

NATIONAL QUALITY FORUM

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NEUROLOGY PHASE II

STEERING COMMITTEE

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THURSDAY

OCTOBER 4, 2012

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The Steering Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 9:00 a.m., David Knowlton and David Tirschwell, Co-Chairs, presiding.

PRESENT:

DAVID KNOWLTON, MA, New Jersey Health Care Quality Institute

DAVID TIRSCHWELL, MD, MSc, University of Washington Department of Neurology

A.M. BARRETT, MD, Kessler Foundation

WILLIAM BARSAN, MD, University of Michigan Health System

JOCELYN BAUTISTA, MD, Cleveland Clinic

RAMON BAUTISTA, MD, MBA, University of Florida, Jacksonville

GWENDOLEN BUHR, MD, American Medical Directors Association

GAIL COONEY, MD, FAAHPM, Hospice of Palm Beach County

JOHN DUDA, MD, Veterans Health Administration

JORDAN EISENSTOCK, MD, CPE, UMass Memorial Health Care

SAM FAZIO, PhD, Alzheimer's Association

RISHA GIDWANI, DrPH, Stanford University

Medical Center

DAVID HACKNEY, MD, Beth Israel Deaconess Medical Center

MICHAEL KAPLITT, MD, PhD, Weill Cornell
Medical College
DANIEL LABOVITZ, MD, MS, Montefiore Medical
Center
THERESE RICHMOND, PhD, CRNP, FAAN, University
of Pennsylvania School of Nursing
JACK SCARIANO, JR., MD, FAAN, private
practitioner
PETER SCHMIDT, PhD, National Parkinson
Foundation
RAJ SHETH, MD, Nemours Foundation
JOLYNN SUKO, MPH, Virginia Mason Medical
Center
JANE SULLIVAN, PT, DHS, MS, Northwestern
University Feinberg School of Medicine
FREDRIK TOLIN, MD, MBA, FACS, Humana, Inc.
MARY VAN DE KAMP, CCC-SLP, RehabCare
SALINA WADDY, MD, National Institutes of
Health

NQF STAFF:

HELEN BURSTIN, MD, MPH
KAREN JOHNSON, MS
SUZANNE THEBERGE, MPH
JESSICA WEBER

ALSO PRESENT:

SUSANNAH BERNHEIM, Yale-New Haven Health
System CORE*
KERI CHRISTENSEN, American Medical

Association

AMARIS CRAWFORD, American Medical Association
ELIZABETH DRYE, Yale-New Haven Health System
CORE
KATE GOODRICH, CMS*
ANU GUPTA, AMA-PCPI
LEIN HAN, CMS

KENDRA HANLEY, AMA-PCPI
JERRY JOHNSON, University of Pennsylvania*

DIEDRA JOSEPH, American Medical Association*

HARLAN KRUMHOLZ, Yale*

ROBERT PLOVNICK, American Psychiatric

Association

SAMANTHA TIERNEY, American Medical Association

*Participating by teleconference

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

(8:31 a.m.)

CO-CHAIR TIRSCHWELL: Good morning everybody, if we could settle down a little bit, I think we are going to go ahead and get started. Thanks for showing up on day two.

Karen is going to start us off with a little recap of day one.

MS. JOHNSON: Thank you, David.

So, hopefully, you guys all remember, we had a very interesting and exciting day yesterday. We looked at 12 measures, and of those 12, three were recommended by you for endorsement.

So today we are going to look at some additional measures. Most of them today will be dementia measures, and one measure that has already been endorsed by NQF, the stenosis measurement in carotid imaging studies.

So all of these measures are put forward by AMA-PCPI. So to start us off

1 today, we are going to ask folks from AMA-PCPI
2 to give us maybe a little five-minute
3 introduction overview to your measure set.

4 MS. TIERNEY: Good morning,
5 everyone. Thank you for your time and the
6 opportunity to offer a few brief remarks about
7 our measures, the 10 measures that are
8 presented for you today.

9 The measures come from two
10 different sets of ours, one in our radiology
11 measure set and one in our -- and many, nine
12 measures, in our dementia measure set.

13 I do want to just point out for
14 you a few highlights of the PCPI measure
15 development process, just so you have a sense
16 of what goes into the development.

17 All of our measures are developed
18 through multi-disciplinary, cross-specialty
19 work groups. We place a strong emphasis on
20 developing measures that are based on clinical
21 practice guidelines.

22 We subject all measures to a 30-

1 day public comment period, and then we review
2 all the comments we receive with the
3 Development Work Group for further
4 consideration by the Development Work Group,
5 and make measure modifications, where
6 necessary.

7 We also subject all of our
8 measures to the membership of the Physician
9 Consortium for Performance Improvement for
10 vote and approval. This is a very important
11 step in our process, given that the membership
12 of the PCPI is very large and diverse. It
13 includes over 170 medical specialty societies,
14 state medical societies, and health care
15 professional organizations.

16 I will just speak a few minutes
17 about -- or one or two minutes about the
18 dementia measures in particular, and then I
19 will turn it over to my colleague who can give
20 you a slight overview of the one carotid
21 measure that is presented for you today.

22 The dementia measures are the

1 result of a collaboration among the PCPI, the
2 American Academy of Neurology, the American
3 Geriatric Society, the American Medical
4 Directors Association, and the American
5 Psychiatric Association. They are the results
6 of a year--plus long collaboration to develop
7 measures to improve care for patients with
8 dementia.

9 As I know that you have noted from
10 several of your calls and probably in looking
11 at the submission forms more closely, there is
12 a challenge with the evidence base for the
13 measures. We do at the PCPI strongly believe
14 in basing our measures on clinical practice
15 guidelines, with a reliance on trying to
16 develop measures that are based on principles
17 with the strongest recommendations and based
18 on the highest level of evidence.

19 Unfortunately, in the area of
20 dementia, there is no a strong research base,
21 and so we identified measures that would be
22 important to improving the quality of care for

1 patients with dementia, but we recognize that
2 there are some challenges with the evidence
3 base. But we strongly believe that the
4 measures do have a great potential for
5 benefit, and strongly outweigh any harms and,
6 I think, in some situations, maybe many, given
7 the weak evidence base, we would ask for the
8 possible exception to the evidence requirement
9 for NQF's criteria.

10 I will also point out to you that
11 the measures are up for time-limited
12 endorsement, because they have not yet been
13 tested for reliability and validity, but they
14 meet all of the other criteria that are
15 required for consideration by NQF under those
16 criteria, and we are in the process of
17 planning a testing project, and I think we
18 will begin later this month.

19 So that is short and sweet,
20 hopefully, and I will just turn it over to
21 Diedra on the phone and see if she has any
22 extra comments to add about the stenosis

1 measure, in particular.

2 MS. JOSEPH: Good morning,
3 everyone. This is Diedra Joseph from the AMA-
4 PCPI. Thank you for the opportunity to
5 introduce the measure.

6 The stenosis measure, number 0507,
7 was developed by a Radiology Work Group. The
8 Work Group was developed in conjunction with
9 the ACR and the NCQA.

10 The measure was developed by this
11 group and approved by the PCPI membership in
12 2007, and received time-limited endorsement
13 status from NQF in 2008, and the measure is
14 supported by two clinical practice guidelines
15 and was tested for reliability and validity,
16 along with the three other AMA-PCPI radiology
17 measures, which also originally had PLE status
18 and were recently reviewed and granted full
19 endorsement.

20 So that is our brief introduction
21 of those measures, and we welcome any
22 questions you have throughout the Steering

1 Committee discussion. Thank you.

2 CO-CHAIR TIRSCHWELL: Thank you
3 very much. With no further ado, I think we
4 will go ahead and start on the first measure.

5 The scheduled first measure is
6 0507. David Hackney is going to talk about
7 stenosis measurement in carotid imaging
8 studies.

9 DR. HACKNEY: Okay. This is, as
10 you heard, an AMA-PCPI proposal for stenosis
11 measurement in carotid imaging studies. It
12 establishes the useful goal of encouraging
13 standardized reporting methodology for
14 patients with carotid stenosis using the
15 NASCET approach.

16 It has been improved and
17 previously endorsed, and as you will hear, I
18 have some problems with it, but the nature of
19 the problems and the potential value of it are
20 such that I would suggest we renew the
21 endorsement, but ask the developer to make
22 some revisions that would better match the

1 apparent goal and avoid some of the problems
2 I see now.

3 I am going to start with the note
4 that this standard uses stenosis severity as
5 the only required on a report of carotid
6 imaging in a patient -- well, in a patient
7 with carotid imaging, and it ignores things
8 like ulceration and plaque composition which,
9 I think, most radiologists would consider
10 important parts of the report and, depending
11 on what is going on with the patient, may be
12 more important than the stenosis.

13 So it kind of implies that, if you
14 have reported stenosis, you have done
15 everything you need to do in characterizing
16 the severity of the vessel abnormality. So I
17 will make that note briefly. Obviously, it
18 would be a big production to add other
19 elements to the report and test them, validate
20 them, and bring them forward, but it is
21 something I would encourage them to think
22 about.

1 I am most worried about the
2 denominator. It seems to assume that the
3 severity of carotid stenosis will be relevant
4 for everybody who undergoes imaging of their
5 cervical arteries.

6 You typically look at the carotids
7 but not the vertebral arteries, for example,
8 when you do an ultrasound, but -- and it is
9 technically possible to do that with MRA, but
10 the way MRA is usually done and the way CTA is
11 done, you get all the cervical arteries.

12 So if you do a study, even with no
13 interest in the carotid arteries, according to
14 this, you have to report the severity of the
15 carotid artery stenosis. I think that is what
16 this means. That is what we have been doing,
17 in any case, because we think that is what it
18 means.

