MR. CORBRIDGE: Fourteen.

20 CO-CHAIR GAZELLE: All right.

21 Next is usability. How many people would like
22 to give this a High? Middle?

1 MR. CORBRIDGE: Nine.

2 CO-CHAIR GAZELLE: And how many
3 people would like to give it a Low? One.

4 Feasibility: High?

5 MR. CORBRIDGE: Six.

6 CO-CHAIR GAZELLE: Middle?

7 MR. CORBRIDGE: Thirteen.

8 CO-CHAIR GAZELLE: And Low? So
9 could we recount the Highs. I think there
10 were seven High. High? Okay.

11 MR. CORBRIDGE: Eight.

12 CO-CHAIR GAZELLE: Okay, let's
13 recount the Middles then. This is Middle.
14 Raise your hand for Middle, please. And Low?
15 Okay, we are at 19. Did anyone abstain?

16 DR. CANTRILL: I don't think I
17 voted on that one. I vote Middle.

18 CO-CHAIR GAZELLE: Add one more to
19 Middle. So that is 12.

20 All right. Now we need to vote

21 either for or against recommending for

22 endorsement. Who would like to vote for

1 recommending for endorsement? All right, one.

2 Again? Okay. One for, 19 against.

3 CO-CHAIR GAZELLE: So now what we
4 will do is we will take a 10-minute break, and
5 over the break I want to think about what we
6 are going to do next.

7 What we are going to do is come
8 back and think about something that we could
9 vote on -- I don't think we need to vote for
10 the individual characteristics so much as
11 approval or not approval, if they were
12 proposed as a package. So think in your mind
13 about what that might be.

14 DR. SNOW: Roger Snow. Are we
15 going to be taking a single vote to approve
16 the concept of a package?

17 CO-CHAIR GAZELLE: No. I think we
18 will take -- We will start by taking one vote
19 of a proposed package, and we can vote on a
20 couple of proposed packages, if we need to,
21 because there are a couple of combinations.
22 The logical one is recall rate, PPV2 and

What should be in the
package! (1, 3, 4)

1 cancer detection rate.

2 CO-CHAIR PETERSON: I am not so
3 sure I could -- Given the fact that -- I am
4 not so sure that this is beyond our task here.
5 I will come back pretty strongly and say that
6 we don't have a set -- We don't know what that
7 package would look like. So it is very hard
8 for us to vote intelligently about that.

9 I am not so sure that they can
10 come up with a package in that short order.
11 This is writing a new measure that we don't
12 have.

13 DR. BURSTIN: The only thing that,
14 I think, would be appropriate to specifically
15 vote on, if you wanted to, is the fact that
16 they proposed them as measures to always be
17 presented together, not as a composite, not in
18 some combined way.

19 CO-CHAIR PETERSON: Okay. So
20 would this be meaningful for the public, had
21 you gotten the three scores together? Would
22 you like that?

1 DR. BURSTIN: That's all. I
2 actually think you might just want to take
3 care of it now, so long as everybody is
4 thinking about it.

5 CO-CHAIR GAZELLE: Do you want to
6 do it now before the break? Okay. So here is
7 the vote. Pay attention.

8 The vote is -- We are going to ask
9 you to vote in favor of recommending for
10 endorsement or not the combination of recall
11 rate as written, PPV2, the second one of the
12 ones, the true PPV2, and cancer detection
13 rate.

14 DR. D'ORSI: Can you give us the
15 numbers, please?

16 CO-CHAIR GAZELLE: Yes. One,
17 three and four, as written.

18 DR. SMITH-BINDMAN: As written.

19 CO-CHAIR GAZELLE: So note, as
20 written there are no specific ranges being
21 proposed. The question is --

22 DR. D'ORSI: And no risk

1 adjustments.

2 CO-CHAIR GAZELLE: And there is no
3 risk adjustments being proposed, and after the
4 break we can come back and talk about possible
5 conditions or modifications.

6 DR. BURSTIN: Usually, you would
7 vote on what you actually want the package of
8 true measures to be. So I think it may make
9 sense to say are there truly conditions on
10 these.

11 CO-CHAIR GAZELLE: What if we
12 approve it as written without, the three as
13 written? I was thinking we could see if we
14 would do that.

15 DR. SMITH-BINDMAN: Hypothetical.
16 You would, as written?

17 CO-CHAIR GAZELLE: So again, we
18 are talking about one, three and four, as
19 suggested by the measure developers that they
20 be endorsed as a group, without further
21 conditions. We will vote on this, and then we
22 will have a break. So we can have discussion

1 during the break, if we want, and come back
2 refreshed.

3 CO-CHAIR PETERSON: Just to be
4 clear, while we might prefer the conditions,
5 if we say we don't want it unless there is a
6 condition, essentially we are pushing -- we
7 are going to end up pushing it off for some
8 number of cycles or it can come back within
9 this cycle with conditions?

10 DR. BURSTIN: No. If there are
11 really reasonable conditions, they could pass
12 them now, which is why I think --

13 CO-CHAIR GAZELLE: So let's take
14 this vote, and then we will talk about it,
15 because I was thinking that was sort of a
16 natural break point.

17 How many people would vote for
18 recommending for endorsement the package of
19 one, three and four, as stated, without ranges
20 and without any modifications? You got a
21 number there?

22 MR. CORBRIDGE: There were nine.

1 I'm sorry.

2 CO-CHAIR GAZELLE: How many people
3 would vote against endorsement?

4 MR. CORBRIDGE: I get 11.

5 CO-CHAIR GAZELLE: So no
6 abstentions. So let's take a 10-minute break,
7 come back ready to discuss possible conditions
8 that we would like to request the developers.

9 (Whereupon, the foregoing matter
10 went off the record at 2:58 p.m. and resumed
11 at 3:11 p.m.)

12 CO-CHAIR GAZELLE: All right.
13 Here is the plan for the rest of the
14 afternoon. We are going to try and get
15 through the remaining discussion and voting on
16 the mammo measures, and then if we have time
17 to move on to some of the measures that we are
18 slated for tomorrow.

19 So we will finish by five. No
20 need to worry, and if we get through some of
21 tomorrow's work before five, then we will have
22 a better chance of finishing easily tomorrow.

1 Before the break, here is what
2 happened. We all voted, I think on balance,
3 favorably for the individual aspects of the
4 four ACR proposed measures, though we had a
5 lot of High and Middle for individual
6 characteristics, but we voted against
7 recommendation, almost unanimously, for all
8 four of them individually.

9 Then we had a nearly split vote,
10 11 versus 9, against for the combination of 1,
11 3 and 4 unmodified.

12 So now what we want to talk about
13 briefly, because there is an unlimited number
14 of potential modifications -- The question is:
15 Is there an easily described and voted on
16 combination of conditions that we would
17 propose to that one, three, four combination
18 that would get people who voted no to vote yes
19 without taking people who voted yes and making
20 them vote no? Right?

21 What I heard is the conditions
22 that some people would like to see added to

1 these measures are stratification -- so it is
2 probably stratification in reporting, since we
3 are not proposing thresholds anyways -- for
4 some or all, and that could be both by age --
5 It could be by age and/or by first versus
6 repeat mammogram.

7 So that is what I heard, but I
8 would like somebody to propose, because I
9 voted for approval without modifications. So
10 I would like for someone who voted no to that
11 combined group of three to propose conditions
12 that they would find acceptable enough to vote
13 yes.

14 So if there is no response to this
15 request, that means that all of the people who
16 voted no, the 11 people who voted no, there is
17 nothing that could get you to vote for these
18 measures. Then we can move on, if that is the
19 case. Is that correct?

20 DR. GEMIGNANI: My vote could be
21 moved. So how many of us would have to move
22 for you to --

1 DR. BURSTIN: It doesn't really
2 mean -- Either way, this is going to go out to
3 the public and membership as a split vote. So
4 I think, unless there is truly a huge --
5 everybody just says stratify it, and we are
6 good, we will present it as is. This is not
7 Congress so don't feel like you've got to go
8 peddle for the vote.

9 CO-CHAIR GAZELLE: Right, but if
10 there was something lurking below the surface
11 that kept -- that you felt, ah, geez, if it
12 was only for that condition or set of
13 conditions, I would have voted for it, this is
14 the time to speak up.

Look for smiths
stratification

15 DR. SMITH-BINDMAN: This is
16 Rebecca Smith-Bindman. If these measures were
17 age stratified, I would be willing to accept
18 them as a group. I would like them to also be
19 stratified by whether mammograms are first or
20 subsequent, but that makes it more tricky in
21 the feasibility category; whereas, the age
22 doesn't seem to add complexity to doing it,

1 and feels it is imperative to making the
2 numbers remain the same.

3 CO-CHAIR PETERSON: To be clear,
4 how many strata do you --

5 DR. SMITH-BINDMAN: By decade.

6 CO-CHAIR PETERSON: By decade. So
7 you are going to have three measures times X
8 number of decades.

9 DR. SMITH-BINDMAN: Forties,
10 fifties, sixty, seventy. So four strata.
11 Four times three is -- It is not bad.

12 CO-CHAIR PETERSON: Twelve
13 numbers.

14 CO-CHAIR GAZELLE: Okay. So now
15 are there other people who voted against the
16 combination for whom that would make it
17 appealing enough to vote for it? So we got
18 three others. So that would -- four others.
19 So that is good information.

20 Are there people who voted for the
21 combined measures unmodified that would be
22 opposed to the reporting of stratified? Carl,

1 did you vote for them?

2 DR. D'ORSI: I voted for them. I
3 am just a little bit worried about the number
4 of events you need when you put that decade
5 in, and I don't know if we can get that much
6 data on decades.

7 CO-CHAIR GAZELLE: So that could
8 be a condition that we asked the measure
9 developer to come back to us with, if they had
10 data about the statistical effect of
11 stratification.

12 DR. SMITH-BINDMAN: Can I add one
13 more thing as well?

14 CO-CHAIR GAZELLE: Yes, please.

15 DR. SMITH-BINDMAN: If the measure
16 developer can give us a sense of what sample
17 size they would want for each of these
18 measures. So how small a facility could they
19 go down to reliably?

20 CO-CHAIR GAZELLE: So let's do
21 this vote. Again, we are going to be asking
22 you to vote for or against, for or against

1 recommending for endorsement, and what it is
2 for, measures 1, 3 and 4 with the two
3 modifications, that they would be reported by
4 decade age strata, and we would ask the
5 measure developer to come back and present
6 information about sample size, the likely
7 sample size, and statistical considerations,
8 if stratified by decade.

9 DR. BURSTIN: Just one other
10 possibility that might be perhaps not as messy
11 would be to actually ask a series of questions
12 to the measure developer we can feed back to
13 you and allow you to re-vote, and see if, in
14 fact -- I mean, you are sort of voting without
15 complete information.

16 CO-CHAIR GAZELLE: You think they
17 could answer those questions now?

18 DR. BURSTIN: No, not today. We
19 will give them a week or so to get back to us,
20 and the committee can easily do it on the
21 phone or e-mail. I am not sure you are going
22 to have enough information today to make an

1 informed decision, unless you feel strongly
2 they already know that information.

3 DR. D'ORSI: I agree.

4 CO-CHAIR GAZELLE: So should we go
5 take the vote first without the additional
6 information, since we had four people, five
7 people that switched over, and at least we
8 know how many people we are losing?

9 DR. RUCKER: But it will be faster
10 if you have the information. We can all vote
11 in a week.

12 CO-CHAIR GAZELLE: So this is what
13 -- Just so we can have this clear since it
14 will be coming by e-mail, what we are going to
15 do is we are going to propose -- We are going
16 to ask for the measure developer to give us
17 information on some likely sample size in the
18 cells, each strata, and then we would be
19 voting on the combination of the three, 1, 3
20 and 4, reported by decade age strata, and we
21 would be able to make that vote after we had
22 some indication of the effect that that would

1 have on statistical --

2 DR. BURSTIN: And how many strata.
3 There is a lot going on here.

4 CO-CHAIR GAZELLE: It would be 12
5 strata, four per measure -- four decades.

6 DR. BURSTIN: So from 50 -- I am
7 just trying to -- So 40 to 50 -- You need to
8 define that.

9 CO-CHAIR GAZELLE: Forty to 50, 50
10 to 60, 60 to 70, and 70 to 80. So one decade
11 -- So those would be the four strata. So what
12 we would like to know from the ACR is an
13 estimate of over, say, if we had it a year
14 reporting period, how many -- what would be
15 the precision of the estimates.

16 DR. SMITH-BINDMAN: And how many
17 facilities would or would not have sufficient
18 data?

19 MR. BACKUS: Is it data to
20 stratify 60 to 70 or are you really talking
21 about for usefulness of data? How many
22 stratifications do you need, and does it make

1 sense to break the line at 65 or 66, since
2 essentially that is where the Medicare data
3 comes into play.

4 My only concern with the
5 stratification is that, all of a sudden, so
6 now you are a 53-year-old woman, and you are
7 looking at where I should go to get a
8 mammogram, and now I am trying to look at that
9 center's data, and then, well, they are better
10 at 50-year-olds, but worse at forty-year-olds,
11 but good at 60-year-olds.

12 I just wonder to what degree you
13 start creating confusion in the general
14 public.

15 CO-CHAIR GAZELLE: Yes. My
16 argument against stratification would be
17 partly that a few of us in the room, and maybe
18 a number of people outside of the room having
19 discussed it, might understand why it is
20 valuable to do, but I think most people would
21 find it confusing.

22 I think, besides that, even though

1 there probably is a difference between the
2 numbers you would obtain in a pure, say, 40-
3 50-year age population and a pure, say, 70-80
4 age population, most practices are blended
5 populations. So that the true range of
6 variability is going to be a lot less than
7 comparing the two extremes.

8 So those would be the arguments
9 against stratification.

10 CO-CHAIR PETERSON: I would agree,
11 but if we are going to get numbers, we are
12 going to get -- Within each of these 12
13 strata, we are going to get the number per
14 hospital that would qualify for that measure.
15 Correct? That is what you were asking for.

16 So how many 50 to 60-year-olds
17 across the data they have -- how many? -- n is
18 that per 100? So that would be the range, and
19 they would give us 1000 to five cases within
20 each strata.

21 The other number that would be
22 somewhat valuable to see would be to see what

1 is actually the range and performance for that
2 measure for that metric, because that would,
3 in fact, inform the issue of do you need the
4 strata at all, because there isn't varying
5 from 50 to 60-year-olds.