19 Now that is sort of a meaningless
20 distraction for the people taking care of the
21 patient when the issue isn't carotid disease,
22 to begin with, but there is also this issue

1 about perhaps referring a lot of patients who
2 are asymptomatic for carotid disease but have
3 carotid stenosis getting endarterectomies or
4 stenting, because they have asymptomatic
5 carotid stenosis.

6 This is a big issue right now.
7 There is a big debate about whether there is
8 any need to any intervention in an
9 asymptomatic patient, if they can undergo
10 medical therapy, but -- and as you do older
11 patients, most of them have some carotid
12 artery disease. So measuring it may lead them
13 into a therapeutic pipeline, where they don't
14 belong.

15 So there is a potential harm to
16 it. There's lots of other reasons people get
17 neck vessel imaging. As I said, it could be
18 trauma, looking for dissection,
19 pseudoaneurysms, tears in the vessels,
20 hematomas, neck AVMs, tumors, and not all of
21 those people is the carotid artery of any
22 interest unless you saw a totally unexpected -

1 - it is significant, because it is there in
2 carotid stenosis, usually isn't significant,
3 just because it is there, again unless the
4 patient is symptomatic.

5 Now applying the NQF standards,
6 there really isn't evidence that doing NASCET
7 stenosis reporting will have a positive effect
8 on patient care. There is good evidence that,
9 in symptomatic patients, the stenosis as
10 measured by the NASCET technique does predict
11 stroke risk, but I don't know of any studies,
12 and certainly the developer didn't indicate
13 any, that show evidence that including that in
14 the report has an influence on patient care,
15 and it is a technical issue that is going to
16 come up when we have to go point by point
17 through the criteria, but I think the link
18 between stenosis severity and stroke risk in
19 patients who have symptoms is strong enough
20 that it is plausible to think that documenting
21 that formally would be a useful thing to do.

22 So with that --

1 CO-CHAIR TIRSCHWELL: Right. We
2 should be focusing on the evidence first. I
3 guess, David, just as a question to the
4 evidence, is there evidence that, if they
5 don't use the NASCET method, that the reported
6 stenoses are inaccurate?

7 DR. HACKNEY: There are different
8 reporting -- There are different methods that
9 have been used, and you get different numbers
10 if you would use a different method. So first
11 of all, if you -- There is another big one
12 that uses what the diameter of the carotid
13 bulb you think would have been in the absence
14 of the stenosis. That has got obvious
15 problems about deciding how tight that would
16 be, but the important thing is, if you use
17 that, you don't get the same number as you do
18 if you use the NASCET.

19 So if you report it without
20 defining the method you are using, people
21 don't know how to use it, and most of the data
22 that has been developed for stroke risk

1 prediction from carotid stenosis severity is
2 with NASCET.

3 So if you don't use NASCET, then
4 it is hard to know how to plug whatever number
5 you get into the existing data. So to the
6 extent that you care about how tight the
7 stenosis is, doing it by NASCET gives you by
8 far the biggest database on which to base your
9 subsequent clinical decision.

10 So that part of it makes perfect
11 sense. Proving that, having that in the
12 report, makes the patient better off, is the
13 sort of thing we were discussing a lot
14 yesterday, that that is tough to do.

15 So as I said, I am willing to
16 accept that it makes so much sense that you
17 need that number, that I am not worried about
18 the fact that you can't prove that putting it
19 in the report matters, because it would be a
20 weird study for someone to do. But it is
21 going to be a point when we talk about where
22 there is evidence and where there isn't.

1 CO-CHAIR TIRSCHWELL: I have one
2 more question on this that maybe you can
3 answer, and it sort of goes to evidence about
4 this way of reporting carotid stenosis, which
5 is the ultrasound question where, you know, as
6 far as I can tell -- and I looked at the
7 consensus report about ultrasound reporting.

8 Ultrasound is kind of a different
9 animal, and they report it in these ranges of
10 stenoses. That is what the recommendation was
11 from the consensus statement that they
12 reference, and this range of stenoses is based
13 on peak systolic velocities, I believe, and it
14 has nothing to do with the distal carotid
15 diameter.

16 So it sort of feels like they are
17 forcing that one in there, too, and it doesn't
18 quite fit with the title of the measure. I
19 don't know if --

20 DR. HACKNEY: Yes, that is true.
21 You really can't -- In the vast majority of
22 people, you can't see the segment of the

1 carotid that is your base for calculating the
2 stenosis severity with ultrasound. It is out
3 of the window. Some people you can, but many,
4 many people you can't.

5 So you can't do it that way. But
6 I think doing a standardized method would also
7 be useful for ultrasound, but you can't really
8 do what NASCET did, and there are papers that
9 try to link ultrasound measurements to NASCET
10 method measurements so that you can derive --
11 you can use that database of information about
12 stenosis severity, but it is an extra step
13 that you have to make in order to get there.

14 CO-CHAIR TIRSCHWELL: Well, but
15 the peak systolic velocities that they do
16 recommend using do correlate pretty well with
17 these ranges of NASCET stenosis. So I guess
18 it just feels a little not quite consistent to
19 be including the ultrasound thing in there,
20 when you are not really doing exactly what the
21 measure is called. I don't know.

22 DR. HACKNEY: Yes, I think the

1 alternative on that issue would be to have a
2 separate measure just on ultrasound, I guess,
3 but I think there is a logic in grouping these
4 two together. Again, if you ask for the
5 direct evidence, again, that the report alters
6 therapy as opposed to the information alters
7 therapy, that -- and there isn't going to be,
8 I don't think.

9 CO-CHAIR TIRSCHWELL: Ramon,
10 Daniel, then Michael.

11 DR. R. BAUTISTA: It sounds like
12 this particular measure has to do with
13 standardization of a certain process. I guess
14 the question is, is there any need to
15 standardize this. Will this result in better
16 patient care and, really, what is the evidence
17 that standardization of this kind of a process
18 is actually good?

19 DR. HACKNEY: There is very good
20 evidence, as I was saying, that using
21 standardized criteria for assessing the
22 severity -- there is a great deal of data on

1 predicting stroke risk using that; and because
2 there is more than one way of measuring
3 carotid stenosis, that gives you different
4 numerical values.

5 If you want to use the largest
6 database with the most studies and the most
7 evidence to stratify stroke risk based on
8 stenosis severity, then NASCET is the method
9 that you want to use. So there is very good
10 evidence that you can predict stroke risk
11 using NASCET, and that if you use a different
12 method, you get different numbers.

13 So you can't use the NASCET
14 database, but can you prove that having that
15 in the report changes therapy? That, I don't
16 think there is any data on.

17 DR. R. BAUTISTA: Then a follow-
18 up, though: Is this process or protocol valid
19 across different procedures discussed, like
20 ultrasound, MRA, CT angiogram, etcetera?

21 DR. HACKNEY: So you do the same
22 thing with CTA as you do with MRA, and those

1 have been validated between the two of them.
2 As we were just discussing, you can't do this
3 in most people with ultrasound. So you use a
4 different criteria entirely, but people have
5 related the ultrasound criteria to the CTA and
6 MRA criteria.

7 MS. JOSEPH: Excuse me. This is
8 Diedra at the AMA-PCPI. May I make a comment?

9 CO-CHAIR TIRSCHWELL: Why don't we
10 let the committee make their comments, and
11 then you can respond to them.

12 MS. JOSEPH: Okay, thank you.

13 CO-CHAIR TIRSCHWELL: Daniel?

14 DR. LABOVITZ: I am stroke
15 neurologist, and I read a lot of ultrasound
16 reports, and I appreciate the notion of
17 standardization. But ultrasound remains
18 probably the most commonly done test to assess
19 for asymptomatic or symptomatic carotid
20 stenosis.

21 When I look at this measure, I am
22 reminded of -- I think it was Sesame Street

1 where they ask you which one of these things
2 is not like the other.

3 CO-CHAIR TIRSCHWELL: Hey, they
4 are not getting funding anymore, by the way.

5 DR. LABOVITZ: Yes.

6 CO-CHAIR TIRSCHWELL: Just want to
7 bring that out. Big Bird is out.

8 DR. LABOVITZ: I think I am little
9 concerned here that the measure is a measure -
10 - It is sort of a standard of convenience:
11 Let's put all of these things together,
12 because they are measuring carotids. But they
13 use very different means.

14 MRA is different from CTA, is
15 different from angiogram, and all the NASCET
16 data comes from angiogram. That is what was
17 used to establish the standard. That is what
18 measuring the proximal and distal portion of
19 the internal carotid artery is from.

20 Carotid ultrasound, when assessing
21 stenosis, looks at flow velocity. It is also
22 useful for looking at plaque morphology, which

1 angiogram can't do. This measure doesn't have
2 anything to say about that, but it does ask
3 carotid ultrasound to do something which it
4 does very poorly.

5 Maybe this is a question for the
6 rest of the committee, but certainly, I think,
7 might be a question for the developers. Do
8 you think that including carotid ultrasound in
9 this standard is useful and valuable? Is
10 there perhaps an unexpected downside to this,
11 forcing the ultrasonographers to generate a
12 report which isn't valid, maybe even
13 misleading? Do you have to have it?

14 CO-CHAIR TIRSCHWELL: Michael?

15 DR. KAPLITT: Yeah. I have two
16 questions to the points you made earlier. One
17 is on this point of reporting the degree of
18 stenosis.

19 Putting the ultrasound question
20 aside, which I agree that there is serious
21 sort of structural concerns about how related
22 ultrasound is and whether the data supports

1 it, if every study that has been done, whether
2 it is asymptomatic treatment of symptomatic
3 treatment, shows that the benefits really
4 occur above a certain level of stenosis.

5 Right, then I guess do you really need a study
6 to show that, actually, reporting in a
7 consistent way the level of stenosis is
8 actually beneficial to outcome, if you have
9 already shown in many, many studies that the
10 degree of stenosis, not just severe versus
11 moderate versus whatever, but the actual
12 percent stenosis, affects the outcome. Right?
13 So that is one question.

14 The second question is with regard
15 to your concern, which I generally share, but
16 with regard to concern about all studies. I
17 guess the issue is: Let's say somebody is
18 getting an MRA or a CTA because they have had
19 a head injury and you are worried about a
20 dissection because of the nature of their
21 injury. It turns out they don't have a
22 dissection, but they have a 90 percent carotid

1 stenosis. Isn't that what radiologists are
2 supposed to do?

3 So I share your concern. Your
4 concern is for the patients where they
5 suddenly report like a 50 or 60 percent thing
6 on a suboptimal study, and what do you do with
7 that. But that is clinical judgment.

8 Same thing when we get an MR and
9 you see some abnormality, some lesion that you
10 didn't expect. Is it a tumor, is it not,
11 whatever? So you got to work it up further.
12 But I think that I am less concerned
13 personally about requiring people to report
14 it, as long as it is standardized.

15 I think, if it was not
16 standardized and you required them to report
17 it, that, to me, raises actually more concerns
18 to some degree. So those are my questions.

19 CO-CHAIR TIRSCHWELL: Bill?

20 DR. BARSAN: Just along the same
21 line as what Daniel said. For the developers,
22 I just don't know how you can fulfill the

1 numerator statement if the only imaging study
2 you did was a neck ultrasound, because the
3 numerator says you are going to do
4 measurements of distal internal carotid
5 diameter, which we have just been told many
6 times you can't do.

7 So I don't know. It just seems
8 like a disconnect.

9 CO-CHAIR TIRSCHWELL: Yes, and I
10 guess I will -- the Developer probably has a
11 number of things to say, and I will suggest
12 the possibility -- I think the title,
13 actually, Stenosis Measurement in Carotid
14 Imaging Studies, is fine, but perhaps the
15 numerator has to be changed to something like
16 what it is now, final carotid imaging study
17 reports that include direct or indirect
18 reference to measurements of the distal
19 internal carotid artery as the denominator for
20 stenosis measurement or, if the assessment was
21 ultrasound, standardized criteria for
22 reporting according to the radiology

1 guidelines, or something along those lines.

2 Does the developer have any
3 comments related to all that?

4 MS. JOSEPH: Hi, this is Diedra at
5 the AMA-PCPI. I just wanted to try to address
6 your concern about the ultrasound.

7 Actually, in the numerator details
8 we include a definition about the direct or
9 indirect reference to measurements of distal
10 internal carotid diameter as the denominator
11 for stenosis measurement.

12 I know that this was a point of
13 discussion during the original review of this
14 measure. So we actually were able to update
15 this definition, hopefully, to address your
16 concern.

17 The definition is that it includes
18 direct angiographic stenosis calculation based
19 on the distal lumen as the denominator for
20 stenosis measurement, or an equivalent
21 validated method reference to the above
22 method; for example, for duplex ultrasound

1 studies, velocity parameters that correlate
2 with anatomic measurements that use the distal
3 internal carotid lumen as the denominator for
4 stenosis measurement.

5 So I think that the reason why
6 that definition was added was to address that
7 concern. I think that perhaps Dr. David
8 Seidenwurm, who I think is in the room there,
9 could address your concerns more specifically.

10 CO-CHAIR TIRSCHWELL: So you are
11 saying that you already included that in the
12 numerator details, a different approach for
13 the carotids?

14 MS. JOSEPH: That is correct.
15 There is a definition in the numerator details
16 that was --

17 CO-CHAIR TIRSCHWELL: I guess that
18 is not reflected well in the numerator
19 statement that is at the top of the page that
20 everybody is paying the most attention to, and
21 you might want to update that a little bit.
22 Dr. Hackney?

1 DR. HACKNEY: Yes. It is
2 2(A)(1)(3), and it is part of the indirect
3 language refers to, that the indirect is a way
4 of saying in part that you are using something
5 else other than actually measuring the distal
6 carotid, but you are able to relate that
7 severity to the severity measured using the
8 CTA or MRA distal carotid method.

9 CO-CHAIR TIRSCHWELL: So,
10 essentially, the ultrasound standards were
11 used compared or set up compared to a NASCET
12 approach and, thus, serve as a proxy for the
13 ultrasound testing?

14 DR. HACKNEY: Yes, and there is
15 good data on that, that you can derive the
16 same -- you can derive equivalent numbers from
17 ultrasound.

18 CO-CHAIR TIRSCHWELL: So that is
19 great. It is already --

20 DR. HACKNEY: But you don't
21 measure.

22 CO-CHAIR TIRSCHWELL: It is

1 already in there, and I guess we just need
2 that reflected to some degree in the short
3 numerator statement that is at the beginning
4 of the measure, but I am sure the -- I am
5 guessing the developer would be happy to make
6 that change.

7 Any other questions or comments
8 about the evidence from the committee? Jack,
9 sorry.

10 DR. SCARIANO: If the actual
11 standards are actually based on the MRA
12 finding or the CTA finding, if that is the
13 actual standard, then when actually someone
14 has the ultrasound, what the surgeons are
15 going to say is, well, you know, the actual
16 standard, the actual standard that, actually,
17 we can see, is on the MRA and also CTA.

18 I have this problem now, that
19 actually, I don't know. If you have an
20 abnormal ultrasound or do you need an MRA or
21 do you need a CTA or do you need an angiogram?
22 It is kind of up to the vascular surgeon.

1 So I think, in having this
2 standard, it may actually confuse it even
3 more.

4 CO-CHAIR TIRSCHWELL: You know, my
5 personal perspective on that is that it is
6 highly variable what surgeons require prior to
7 doing endarterectomy, whether they are
8 asymptomatic or symptomatic, how much they
9 trust their local lab, how much they like
10 their radiologist. So I don't think we can
11 answer that or really even address it with
12 this particular measure.

13 David, then Michael.

14 DR. HACKNEY: Just the
15 asymptomatic versus symptomatic, I don't want
16 to get lost in there, because I think that is
17 a substantive issue. The technical thing
18 about the ultrasound versus CTA, MRA, I think,
19 they have dealt with, and they can update a
20 little.

21 I think the significance of a
22 given severity of stenosis is drastically

1 different in the asymptomatic than in the
2 symptomatic patients. In the asymptomatic
3 patients, at least at my place, what will
4 happen to you if you have a carotic stenosis
5 depends very much on whether you see a stroke
6 neurologist or you see a vascular surgeon.

7 If you have a 60 percent
8 asymptomatic stenosis and get sent to a
9 vascular surgeon, you are going to get
10 recommended to have that fixed. They are
11 going to stent it or they are going to do an
12 endarterectomy.

13 If you go to a stroke neurologist,
14 they will say that, with proper medical
15 management, your risk of stroke is so low that
16 it is almost impossible to document that there
17 is a method to make it lower.

18 So showing somebody who is
19 asymptomatic as a 60 percent stenosis and
20 putting him in a mechanical therapy pipeline,
21 you have done that patient a disservice. That
22 is the element that I am worried about.

1 I don't think there is any problem
2 with reporting a standardized measure of
3 stenosis in those patients, but I don't see
4 that they are benefitting, and I think they
5 could be harmed by it. That is my concern
6 about the asymptomatic ones, and then it
7 becomes tricky to know whether somebody is
8 symptomatic or not.

9 CO-CHAIR TIRSCHWELL: I guess,
10 seems to me that is not the radiologist's job
11 at that point. Michael?

12 DR. KAPLITT: That was the point
13 that I was going to make. Whether or not
14 different groups of providers are intervening
15 based on something -- I mean, this is a
16 radiology reporting measure, and I think we
17 are extrapolating many steps down the road.

18 I can tell you that a surgeon who
19 already feels that ultrasound is enough for
20 them to go ahead and operate on a patient is
21 not going to be changed by this, and vice
22 versa. A surgeon who doesn't feel ultrasound

1 is adequate and wants an anatomic study is not
2 going to suddenly operate on people because we
3 are standardizing the measure.

4 In fact, it could be the opposite,
5 which is that you will get more consistent
6 practice, because you are standardizing the
7 measure, but I think we are extrapolating too
8 much. I think ultimately the question from
9 the evidence standpoint, which is the question
10 we are still on, I think, is whether or not
11 there is adequate evidence that standardizing
12 the actual measurement has value.

13 I come back to the question I
14 asked earlier, which is that, if the clinical
15 data really does show that the degree of
16 stenosis, not just the qualitative measure,
17 actually influences therapeutic outcome, then
18 isn't that evidence that there is value in
19 actually standardizing it?

20 Now whether each modality in here
21 is justifiable, I think, is a reasonable
22 argument, but that is a separate question.

1 CO-CHAIR TIRSCHWELL: Okay. Any
2 other comments before we vote on the evidence?
3 Let's go ahead and vote then on the evidence.

4 MS. THEBERGE: Seventeen Yes; six
5 No, evidence does not meet guidance; one No,
6 insufficient information.

7 CO-CHAIR TIRSCHWELL: So check my
8 math, but I think we continue to proceed here.

9 The next topic probably can be
10 pretty brief: High impact. Yes. Okay, I
11 propose we vote on that. Any other comments
12 before we vote? Okay.

13 MS. THEBERGE: Twenty-one, High;
14 three, Moderate.

15 CO-CHAIR TIRSCHWELL: And then is
16 there evidence of a performance gap or an
17 opportunity for improvement?

18 DR. HACKNEY: Again, yes, they
19 present very good evidence that a lot of
20 people don't do this.

21 CO-CHAIR TIRSCHWELL: Let's go
22 ahead and open the voting. Go ahead and start

1 voting now.

2 MS. THEBERGE: Can everyone vote
3 one more time? Okay.

4 Twenty-one, High; three, Moderate.

5 CO-CHAIR TIRSCHWELL: Moving on to
6 scientific acceptability, starting with
7 reliability. David?

8 DR. HACKNEY: This one, I was a
9 little tough with. There are some precision
10 problems in those reports, but I think there
11 is good data that you can get precision that
12 is good enough to make useful predictions.