6 CO-CHAIR GAZELLE: How much of
7 that would you be able to give us, do you
8 think? Well, one to two weeks, right, Helen?
9 Re-vote would need to be then.

10 DR. SMITH-BINDMAN: Do you have
11 data on performance for these facilities?

12 MS. BURLESON: So the issue is it
13 involves new. So the amount of facilities
14 that we have a full year just started this
15 year, and have a full year of outcome data for
16 some of this. But we won't have a full year
17 of outcome data until next year, even the year
18 following.

19 DR. SMITH-BINDMAN: So the data
20 that you are asking for from this source is
21 not available.

22 MR. BACKUS: So I guess the

1 question, to me, that comes back to the
2 committee then is are we comfortable in an
3 issue like breast cancer saying that, if we
4 don't have strata or the set of performance
5 measures, that we are willing to just let the
6 core combination of the three, which is
7 essentially good enough for a lot of Europe
8 and stuff to use as a basis for at least some
9 measure of reporting -- Are we willing to let
10 that measure die out until whatever the next
11 cycle is, two years, three years, four years.

12 DR. SMITH-BINDMAN: Versus using a
13 measure that we don't know the association of
14 quality.

15 MR. BACKUS: You know it is
16 directionally correct.

17 DR. D'ORSI: And we won't know
18 that even with stratification. Do you know
19 that with stratification, what the cancer
20 detection rate should be at 40 to 50?

21 DR. SMITH-BINDMAN: Yes.

22 DR. D'ORSI: Then you should know

1 it from 40 to 60.

2 DR. SMITH-BINDMAN: I do know it
3 from 40 to 60.

4 DR. D'ORSI: Then you should know
5 it from 40 to 90. You should know the whole
6 range.

7 DR. SMITH-BINDMAN: If you find
8 two cancers per thousand in a 40-year-old, you
9 are doing just fine. If you find one cancer
10 per thousand in a 28-year-old, you are doing
11 fine. If you find one cancer per thousand in
12 a 70-year-old, you are doing horrifically, and
13 I think averaging these measures gives you a
14 very meaningless summary.

15 DR. D'ORSI: Well, I agree with
16 you that, statistically speaking, you are
17 absolutely correct. Clinically speaking, I
18 don't think it is meaningless. It is often
19 meaningless, but I think you can group these
20 together in a reasonable range and still get
21 some performance metrics, but I understand
22 what you are saying. It is a much stricter

1 criteria, and you get some more information.

2 But I don't know if it is necessary for what
3 we are aiming at, at the NQF.

4 MR. BACKUS: This is Mike Backus.
5 See, your are hypothesizing, though, then
6 that, first, sites -- let's say they are doing
7 2000 exams, so that we are in the realm of
8 reasonable -- that there is significant enough
9 differential in the age of the patient
10 population to swing that data.

11 You think that -- I mean, I am
12 just hypothesizing, but I would guess that the
13 average center that is doing mammos, the
14 distribution of ages of the patients that they
15 see is very similar. Maybe that is an easy
16 piece of data.

17 If age is in the stratification,
18 maybe the easy piece of data that you can get
19 in one week or two weeks out of that MQSA or
20 whatever is look at the age distribution of
21 centers and see whether or not there is
22 statistically meaningful differentiation in

1 that age band.

2 CO-CHAIR GAZELLE: That would
3 answer the question as to whether or not
4 stratification is out there.

5 MR. BACKUS: Right. If there is
6 not --

7 DR. RUCKER: Don Rucker. There is
8 a lot of reason to believe it might be right.
9 If you are in someplace like Scranton,
10 Pennsylvania, where people are moving out on
11 a continuous basis versus Scottsdale, Arizona,
12 where that may have retirees in Phoenix that
13 is booming, you are going to have quite
14 different populations.

15 In places where there is more
16 Medicaid or more Medicare or something, you
17 are going to have very selective age mixes.

18 CO-CHAIR GAZELLE: It is an
19 answerable question. Right?

20 DR. RUCKER: Yes.

21 DR. GIBBONS: I will just offer
22 the thought that from Cleveland to Rochester,

1 Minnesota, to Jacksonville, Florida, Mayo to
2 Scottsdale, Arizona, Mayo, very different age
3 distributions.

4 DR. SMITH-BINDMAN: Give us some
5 magnitude to understand.

6 DR. GIBBONS: Oh, percentage of
7 people over Medicare is 30, 38; Scottsdale,
8 61; Jacksonville, 58.

9 MR. BACKUS: So you can give me
10 the outliers, but if I am the consumer, again,
11 or the public trying to interpret --

12 DR. SMITH-BINDMAN: No, but 30
13 versus 60 percent being old versus young.

14 MR. BACKUS: But if I am the
15 public trying to interpret this measure for
16 quality, I am not picking my mammo, should I
17 go to Scottsdale or should I go to Rochester.
18 I am like should I go to Sloan Kettering or
19 should I go to NYU.

20 DR. SMITH-BINDMAN: I think your
21 point is completely -- This is Rebecca Smith-
22 Bindman. I think you are raising a really

1 valid point. I think that, before we put it
2 out there as a measure, it would be nice to
3 have some sense of how much difference it
4 would make it. I think the narrower the
5 allowable that they decide the criteria should
6 be, the more important it is, and the broader
7 it is.

8 Your point is you want one
9 measure. So the ideal metric would be some
10 relationship within each age category
11 combined, but it would be nice to know that
12 from the data. Is there a big difference
13 based on the distribution of age?

14 DR. STILLMAN: This is Art
15 Stillman. Scott, you raise an issue about how
16 confusing it might be for patients having risk
17 stratified data. But I think, even more
18 confusing, at least for me -- I am confused --
19 is how we are going to be using three
20 different metrics that are coupled and use
21 that to rate different facilities, so that
22 patients know that they would rather go to

1 this facility rather than that one.

2 CO-CHAIR GAZELLE: Well, as I
3 understand it, we are not proposing a rating
4 mechanism. We are just proposing public
5 reporting.

6 DR. STILLMAN: But public
7 reporting doesn't happen in a vacuum. It is
8 going to be used for something.

9 CO-CHAIR GAZELLE: I would assume
10 that patients would do it and --

11 DR. STILLMAN: Well, but then it
12 needs to be something that is understandable
13 to a patient. It is not understandable to me.

14 CO-CHAIR GAZELLE: That would be
15 the basis on which you would vote then, I
16 suppose.

17 CO-CHAIR PETERSON: Okay. So we
18 have clarified what the request is. I think
19 at least we put in our request, and we say we
20 would want the Ns, range in hospital Ns, and
21 we would want -- secondly, would be the
22 average or mean age distribution for those

1 hospitals, how much variance there is among
2 hospitals.

3 DR. SMITH-BINDMAN: The mean or
4 median age?

5 CO-CHAIR GAZELLE: You would get
6 both.

7 CO-CHAIR PETERSON: Range and
8 mean.

9 CO-CHAIR GAZELLE: I mean, the
10 real question is within a given region.

11 DR. SMITH-BINDMAN: No. No, it
12 isn't.

13 CO-CHAIR GAZELLE: It isn't,
14 because again you want everybody in Florida to
15 go bad, because they are all on the bad side
16 of the score. So it is not going to be
17 popular.

18 DR. RUCKER: Don Rucker. It also
19 varies by practice within a city. Honestly,
20 within a city --

21 CO-CHAIR GAZELLE: Well, that is
22 the question.

1 DR. RUCKER: -- it is surreal.
2 Somebody made the point -- I think, Mike --
3 about, you know, you are not going to go to
4 Scottsdale or Rochester, but I think within a
5 city, you know, if you are in a clinic
6 situation or something that has some sort of
7 catchment mix, I think these things vary a
8 lot; and if we are asking people, even before
9 the confusion, which I am sort of also quite
10 confused, but even before the confusion, I
11 think it has to have just an intellectual
12 honesty about, if you made the effort of
13 understanding it, that this represents
14 reality, that this represents sort of total
15 stand-alone data.

16 MR. BACKUS: As you get down in
17 the city -- This is what I do all the time --
18 you know, the acuity of a practice is always
19 something -- For any practice that is an
20 outlier in utilization, the first discussion
21 is about the acuity of that practice's
22 patients.

1 I am just a fan of even getting
2 some version of a measure out there, and if
3 you say that your practice is different and
4 you can document it and things -- Remember,
5 you know, we have talked about there is a
6 range, and we are trying to look at the
7 outliers.

8 If you are really, truly that
9 outlier and you can really, truly document
10 that acuity or whatever that argument is, then
11 I think you've got a very valid explanation,
12 and there are things that make that practice
13 unique and understandable. But I think, until
14 we get at least some version of measures even
15 under discussion, we will just forever be in
16 conjecture.

17 DR. D'ORSI: Carl D'Orsi. One
18 other thing is feasibility. There are people
19 now who are on the edge of not doing
20 mammograms. So there is a possibility of an
21 access issue if we add more, which is the
22 three general measures. If we then ask for 12

1 strata, you are going to drive a lot of people
2 out, maybe for no good reason.

3 Even the three general conditions
4 are going to be difficult to get, even with an
5 electronic model or module, unless you go to
6 some organized database where you can get
7 feedback. If you have to do that by hand,
8 there is no way you are going to do it.

9 So this, on the feasibility side,
10 may be an impetus to drop access. I just
11 think we should keep this in the back of our
12 heads.

13 CO-CHAIR GAZELLE: So we have time
14 for maybe one or two, three more comments, and
15 then we are going to need to move on. So,
16 Troy, and then Judy.

17 DR. FIESINGER: I will be brief.
18 I agree. I think some measures would be
19 better than nothing. I think the
20 stratification will matter a lot if I am the
21 medical director, depending on my practice.

22 To me, as a physician, is it

1 important? Is it close enough to the patient
2 they can get there? Where was the patient's
3 last mammogram? That is really what I am
4 going by.

5 Kaiser Foundation did a great
6 study five years ago on whether patients use
7 quality measures to choose surgery and
8 physicians and hospitals. No. They ask their
9 neighbors and their friends, and I have seen
10 that true in five years of practice, which is
11 frustrating to NQF, but that is the reality.

12 DR. BURSTIN: The end user is not
13 just consumers. It is those who purchase care
14 on their behalf. It goes beyond just whether
15 an individual consumer can figure it out. So
16 just keep it really broad, and again, lots of
17 people -- The number one consumer of a lot of
18 the information on these various compare sites
19 are actually clinicians looking for stuff for
20 their patients. So don't limit ourselves to
21 thinking it would --

22 DR. GEMIGNANI: A brief comment

1 about the age stuff. I think that it would
2 make sense from my view to stratify it into
3 two age groups, under 65 and 65 and older,
4 because of the Medicare payer issue, and then
5 it is not too many different age categories.

6 I recognize that it is not perfect
7 in terms of where cancer is diagnosed, but in
8 terms of access it makes sense in that way.

9 I would absolutely second that I think these
10 measures are more used on the facility level
11 to say why are we a total outlier.

12 No one wants to look bad, and in
13 terms of payers and system issues, I think
14 that this moves quality that way, although it
15 is less understandable to an individual
16 patient.

17 CO-CHAIR GAZELLE: Thank you.

18 DR. SPENCER: Just to answer
19 Mike's question -- So I voted no, but if this
20 data is not available, I am not in favor of
21 seeing the measures die.

22 CO-CHAIR GAZELLE: You would vote

1 for it?

2 DR. SPENCER: Yes, if this data is
3 not available.

4 CO-CHAIR GAZELLE: If we couldn't
5 stratify it. Okay.

6 All right. I think, as hard as it
7 is to vote by e-mail because there is really
8 no opportunity for a dialogue that we can sit
9 and look at each other -- I think we have
10 probably had all the dialogue we can have
11 about this measure.

12 Clearly, there is a lot of
13 sentiment for this combination, and also a lot
14 of concerns about -- you know, the devil's in
15 the details sort of thing -- about how they
16 would be used and understood.

17 I think it is time now to move on
18 to the remaining mammo measure. So we are
19 going to go through the voting again, all four
20 levels plus an overall. Luckily, I don't
21 think we are going to propose to combine it
22 with others. So that part should be shorter.

1 So we are now voting on measure
2 009-10 mammography.

3 MR. CORBRIDGE: Scott, I hate to
4 just interrupt. Quickly, I forgot on the last
5 measure set, is anyone on the public line who
6 would like to make a comment?

7 CO-CHAIR GAZELLE: Is anyone still
8 on? Or anyone from the public, and I know we
9 have measure developers, but anyone from the
10 public that would like to make a comment
11 before we proceed to voting?

12 So we are going to go to 009-10,
13 mammography follow rate in the Medicare
14 population. I think, before we vote, we
15 should -- My sense was all agreed that it
16 should not be limited only to hospital
17 outpatients, that it should be -- So that
18 would be a condition we would propose.

19 We, I think, all agreed that there
20 wasn't a specific range that was going to be
21 part of this measure. So we are not voting on
22 a specific range so much as publicly reporting

1 all Medicare beneficiary hospital outpatient
2 and other facilities.

3 So we need to go by the four
4 categories ago. Importance: Who would --

5 DR. SPENCER: I'm sorry. With the
6 change we are voting, or without?

7 CO-CHAIR GAZELLE: With the
8 changes.

9 CO-CHAIR PETERSON: The changes
10 that we are going to do outpatient --
11 hospital and outpatient.

12 DR. BURSTIN: And the developer
13 has already agreed.

14 CO-CHAIR GAZELLE: Okay. So we
15 are voting on the importance of the measure
16 and report. We all have it. Who would give
17 it a High? Nine? Middle?

18 MR. CORBRIDGE: Ten.

19 CO-CHAIR GAZELLE: And Low?

20 MR. CORBRIDGE: One.

21 DR. FIESINGER: I voted High.

22 CO-CHAIR GAZELLE: Do we have an

1 abstention? Did somebody Abstain? Let's have
2 it again. High? How many Highs?

3 MR. CORBRIDGE: Still nine.

4 CO-CHAIR GAZELLE: How many
5 Middle?

6 MR. CORBRIDGE: Eleven.

7 CO-CHAIR GAZELLE: Good. Lows?
8 Good. Okay, now we are moving to the second
9 category, which is scientific acceptability of
10 the measure properties. High?