13 So I think it is reliable, and the
14 specifications are precise enough. I would
15 like them to clarify some of the issues I was
16 raising earlier about who is included in the
17 numerator and denominator, but how you do the
18 measurement is quite reliable.

19 CO-CHAIR TIRSCHWELL: Anybody have
20 comments or questions on that? Let's go ahead
21 and open the voting then. Go ahead and start
22 voting now.

1 MS. THEBERGE: Nine, High; 15

2 Moderate.

3 CO-CHAIR TIRSCHWELL: Okay. then
4 validity?

5 DR. HACKNEY: In their study where
6 -- they reported that expert opinion was the
7 criteria for validity, and the expert opinion
8 strongly supported it. That is the only
9 evidence of validity, but it was unanimous, I
10 believe, among their experts.

11 CO-CHAIR TIRSCHWELL: Anybody have
12 any questions or comments about the validity
13 issues? Okay, let's go ahead and open the
14 voting up. Go ahead and start voting.

15 MS. THEBERGE: Three, High; 20,
16 Moderate; one, Low.

17 CO-CHAIR TIRSCHWELL: Moving on to
18 number 3, usability.

19 DR. HACKNEY: I was at moderate.
20 As I said, since it is an impact on clinical
21 care by proxy, the measurement is useful to
22 know. No data on the measurement being

1 included in the report is critical, but you
2 could assume it.

3 It is understandable, with some
4 confusion I brought up about the denominator;
5 useful for public reporting, because it would
6 have the effect of improving performance,
7 information on performance, I would say, for
8 a subset of the patients. But it could also be
9 misleading for patients who undergo neck
10 vessel imaging for other reasons, but
11 meaningful, understandable, and useful for
12 public reporting. I was at moderate for those
13 reasons.

14 CO-CHAIR TIRSCHWELL: Any
15 questions or comments from the committee?
16 Let's go ahead and open the voting. Go ahead
17 and start voting now.

18 MS. THEBERGE: Three, High; 20,
19 Moderate; one, Low.

20 CO-CHAIR TIRSCHWELL: Then number
21 4, the last main criteria, feasibility.

22 DR. HACKNEY: Feasible

1 demonstrated by product of care processes.

2 Yes, High.

3 CO-CHAIR TIRSCHWELL: Okay, let's
4 go -- any comments or questions from the
5 committee? Let's go ahead and vote.

6 MS. THEBERGE: Eighteen, High;
7 five, Moderate; one, Low.

8 CO-CHAIR TIRSCHWELL: Then one
9 last vote, which is on the overall suitability
10 for endorsement. Any further comments or
11 questions before we go ahead and vote? Okay,
12 let's go ahead and open the voting.

13 MS. THEBERGE: Twenty-four, Yes.

14 CO-CHAIR TIRSCHWELL: Very good.
15 Moving on to the next measure, Fred, first
16 dementia measure, Neuropsychiatric symptom
17 Assessment. Oh, I'm sorry. Jocelyn, go ahead
18 first.

19 DR. J. BAUTISTA: Just a
20 procedural question. So this measure was
21 first endorsed in 2008 under time-limited
22 endorsement, and it is still under time-

1 limited endorsement four years later,
2 according to the --

3 CO-CHAIR TIRSCHWELL: I think they
4 said that they had gotten full approval in the
5 interim.

6 DR. J. BAUTISTA: It says time-
7 limited status not yet removed.

8 MS. JOSEPH: I can address that.
9 This is Diedra. We originally received time-
10 limited endorsement status in 2008. At that
11 time, with time-limited endorsement we were
12 allowed two years to test the measure.

13 Additionally, we applied for an
14 extension for EHR testing, and that was for
15 one year, and the measure was submitted at the
16 end of 2011 for review of the time-limited
17 status endorsement with the testing data.
18 However, because of the neurology endorsement
19 maintenance coming up, we were asked to submit
20 this measure for full review. So that is why
21 the lag.

22 DR. BURSTIN: It is no longer

1 time-limited.

2 DR. J. BAUTISTA: So the measures
3 that we approved yesterday for time-limited --
4 is that 12 months?

5 DR. BURSTIN: WE have changed that
6 policy now. It is 12 months.

7 DR. J. BAUTISTA: But,
8 potentially, they could extend it.

9 DR. BURSTIN: No. No more
10 extensions.

11 CO-CHAIR TIRSCHWELL: All right.
12 So back to dementia again, Neuropsychiatric
13 Symptom Assessment.

14 DR. TOLIN: This is measure 2009,
15 the first of the dementia assessments. This
16 measure deals with the evaluation of
17 neuropsychiatric symptoms in individuals who
18 have dementia. Let me start over again.

19 Dementia assessment: This is a
20 measure to evaluate the neuropsychiatric
21 symptoms of individuals who are diagnosed with
22 dementia, and it is meant to evaluate this

1 assessment being done at least annually or at
2 least once a year.

3 In the numerator statement the
4 assessment is divided into a couple -- three
5 main groups, activities, moods, thoughts and
6 perceptions, and there is a list generated in
7 the numerator which is not meant to be
8 exhaustive. It is just not an inclusive list,
9 just more of an example list, listing a number
10 of these, and there's also some suggestions,
11 although not mandatory, about several types of
12 scales that can be used which are commonly
13 used in research settings.

14 In the denominator, it is all
15 patients who carry a diagnosis of dementia,
16 and this is not limited to any setting. So it
17 can be either in a facility or living semi-
18 independently. I would assume that dementia
19 patients usually don't live completely
20 independently.

21 As far as the question of outcome
22 or how it is related to outcomes, this measure

1 is paired with measure 2011, which is the next
2 measure we will be discussing, and it has to
3 do with the treatment of the neuropsychiatric
4 symptoms.

5 The evidence for this measure is
6 not based on any trials, but is, in fact,
7 based on expert opinion.

8 I will stop there, David.

9 CO-CHAIR TIRSCHWELL: Okay. Thank
10 you.

11 DR. TOLIN: Oh, I meant to -- This
12 is part of the PQRS. This is the dementia
13 measures group of PQRS.

14 CO-CHAIR TIRSCHWELL: This is a
15 physician level measure.

16 DR. TOLIN: Yes, physician.
17 Sorry, I should have included that.

18 CO-CHAIR TIRSCHWELL: I will just
19 add just a little bit about the evidence
20 thing, and this is in the summary document.
21 A couple of different recommendations
22 statements were referenced as evidence, and

1 the process/outcome relationship included
2 something along the lines of assessing
3 neuropsychiatric symptoms leads to their
4 identification, and then can trigger
5 appropriate intervention.

6 So it is another one of those
7 multi-step situations that the evidence is
8 based one. I think, for this measure, as for
9 many of the subsequent measures, specifics of
10 evidence, types of trials, things like that,
11 were not really included in the form that was
12 submitted.

13 This came up again and again, I
14 think, on multiple conference calls, and some
15 of the recommendations were graded. Some of
16 them weren't. Many were based, as you said
17 exactly, Fred, on expert opinion.

18 Anybody want to add to that before
19 we vote on the evidence? Does the developer
20 have any comments before we proceed with a
21 vote?

22 MS. TIERNEY: Yes. Hi, This is

1 Sam Tierney. I just would like to make a few
2 comments about the evidence. The challenge
3 has been in answering the quantity/quality
4 question.

5 So as I said in the introduction,
6 we based on measures on the practice
7 guidelines, and many of those are evidence
8 based. Actually, probably all of them we used
9 are evidence based, and do some sort of review
10 on the evidence, oftentimes also supplements
11 it by expert opinion, where needed.

12 Unfortunately, the various
13 guidelines that we have relied on for these
14 measures from the American Psychiatric
15 Association, from the Third Canadian Consensus
16 Conference on Diagnosis and Treatment of
17 Dementia, and from the California Work Group
18 on Guidelines for Alzheimer's Disease
19 Management -- they include some indication
20 that they done a thorough review of the
21 evidence, but that information is not
22 available to the reader of the guidelines.

1 So where possible, we have tried
2 to include any sort of information that might
3 address to some extent the questions that were
4 asked in the submission form, but I think
5 ultimately the challenge is that, for
6 dementia, there is not a very strong evidence
7 base out there, particularly for assessment
8 type measures or counseling measures, and
9 those are unlikely to be subject to randomized
10 controlled trials.

11 I know that NQF in their Evidence
12 Task Force Report has recognized that some
13 aspects of health care are more difficult to
14 study with quantitative methods, particularly
15 randomized, controlled trials, and that some
16 process steps may be unlikely to be subjected
17 to research.

18 so we believe that many of these
19 measures may fall within that area. So I
20 think, as you are voting on evidence, if you
21 find that it isn't sufficient, which we
22 recognize that, we might ask that you could

1 consider the exception to the evidence
2 requirement.

3 So that is just all I will add. I
4 don't know -- I think we might have Dr.
5 Johnson on the line. I don't know if he has
6 anything he would like to add about the
7 evidence. Thank you.

8 CO-CHAIR TIRSCHWELL: thank you.
9 Is there a doctor on the line that wants to
10 comment?

11 DR. JOHNSON: Sure. This is Jerry
12 Johnson. The evidence from observational
13 studies --

14 CO-CHAIR TIRSCHWELL: Can you talk
15 a little louder, please?

16 DR. JOHNSON: Yes. Yes, there is
17 evidence from observational studies about
18 performance gap, not evidence, that speaks to
19 whether assessment itself leads to changes in
20 outcomes. That evidence doesn't exist now,
21 and I don't know that that type of a study
22 will ever be done.

1 So I agree with the comments that
2 were just made.

3 CO-CHAIR TIRSCHWELL: Okay. thank
4 you very much. A.M.?

5 DR. BARRETT: I have a specific
6 question to ask the developer about this kind
7 of evidence. Dr. Johnson, this is A.M.
8 Barrett.