11 MR. CORBRIDGE: Six.

12 CO-CHAIR GAZELLE: Medium?
13 Middle?

14 MR. CORBRIDGE: Thirteen.

15 CO-CHAIR GAZELLE: And Low?

16 MR. CORBRIDGE: One.

17 CO-CHAIR GAZELLE: Next is
18 usability. High? We are talking about
19 usability. Feasibility is the next one. How
20 many want to vote High for usability.

21 MR. CORBRIDGE: Eight.

22 CO-CHAIR GAZELLE: Now Medium for

1 usability?

2 MR. CORBRIDGE: Twelve.

3 CO-CHAIR GAZELLE: Okay, no Lows.

4 And now feasibility. High for feasibility?

5 DR. RUCKER: This is just getting
6 it from Medicare data themselves. Right?

7 CO-CHAIR GAZELLE: Should be 20.

8 Okay. Now we are voting either to recommend
9 for endorsement or not to recommend for
10 endorsement.

11 DR. SMITH-BINDMAN: With the
12 condition.

13 CO-CHAIR GAZELLE: With the
14 condition which we talked about. Who would
15 like to vote for -- to recommend for
16 endorsement, with the condition meaning all
17 instead of just hospital? Four. No range,
18 yes.

19 MR. CORBRIDGE: Looks like nine.

20 CO-CHAIR GAZELLE: And who would
21 like to vote against recommending for
22 endorsement.

1 MR. CORBRIDGE: Eleven.

2 CO-CHAIR GAZELLE: No abstentions?

3 All right. We have finished the mammo.

4 DR. BURSTIN: Identical.

5 CO-CHAIR GAZELLE: Yes. Okay.

6 Yes, Don?

7 DR. RUCKER: Do we want to do
8 anything -- Some of this, I could imagine, is
9 on what we do with the other mammo in terms of
10 the overlap, or are we sort of saying there is
11 just no real overlap. I would be curious to
12 see, because the group of four, or group of
13 three mammo things -- I am just still --

14 DR. DEHN: I think we can
15 certainly do combinations, but I would just
16 ask on the last three, you would ask if there
17 was anything on their mind that we could
18 include that would change their mind. I would
19 ask, and we are entitled to that.

20 CO-CHAIR GAZELLE: Sure.

21 DR. SMITH-BINDMAN: The same as
22 the prior.

1 CO-CHAIR GAZELLE: The same as the
2 prior, yes. We talked about that with
3 conditions, but are there other conditions?

4 DR. SMITH-BINDMAN: Rebecca Smith
5 Bindman again. It would be nice -- I would be
6 more favorable to the measure if the results
7 were age stratified, and if there were some
8 validity data provided on the new Medicare CPT
9 codes.

10 CO-CHAIR GAZELLE: So the request
11 would be age stratification, and it would be--

12 DR. SMITH-BINDMAN: And it is less
13 than 40 in this measure, but there is no
14 reason not to have a 65 to 70 in this
15 population. It is less important than the
16 other one.

17 MR. BACKUS: How much do those
18 ranges change, the 65-70, 70 and 75, 75 above.
19 How much is that?

20 DR. SMITH-BINDMAN: There are two
21 reasons the recall rate changes. Partly, the
22 incidence of cancer, but that is a trivial

1 amount. Most of it is breast density
2 continues to decline, and so the false
3 positives just happen to go down a lot, not
4 the same rate as 40 to 80, but --

5 MR. BACKUS: What was the
6 discrepancies in screening and diagnostic?
7 What was the range in the code? The issue of
8 the accuracy of the code?

9 DR. SMITH-BINDMAN: For the old
10 code? About half of the screening exams were
11 coded as diagnostic. So my guess is the
12 purpose of these codes was to fix that
13 problem, but it was an enormous issue.

14 CO-CHAIR GAZELLE: So then, just
15 to be clear, I think we can all -- I am
16 presuming we can all agree that that is an
17 important piece of information we would like.

18 Let's take a quick look to ask for
19 how many people is stratification for the CMS
20 measure important? How many people feel that
21 that should be done? One, okay.

22 How many people feel that it

1 shouldn't be done. Then I think I am going to
2 ask how many people are neutral and how many
3 people feel that it shouldn't be done.

4 So how many people are neutral,
5 don't care one way or the other? And how many
6 people would prefer that it not be stratified?

7 MS. DaVANZO: I think Medicare
8 patients include -- presumably dominated by
9 the Medicare 65 and older. The disability
10 population doesn't consider it at all.

11 MR. GIBBONS: Mr. Chairman, just
12 to clarify. You said this condition of the
13 CPT codes was something everyone would accept.
14 I didn't accept it. That is why I was the
15 single low vote on scientific acceptability.

16 CO-CHAIR GAZELLE: No, the
17 question was whether or not we want to ask
18 them to provide that information.

19 MR. GIBBONS: Okay, but in terms
20 of the previous vote, that was the basis for
21 my low scientific acceptability vote.

22 CO-CHAIR GAZELLE: We are only

1 voting now on approve or no. So the question
2 is whether or not we would all like to have
3 that information, and I was just presuming we
4 would all like to have that information.

5 DR. SMITH-BINDMAN: In fact --
6 This is Rebecca Smith-Bindman. So the
7 information -- it doesn't have to be a perfect
8 reference standard. If you can show that the
9 distribution of current mammograms is about 90
10 percent with your screening code and 10
11 percent or 15 percent of your diagnostic code,
12 that would be consistent with the distribution
13 that I have --

14 DR. BURSTIN: The problem is you
15 just let that information flow back to the
16 committee. Again, it was equally split vote.

17 CO-CHAIR GAZELLE: Carl. Then
18 Don.

19 DR. D'ORSI: I just want to make a
20 point. We don't have to discuss it. Since
21 this metric is very close to what we think of
22 as follow-up rate or recall rate, I would

1 think we need the same kind of information
2 that we requested on the other recall rate;
3 and if CMS has a valid way to produce that
4 information, I think that would be nice, but
5 I am just saying that I know we are not
6 thinking of this with other metrics, but just
7 as a point of discussion, I think it becomes
8 not as relevant when you don't have that
9 information. It is very similar to recall
10 rate.

11 DR. GEMIGNANI: My only point, I
12 guess -- This is Mary Gemignani -- is that
13 this group is so uniform that you probably
14 have data on cancer detection rates already.
15 So you don't really need to collect it, as you
16 would in the other three measures, and this is
17 separate.

18 So I think that, when you have got
19 a recall rate within whatever center and you
20 wanted to evaluate it, you could get the
21 cancer detection rate, because of where the
22 data is coming from and the population that is

1 cited.

2 DR. D'ORSI: But I would like that
3 bundled in automatically, not that somebody
4 has to -- I would like it as a package, not
5 that this goes out and that somebody says,
6 okay, what is the cancer detection rate.

7 DR. DEHN: Carl, you would like us
8 to report out not only the indeterminate rate,
9 but also whether that indeterminate rate seems
10 to be generating more cancer.

11 DR. D'ORSI: And if you can -- I
12 don't know if you can get the type of cancer.

13 CO-CHAIR GAZELLE: Carl, I think
14 what you are proposing is another measure.

15 DR. D'ORSI: That is true. I said
16 it is not for discussion. I am just pointing
17 it out as a point of information that, to me,
18 it becomes not as relevant as when we discuss
19 recall rate. That is all.

20 CO-CHAIR GAZELLE: Okay.

21 DR. SMITH-BINDMAN: Can I just
22 give you numbers for the recall rate by age,

1 just because we talked about it.

2 The recall rates for women less
3 than 40 goes from nine, and it drops to 8 for
4 women in their fifties, 7 1/2 for women in
5 their sixties, and 6 1/2 for women in their
6 seventies. Those are the average.

7 MR. BACKUS: So the
8 stratification, though -- what you are saying,
9 if those are the recall rates -- I mean, the
10 stratification that you are talking about is -
11 - I mean, you are only going to move -- You
12 moving such a trivial --

13 DR. SMITH-BINDMAN: For the older
14 women, it is much smaller. For the young
15 woman, I think it is a much --

16 MR. BACKUS: Well, no, you said it
17 goes from like 9 to 8 to 7, 7.

18 DR. SMITH-BINDMAN: Six to nine is
19 a 50 percent difference based on --

20 MR. BACKUS: Understood. But so
21 if you think of a distribution of age of
22 people in the practice, now for that

1 stratification I would have to have -- A 10
2 percent or 15 percent change of old people to
3 young people within a practice will get ground
4 out in there, because I am looking at 15
5 percent on four. So I am looking at a half a
6 percent of recall rate.

7 DR. SMITH-BINDMAN: I think that
8 is why it matters whether you are talking
9 about coming up with really narrow ranges of
10 quality or really broad. At the really broad
11 ones, I completely agree with you. If you are
12 getting a narrow, we are talking about 10 to
13 fourteen.

14 DR. GEMIGNANI: We eliminated the
15 rate.

16 CO-CHAIR GAZELLE: We eliminated
17 the rate.

18 DR. GEMIGNANI: We weren't
19 thinking a rate. We were just going to
20 report.

21 CO-CHAIR GAZELLE: We are not
22 thinking a rate. All right. Just to tie up

1 the discussion on this, we had a split vote.
2 We are asking the measure developer to come
3 back to us with information on the accuracy of
4 coding screening versus diagnostic, and I
5 think we are of a mixed mind on
6 stratification, one person strongly in favor
7 of reporting the stratification, a handful of
8 people against it, and most people neutral.

9 So we will vote again on this as
10 well, Helen? Is that -- We will vote again
11 with the additional information on this, but
12 cement it in your memory.

13 We are going to now change
14 direction, and I am going to pass the gavel to
15 my colleague, and we are going to move to
16 measures number --

17 CO-CHAIR PETERSON: Measures
18 number 7 and 8. For those who are not aware,
19 one of our members is going to be leaving
20 tomorrow and will not be around in the
21 afternoon. So we might do these two measures,
22 and get through the day without him.

1 Some people didn't get 7 and 8.

2 DR. BRUETMAN: Based on the
3 discussion we had previously, I would like to
4 know from the committee if that information
5 that was requested, the stratification work to
6 be done and the new CPT codes were in the
7 range and would be accessible, would the
8 committee endorse it or not? The other --

9 CO-CHAIR GAZELLE: We are going to
10 vote again. We are going to vote again. We
11 are not going to make a commitment based on
12 information we don't have.

13 DR. BRUETMAN: I ask because the
14 other one, the age based, all those things
15 were endorsed.

16 CO-CHAIR GAZELLE: No, we didn't.
17 We didn't vote on either of them. We are just
18 asking for information, and going to vote
19 again by e-mail.

20 Okay, now we will move on to seven
21 and eight.

22 CO-CHAIR PETERSON: Seven and

1 eight. The measures are appropriate head CT
2 imaging in adults with mild to traumatic brain
3 injury.

4 So EP-007-10. Numerator is the
5 number of denominator patients who have a
6 documented indication consistent with the
7 clinical quality for mild traumatic brain
8 injury prior to imaging.

9 The denominator is the number of
10 adult patients undergoing head CT for trauma
11 and presenting within 24 hours of a non-
12 integrating head injury, which is Glasgow Coma
13 Scale.

14 DR. FORMAN: So just as background
15 for this --

16 DR. BURSTIN: Is the measure
17 developer here or available? The only issue
18 in us reviewing the measure in their absence
19 is they are having to be here tomorrow.

20 CO-CHAIR GAZELLE: And is somebody
21 from Brigham coming tomorrow? Do we know?

22 DR. BURSTIN: I don't know.

1 MR. CORBRIDGE: I haven't heard,
2 actually, if anyone is coming in person. They
3 may be on the phone, but I don't --

4 CO-CHAIR GAZELLE: Is there a way
5 to find out, because if they are not going to
6 be here anyway, then there is no reason to do
7 it today versus tomorrow.

8 DR. BURSTIN: Well, they would at
9 least be on the telephone.

10 CO-CHAIR GAZELLE: Can we do the
11 cardiac, start off with the cardiac?

12 CO-CHAIR PETERSON: The cardiac?
13 Well, the cardiac -- they are not here either.
14 What is the other? The third one is fine?

15 DR. SPENCER: Well, there are two
16 cardiac studies here now.

17 MR. CORBRIDGE: I can go place a
18 call with them to see if they are going to be
19 on the line early in the morning, and we could
20 run through this maybe right in the beginning.

21 DR. BURSTIN: We could do them
22 right now, if they could call us.

1 CO-CHAIR PETERSON: Shall we start
2 then?

3 DR. BURSTIN: Just call them, just
4 so that we would hate to have to rehash it if
5 they are not here.

6 (Whereupon, the foregoing matter
7 went off the record at 3:52 p.m. and resumed
8 at 3:57 p.m.)

9 CO-CHAIR PETERSON: Could we do
10 some very quickly?

11 DR. CANTRILL: It won't be so
12 fast. There is a lot of good stuff.

13 DR. ZERZAN: How about the
14 applicability of their ratings?

15 DR. CANTRILL: Applicability is an
16 issue, but I think, especially now with the
17 number of denials that people are seeing, they
18 are learning that they have to have an
19 ordering system that gives you not a process,
20 not rule-out, but an indication. That is
21 where this falls in with that very nicely.

22 All I need to do is give you one

1 reason, one thing that the patient has that is
2 consistent with that guideline, and then that
3 is success.

4 DR. ZERZAN: One is a guideline,
5 not quality. Is that linkage hard to find?
6 Everyone who knows computer order entry will
7 game, once they learn the right thing. So
8 proving that they really have that condition
9 is much harder.

10 DR. CANTRILL: That is true with
11 anything, without question, and they can be
12 gaming and can game almost anything, as we
13 have seen.

14 DR. ZERZAN: Absolutely.

15 DR. CANTRILL: Certainly, with a
16 lot of the guidelines.

17 DR. ZERZAN: With me, in my world,
18 people do it all the time. Then we change the
19 rule.

20 DR. CANTRILL: Are we just going
21 to give up and go home? I think that the
22 issue is overuse. There clearly is overuse in

1 head CTs. The question is how do we go about
2 addressing that issue. Do we just say order
3 less? What the hell does that mean?

4 Does that mean on Thursdays I
5 don't order head CTs or do I try to about it
6 in an organized fashion, looking at what we
7 have in the literature based on clinical
8 guidelines.

9 So they are guidelines that
10 address the patient population that we want to
11 address in terms of the emergency department,
12 and we look at graded literature, not to
13 someone's notions, not a consensus panel. So
14 this is done based on a guideline that is
15 pretty rigorous in the way it is put together.