9 With regard to these dementia
10 measures, a question that came up about many
11 of the aspects of quality clinical practice
12 which are included in these measures, is that
13 internal data may be available, since many of
14 these measures may be overrepresented in
15 quality settings, such as specialty clinics.

16 Therefore, there may be a
17 possibility of assessing outcome data in
18 comparing patients who have had these measures
19 versus those who have not had them, to
20 demonstrate the value of such assessment. Has
21 that been performed?

22 DR. JOHNSON: No, that hasn't been

1 performed either, just whether or not -- What
2 we know is that persons with dementia, who are
3 documented to have dementia, seldom have a
4 precise assessment necessary to make clinical
5 decisions, in this case about neuropsychiatric
6 symptoms. So we have that kind of data.

7 CO-CHAIR TIRSCHWELL: So that is
8 the evidence of a performance gap.

9 DR. JOHNSON: Yes, and that is
10 true across a variety of different settings,
11 primary care settings as well as specialty
12 clinics.

13 CO-CHAIR TIRSCHWELL: Okay, thank
14 you. Michael.

15 DR. KAPLITT: So given that it is
16 clear what the evidence vote is going to be,
17 because the developer themselves, everyone of
18 them, said there is no evidence on this point,
19 but they have several times requested the
20 exception -- so personally I would like to
21 hear the argument for that. I would like to
22 hear the argument for it, because we are not

1 going to vote unless someone raises it,
2 because this is going to be, it sounds like,
3 the same thing for like a lot of these coming
4 after.

5 So I would personally like to hear
6 what the argument is in favor of the
7 exception, given the discussions of how the
8 exception should be invoked yesterday.

9 CO-CHAIR TIRSCHWELL: So, Michael,
10 you are asking the developer what their
11 argument is?

12 DR. KAPLITT: Or even on the
13 committee. Does anybody on the committee have
14 an argument in favor of the exception that we
15 should be discussing. I guess, if not, then
16 that's it, but since the developer
17 specifically asked for that, I would like to
18 know what the argument is.

19 CO-CHAIR TIRSCHWELL: Let's get
20 these few comments, and then I will
21 specifically ask --

22 DR. KAPLITT: If they say there is

1 no evidence, so that's that.

2 CO-CHAIR TIRSCHWELL: Peter,
3 Daniel, then Gwen.

4 DR. SCHMIDT: So if you accept
5 that there is evidence that the differential
6 diagnosis of different characteristics of
7 dementia will inform -- it can be used as
8 evidence to inform therapeutic decisions, then
9 you have got what the UK NICE guidelines would
10 refer to as a none or some criteria, which
11 they classify as Class I evidence.

12 If no one is going to get that
13 evidence based therapy based on there not
14 being an assessment, but some people will
15 based on their being an assessment, the UK
16 would classify that as Class I. So you don't
17 have to -- It doesn't necessarily mean there
18 is not evidence if no one is going to get this
19 therapy in the absence of this assessment, and
20 some people will.

21 Many groups that assess evidence
22 do not consider that to be a leap of faith.

1 So in the absence of doing this assessment, no
2 one will -- If we believe that the evidence
3 for differential therapy -- So for example, in
4 Parkinson's Disease there is a poster at the
5 Movement Disorder Society saying that people
6 with higher executive -- people whose dementia
7 or whose cognitive decline is more in the
8 executive dysfunction domain have a higher
9 incident of false.

10 So in Parkinson's Disease, if you
11 assessed a higher level of executive
12 dysfunction, those people would need more
13 false counseling. You would do an OT home
14 visit, things like that, and if they have a
15 more generalized dementia, it is less of a
16 risk.

17 So if you don't do that
18 differential assessment, then you cannot --
19 you could give everybody the OT home visit,
20 but there is a difference in the way that you
21 would address the disease in these people
22 based on this differential assessment; and if

1 you don't do the differential assessment, then
2 you can't make that decision.

3 So no one would get the benefit of
4 having the therapy tailored to the
5 characteristics of their dementia, if you
6 don't do the assessment, and some people will
7 get it, if you do. So in the UK that would be
8 considered Class I. Does that make sense? No?

9 CO-CHAIR TIRSCHWELL: I understand
10 what you are saying. I am not sure that that
11 evidence grading system is what we are working
12 with here. Do you want to comment on that,
13 NQF staff?

14 MS. JOHNSON: I do just want to
15 remind you that, when we ask you to evaluate
16 a measure based on evidence, we do ask you to
17 look at the quantity, quality, and consistency
18 of the body of evidence. So you have to be
19 able to look at the submission and see what
20 they have provided in terms of that.

21 CO-CHAIR TIRSCHWELL: Okay.
22 Daniel?

1 DR. LABOVITZ: I enjoy beating
2 dead horses. So just indulge me for a minute,
3 because I don't think I will get much
4 opportunity to say this again.

5 I think all of these measures have
6 the same fundamental problem. This is an
7 evidence based committee. I figured that out
8 after about a minute, and I think everybody
9 else did, too. It demands evidence and, if
10 you don't have evidence, there are exceptions,
11 but I don't think this is really a question
12 for the developers. It is more a question for
13 NQF.

14 There are going to be times when
15 you come up with a measure where there is no
16 evidence or no evidence that would meet the
17 template that we use for evaluating these
18 measures, and I would suggest that developers
19 would have had a better time of it and could
20 have made a better case if there were a
21 process for that kind of measure, where you
22 have no data but we have a compelling reason

1 to put this out anyway.

2 Instead, developers are forced to
3 sort of twist through hoops, then finally
4 today say, well, yeah, you are right, you
5 know, there really isn't anything; and I hate
6 to see them have to do that. I would rather
7 see them put out something we can use.

8 CO-CHAIR TIRSCHWELL: Gwen?

9 DR. BUHR: And speaking about the
10 exception, I don't think this one would
11 qualify for an exception, personally, because
12 it is not something like your analogy of the
13 Parkinson's executive dysfunction. These
14 neuropsychiatric symptoms are not subtle and,
15 in my experience, the patient's caregivers are
16 coming complaining of these things.

17 It is not something that -- and if
18 they are not coming complaining, then fine,
19 they are doing okay, I think, and we have
20 already discussed they are not supposed to be
21 on any psychotic.

22 So if everybody is assessing for

1 subtle things and there is nothing really to
2 do about it except for complicated
3 nonpharmacologic things, then why should we
4 assess it? So I don't think it should be an
5 exception.

6 CO-CHAIR TIRSCHWELL: Okay, round
7 two of the comments. A.M.?

8 DR. BARRETT: First I would like
9 to clarify that I am not requesting an
10 exception, but I would disagree with what you
11 said, respectfully. I think the rationale is
12 what Michael asked for was a rationale for an
13 exception rests on three arguments, the first
14 being the value of assessment of adequate or
15 clinically standard assessment and initial
16 diagnosis. I think that many of us appreciate
17 that and that, indeed, there will never be any
18 randomized controlled study of that.

19 Secondly, the value of initial and
20 repeated assessment of clinically standard
21 symptoms such as neuropsychiatric symptoms in
22 targeting care appropriately; and I wish I

1 could say that I had confidence that
2 neuropsychiatric symptoms are always assessed
3 adequately by history.

4 Unfortunately, having observed,
5 for example, someone who came into a memory
6 disorder clinic I was heading saying I have
7 familial Alzheimer's disease, who after alone
8 giving that history after five years of being
9 treated in a specialty clinic, and actually
10 most likely had depression causing persistent
11 static cognitive symptoms. I don't believe
12 that that is the case personally.

13 Again, I think there is an
14 opportunity for the developers to present
15 evidence of this based upon administrative
16 data.

17 Thirdly, the argument is of public
18 health -- Sorry, that second argument also is,
19 I think, the argument that Peter was
20 addressing in which other countries have had
21 different standards for evidence.

22 Thirdly, the argument is for

1 public health. Of course, the burden of
2 Alzheimer's Disease is going to be a
3 significant problem for all of us, and we need
4 to -- I was going to say instantiate -- We
5 need to establish certain behaviors in our
6 clinicians in order to take advantage of
7 treatments that may reduce the burden of
8 Alzheimer's Disease, and specifically, for
9 example, cholinesterase inhibitors and other
10 treatments have been suggested for
11 neuropsychiatric symptoms as contrasted with
12 other symptoms.

13 So that is the argument: Initial
14 diagnosis; targeted treatment; public health.
15 Again, I think it is an opportunity for
16 presenting data in the second category.

17 CO-CHAIR TIRSCHWELL: Jordan, then
18 Gail and peter.

19 DR. EISENSTOCK: I just wanted to
20 add one thing really briefly. I am the lead
21 discussant for the next one, which is 2011,
22 and it is paired with this one. So I think

1 the head is about to get cut off of the body
2 of the one that I am about to talk about and,
3 because of that, I just felt it might be
4 necessary to add one piece of information
5 about the performance gap, which might lead to
6 us invoking the exception.

7 Again, to A.M.'s point, I don't
8 know that this is being done. In fact, there
9 were a couple of studies cited in 2011 that
10 suggest that only one-fifth or one-third of
11 patients are actually getting the
12 intervention, when in fact they already know
13 they have one or two neuropsychiatric
14 symptoms.

15 So I know I am bringing 2011 into
16 2009, but 2011 is sort of dead on arrival if
17 this one doesn't go through. So I thought I
18 had better say it now.

19 CO-CHAIR TIRSCHWELL: Okay. Gail?

20 DR. COONEY: And my comment is
21 really just toward the group, because they are
22 assessed -- because there are a number of

1 assessment measures, and I don't think we
2 should -- I think assessment is important if
3 we are ever going to assess interventions and,
4 if people are not assessing, then they can't
5 be appropriately looking at their
6 interventions.

7 So I would argue that we need to
8 look more at the specifics of the measure and
9 whether or not they are going to be valid
10 measures, rather than whether the -- and then
11 use the exception criteria for those that are
12 important and have valid measures associated.