16 Now I will also divulge, I was
17 part of the panel that put that together. I
18 have the scars to show for it, but I think
19 that this is a reasonable approach.

20 The CMS guideline -- all that is,
21 is a count. You know, how many head CTs did
22 you do per head. That doesn't get at the

1 issue. The issue how many appropriate or
2 inappropriate head CTs did you use.

3 That is where this, although, yes,
4 there are some difficulties with
5 applicability, I think that this really does
6 get to clinical medicine, not just someone
7 with a dull sword trying to cut down the
8 number of studies.

9 Other than that, I don't have
10 anything.

11 DR. FORMAN: He is calling in. So
12 I can give a preamble. I don't think he will
13 miss the preamble.

14 CO-CHAIR PETERSON: Okay, good.

15 DR. FORMAN: I think the preamble
16 about both of these are -- and I will state
17 for both of them first, both the CT and the
18 cervical spine CT in the setting of trauma, is
19 that there are good evidence based guidelines
20 in both cases.

21 There is evidence in the
22 literature, to begin with, that - both

1 evidence based guidelines -- that current
2 imaging far exceeds the evidence based
3 guidelines, and that there is evidence of
4 overuse, and perhaps the only limitation --
5 and we will go through it point by point, but
6 the only limitation for all of this is that
7 much of the evidence based guidelines were
8 first predicated on cervical spine
9 radiographic imaging, not necessarily cervical
10 spine computed tomographic imaging.

11 Cervical spine computed
12 tomographic imaging has been available for
13 both head and cervical spine for over 20
14 years, has been used. So we have very good
15 evidence that it is more sensitive than
16 radiographs in the detection of injury.

17 There is no evidence existing to
18 date, even anecdotally, that the incremental
19 cases that are picked up are actually -- that
20 affect outcome in a meaningful way, although
21 they are more sensitive, and they are useful
22 in the guidelines that have been presented.

1 So then starting with the
2 appropriate head CT in adults for mild
3 traumatic brain injury -- So the main reason
4 why I am just using that whole preamble is it
5 is not that CT has not been available 10 years
6 ago when many of these evidence based
7 guidelines were used. It is just that we were
8 still under the paradigm of using cervical
9 spine radiography.

10 Now in most practices, a lot of
11 the radiography has just migrated right over
12 to CT imaging. So it is just something to
13 consider in terms of judging the evidence.

14 Just starting with the importance
15 of the measure and, of course, in looking at
16 the demonstrated high impact aspect of health
17 care, it is an enormous part of both the
18 radiology practice as well as the emergency
19 room/trauma practice in head CTs and cervical
20 spine imaging in the setting of trauma.

21 So following down, I don't know if
22 we give the rating as I go alone. So as far

1 as high impact, I think you meet completely
2 the standards.

3 Opportunity for improvement:
4 There is also substantial evidence in the
5 literature of both the use of the CT head
6 rules in the setting of trauma and the fact
7 that, despite the fact that these rules have
8 existed for quite sometime, that there is
9 still excess use and considerable variability
10 in the use of head CT in the setting of
11 trauma.

12 So again, I would argue that for
13 this, more so than on the cervical spine,
14 there are still some questions. It meets
15 completely the opportunity for improvement
16 standard.

17 Under outcome our evidence to
18 support the measure, there is considerable
19 purity in the literature that goes way back.
20 Like I said, CT in the setting of trauma has
21 been used for well over -- probably into 30
22 years now, but really in broad usage for at

1 least 20 years, and really considerably bigger
2 usage over the last couple of decades as CT
3 imaging has been a lot quicker and easier to
4 do.

5 So there is the Canadian CT head
6 rule CTOHR, which has both been -- you know,
7 initially validated and then subsequent
8 studies were applied, and in the subsequent
9 studies, they compared that rule to the New
10 Orleans Criteria, and so that the Canadian CT
11 head rule was more specific overall, and that
12 both rules were 100 percent sensitive to
13 patients with injuries requiring intervention.

14 So overall, on that basis, again I
15 think it meets completely the standard of
16 outcome or evidence to support the measure
17 focus.

18 Then subsequently, the strength
19 and the quality evidence: Like I said, there
20 is considerable evidence, particularly on the
21 CT standard, and there really is no quarreling
22 about the previous applications, since

1 radiography for the head CTs has just been
2 doing head CTs throughout this entire period
3 of time.

4 Let me see what we are down to
5 then. I think we are up to number 2 now,
6 scientific acceptability of the measure
7 properties, bench specifications.

8 The numerator statement is
9 basically the number of denominator patients
10 who have had trauma, as we will define, who
11 meet the criteria for imaging prior to
12 imaging. It is basically affecting just the
13 initial visit, does not really include cases
14 of follow-up imaging in the setting of trauma
15 where either there is a known finding or a
16 questionable finding.

17 Then the listed indications that
18 you see below are from the evidence based
19 criteria, which either include loss of
20 consciousness or post-traumatic amnesia and at
21 least one of the following findings, as you
22 see below, and again I am on page 70 of this

1 guideline, patients without loss of
2 consciousness or post-traumatic amnesia, and
3 either severe headache or vomiting -- and it
4 goes on, age over 65, etcetera.

5 We said the denominator is all
6 those that present in the setting of trauma.

7 DR. CANTRILL: I think there is a
8 typo there. I think the denominator is
9 supposed to be people with GCS greater than or
10 equal to 14.

11 DR. FORMAN: Oh, okay. I didn't
12 know that.

13 DR. CANTRILL: Right. By reading
14 it very carefully --

15 DR. BELLO: Comparing it with the
16 one at the top.

17 DR. FORMAN: Yes. There is a
18 definite little typo in line 1.

19 Okay. So what are we up to now.
20 And the denominator exclusions are listed
21 here. And I think that is it for 2(a).

22 I think we are on 2(b). So

1 reliability testing: There is evidence on all
2 this, and it has been validated, although I
3 believe that they are -- well maybe it is just
4 the c. spine one that they are actually
5 undergoing validity testing right now as well.

6 So I think, actually, on the
7 reliability testing you do have -- it does
8 meet completely the standard for reliability
9 testing. Right?

10 DR. RUCKER: Are you talking about
11 7 or 8?

12 DR. FORMAN: I am on 7. Yes.
13 Same thing for validity testing. They are not
14 presenting validity testing. So I don't know
15 what -- I guess I need some guidance on that.
16 They have -- These measures have been tested
17 over and over. I mean, we have the 2005
18 paper, a comparison of the Canadian CT head
19 rule and the New Orleans Criteria.

20 So what level do you need to
21 actually judge something that is being ruled
22 as valid when you have already done a

1 validation study?

2 DR. BURSTIN: Those are research
3 studies, and the difference would be this
4 would be in real practice. Can you reliably
5 collect these data elements, they are saying
6 here, either in terms of paperwork or
7 electronically.

8 DR. CANTRILL: Several of those
9 studies, in fact, are from their practice.

10 DR. BURSTIN: Oh, good. That is
11 good to know. It is not clear. This would be
12 the kind of thing we would love to have --

13 DR. SMITH-BINDMAN: The data
14 weren't collected for the research project.
15 They were collected from routine clinical
16 practice?

17 DR. CANTRILL: Some were,
18 especially if you look at some of the Dutch.
19 They have a very good registry, and they did
20 everybody for a period of time.

21 DR. RUCKER: This was a
22 prospective research study? It is not?

1 DR. CANTRILL: This? Well, this
2 is the culmination of a lot of - multiple
3 sites in terms of the setting of the criteria.
4 Now I don't know if Jay in terms of his work -
5 - I don't know if he did a study on this or
6 not.

7 DR. GEMIGNANI: This is Judy.
8 What is the range? You know, if people
9 measure it, what do you get out of that, which
10 wasn't clear from this measure. What are you
11 measuring? What is an appropriate -- You
12 know, presumably they have applied this to
13 their practice, and so they have a range of 10
14 percent or --

15 DR. FORMAN: Ten percent that are
16 outside the guidelines?

17 DR. GEMIGNANI: Right.

18 DR. FORMAN: Okay.

19 DR. GEMIGNANI: You know, there is
20 no -- It is hard to figure out what they mean
21 by their ratio and what gives you.

22 DR. RAKSIN: This is Patti. This

1 is going to come up tomorrow. It came from
2 the Brigham. It is the same issue of what
3 you are really assessing here is adherence to
4 a single clinical guideline, and what kind of
5 QI initiative is that, really.

6 DR. BELLO: My interpretation --
7 This is Jacqueline Bello. My interpretation
8 of it was that range in the sphere of overuse
9 and efficiency, that the ratio would tell us
10 what percentage of the gazillion CT scans that
11 you are doing from that ER are actually
12 meeting some criteria.

13 So, back-pedaling, they go and
14 they evaluated the Canadian head criteria, the
15 New Orleans Criteria, and then came up with
16 this nice little A set list which they
17 published, which is a collaboration of
18 radiologists, ER physicians, and others.

19 So once we know how many of your
20 gazillion head CTs would really meet these
21 criteria, and they are trying to balance it
22 with "and, no, we are not being dangerous,

1 because you have to have a Glasgow Coma Scale
2 of 14 or better," so we are not talking about
3 not scanning the comatose -- No, their
4 implication is -- Well, that is another issue,
5 I guess. But anyway, their implication is
6 that may be somewhere between -- they say 37
7 percent scans could be deemed as overuse.

8 So the measure is to get a handle
9 on, institution by institution, ideally,
10 whether the number of scans you are actually
11 doing meet any criteria at all. In today's
12 operations, it has got the balance of the
13 radiation use and, other than the dollar,
14 attached to it.

15 DR. CANTRILL: What is really
16 going to happen -- you all know this; anyone
17 who practices clinical medicine. It is the
18 Hawthorne effect. We start looking at this,
19 and the numbers are going to drop
20 dramatically.

21 When I am told, well, they are
22 going to be looking to see for every head game

1 that they have at least got something -- you
2 know, show me something in this guideline.
3 Then suddenly you are going to start seeing
4 adherence, and your number of head CTs is
5 going to drop or at least the rate of climb is
6 going to slow.

7 So that really -- So it is going
8 to be very hard to say, well, look at the
9 quality that we have given here. We don't
10 have a baseline. If we could sneak in there
11 right now and get a baseline across different
12 institutions and then put this in place, then
13 we could say look at what we have done.

14 DR. RAKSIN: Patti again. I think
15 this is going to come up again tomorrow as
16 well. The other thing that is missing here is
17 we don't know how many positives show up out
18 of the ones that don't have indications. That
19 is part of you need to really understand
20 overutilization.

21 DR. SMITH-BINDMAN: Although --
22 This is Rebecca Smith-Bindman. What the

1 writers have said is they have cited
2 guidelines that have 100 percent -- I am not
3 defending this, but I am saying in application
4 we have a guideline that you know are not
5 going to miss anything significant. Then you
6 can just start looking at adherence to the
7 guideline. You don't need to worry about the
8 primary misses that you are asking about.

9 DR. CANTRILL: If you really want
10 to understand that -- Steve Cantrill -- you
11 need to understand the evidentiary table that
12 goes along with this guideline, which is about
13 16 or 17 pages long. It goes into detail of
14 the evaluation of all the different papers,
15 and that is how -- We agonized over that. We
16 really did, in terms of -- because no one
17 wants to miss a -- But you can't, by the same
18 token, head buzz everyone who walks in the
19 door. So you use random criteria or no
20 criteria or you try to be somewhat scientific.

21 DR. FORMAN: Can I just finish up
22 a couple of other points, just to add on there

1 as somebody who practices in the environment
2 of trauma imaging for 15 years right now.

3 I agree with you fully, but I
4 actually think that a guideline put into place
5 appropriately will influence practice. It
6 will influence the adoption of computerized
7 physician order entry. It will have so many
8 external effects that will be favorable to the
9 overall system that, without overdoing the
10 pun, this is a no-brainer to me.

11 I think you really -- You know,
12 the opportunity here is to take something --
13 This is, to me, like aspirin after MI. It is
14 something where you try to find institutions
15 that come very close to 100 percent compliance
16 with the guidelines.

17 Now there is no question, we will
18 find a certain degree of gaming by physicians
19 that are ordering. They are going to remember
20 a few symptoms that they have to put in there.
21 That is the only way they are going to get it,
22 and they are going to improvise about whether

1 it was really a high impact collision with,
2 you know, intrusion of more than 18 inches or
3 whatever the criteria are to make a major high
4 impact accident. But I do think that you will
5 actually -- because they have these very
6 specific criteria.

7 I do think that you will have an
8 opportunity to really impact and improve care,
9 just by a relatively simple guideline. I
10 would say you go in academic institutions; you
11 find very -- Well, I won't say important
12 clients -- you have some people with excellent
13 clients who are telling you precisely why they
14 are ordering a head CT on everyone, and as we
15 have joked since I was trained at Wash U 20
16 years ago, that the indications for a head CT
17 is if you have a head.

18 DR. CANTRILL: And we prefer a
19 pulse as well.

20 DR. RAKSIN: Two other things.
21 Having said what I said earlier, there are
22 indications for ordering a head Ct are pretty

1 loose and far encompassing. So virtually
2 anyone who has a headache, who has a head,
3 would qualify for a head CT scan criteria.

4 DR. FORMAN: I am not sure about
5 the -- I mean, they show applications --

6 DR. RAKSIN: Right. The other
7 thing was that I think we have to ask the
8 developers has to do with the definition of
9 mild traumatic brain injury and who they are
10 actually including, because traditionally,
11 the GCS is 13 or 14 or 15, and they seem to
12 have excluded the 13s.

13 CO-CHAIR PETERSON: So can we get
14 back? I am just going to keep a little -- We
15 have got a lot of discussion going on. I
16 believe you are at -- You have gone down
17 through reliability. Are you at reliability?

18 DR. FORMAN: I was, and then I
19 backed up. So let me get back to that.

20 DR. BURSTIN: The measure came in
21 as non-tested. So it will be time-limited.

22 DR. FORMAN: Okay. So let's go to

1 -- We can skip over SC analysis, and there is
2 some degree of evidence supporting exclusions.
3 They mainly point out the populations that
4 weren't included in the previous studies,
5 because they were either perceived to be a
6 virus with serious injury or indicates a
7 pregnancy, either concerns with radiation
8 exposure to the fetus. So I felt those were
9 at least either partially or completely
10 supportive based on the evidence that we have.