13 CO-CHAIR TIRSCHWELL: So are you
14 asking for the exception on this one, Gail?

15 DR. COONEY: Asking for the
16 exception on this one? Yeah, I will ask for
17 the exception on this one.

18 CO-CHAIR TIRSCHWELL: Okay.
19 Peter?

20 DR. SCHMIDT: I just wanted to
21 clarify. First, in my comment I was not
22 specifically arguing that this measure,

1 everything that is addressed here, has
2 evidence behind intervening in that case, but
3 I think that we have had a number of
4 situations where we have said there is no
5 evidence for something that would be unethical
6 to run an RCT on.

7 You would not get through an IRB
8 something where you say I am going to
9 randomize people into a cohort where they are
10 or are not assessed for specific complaints.
11 No one would do that. I had to negotiate with
12 an IRB last week about how many digits of the
13 Canadian ZIP Code it was ethical for me to
14 collect. So they get very strict about a lot
15 of these things.

16 You cannot run these things as
17 RCTs. At the best, you can do a retrospective
18 observational study, which is going to have a
19 lot of confounding factors in it.

20 CO-CHAIR TIRSCHWELL: I guess I
21 would say that a good retrospective study or
22 a prospective cohort, things that are not

1 randomized for the reasons that you suggest,
2 certainly fit into the multiple levels of
3 evidence that exist and are consistently based
4 as greater than expert opinion.

5 So opportunities exist outside of
6 randomized trials to try to answer these
7 questions.

8 DR. SCHMIDT: I accept that.

9 CO-CHAIR TIRSCHWELL: John and
10 then David.

11 DR. DUDA: To that point, I think
12 they are talking about using things like the
13 NPI. You could easily do a trial where you do
14 the NPI annually in a cohort and you don't do
15 it in the other cohort, and still allow for
16 patients to complain about their mood, and
17 treat that.

18 I think that would give you some
19 evidence on whether or not this is meaningful.
20 But I guess I don't see how we would invoke
21 the exemption for yesterday's Parkinson's
22 Disease neuropsychiatric symptom measure and

1 not do it here. It is just a different -- It
2 is Alzheimer's Disease neuropsychiatric
3 symptoms. It is not just looking at memory.
4 It is looking at mood. Right?

5 We know that mood is probably --
6 Depression and anxiety are probably poorly
7 recognized in Alzheimer's Disease as well. I
8 am not a dementia person, but I don't see a
9 big difference between this one and that one,
10 and it may very well fail for other reasons,
11 but I think it is hard to make a compelling
12 argument that we should have done it for the
13 one yesterday and we shouldn't do it for this
14 one.

15 CO-CHAIR TIRSCHWELL: Okay.
16 David, are you withdrawing your comment?

17 DR. HACKNEY: People already said
18 what I was going to say.

19 CO-CHAIR TIRSCHWELL: Okay. Bill?

20 DR. BARSAN: I was going to say,
21 you know, the -- Jordan, you were mentioning
22 about the next one that linked to this, that

1 if this one goes down, the next one --

2 CO-CHAIR TIRSCHWELL: That is not
3 necessarily true.

4 DR. BARSAN: That was going to be
5 my point. I almost see, there might even be
6 more sense of doing the second one to show
7 that, in fact, if you notice these things,
8 there is a difference in terms of what
9 happens.

10 Well, in this one, which seems to
11 go one step back, at least that one is one
12 step closer to something that actually --
13 where something happens, where this one is two
14 steps away.

15 CO-CHAIR TIRSCHWELL: Thank you.
16 Fred, you have one more comment?

17 DR. TOLIN: It sounds like we are
18 about ready to vote on it. I will just get a
19 final comment in as the defender of this
20 measure.

21 I agree with most of everything
22 that was said, and thank you, Jordan, for

1 bringing out the point again that this is
2 paired. I think the spirit here really is we
3 need to look at -- We need to measure it. We
4 need to see that it is measured, and then we
5 need to look at the intervention.

6 Ideally, the progression would be
7 that at some point in time we no longer need
8 to be looking to make sure that people are
9 evaluating this but, in fact, looking to make
10 sure that the intervention is being done. So
11 I see this as a progression, and this as the
12 first step.

13 You are right. There is not a lot
14 of evidence. It is all expert opinion, but
15 there is evidence to suggest, and it was
16 pointed out, that this is not being done in
17 some number of patients. So it just
18 teleologically is a good idea to look at it
19 and that it all makes sense, and it fits in
20 with the intervention part that Jordan will be
21 discussing in a little while.

22 CO-CHAIR TIRSCHWELL: Yes. Just

1 one final musing on this. I almost wonder
2 whether a combined measure where -- You know,
3 there are a number of ways to pass. It
4 includes assessment and treatment. If you are
5 assessed and there are none, you pass. If you
6 are assessed and there are some, then you then
7 have to move on to treatment before you can
8 pass the measure. That might be a more
9 comprehensive way to evaluate it and one that
10 would sort of feel like the rubber is hitting
11 the road a little bit better. But that would
12 take a substantial revision from the
13 developer.

14 Any further comments from the
15 developers before we vote. Well, Michael, go
16 ahead, and then we will go back to the
17 developer.

18 DR. KAPLITT: I see the arguments
19 for potential exception. The problem is I
20 don't know what we are voting on here, because
21 while this may relate more to the
22 specification issue, I think it is important

1 to consider here, which is that what we are
2 voting on is a non-exhaustive laundry list,
3 and I don't know what it is.

4 I don't know what the actual
5 measure is that we are going to be voting an
6 exception on. We are saying it is important
7 to look for these things, but this is not a
8 specific thing. This is a laundry list of
9 things that you could do anything you want,
10 and some of it is not even on here.

11 So the question is: If we are
12 going to say there is no evidence to support
13 this but we are going to make an exception, we
14 are going to make an exception for this -- I
15 am not saying compelling argument -- for a
16 thing that may not have enough evidence, but
17 it is really important. What is it that we
18 are even voting on here?

19 CO-CHAIR TIRSCHWELL: And I am not
20 sure there is a clear answer to that. I think
21 they have made this long list that is only a
22 suggestion of some of the possibilities,

1 because there is an infinite variety of things
2 that could come under this topic.

3 it is true, I think, that this is
4 a measure that can be satisfied by
5 documentation only, a checklist, which
6 supposedly are not the type that are
7 particularly preferred by the NQF.

8 So specifically, what we are going
9 to vote on in a minute, we will talk about,
10 because Gail at least has endorsed the
11 possibility of an exception. Then one final
12 comment from the developer before we go ahead
13 and do the vote.

14 DR. JOHNSON: Yes. This is Jerry
15 Johnson speaking. I think the case has been
16 made for the exception by several persons who
17 just spoke. I will just speak to this last
18 question of what is being voted on, given the
19 long list.

20 What we don't want to do here is
21 try to specify for practitioners just which
22 behavioral symptoms or neuropsychiatric

1 symptoms they have to be mindful of. The big
2 gap -- One of the big gaps in caring for
3 persons with dementia is just overlooking and
4 not paying attention to these behavioral
5 symptoms at all.

6 The purpose of this measure is to
7 point out that that is a crucial part of
8 assessment, and then that is linked to the
9 next measure which gets to management.

10 CO-CHAIR TIRSCHWELL: Okay. Thank
11 you. AMA in the room, any comments?

12 MS. TIERNEY: I think, just to
13 emphasize Dr. Johnson's point and to your
14 point about possibly a better measure, I think
15 the intent of having the two measures is that
16 it is exactly what you described, that you
17 would have firstly, if there are no symptoms,
18 then you they don't move on to the next
19 measure. If there are symptoms, then there is
20 an expectation that there is symptom
21 management, and that is why the measures are
22 paired.

1 CO-CHAIR TIRSCHWELL: Okay, thank
2 you. So if we are going to move on to voting
3 -- and somebody correct me if I get this
4 wrong, which is possible -- if you think there
5 is evidence by whatever standard you believe
6 in, then vote 1. If you want to invoke the
7 exception, I think you need to vote for number
8 2, and if you think there is insufficient
9 evidence and there is no cause for the
10 exception, you have to vote number 3. Is that
11 correct? Okay, so let's go ahead and open up
12 the voting for this. Go ahead and start
13 voting now.

14 MS. THEBERGE: Zero, Yes; 16, No,
15 evidence does not meet guidance; and 8 No,
16 insufficient information submitted.

17 CO-CHAIR TIRSCHWELL: So because
18 we were invoking the exception, do we then
19 need to go on to a second vote specifically
20 about the exception? Is that right? Okay.

21 I am going to just read this out
22 loud about what we are voting on: If there is

1 no empirical evidence, e.g., only expert
2 opinion, and expert opinion was systematically
3 assessed with a group with agreement that the
4 benefits of the process that we are talking
5 about, which is the assessment of
6 neuropsychiatric symptoms, that the benefit of
7 this to patients greatly outweighs potential
8 harms, the question is, is there an
9 exceptional and compelling reason that the
10 measure should be considered further?

11 Vote 1, Yes; or 2, No. Don't
12 start voting yet. Please open the voting.
13 Go ahead and start voting not.

14 MS. THEBERGE: Eight, Yes; 16, No.

15 CO-CHAIR TIRSCHWELL: So I think
16 we are done with this measure then. Is that
17 right? All right.

18 Moving on to the next measure,
19 2011, management of neuropsychiatric symptoms.
20 Jordan?

21 DR. EISENSTOCK: Okay. We have
22 had a lot of discussion already about this

1 measure, just by nature of 2009 being paired.
2 Lots of the information is the same. Just as
3 some background, this is taking it to the next
4 step.

5 This is now the percentage of
6 patients who had been assessed and have a
7 known neuropsychiatric symptom, at least one,
8 who actually received some kind of
9 intervention.