11 No risk and non-applicable for
12 risk adjusted for outcomes in equal difference
13 in performance, I think, we are not
14 evaluating.

15 Overall, to what extent is the
16 criteria of scientific acceptability of the
17 measure properties met? I would say
18 completely, notwithstanding the small groups.

19 Then on the usability, whether it
20 is meaningful, understandable, and useful
21 information, still undergoing current testing.
22 So we don't really know what the findings will

1 be from various institutions, but we would
2 imagine that it would be along the spectrum of
3 like it did with aspirin where you have a
4 percent compliant with the guidelines, and
5 that it would probably be less than 100 --
6 obviously, be less than 100 percent.

7 These institutions will have some
8 latitude within the guidelines where other
9 measures may be taken, but in general, it
10 would be that type of measure.

11 No harmonization, because there is
12 no prior guidelines at NQF.

13 So to what extent was the criteria
14 usability met? You know, I would say at least
15 partially in the absence of actual
16 applicability and data.

17 Under feasibility, this is
18 probably the most contentious issue, and this
19 is, I think, the challenge. I don't know
20 where the group comes down on this, but I will
21 tell you, feasibility-wise these are not easy
22 to institute in terms of capturing the

1 information.

2 This is not dissimilar in terms of
3 getting the information from PQRI and the
4 Physicians Quality Reporting Initiative, and
5 I can tell you that, even a huge practice like
6 we have at Yale, if you don't have well
7 coordinated, computerized physician order
8 entry and coordinated with data collection, it
9 is an administrative burden.

10 It is possible, and I think it is
11 possible for everybody to use, but how you
12 define usability is an open question. I would
13 say that, on this count at least, one would
14 have to say partially.

15 You know, how are the data
16 measures generated? I think it is a by-
17 product of care processes, but it is not
18 easily generated. It is not necessarily
19 captured automatically, and you will find, I
20 think, that at smaller institutions, which is
21 where the majority of patients are cared for,
22 it may be more difficult to capture that

1 information.

2 They mention computerized
3 physician order entry, and I think that that
4 is the way to do the validation studies, and
5 it certainly is the future of being able to
6 use a measure like this, but I think this is
7 the only limitation around the measure itself.

8 DR. SMITH-BINDMAN: Can I ask you
9 a question. this is Rebecca Smith-Bindman.
10 When you say the feasibility, I think what
11 they are saying is that, if you have ordered
12 a head CT and you have ordered it for mild
13 traumatic brain injury, then you need one of
14 these indications.

15 So you need two steps. You need
16 defining the patient population, and within
17 that population defining the category.

18 DR. FORMAN: Right.

19 DR. SMITH-BINDMAN: Is that
20 feasible within the data order entry? The
21 specific category, I get, so vomiting or not
22 vomiting.

1 DR. FORMAN: Right.

2 DR. SMITH-BINDMAN: But the
3 denominator -- is that possible at Yale?

4 DR. FORMAN: The denominator is
5 stated as a positive finding of --

6 DR. SMITH-BINDMAN: No, mild
7 traumatic brain injury.

8 DR. FORMAN: That is a clinical
9 finding, mild traumatic brain injury.

10 DR. SMITH-BINDMAN: Right. So I
11 don't know if this is defined from the
12 radiology point of view, from the data that
13 the radiologist could have had access to, or--

14 DR. RAKSIN: It is probably --
15 What happens at our institution is that,
16 especially in trauma or in the emergency
17 department, it is the emergency room physician
18 who is ordering the study who has to list an
19 indication for the study.

20 Now sometimes they will, in their
21 indications, put mild TBI rather than headache
22 or nausea and vomiting. So that is an

1 education issue, but I know that we certainly
2 do our share of trauma head CTs, and for us
3 data collection in the trauma unit -- we are
4 not computerized in the emergency department.

5 CO-CHAIR GAZELLE: Even in the
6 measure as submitted, 4(b).2, it says "All
7 data elements are not likely to be available
8 electronically to most providers currently.
9 Although many electronic health records
10 include CPOE, most are not programmed to have"
11 -- and they go on to say how they are doing it
12 at the Brigham and this and that.

13 They say it would be technically
14 feasible to reprogram the system to do this.
15 Then they go on to say that it would also be
16 possible to do chart review, but that is not
17 likely to be useful, since a lot of times the
18 information isn't in the chart at the time,
19 and it is not feasible.

20 So I think this is the Achilles
21 heel of this measure, if it can only be done
22 at a small handful of institutions.

1 DR. RUCKER: It is not that they
2 actually use their core HIS system to do this.
3 Right? This is a stand-alone separate order
4 entry system, is my understanding of it, that
5 was custom built for this. So this is not --

6 DR. FORMAN: But integrates with
7 their --

8 DR. RUCKER: It may integrate, but
9 it is not like they used a commercial CPOE
10 system and quote/unquote "reprogrammed it."
11 This is a hand-built custom system.

12 DR. GRIFFEY: Actually, no. I
13 work there. So I know that they use a
14 Precipio proprietary system for CPO. It sits
15 on top.

16 CO-CHAIR GAZELLE: No, no. They
17 built the interface between that and the
18 electronic medical records system. That is
19 what they built.

20 DR. GRIFFEY: I think that is
21 right. No, I agree with you. I think it is
22 a great measure, but the difficult piece of it

1 is this piece, and they talk about putting
2 together a template to try to collect this
3 data, and your concern, I think was how do you
4 define the denominator. Is that right?

5 DR. SMITH-BINDMAN: Right. If it
6 is two separate populations, one is an ED
7 defined variable. The other is a radiology
8 defined variable. I am not sure if --

9 DR. GRIFFEY: You would have to
10 use the ED defined variable, I would think,
11 and it would have to -- Typically, the
12 indication almost never is going to say, you
13 know, TBI. It is going to say evaluate for
14 intracranial hemorrhage or --

15 DR. SMITH-BINDMAN: Right.

16 CO-CHAIR PETERSON: So this
17 system, a proprietary system that does measure
18 this, is proprietary to? Who owns that?

19 CO-CHAIR GAZELLE: It was
20 developed at the Brigham, and it is now
21 licensed to a company that you can buy. That
22 is the order entry system, but the interface

1 between the order entry system and the
2 electronic medical record is a Brigham system.

3 CO-CHAIR PETERSON: Okay. So is
4 there other proprietary systems out in the
5 market, other than this one, that would allow
6 you to measure this measure?

7 CO-CHAIR GAZELLE: There is one
8 other one, but again you would need to develop
9 the interface between that one and the medical
10 record system.

11 DR. CANTRILL: You don't need a
12 computerized system. You can do this
13 manually. It might require some work, but you
14 can get it. We don't need to worry about
15 proprietary systems.

16 I think the other issue is what
17 direction do we want to push American medicine
18 in? This is the direction. We would like to
19 have studies done for a valid indication, and
20 we would like to have the appropriate
21 information conveyed to the radiologist. Does
22 this push us in that direction?

1 DR. SMITH-BINDMAN: What would
2 this system be, just to understand this.
3 someone has to define it.

4 DR. CANTRILL: We are working on a
5 paper system right now that we would be able
6 to use.

7 DR. SMITH-BINDMAN: So just walk
8 me through how you would do this with paper.

9 DR. CANTRILL: Sure. Well, it is
10 partially computerized, but I click on the
11 patient's name, and I said I want to order a
12 CT, and then it says what are the indications,
13 altered mental status, whatever and listing
14 the mechanism, and what study do I want. I
15 want a head CT. And what am I trying to rule
16 out? I am trying to rule out intracranial
17 hemorrhage.

18 Then that has all the necessary
19 information on it, and that goes to our
20 radiologist.

21 CO-CHAIR PETERSON: So how could
22 you get it out of that to somebody to do NQF

1 reporting?

2 DR. CANTRILL: Well, as was
3 pointed out, that is the tough question here.

4 CO-CHAIR PETERSON: So, currently,
5 the only way that that could be done -- that
6 is what I am getting back to, using one or two
7 proprietary systems, one developed by the
8 persons putting forth this measure -- just
9 bringing this out. That is pretty clear.
10 This would generate a large market.

11 DR. BURSTIN: Just to be fair,
12 what they are actually putting forward is --
13 There was an attachment as well and a link to
14 their website. It is actually really a paper
15 based chart reporting.

16 They are indicating they can
17 collect this electronically using their
18 system, but they are putting it forward as any
19 other process measure which you need to go to
20 the chart to collect the data, and currently
21 we don't have reliability capabilities to this
22 measure. It could only go forward as for time

1 limited endorsement, since the measure has not
2 been tested.

3 We don't know, for example, how
4 well that paper form performs. How often can
5 you -- Just looking at the extra data here,
6 how often can you find evidence of a sticky
7 one, short term memory deficit, clearly
8 indicated in the chart?

9 That is what I think the time-
10 limited endorsement period is for, is to look
11 toward that.

12 CO-CHAIR GAZELLE: I am with you,
13 Steve, on the importance of pushing American
14 medicine to get to this. I just think that,
15 for us to vote to recommend for endorsement a
16 measure where it can't be done now, is too
17 early.

18 DR. FORMAN: It is relative. We
19 have been doing PQRI, which is not dissimilar
20 to this. For radiology PQRI has been a paper,
21 completely paper based --

22 DR. SMITH-BINDMAN: Can you give

1 us an example?

2 DR. FORMAN: On our head CTs --
3 and I can get the exact measure; you all may
4 remember it -- we have to put down the time
5 the patient hit the emergency room and the
6 time they did the study, and whether we
7 documented it as an intracranial mass,
8 hemorrhage or shift.

9 DR. D'ORSI: But what percentages
10 of practices are participating in PQRI?

11 DR. FORMAN: Not a lot. I don't
12 know. A minority.

13 DR. BURSTIN: But we can. Fifteen
14 to 18 percent.

15 DR. CANTRILL: How about the
16 concept of sampling? We haven't discussed
17 that. Is that an acceptable approach here?
18 So you are not doing 100 percent, but you are
19 doing a specific sampling, and that gets away
20 from some of your concerns.

21 I hate to see a good idea really
22 turned off, because we don't think we can do

1 it. How can we maybe get this thing so it
2 might be acceptable?

3 DR. RUCKER: Don Rucker. I think
4 one of the challenges with this, and sort of
5 follow the stuff above the neck, the neck and
6 above as opposed to the knee and ankle and
7 maybe heart. You know, it is sort of in the
8 definition.

9 So, for example, a Glasgow Coma
10 Scale of 14 is something where the person is
11 potentially messed up and can't hold a job
12 again. I understand it could go away tomorrow
13 or later in the day or when they are sober,
14 but if you came to me with a Glasgow Coma
15 Scale of 14, there is some potential serious,
16 life altering deficit there that, I think, in
17 this particular thing -- again, this could be
18 in the comment -- that needs to be shown.

19 Then when you get to --

20 DR. GRIFFEY: But, Don, if someone
21 had a life altering injury like that, you
22 would hope to have seen one of these other

1 elements there, and that is what those other
2 studies addressed and bore out.

3 DR. RAKSIN: There are so many
4 reasons that someone might be a 14, I mean, he
5 might be an adult football player.

6 DR. RUCKER: I understand you can
7 find counter-examples, but I am just saying
8 that, when you have somebody who has a neuro-
9 deficit, for whatever reason, I think -- and
10 certainly in the emergency department setting,
11 that is something you have to give some
12 significant benefit of doubt to.

13 I think the other issue is severe
14 headache without loss of consciousness or
15 post-traumatic amnesia and severe headache.
16 I mean, many of these people come in with
17 severe headache, the number of worst headaches
18 in their life. I mean, we all do.

19 DR. RAKSIN: That is a different
20 measure.

21 DR. SETZEN: What about the person
22 who hit his head walking down the street, hit

1 it on the side, didn't have loss of
2 consciousness, and GCS is over -- you know,
3 is normal. Those are the ones you are trying
4 to get rid of. Right? All the BS. Right?
5 So that is the value.

6 DR. RUCKER: I understand that,
7 but I am just saying, if you have severe
8 headache, this is a very judgmental -- It is
9 a very judgmental standard.

10 DR. CANTRILL: But, Don, you know,
11 we are not worrying about those. We are not
12 even into the gray zone. They are the stuff
13 that, you know, this shouldn't even see the
14 inside of a department of radiology. You guys
15 never seen those, right? Every day.

16 DR. FORMAN: No.

17 DR. GEMIGNANI: Actually, I would
18 say that, contrary to the one that will be
19 about the headaches tomorrow, this one at
20 least has evidence, and it has got really good
21 studies, better than others. It is hard to
22 measure, which is the hard part of this, but

1 I would say that out of our options, this is
2 one very obvious place that there is overuse,
3 and that there is good evidence that there is
4 overuse.

5 CO-CHAIR PETERSON: Any other
6 comments?

7 DR. STILLMAN: I have a question
8 which reflects my ignorance perhaps. How
9 reliable do we think the Glasgow Score is in
10 the medical record to be extracted or is it
11 going to be in there in some other form? So
12 if we have a cutoff for a metric, then we
13 should be able to pull out a score and make
14 sure that it is there.

15 DR. FORMAN: There are
16 institutions who reliably document anybody
17 below 15. So it is pretty reliable.

18 DR. GRIFFEY: If it is not there
19 now, it would be when you went to get the
20 measure or else it would probably fail the
21 measure.

22 DR. RUCKER: It should be. It is

1 not like -- Take an Apgar score. It is really
2 something that --

3 DR. STILLMAN: So anybody who
4 walks in the emergency department with mild
5 head trauma will have a Glasgow Score in the
6 record?

7 DR. RUCKER: Yes.

8 DR. CANTRILL: As soon as this
9 becomes part of a measure, it will be in the
10 record.

11 DR. RUCKER: I think -- I am not
12 sure about that, because I think a lot of
13 times what is in the chart is the actual
14 lesion, depending on how severe the thing is.
15 You have an XYZ in the scan or you don't.

16 If you look at people who are hand
17 scanned in these traumas now, all that -- I
18 mean, there is sort of a crowd that is getting
19 the major trauma. This is what I was getting
20 at, the walkie-talkie crowd. I am not sure
21 these people have Glasgow Coma Scores.

22 DR. FORMAN: They should. Look at

1 the nurse's notes.

2 DR. RAKSIN: They do. It is part
3 of a primary trauma survey where a patient
4 comes to the resuscitation -- Granted, if they
5 are a walkie-talkie, they are a 14 or a 15,
6 but that is part of what is documented for
7 every patient that comes through the trauma
8 center.