10 So the numerator statement is
11 patients who received or were recommended to
12 receive an intervention for neuropsychiatric
13 symptoms within a one-year period. The
14 denominator is all patients, regardless of
15 age, with a diagnosis of dementia who have one
16 or more neuropsychiatric symptoms. There were
17 no denominator exclusion noted. It is again
18 at the clinician level. It is a process.

19 As far as evidence goes, it is
20 really a redundant conversation, I think, to
21 2009. The same consensus arguments from the
22 Canadian group as well as the California Work

1 Group were cited here.

2 With one exception, the comments
3 were the same in our Work Group as well.
4 There was some information about the quality
5 of evidence from the Canadian group who
6 suggested that nonpharmacologic interventions
7 were Level 1, where pharmacologic
8 interventions as far as quality were rated as
9 Level 3 or expert. So there was at least one
10 randomized controlled study to show that
11 nonpharmacologic interventions were useful in
12 this population.

13 I think that we covered everything
14 else in the last argument. So I think maybe
15 stopping there for comments.

16 CO-CHAIR TIRSCHWELL: I guess the
17 big question here is do people think that this
18 measure, which is closer to actions, and I
19 guess it is my impression that there is
20 evidence that treating these neuropsychiatric
21 symptoms -- is that what you were referring
22 to, Jordan? -- is supported by some evidence?

1 DR. EISENSTOCK: Well, the
2 clinical practice guidelines -- that was based
3 on evaluation --

4 CO-CHAIR TIRSCHWELL: It doesn't
5 specify particularly whether they were trials
6 or --

7 DR. EISENSTOCK: For
8 nonpharmacologic interventions, and that is
9 why there was one comment within the Work
10 Group of maybe pairing off nonpharmacologic
11 and pharmacologic, because of the level of
12 evidence quality was different.

13 CO-CHAIR TIRSCHWELL: Okay. It
14 sounds like there is at least some reason to
15 consider whether the evidence isn't a little
16 bit better in this situation than for the
17 previous one, but I would be very open to
18 hearing people's opinion about that. Gail?

19 DR. COONEY: I am never sure if I
20 am in the right section, but my concern with
21 this one is that it doesn't separate
22 pharmacologic and nonpharmacologic measures,

1 and the evidence strongly supports
2 nonpharmacologic measures over pharmacologic
3 measures.

4 Yet in clinical practice, it is a
5 whole lot easier to write a scrip and either
6 one of those will qualify you for this
7 measure. So I have a real problem with it.

8 CO-CHAIR TIRSCHWELL: So the
9 potential harm is that we might be fostering
10 something that in another measure was
11 suggested was harmful, which is the use of the
12 anti-psychotics or something like that. Any
13 further comments from the committee? Gwen?

14 DR. BUHR: I think, just speaking
15 about evidence, there is evidence for both
16 pharmacologic and nonpharmacologic. There's
17 randomized controlled trials for both, and
18 they show that both improved. It just happens
19 to also show that pharmacologic kills you, but
20 it treats the symptoms, the neuropsychologic
21 symptoms.

22 The number needed to treat for the

1 neuropsychiatric symptoms is much lower than
2 the number needed to harm. So there is
3 evidence.

4 CO-CHAIR TIRSCHWELL: Any other
5 comments from the committee? Jordan, any
6 other final comments before we vote? No.

7 Okay, let's go ahead. Daniel, go
8 ahead. Then I have one more thing to say
9 before we vote.

10 DR. LABOVITZ: I think this just
11 is another example where we would have a lot
12 better time figuring out whether the exception
13 applied if there were a process by NQF to
14 allow the developer to make that case.

15 CO-CHAIR TIRSCHWELL: Okay. Does
16 anybody on the committee want to invoke the
17 exception, which sort of changes the quality
18 of the voting, the meaning of some of the
19 responses? I am not seeing that here. So
20 let's go ahead and vote.

21 So to move past this point, you
22 have to vote number 1, Yes. Either of the two

1 or three will contribute to not passing the
2 measure or going further. Go ahead and vote.

3 MS. THEBERGE: Ten, Yes; 8, No,
4 evidence does not meet guidance; and 6, No,
5 Insufficient.

6 CO-CHAIR TIRSCHWELL: So I made
7 this mistake yesterday. I will try not to
8 make it again. I think that means that the
9 eight plus six is 14, which is greater than
10 10. So we will not move on any further with
11 this measure. So I passed for today anyway.

12 Moving on to the next measure,
13 2016, Screening for Depressive Symptoms. Sam?

14 DR. FAZIO: Sure. This is
15 dementia screening for depressive symptoms.
16 It looks at the percentage of patients,
17 regardless of age, with a diagnosis of
18 dementia who were screened for depressive
19 symptoms within a 12-month period.

20 They give a whole list of what
21 those depressive symptoms could be. I am not
22 going to read those. They are pretty

1 extensive, and also some examples of different
2 scales that are commonly used in clinical
3 practice.

4 The denominator statement is all
5 patients with a diagnosis of dementia, no
6 exclusions, and it is a process measure at the
7 clinician level.

8 I guess in looking at evidence,
9 similar to some of the discussions we have
10 just had, this is based on some practice
11 guidelines, but one from APA as well as the
12 California Work Group. So no specific
13 evidence listed and more clinical practice
14 guidelines.

15 CO-CHAIR TIRSCHWELL: So they
16 don't call out any trials where people were
17 screened for depression more consistently and
18 had better outcomes?

19 DR. FAZIO: No. They do cite --
20 not cite, but list the number of articles that
21 were in all the practice guidelines.

22 CO-CHAIR TIRSCHWELL: That is

1 always a high number.

2 DR. FAZIO: Five hundred fifty-
3 four for APA and 400 for the California Work
4 Group.

5 CO-CHAIR TIRSCHWELL: Yes,
6 tremendously high number. I guess it is hard
7 to know what to do with that, in particular.

8 Does anybody have any knowledge
9 outside of what was put in the document to
10 suggest that this screening leads to better
11 patient outcomes? salina, did you have a
12 comment? Any comments are welcome.

13 DR. WADDY: I was just wondering
14 from the developer where the depressive
15 symptoms exactly coming from, because I was
16 just a little confused.

17 CO-CHAIR TIRSCHWELL: You mean
18 calling that out as a specific
19 neuropsychiatric one as opposed to it being
20 lumped or --

21 DR. WADDY: No, no. Like the
22 depressive symptoms, they just put one of them

1 could be retardation. I assume they are
2 talking about psychomotor retardation. Some
3 of them are a little vague and -- Certainly,
4 they can be associated with depression, but
5 not specific. I was just wondering how that
6 list came about.

7 MS. TIERNEY: That list, I think,
8 is mostly based on the Cornell scale for
9 depression. The purpose of the list really is
10 to offer a guidance. So we realize that, as
11 we continue in our development of measures,
12 that a lot of users of the measures need a
13 little bit more guidance.

14 I think, particularly with
15 depression and dementia, we wanted to be
16 explicit about what might be symptoms. So
17 that list primarily comes from many of the
18 elements that are included in the Cornell
19 scale.

20 I don't know, Dr. Johnson, if you
21 have anything additional to add. We did have
22 a geriatric psychiatrist on the Work Group

1 specifically to work on developing this list.

2 DR. JOHNSON: This is Jerry
3 Johnson. The point here is that we did not
4 want to restrict the physicians to have to
5 proclaim a formal diagnosis of depression, for
6 example, a major depressive disorder which
7 itself consists of a list of symptoms, that
8 instead we wanted to make sure that
9 practitioners are attentive to the fact that
10 depression is a prevalent and potentially
11 management problem in patients with dementia,
12 and that they would, therefore, screen for
13 depressive symptoms.

14 Whether or not they used the best
15 ones or the formal ones that would lead to a
16 DSM-III or IV or V diagnosis, we thought,
17 would be too restrictive. So that is why we
18 listed the symptoms the way we did.

19 CO-CHAIR TIRSCHWELL: Okay. Gwen,
20 then John, Bill, Salina.

21 DR. BUHR: This one is one that I
22 think that our discussion about the first one

1 applies, and what A.M.'s point was, is that I
2 totally think that depression is often missed
3 in people with Alzheimer's or dementia and
4 that it is potential for the exception,
5 because it would be important to find
6 depression. There are good treatments for
7 depression, and it is not easy to -- It is
8 easy to find it if you ask for it or screen
9 for it, but it doesn't just come up in regular
10 conversation sometimes.

11 CO-CHAIR TIRSCHWELL: So you are
12 asking for the exception. Okay, thank you
13 very much. John?

14 DR. DUDA: I second the request.

15 CO-CHAIR TIRSCHWELL: Great.

16 Bill?

17 DR. BARSAN: Some of the same
18 things. I mean, I feel like if -- It sounds
19 like there is good, is very common. Is there
20 good data that treatment gives better outcome?
21 I assume there is, but I don't know the data
22 personally. I would be more convinced about

1 an exception if (a) we know it is really
2 common; (b) we know, if you treat it, it
3 really helps, which would maybe carry me over
4 for an exception on detecting it.

5 CO-CHAIR TIRSCHWELL: Salina, did
6 you have another comment?

7 DR. WADDY: Yes. I completely
8 agree with the previous comment. It is much
9 easier, I think, to vote for this, one,
10 because it is so important and, two, it is not
11 this larger grab bag, but now because of the
12 comments of the speaker on the phone, I am
13 just concerned in terms of how hard the
14 evidence is for the description that you are
15 giving for depression, since you are not
16 talking about diagnosing people with a major
17 depressive episode.

18 You are really talking about a
19 more squishy kind of diagnosis of depressive
20 symptoms. I am taking on Daniel's language
21 now.

22 CO-CHAIR TIRSCHWELL: That is not

1 a good sign, I don't think. So you would be
2 more comfortable if they said something like
3 dementia was screened for using a validated
4 scale or something like that, without even
5 specifying which scale it was? Depression --
6 sorry, what did I say? Yes, depression.