9 DR. RUCKER: Well, we are trying
10 to improve the trauma center per se.

11 CO-CHAIR PETERSON: Mike, you had
12 a comment.

13 MR. BACKUS: Yes. The only thing
14 -- You know, we are in the radiology benefit
15 management area, and we do outpatient preop,
16 and every insurance plan comes to us and says,
17 well, what are you going to do about the ED.
18 What can you do about the ED?

19 You know, we have looked at it a
20 lot, and from a straight preop perspective,
21 there is not a ton that you can do. I
22 completely agree that you will generate

1 Hawthorne Effect here by saying that you are
2 going to look at it, and I agree with that
3 completely as well.

4 I think that the really tough
5 piece is, if I compare it to the breast stuff
6 that we just talked about where you have kind
7 of this mandatory BIRAD and the data is easily
8 extractable -- you know, CMS's stuff is easily
9 extractable out of the claims and everything.

10 I think I completely agree with
11 the measure, and I have no issues or basis to
12 have issues with the scientific judgment of
13 them. The data collection is just so, so
14 tough for me on this one.

15 If you are running a Medicalis or
16 a Precipio or whatever, you can get it. I
17 think, as a national body, that becomes very
18 tough. To me, it is like an unfunded mandate.

19 You know, we want to be taken
20 seriously in the provider community, and
21 accepted; and to say, oh, we want you to do
22 this and, by the way, all the ED physicians

1 got to work with a piece of paper now, and you
2 got to fill this thing out; you are going to
3 send it in, and we somehow going to get the
4 stuff in Excel and pull it together, it
5 becomes very expensive.

6 All that said, I would love to see
7 progress made on the measure in some method,
8 because what you are getting at -- and we have
9 all made jokes about the ED -- I mean, the
10 running one in our shop is that the door to
11 the ED is not a set of bifolds; it is a tube.

12 So I am hugely in favor of the --
13 I am huge in favor of doing something down the
14 road.

15 DR. MECHTLER: Without being
16 selfish, I am very pleased we are not talking
17 about mammograms.

18 My issue at this stage is that the
19 Glasgow Coma Scale, among neurologists, is
20 really a poor -- poorly associated with mild -
21 - moderate and severe maybe more, but mild
22 head trauma.

1 A couple of issues that I have is:
2 (a) in the previous discussions we have looked
3 at EDs, but then a comment was made that we
4 may look at outpatient facilities. Let's be
5 fair. Nobody does CT in outpatient facilities
6 for mild head trauma. So the science has gone
7 in a different direction.

8 We are looking at ERs or EDs that
9 have 24/7 MRI right now. I am very
10 interested, and I agree there is over-
11 utilization of imaging in EDs and outside of
12 EDs. The real question in my mind is, if we
13 put these rules for CT, would you think, with
14 mild head trauma, that the frequency of MRI
15 may increase in emergency room 24/7 coverage?

16 The other issue may be that it has
17 in outpatient. If this discussion here is
18 going to not only represent for ED but will be
19 at freestanding centers, hospital imaging
20 centers off-campus, then I promise you that in
21 our practice we actually have the largest
22 neuroscience center in the country. We see

1 130,000 patients a year, and our CT numbers
2 are decreasing with MR increasing, and we have
3 both modalities within the facility.

4 So the reality is MRI in
5 tomorrow's discussion for headache and mild
6 head trauma -- I mean, that has to be on the
7 table also, the evaluation and utilization of
8 MRI and CT.

9 DR. CANTRILL: Steve Cantrill. I
10 think you bring up a valid point, but I don't
11 think it is our concern in the immediate
12 future. I can get a head CT in 18 seconds.
13 I can get a head MRI in 45 minutes. That is
14 after I go through 27 different hoops.

15 So that is not going to happen
16 very soon.

17 DR. MECHTLER: We have trauma
18 protocols less than 15 minutes. We do.

19 DR. CANTRILL: Say 15 minutes, 15
20 seconds.

21 DR. MECHTLER: Of mild head
22 trauma.

1 DR. BELLO: I think the other
2 issue is -- Jacqueline Bello. I think the
3 other issue is the monitoring through the
4 study and the other CT scans in a trauma
5 setting that that same patient is getting.

6 So we are here to discuss
7 efficiency. Way before you start sending the
8 patient to four different ZIP Codes, they are
9 going to see CAT anyway for the chest. They
10 get a CT of the head.

11 So I really think that we are
12 stuck, like it or not, with a CT. I also
13 really think that we bear the burden of having
14 some sense of responsibility when it comes to
15 the repeated radiation dose. Yes, this starts
16 at 16; so we are not going to say the 10-year-
17 olds, but I take an ER shift every month, and
18 there are people who come in from nursing
19 homes once a month, because they have fallen
20 at the nursing home -- instant CT of the head
21 and C-5, and these are patients who -- They
22 are unchanged over 12 months, and hello,

1 Medicare, you know. I mean, these are there.
2 They are not going to die of the radiation
3 dose, but they are going to kill our medical
4 system.

5 DR. SPENCER: But they get a scan
6 if they are over 60.

7 DR. FIESINGER: Troy Fiesinger.
8 Just a technical question. In the numerator
9 it says mild traumatic brain injury, in the
10 denominator nonpenetrating head injury. Are
11 those equivalent terms or synonymous terms?

12 DR. BELLO: No.

13 DR. FIESINGER: Because it is a
14 technical problem. It may be a minor one, but
15 using two different terms -- We are arguing
16 about definitions.

17 DR. BELLOW: No. It is an
18 additional requirement. Once it is
19 penetrating, it doesn't matter --

20 DR. FIESINGER: Right, but the
21 language should be the same in the numerator
22 and denominator and not different between the

1 two.

2 DR. GIBBONS: I think I feel
3 totally ignorant in terms of this discussion
4 of feasibility with respect to a couple of
5 things, and maybe some of the people in the
6 room can clarify this, which is: (1) the
7 actual current level of penetration of
8 electronic medical records into emergency
9 rooms which, at least in our area of the
10 country, is clearly lower than the rest of the
11 medical system; (2) whether insurers have
12 already tried to do something about this with
13 respect to indications, and that might include
14 CMS, which at least as I have asked questions
15 over the years regarding chest pain, some of
16 the things that are done in the outpatient
17 sphere seem to be handled so differently
18 administratively within emergency care that it
19 is like a mystery to me.

20 So maybe other people in the room
21 could shed light on that.

22 CO-CHAIR PETERSON: Clarify the --

1 What you are asking for the EHR is how many
2 could do this measure?

3 DR. GIBBONS: Yes, or how many
4 even have an EHR currently in --

5 CO-CHAIR PETERSON: And a CPOE
6 system that has indications.

7 DR. GIBBONS: Yes. In an emergency
8 room setting.

9 CO-CHAIR PETERSON: Less than 15
10 percent.

11 DR. FIESINGER: I think maybe 25
12 percent or something, but it is in that range,
13 certainly not the vast majority.

14 CO-CHAIR PETERSON: Okay. That
15 help?

16 DR. GIBBONS: Yes, that helps, but
17 how about this issue of handling it from an
18 insurer standpoint, and indications, because
19 certainly, CMS tries to regulate indications
20 for procedures in the outpatient sphere and
21 denies payment. Is this something that
22 insurers have tried to do already and, if so,

1 what happened?

2 CO-CHAIR GAZELLE: I can tell you
3 our experience in the northeast is that, for
4 the most part, they don't get into ED image.

5 DR. ZERZAN: And especially --
6 This is Judy from Medicaid -- there is no way
7 to narrow with administrative data. There is
8 certainly no way to narrow at point of
9 contact.

10 The best we could do, I think, is
11 similar to one of those CMS measures that is
12 proposed to sort of find out what the rate of
13 things are, and maybe in that way encourage
14 people to change their rates, if they are an
15 outlier. But that is super-blunt tool.

16 This is much more specific and
17 evidence based, but there would be no way that
18 we could collect that data, and if we asked
19 our managed care providers to give us that
20 data, what percent, they would run screaming
21 and yelling at us, and say no.

22 You know, honestly, we pay crappy,

1 and we are certainly not paying for this
2 additional thing that they would feel was
3 burdensome, even though this is a huge problem
4 of overuse.

5 CO-CHAIR PETERSON: Carl?

6 DR. D'ORSI: I just wanted to back
7 up a little. We are creating a metric. What
8 is a good event metric? One is ideal. So
9 what is acceptable --

10 CO-CHAIR PETERSON: Can't hear
11 you, Carl.

12 DR. D'ORSI: I'm sorry. We are
13 creating a metric which, to me, means that it
14 is a measure of something that is going to
15 tell whether you are abusing it or not. So
16 what is an abuse, and attached to that, what
17 is the false negative rate or the true
18 positive rate of doing a CT without these
19 criteria?

20 Also, related to something a
21 radiologist stated before, are we thinking of
22 malpractice issues in this at all, or is that

1 excluded?

2 DR. CANTRILL: The guidelines --
3 Practice guidelines are practice guidelines,
4 and malpractice is always a concern. I think
5 the tort issue is less of an issue here than
6 it is for some of the other measures that will
7 come before us while we are here.

8 DR. SMITH-BINDMAN: I am not sure
9 that I would agree with that. We have a paper
10 on this topic exactly looking at mild
11 traumatic brain injury in the Medicare
12 population over time, and imaging is basically
13 approaching 100 percent across the board.

14 DR. CANTRILL: I am not saying it
15 is not an issue, but what I am saying is here
16 you are trying to give guidance to decrease
17 overuse, as opposed to just saying decrease
18 over use with no guidance. So I think that is
19 the difference.

20 I think the whole issue of tort
21 concerns is something that this committee
22 should think long and hard about, because why

1 do we overuse? Because we don't want to make
2 a mistake or because we are lazy. There are
3 a couple of reasons for that.

4 DR. SMITH-BINDMAN: Any other
5 reason?

6 DR. CANTRILL: There's several,
7 but we don't want to make a mistake in terms
8 of our patients. So if we are going to be put
9 in the position where the chance of making a
10 mistake goes up, then we do need to worry
11 about the tort issues. I think every
12 practicing clinician is worried.

13 DR. D'ORSI: So what is a good and
14 bad metric in this?

15 DR. CANTRILL: Well, here -- I
16 don't know what -- I can't tell you what a
17 good would be. Good would be probably close
18 to, you know, above 90 percent, 95 percent.
19 Who knows?

20 DR. SMITH-BINDMAN: This is
21 Rebecca Smith-Bindman. I can't remember from
22 the papers, but they are close in numbers.

1 What would the impact of this be on
2 utilization in the setting of mild brain
3 trauma? How much would this decrease imaging?
4 So you would reduce a pretty common indication
5 imaging by 40 percent, potentially.

6 DR. FIESINGER: We talk about
7 demand side changing practice.

8 DR. SMITH-BINDMAN: This is big.

9 DR. FIESINGER: This is huge.

10 CO-CHAIR PETERSON: So in the
11 interest of our developer, are there
12 questions? We have our developer on the line.
13 Dr. Schuur, are you on the line?

14 DR. SCHUUR: Yes. Jay Schuur
15 calling from Boston. I am joined in the room
16 by Ali Raja who is an emergency physician and
17 works on evidence based imaging. Good
18 afternoon.

19 CO-CHAIR PETERSON: Good
20 afternoon. Were any things that you wanted to
21 specifically address to us relative to the
22 comments you have heard, and then afterwards

1 we will have a short Q&A for you from anybody
2 on the panel who might other questions.

3 DR. SCHUUR: Sure. I think I will
4 take just one minute and give you a brief
5 background on the measure development process,
6 and that should sort of apply to all four
7 measures. Then we can both try to address a
8 couple of the questions.

9 These four measures were developed
10 primarily by four emergency physicians, none
11 of whom have any financial interest in the
12 Precipio system or any other decision support
13 system, and have been vetted through providers
14 in multiple fields at the Brigham and other
15 Harvard hospitals.

16 We are practicing emergency
17 physicians, and know that the evidence shows
18 that there is widespread variation in the use
19 of CT, that there is evidence that CT
20 radiation exposure is high, driving high
21 Medicare costs, and the use has gone up in the
22 last 10 years.

1 So we looked for clinical
2 indications where there were consensus
3 evidence based guidelines primarily applicable
4 to the emergency department, and then we
5 developed measures for those indications.
6 That is why we focused on these four areas.

7 All of the measures were set up
8 with the same general construct, which is that
9 the denominator would be the population
10 getting a CT, and the numerator would be the
11 patients who had received a CT who had an
12 appropriate indication.

13 An alternate approach might be to
14 define the population that had a traumatic
15 brain injury, but as published literature has
16 shown, ICD-9 codes and other administrative
17 data are not reliable to define these
18 populations.

19 So we set up the measures in that
20 structure. We have also submitted them to be
21 reported at the emergency department or
22 facility level, not at the individual level,

1 because as we all know, guidelines are
2 developed for populations, and we didn't want
3 to put pressure on any individual clinician.
4 We didn't think the evidence was strong enough
5 to not order that one individual test.

6 We did think it would be very
7 useful to know if one emergency department --
8 80 percent of their scans were consistent with
9 evidence based guidelines, and another ED 20
10 percent of their scans were in that form.

11 So let me just turn it over to Dr.
12 Raja for a second, who works with the Center
13 for Evidence Based Imaging, and he can
14 describe the work that they have done from the
15 published research.

16 DR. RAJA: I know that at least
17 two or three of you are very familiar with our
18 system here at the Brigham, since you guys
19 have worked here in the past or you were with
20 one of our partner institutions. So I won't
21 belabor the point here. I have heard your
22 discussions. I think they are right on.

1 It is very easy to do this kind of
2 data gathering with our Precipio and Medicalis
3 systems that we have here, but what we have
4 been doing is we have been actually looking at
5 how many of our CT scans have evidence based
6 indications for them.

7 One of the most amazing things we
8 have found is that there is such broad
9 variation. Among the traumatic head CTs, we
10 found variation, everywhere from five to 17
11 percent of patients specifically by emergency
12 physicians.

13 So there is some sort of a need
14 for some sort of a better practice to see if
15 we can diminish this variation. I know you
16 guys all agree with that in general concept.
17 Now as far as making this happen in
18 feasibility, what we are envisioning for
19 emergency departments that weren't able to --
20 for the vast majority of emergency departments
21 who aren't currently able to do this on a
22 complete computerized fashion, a simple paper

1 form.

2 Dr. Schuur and I just e-mailed a
3 paper form to you guys as well, but you can,
4 I am sure, envision with, for example, a head
5 CT for trauma a simple paper form with the
6 indications that were outlined here requiring
7 only a checkbox if they applied to that
8 patient, which would then meet the criteria
9 for the imaging efficiency guideline.

10 It wouldn't take that much more
11 work for the emergency physician. It would
12 allow for pretty good review of those scans
13 that did actually meet these guidelines.

14 That is what we were actually
15 going with this, but we would love to hear
16 whatever other questions you guys have for us.

17 DR. SCHUUR: And just to address a
18 couple of specific questions, I think there
19 was a discussion around the GCS and some other
20 questions on -- I think the discussion was
21 around the traumatic brain injury measure.

22 The traumatic brain injury measure

1 is based on a consensus guideline that was
2 developed by the American College of Emergency
3 Physicians, and included a representation from
4 multiple specialties and include both the
5 evidence behind the Canadian head CT rules and
6 what are called the New Orleans head CT rules,
7 and a long discussion about which one of those
8 is preferable, and there actually have been
9 comparison studies. But in order to be
10 inclusive, our measure would allow any
11 indication from either of those two measures.

12 So this is really the broadest
13 inclusion of accepted consensus evidence based
14 standards that have been promulgated by the
15 larger specialty society for emergency
16 medicine.

17 CO-CHAIR PETERSON: Perfect.
18 Questions at all for the measure developers?

19 DR. D'ORSI: Just one -- Oh, I'm
20 sorry.

21 DR. SMITH-BINDMAN: No, no. Go
22 ahead.

1 DR. D'ORSI: What was the gold
2 standard for these ACEP finding? What did
3 they find to say, wow, okay, it is worthwhile
4 to do this to find hemorrhage trauma, and how
5 often did they find hemorrhage trauma, and how
6 often did they find it to say this was a valid
7 indication?

8 DR. SCHUUR: Let me make sure I
9 understood the question. What was the gold
10 standard in these clinical studies for
11 comparing to the CT?

12 DR. D'ORSI: In other words --
13 Yes, what did they find to say, yes, these are
14 great --

15 DR. SCHUUR: So both of these
16 studies used follow-up with either direct
17 contact by telephone and/or review of medical
18 record. Both were -- One was published in
19 JAMA, the other one in the New England
20 Journal, or actually in Lancet and the New
21 England Journal, and they have been -- The
22 Canadian study has been replicated with over

1 95 percent follow-up.

2 They are considered the gold
3 standard of diagnostic test studies. So the
4 difference between the two measures -- the New
5 Orleans criteria, which were developed at
6 Charity Hospital, used many CT significant
7 findings on radiology; whereas, the Canadian
8 gold standard outcome was any finding that
9 would require a neurosurgical intervention.

10 Since there are things you will
11 find on a CT, say a small subarachnoid
12 hemorrhage, which do not end up requiring
13 neurosurgical intervention, by definition the
14 Canadian rules will use less scan -- will
15 require less scan.

16 They have studied them head to
17 head, and in the head to head study,
18 actually, the Canadian rule was as sensitive
19 and more specific, but a lot of doctors in the
20 United States use the New Orleans criteria
21 because of their concern about medical legal
22 liability associated with missing a

1 craniographically visible hemorrhage, such as
2 small subarachnoid, even if it doesn't require
3 any specific treatment.

4 DR. D'ORSI: thank you.

5 CO-CHAIR PETERSON: One other
6 question?

7 DR. BELLO: Yes. This is
8 Jacqueline Bellow. One of the points that
9 came up in discussion earlier was wouldn't it
10 be great to be able to sneak in there and see
11 what is going on now in terms of this being --
12 these criteria being met and, therefore, you
13 would have something to compare the measure
14 to.

15 Did you do any preliminary
16 snooping around before you instituted this
17 that you could answer that question for us?

18 DR. SCHUUR: So I am going to turn
19 it over to Dr. Raja, and he can address that.
20 There is data on what the current variation is
21 and they are now implementing these.

22 DR. RAJA: So right now we are

1 actually implementing these rules, and that
2 is, obviously, ongoing.

3 What we have found is that at this
4 point -- and again, we only have a few months
5 worth of data where we have implemented this
6 rule, but at this point we are looking at
7 somewhere between a 60 to 80 percent
8 compliance with one of these rules.

9 Now, obviously, as you know, as
10 you guys have already discussed, there is the
11 Hawthorne effect where, now we are asking
12 people to click on a box, they may be clicking
13 on a box that they wouldn't have necessarily
14 have clicked on otherwise, but there seems to
15 be somewhere 60 and 80 percent compliance with
16 these rules.

17 DR. SCHUUR: But multiple
18 published studies that are referenced in our
19 application and also in the Canadian head CT
20 rules in the literature show that in sharper
21 views of current practice, there is a large
22 gap between what is the number of scans --

1 around the country, the number of scans that
2 are done without evidence based indication.

3 DR. RUCKER: Don Rucker. Three
4 definitional questions. One, what is your
5 operational question of loss of consciousness,
6 because patients are often goofy on that.

7 The second is how do you
8 distinguish severe headache from non-severe
9 headache, because it was my experience
10 patients sort of tend to say their headache is
11 severe.

12 The third one on the numerator and
13 on the denominator, I was wondering why choose
14 the Glasgow Coma Score of under 14 as opposed
15 to under 15?

16 DR. SCHUUR: Going by our
17 standards, we are basing this on a consensus
18 of a published evidence based guideline based
19 on multiple, well done follow-up studies
20 through the Canadian and the New Orleans
21 Criteria, and those studies use clinicians'
22 decision about loss of consciousness and

1 clinicians' decision about severe headache.

2 Although I agree that one could
3 say that those are subjective, when actually
4 studied with tens of thousands of patients,
5 they have been shown to be highly sensitive.

6 DR. SMITH-BINDMAN: I have one
7 question. This is Rebecca Smith-Bindman. The
8 way you described just minutes ago this would
9 be applied, you talked about all CTs, how many
10 fit within some appropriateness criteria.

11 I want to understand it. Is this
12 measure limited to a patient population
13 defined at the point of referral from the
14 emergency department as having mild traumatic
15 brain injury or is it meant to be applied from
16 a point of view of all CTs that are done, and
17 how many fall within an appropriateness
18 criteria?

19 So one of those you could use
20 decision support software or entry from the
21 radiology point of view to get at. The other,
22 you would have to do from the ED point of

1 view.

2 DR. SCHUUR: It is my
3 understanding that all the CT scans that get
4 reimbursed require a physician's order. so
5 that would be the way that we implement --
6 constructed the measure to occur for all CTs.
7 So it is based on -- If you look at the
8 documentation, the denominator statement, the
9 number of adult patients undergoing head CT
10 for trauma who present within 24 hours of a
11 nonpenetrating head injury with a Glasgow Coma
12 Score greater than or equal to 14.

13 There are then five denominator
14 inclusion criteria, and there are a set of
15 exclusions that define who would not be
16 included in the measure.

17 DR. SMITH-BINDMAN: So my question
18 is: The data form that you have provided to
19 us or that we just got by e-mail is creating
20 a cohort and denominator from the point of
21 view of the emergency room, and creating that
22 cohort based on mild traumatic brain injury.

1 The way you have described the
2 measure right now is defined from the
3 radiology database point of view, where I am
4 not sure if that information on trauma, mild
5 traumatic injury would necessarily be included
6 in those data.

7 So you might understand vomiting
8 or severe headache, but you wouldn't know if
9 that was a patient who was post-stroke or
10 post-trauma. You are describing it from a CT
11 point of view. The data that we have just
12 been sent is from the ED point of view. How
13 is the cohort defined, and how do you define
14 it?

15 I can easily imagine applying it
16 from the radiology point of view, but we
17 couldn't get the cohort on trauma defined.

18 DR. SCHUUR: Well, I think there
19 are two questions. One is how do you define
20 the cohort, which is think is very explicitly
21 defined in the measure. The second is how do
22 you collect the data.

1 That would depend on what
2 hospital, what system the hospital would have
3 and would want to implement. If a hospital
4 has an EMR with physician entry, this could be
5 programmed into the radiology ordering
6 platform.

7 If they did not have that or they
8 did not want to use that, they could make up
9 a paper form that applied every time a head CT
10 was ordered and have the exclusions and then
11 the inclusions, and it would be a simple check
12 process.

13 CO-CHAIR PETERSON: I think that
14 answers it. Other questions?

15 DR. MECHTLER: I have a question.
16 Laszlo Mechtler, neurologist. Your category
17 of patients with head injury, no loss of
18 consciousness, no post-traumatic amnesia who
19 have a severe headache and nausea, you have
20 just described a post-traumatic migraine.

21 So are you saying that every post-
22 traumatic migraine should have a CT? These

1 type of headaches are very common, especially
2 if you have a previous migraine history. I
3 think Donald alluded to that, and many of
4 these patients of head injury have also
5 whiplash injuries. So many of them come with
6 cervicogenic headaches.

7 Are you presuming that a
8 cervicogenic headache or so called acute or
9 episodic tension type headache or a post-
10 traumatic migraine -- are these individuals,
11 by your measures, your numerators, these
12 individuals will be getting CT scans, and are
13 you concerned that the frequency of CT scan,
14 in fact, may increase in that subset of that
15 population, and should you define headache
16 somewhat more specifically than just saying
17 severe headache?

18 DR. SCHUUR: I think these are
19 good questions. Again, the numerator details
20 are not based on something that we sat around
21 and made up. This comes from the evidence
22 based consensus guideline published by the

1 American College of Emergency Physicians, and
2 their evidence based consensus guidelines were
3 based on those two large studies, and all of
4 those terms were what were used in those
5 studies.

6 It is possible that someone with a
7 post-traumatic migraine would meet these
8 criteria. The clinical question that is
9 presented to the emergency physician is does
10 this patient in front of me who has a mild
11 traumatic brain injury and a headache require
12 scanning?

13 That is the question that the
14 guidelines attempt to address. So whether --
15 They may ultimately have a migraine, but that
16 is the clinical question people are addressing
17 and what the clinical decision rules have been
18 addressed for.

19 It is very unlikely that these
20 measures would increase imaging, because what
21 they are going to do is they are going to
22 measure patients who received an image and

1 said whether or not it was appropriate. They
2 are not setting up a population with a
3 diagnosis and saying you didn't get an
4 appropriate scan.

5 So everyone who is in this
6 population already has had a scan. The only
7 way you will look worse is by ordering scans
8 on patients -- or your institution ordering
9 scans on patients without indications.

10 DR. GRIFFEY: This is Rich
11 Griffey. Jay, you may have heard Howard say
12 that I like this measure. I think it is a
13 good measure, and the Achilles heel of this
14 measure may be the feasibility component in
15 terms of reporting.

16 It is great to have a paper form,
17 but a number of people have brought up that,
18 well, then we've got to do something with
19 those forms or you have to have someone to
20 enter that data, and it is sort of an unfunded
21 mandate, a lot like the pneumonia measures,
22 for example. That is all chart extraction in

1 a similar way.

2 Do you have any thought about how
3 to get around that or how to make that
4 simpler? I know you talked about sampling.
5 If you did that, you would want to make sure
6 you had a denominator, so that not just the
7 good papers or the compliant studies were
8 filled out. Do you have any thoughts about
9 that?

10 DR. SCHUUR: I may refer to Dr.
11 Raja the technical aspect.

12 DR. RAJA: Dr. Griffey, that is a
13 great point. This is, obviously, an unfunded
14 mandate. It would take a lot -- It would take
15 some time. It would take somebody to actually
16 collect the data. It would take somebody to
17 actually go through and measure it.

18 I guess our biggest overarching
19 point is simply that this is somewhere that we
20 need to move toward, and I think this is a
21 first step. If we can figure out a better way
22 to do this that would take less man-hours or

1 if we more widely implement electronic
2 physician order entry, that would be great,
3 and it would make this a lot easier. But to
4 get things started, it takes a paper form, and
5 that actually pushes people to spend money on
6 electronic order entry systems rather than
7 having to fund somebody to go through and
8 collect forms, great, because that is where we
9 want to go.

10 Unfortunately, you are absolutely
11 right. We don't know how to get this funded,
12 but I think we all agree that this is where we
13 want to go.

14 DR. SCHUUR: The second point I
15 would make is that I don't think the term
16 unfunded mandate is correct, because the
17 facility and the reviewing physician are both
18 getting well compensated for each of these
19 scans. So the time and effort to properly
20 document indications doesn't seem onerous.

21 The second comment is that, like
22 the pneumonia measures and other core

1 measures, I think sampling would be very
2 appropriate for facilities that could not
3 easily collect data on all of them, and CMS
4 has well validated sampling numbers and what
5 would be appropriate.

6 CO-CHAIR PETERSON: Helen.

7 DR. BURSTIN: Just a couple of
8 points of information. This is Helen Burstin.
9 Hi, Jay.

10 So I just want to point out that
11 this measure would only go forward for time
12 limited endorsement. I just want to emphasize
13 that again. NQF has endorsed numerous
14 measures based on medical records. I don't
15 want this to seem as if it is a real
16 aberration.

17 Oftentimes in new areas, the first
18 thing that happens is a medical record based
19 measure. It gets tested. There may be other
20 feasible ways to follow it, but I just don't
21 want it to seem like this is actually all that
22 different than the majority of core measures

1 we require hospitals to do, which are all
2 paper based at the moment.

3 So I guess a major question for
4 Jay is I just want to understand that. If it
5 is time limited, do you have a plan and the
6 capacity to test it within 2 months and report
7 back to NQF?

8 DR. SCHUUR: Absolutely. We are
9 actually doing that right now.

10 DR. BURSTIN: Just one last
11 comment. You know, if there is anything we
12 hear a cry for, particularly -- and this
13 committee doesn't have as many consumers and
14 purchasers on it; one is out sick, and we have
15 a limited number at the table on Medicaid. It
16 is for overuse measures.

17 So I think this is where those
18 four criteria are intended. They are not
19 weighted. They are not do one versus another.
20 You have to make an overall assessment of how
21 you think those four play out.

22 Feasibility is a concern, but you

1 have to weigh it against the other things.

2 CO-CHAIR PETERSON: Any final
3 comments?

4 DR. RUCKER: Is there a worry that
5 the studies -- you know, about the gaming in
6 terms of the severe headache versus headache,
7 because I think it is a different crowd when
8 the study researchers who are motivated in
9 these big studies to prove the point that we
10 don't need the image is sort of a very
11 different dynamic than ER docs who are
12 ordering these studies for some intrinsic
13 reason, presumably since they are actually not
14 paying to get radiology studies, contrary to
15 what was mentioned, who might just say, well,
16 it is a severe headache; because that is sort
17 of what the patients typically say in this.

18 You know, I hate to harp on this,
19 but that is -- It is the severity of this
20 nebulous symptom that is the big clinical
21 concern when you are seeing these people. It
22 is that sort of subtle judgment, I think.

1 DR. SCHUUR: I would strongly
2 recommend that, if people have questions about
3 this measure, that they review the original
4 studies from the Canadian and/or the New
5 Orleans Head CT rule.

6 The way that those studies and
7 well designed diagnostic tests on decision
8 rules are designed, the clinicians were not
9 pressured to do anything.

10 They just had an order form, and
11 they implemented this in a number of emergency
12 departments and basically said do what you
13 would normally do, and then after a period of
14 time, they compared what was on order forms to
15 patients' eventual outcomes, and using
16 regression and sorting statistical techniques,
17 they figure out which indications have the
18 most association with the outcome.

19 CO-CHAIR PETERSON: Okay. I
20 think, in the interest of time, we are going
21 to -- Thank you very much for your effort of
22 answering our questions and for putting forth

1 this measure.

2 Helen, I think in the interest of
3 time -- we are beyond the hour. I assume we
4 will hold votes until tomorrow. Do you want
5 to vote tonight?

6 DR. BURSTIN: Let's finish up.

7 CO-CHAIR PETERSON: I am all for
8 voting. I don't want to short-change, if there
9 are questions.

10 DR. SMITH-BINDMAN: Before we
11 vote, can the people who read it carefully
12 sort of give us a summary of their review?

13 DR. FORMAN: I would just say,
14 from my point of view, the only issue that is
15 really a question -- I am not that concerned
16 about people dealing with this anymore than
17 anything else, and I think that goes on.

18 The fact that you might have five
19 percent gaming and still get rid of 25 percent
20 of excessive imaging, I think, is acceptable
21 to me. So that doesn't concern me much.

22 The only part of this that I think

1 raises any real concern is the feasibility.
2 You know, I am speaking from an institution
3 not dissimilar from the Brigham, but without
4 the computerized physician order entry piece
5 in place, and I think it will be difficult to
6 implement for even us. I think it becomes
7 that much more difficult at other levels.

8 I do agree that the form that they
9 are presenting is so simple that you could
10 plot this data, and it is such a high dollar
11 item that it should motivate practice change.

12 CO-CHAIR GAZELLE: If you look at
13 that paper form, I can't imagine ordering a
14 head CT for mild traumatic brain injury and
15 not circling at least one of those
16 indications. You are getting it 100 percent.

17 DR. FORMAN: You know, I disagree.

18 MR. BACKUS: No. You might get
19 100 percent of people that, when they say --
20 You say you can't imagine ordering it and not
21 circling one of those. But the question is:
22 Can you not order it, because then you really

1 look down on that list and go like, ah, there
2 is nothing really here for me.

3 DR. GRIFFEY: That is why it is
4 time limited, and that is why you will learn
5 what you learn, I would think.

6 DR. ZERZAN: Prior authorization,
7 you don't really -- Especially in Medicaid,
8 if you fill out a prior authorization form, we
9 pretty much approve it, but the part where you
10 say is that barrier to get there, and I think
11 that this is exactly that same thing.

12 You will probably approve everyone
13 that fills out the form, but there will be
14 some statement that you have avoided, and that
15 is what you are looking for.

16 MR. BACKUS: You are just bringing
17 that thought to top of mind. That is all that
18 form does. It just brings that score to top
19 of mind before you order the CT, and that is
20 all you can hope for.

21 CO-CHAIR PETERSON: So, Helen,
22 just a point of clarification. Time limited

1 data that you would require -- Clarify for the
2 committee here what that really means.

3 DR. BURSTIN: Right, and it is
4 spelled out in the form. Essentially, what it
5 means is you guys agree this measure would
6 pass all the other NQF evaluation criteria
7 with the exception of the fact that it has not
8 been tested.

9 They would need to go back and
10 test whatever form the measure is going to be
11 used in, in this instance the paper form,
12 maybe to look to see how reliably they could
13 collect the individual data elements, whether
14 the reliability is tested, probably in this
15 instance whether they have an electronic
16 system. It would be particularly interesting
17 to understand if, in fact, the results are
18 similar between the electronic system and
19 paper record.

20 That should, at the end of the
21 day, allow enough to say can you validly and
22 reliably collect this data; and given the

1 feasibility concerns, I would hope they would
2 also give us some information about how
3 difficult it is to collect.

4 CO-CHAIR PETERSON: I am just
5 curious about what would be considered a
6 reasonable test of this? Can this be one
7 institution?

8 DR. BURSTIN: No. It cannot be
9 one institution. There is actually specific
10 guidance. It depends on the kind of measure.
11 It is probably at least five to 10
12 institutions or a certain number of patients.

13 It really depends on the level of
14 analysis of the measure. So we will need to
15 take a look.

16 DR. SMITH-BINDMAN: So they have
17 to test it?

18 DR. BURSTIN: They have to test
19 it.

20 DR. SMITH-BINDMAN: They have to
21 test this measure on 10 institutions?

22 DR. BURSTIN: I can't remember the

1 exact protocol, but whatever the protocol is
2 they need to undertake efforts to test the
3 measure, provide information back on
4 reliability and validity, or the measure isn't
5 endorsed. So that is the issue.

6 That is the fail safe for measures
7 like this, if you think it otherwise meets all
8 the criteria. We just don't know how well it
9 is going to perform in the real world on
10 paper, since not everybody is like The Brigham
11 or other places like that.

12 DR. RUCKER: I had a question. It
13 wasn't clear to me that they were actually
14 going to do a multi-site study on that. I
15 don't know if that is a question to them or
16 somebody else.

17 DR. BURSTIN: They understand the
18 requirements for time limited.

19 DR. RUCKER: So they know that
20 that is sort of part and parcel of what --

21 DR. BURSTIN: We will give them
22 further --

1 DR. RUCKER: It would need to be a
2 place that don't have computerized ordering.
3 Right?

4 DR. BURSTIN: They are going to
5 need to test the paper form, if that is what
6 they are arguing is the dominant mode of
7 collection.

8 CO-CHAIR PETERSON: Roger.

9 DR. SNOW: Yes. Multiple sites,
10 but do they have to be outside of the same
11 network or could they be within the network?

12 DR. BURSTIN: They could be within
13 the network. Again --

14 DR. SNOW: I know it is a detail,
15 but I just raise the question.

16 DR. D'ORSI: do they have to have
17 any discussions about what they produce, what
18 it does, that number? Is there any discussion
19 that it is useful in any way or just proving
20 that it can be done?

21 DR. BURSTIN: At this point, you
22 should be making the assessment that you think

1 it is already useful, usable. I think --

2 DR. D'ORSI: Okay. So my number
3 is 8 -- .8. Why would it not be like aspirin?

4 DR. BURSTIN: This is proportion
5 of CTs for mild traumatic brain injury that
6 meets some guideline. You would like it to be
7 fifty.

8 DR. D'ORSI: Oh, no.

9 CO-CHAIR GAZELLE: Can I just say
10 quickly, I think -- You know, Helen, you said
11 that some measures rely on chart abstraction.
12 I think there is a very big difference between
13 going through the medical record to see
14 whether or not these criteria are met, versus
15 forcing someone to fill out a form where the
16 only things they can check off are the
17 criteria that is needed.

18 I think, for this to be a useful
19 measure, the paper form is not enough. You
20 have to do the review of the medical record,
21 either manually or using the MR, because in my
22 opinion this form is just not acceptable.

1 DR. GRIFFEY: Why? Because you
2 think that it is going to be garbage in,
3 garbage out?

4 CO-CHAIR GAZELLE: Yes. You are
5 asking some intern in the emergency
6 department, while the patient is on the way to
7 the head CT, to fill this thing out. They are
8 just going to check the --

9 DR. SMITH-BINDMAN: These are your
10 choices of why you ordered that scan.

11 DR. GRIFFEY: Well, that may be
12 the case. The proof is in the pudding with
13 the utilization data.

14 CO-CHAIR GAZELLE: But we are not
15 going to be tracking utilization. We are only

16 DR. GRIFFEY: But computerized
17 tracking the percentage of the head CTs that
18 have the ACS criteria. So I would argue that
19 you either have to do it by looking at the
20 medical record to show that it has been
21 documented as opposed to a paper form filled
22 out, or EHR. I just think this is absolutely

1 not acceptable.

2 DR. CANTRILL: To mis-fill out
3 this form, we call that lying. No, but his
4 question is how do you get the denominator?

5 CO-CHAIR PETERSON: They have yet to produce
6 evidence. They are getting it now, but they
7 have yet to produce evidence to say we
8 influenced the system and utilization of this
9 test goes down.

10 DR. BURSTIN: And that is why I am
11 just trying to get at the denominator.

12 CO-CHAIR PETERSON: There is not
13 multiple studies that say that, if we have a
14 system that has to check this box, it will
15 reduce the number of ordered tests. There is
16 30 percent of tests that don't meet this
17 criteria under current --

18 DR. GRIFFEY: But computerized
19 decision support tools outperform education or
20 Physician Champion or CME or any other
21 intervention you have. This is the best thing
22 you have. Now they won't all be computerized.

1 There will be a paper, a piece of paper, but
2 it is --

3 CO-CHAIR PETERSON: Clarifying
4 where we are. Okay.

5 DR. GIBBONS: I understand the
6 points that have been made, but I would just
7 point out that there is a fair literature that
8 just -- as we have pointed out, if you audit
9 something, it will get better.

10 DR. SPENCER: the one thing that
11 is going to come up again tomorrow and
12 tomorrow about the NQF stuff is the
13 feasibility stuff. Again, what I don't
14 understand is we don't make people follow
15 these things, and there are several things we
16 are going to look at that are just
17 exceptionally clear that are overused in the
18 scientific literature, that there are
19 exceptionally clear criteria for what these
20 should be.

21 We are going to see lots of those
22 type of things, another easy-easy, and then we

1 hit this feasibility thing, and we get stuck.

2 So what is wrong with saying that these are
3 just good and right things, and -- The
4 accreditation on a payer say, hey and, you
5 know, NQF says these are important; you start
6 reporting these or we are not going to credit
7 your ER or we are not going to pay for these.
8 Then people have to do them.

9 What is our obligation to say that
10 it is a really easy thing to do or not? That
11 is what I am struggling with, because this is
12 -- No one argues about this. These are
13 exceptionally well ordered, and they are
14 unbelievably good criteria for when they
15 should be ordered.

16 This is like one of the best
17 things of all the things we have done here
18 that is supported with literature, but we are
19 stuck on what a pain in the rear it is to do.
20 But nobody has to do it. Right? There is no
21 Federal thing that says everybody must follow
22 the NQF or CMS does it or Wellpoint does it or

1 somebody says we got to do it.

2 DR. BURSTIN: NQF does not
3 implement the measure.

4 DR. SPENCER: Right. That is why
5 I am stuck on feasibility with a lot of our
6 measures.

7 DR. BURSTIN: If it is
8 appropriate, the public supports it.

9 CO-CHAIR PETERSON: Shall we get
10 to the vote?

11 DR. SPENCER: So does feasibility
12 kill the deal? Well, we will find out. We
13 will find out in a few minutes here.

14 CO-CHAIR PETERSON: Any other -- I
15 think people have stated pretty clearly where
16 they stand. Okay. Can we call for the vote?
17 We'll go through the criteria. I know how the
18 first scores will go.

19 I guess there will be 19 voting.
20 Right?

21 DR. BURSTIN: Yes. We lost one.

22 CO-CHAIR GAZELLE: Oh, she gave me

1 her proxy vote.

2 DR. SPENCER: No. She gave it to
3 me.

4 CO-CHAIR PETERSON: Okay. How
5 many think the importance rating is High?

6 MR. CORBRIDGE: I've got two
7 laptops. I can't really stand up.

8 DR. BURSTIN: I can do that.
9 Eighteen.

10 CO-CHAIR PETERSON: Moderate?
11 Okay. Low?

12 MR. CORBRIDGE: Moderate was one?

13 CO-CHAIR PETERSON: Yes. Okay,
14 now we are to scientific acceptability. Okay,
15 High? Moderate? Three. Low?

16 Okay, usability: How many say
17 High? That would be a zero. Moderate? And
18 Low? One.

19 Okay, feasibility: High?
20 Moderate? Low? Okay.

21 We have the yes or no. So let's
22 do Yes?

1 MR. CORBRIDGE: Before we do that,
2 we have to open up -- Sorry. Just to make
3 sure, is anyone on the line for public
4 comment? Okay.

5 DR. SCHUUR: Yes. Record my vote.

6 CO-CHAIR PETERSON: The vote on
7 this is Yes?

8 DR. BURSTIN: Sixteen.

9 CO-CHAIR PETERSON: No? Two,
10 three.

11 DR. BURSTIN: Three, okay.

12 MR. CORBRIDGE: It is 15.

13 DR. BURSTIN: Sixteen and three.

14 DR. MECHTLER: Could we add
15 comments, too, that can be added even to the
16 vote?

17 DR. BURSTIN: Sure. Anything you
18 want to recommend.

19 DR. MECHTLER: As I mentioned, I
20 think this should be -- I would not like to
21 see this presented for headache centers around
22 the country. It would not make sense for

1 urgent care centers and even probably a fusion
2 labs that deal with headache.

3 So if this is ED, that will
4 probably be --

5 DR. BURSTIN: This is just ED.

6 DR. D'ORSI: This is acute trauma.
7 This is for time limited.

8 DR. BURSTIN: It is time limited.

9 CO-CHAIR PETERSON: Any other
10 comments?

11 DR. FIESINGER: I like the
12 comments that at least we would have a paper
13 system. What about testing that?

14 CO-CHAIR PETERSON: For the
15 morning, everybody okay starting at nine?

16 (Whereupon, the foregoing matter
17 went off the record at 5:23 p.m.)

18

19

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21

22

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