7 DR. WADDY: Something less open-
8 ended than just some of the things that you
9 put in this list, which a lot of elderly
10 people may have, but they aren't depressed.

11 CO-CHAIR TIRSCHWELL: Okay, fair
12 enough. Hang on one second. Can anybody
13 address Bill's question, which was supporting
14 the fact that there is evidence that treating
15 depression in dementia leads to better
16 outcomes? Gwen?

17 DR. BUHR: I know that there are
18 not big randomized controlled trials, but
19 there are randomized controlled trials of
20 people with dementia and depression who also
21 had agitation or behavioral symptoms and were
22 treated and improved. They are usually small

1 trials, but they are randomized controlled
2 trials, and there's quite a few of them.

3 CO-CHAIR TIRSCHWELL: Thank you.
4 John, you had your card up? You are okay?
5 Any other comments? A.M.?

6 DR. BARRETT: I was just looking
7 at the California guidelines with regard to
8 this point, to Bill's question. Actually, I
9 didn't find anything regarding treatment, but
10 I did find a point that addresses Salina's
11 comment about the randomized -- about using a
12 validated tool we do have to consider.

13 At the expert guideline level,
14 they cite several studies that describe
15 difficulty in administering standardized tools
16 to people with Alzheimer's Disease.

17 CO-CHAIR TIRSCHWELL: Michael?

18 DR. KAPLITT: I guess I have to
19 ask -- this is more of an NQF question. I am
20 much more enthusiastic about this than the
21 earlier one, because it is a big problem. It
22 is more specific, and I think the arguments

1 are well taken.

2 The problem is that, while the
3 California argument is somewhat reasonable,
4 Salina is right, that if you look at some of
5 this list, the question is, if it is just
6 going to be sort of a nonvalidated or -- as
7 difficult as that may be, if it is going to be
8 a nonvalidated measure that we are using, if
9 you are going to use things like difficulty
10 falling asleep or multiple awakenings, old men
11 get up three times a night to go to the
12 bathroom, you know, and that fits under this
13 criteria.

14 I am not being sarcastic on the
15 point. It is the problem with when it is sort
16 of vague like that. We all -- I think,
17 emotionally, it sounds like the committee is
18 moving very close to wanting this, because
19 depression is a very different thing than that
20 kind of laundry list of vague, sort of
21 affective symptoms earlier. But this is an
22 issue.

1 So if overall we kind of support
2 this, but the specifics of it, which really
3 get more to point number two, I guess, are a
4 problem, how do we deal with it? Do we give
5 the developer a chance to respond and adjust
6 it or do we say, look, you know, then that's
7 it, and they got to come back next time with
8 something different?

9 DR. BURSTIN: In some ways, I
10 would like to try to separate what is evidence
11 from validity, and I think what you are really
12 bringing up is validity. So it would be good,
13 I think, to get through the evidence, but I
14 think your point is well taken, of can this be
15 as precise measure in the way that it is
16 specified? I think we will get to that. We
17 will deal with it as soon as it gets through
18 evidence, if it gets through evidence.

19 CO-CHAIR TIRSCHWELL: Okay.
20 Peter?

21 DR. SCHMIDT: In the numerator
22 statement, they talk about using valid,

1 reliable instruments, including but not
2 limited to, and then a list of instruments.
3 We should be careful about having using expert
4 opinion to contradict a validated instrument,
5 if we accept that these instruments are
6 validated.

7 CO-CHAIR TIRSCHWELL: I am sure
8 they are validated in the general population.
9 Whether they are specifically validated in
10 dementia, I guess, is the issue at hand, and
11 you are right. It is already in there. So I
12 don't know why we would necessarily have to
13 add it. Maybe we have to make the wording
14 more strongly that they need to do it or
15 something. Salina?

16 DR. WADDY: Yes. I definitely saw
17 these, and I saw that the Cornell Scale for
18 depression, which was actually in dementia was
19 there, but that really -- That gets back to
20 the question that I asked the person who is on
21 the phone, as well as the developer, you know,
22 how they came up with these. If they said

1 that all of these symptoms came from these
2 three scales and how they were used, then I am
3 fine with that. But that is really not what
4 they said.

5 CO-CHAIR TIRSCHWELL: Ramon, and
6 then John.

7 DR. R. BAUTISTA: What about the
8 patients with severe dementia? Can we really
9 assess them for depression? These people are
10 pretty much nonverbal at that point. How do
11 you account for them?

12 CO-CHAIR TIRSCHWELL: Okay. John?

13 DR. DUDA: I just want to request
14 that we vote on the evidence, because I think
15 these arguments are going to play too much
16 into that decision, and I don't think it is
17 appropriate.

18 CO-CHAIR TIRSCHWELL: That's fine.
19 Let's go ahead and vote. I think at least one
20 person has called out -- More than one person
21 has called out the exception. So when we vote
22 on the evidence, again number 1, there is

1 evidence to proceed; number 2 means you are in
2 support of the exception; and number 3 means
3 you think neither is there evidence nor should
4 the exception be applied here. So let's go
5 ahead and vote, starting now.

6 MS. THEBERGE: One, Yes; 19, No,
7 evidence does not meet guidance; and four, No,
8 insufficient.

9 CO-CHAIR TIRSCHWELL: So now we
10 will move on to the voting on the exception,
11 if you could throw up that slide. John, do
12 you have a point first?

13 DR. DUDA: Maybe I should have
14 done this with the other one, but I would like
15 to hear some argument. I was kind of
16 expecting the other one to get the exception
17 as well. I would like to hear the argument
18 against the exception for this one, if people
19 are planning on doing that.

20 I think it is an easy argument to
21 make that there should be an exception, that
22 this is a compelling and, whatever the wording

1 it, exceptional case where there is little
2 chance of harming a patient if you ask them
3 about depressive symptoms, and a compelling
4 reason that it might be helping them.

5 CO-CHAIR TIRSCHWELL: Exceptional
6 and compelling reason. David, did you have a
7 comment? Then Daniel.

8 DR. CO-CHAIR KNOWLTON: I can't
9 give an argument one way or the other, John,
10 but I can say that I am troubled with the
11 exception in general. I think that we forget
12 that NQF has a whole bunch of committees doing
13 a whole bunch of things that are making a
14 whole bunch of providers go through all kinds
15 of hoops, and I think the standards for those
16 should be very high.

17 I am a quality advocate. That is
18 my day job. That is what I do. So I am in
19 favor of quality, and I want us to kick butt
20 with quality. But I feel that we already have
21 providers beside themselves with stuff they
22 have to report, that they have to comply with.

1 Part of what I do is defend it by
2 saying this is a high standard, harmonized
3 measure, and I was part of the committee that
4 worked on harmonization with Leapfrog and NQF
5 and feeling strongly that you can't be jumping
6 through everybody's different hoop.

7 What happens when provider groups
8 come in? They don't want to be prescriptive.
9 They really don't. They want to say, well, I
10 got to refer to another doctor, and NQF
11 doesn't let them do that. Then they say, we
12 don't want to impose upon clinical judgment.
13 NQF doesn't want to let them do that. They
14 want to say you can say professional judgment
15 has a place, but you have to document it, and
16 you have to make other decisions.

17 So it is trying to make it robust.
18 I can't speak to this particular measure,
19 because I am not the clinician here, but I do
20 get troubled with this exception, and it is
21 has been troubling with every single vote,
22 same issue. I guess, but on the other side of

1 that argument, you guys are the clinicians,
2 and I say you want to go through those hoops,
3 that's okay with me. But it seems to me that
4 we are trying to get standards that we can
5 hold people accountable.

6 When we look at making the
7 exception, we are talking about it being
8 exceptional and compelling. I understand
9 that. Peter made that argument during the
10 break, and he is right, but sometimes they are
11 just compelling arguments.

12 I believe we were talking about
13 the epilepsy and pregnancy where it is sort of
14 like the HIV argument we talked about and so
15 forth. You know, safe sex was just a good
16 idea. You could think about it logically, and
17 maybe we haven't got the measures yet. We
18 need to get them, and so forth. I get all
19 that, but I think that -- I think this should
20 be a very high jump bar.

21 It should be a very high bar to
22 have somebody get an exception. I was

1 troubled the last time with somebody coming
2 in, and I'm with John. I thought we were
3 going to debate it, and we went right to a
4 vote.

5 I was troubled in the last one
6 that the person presenting the evidence said
7 I think an exception would be appropriate, and
8 I am uncomfortable with that.

9 So that is not an argument for or
10 against. It is just a statement of how I feel
11 about the whole exception thing.

12 CO-CHAIR TIRSCHWELL: A word of
13 caution that there are costs associated with
14 all these things. Daniel?

15 CO-CHAIR KNOWLTON: Absolutely.

16 DR. LABOVITZ: I heartily second
17 Dr. Knowlton's comments here. As one of the
18 guys who has to actually do these measures and
19 flog my people to do them as well, there is a
20 very heavy penalty for adding another set of
21 checkboxes that have to be done when you are
22 trying to evaluate a patient.

1 I don't find this compelling, and
2 here is why. It is not that I don't care
3 about depression in demented patients, because
4 I deeply do. I think depression has a huge
5 impact on quality of life in almost every
6 disease where it is more common than in the
7 general population. Often it is more
8 important to treat the depression than it is
9 to treat the disease. In epilepsy, I wrote a
10 paper with my wife that seemed to show that.

11 In this case, we are not talking
12 about depression. We are talking about
13 depressive symptoms. We are removed from the
14 remove. I don't find that compelling.

15 CO-CHAIR TIRSCHWELL: John?

16 DR. DUDA: I think, David, you
17 were making the argument that it was not
18 exceptional and compelling, and I accept that.
19 I think that, Daniel, in your practice, you
20 know, the argument that we are going to be
21 making people in practice centers jump through
22 more hoops -- I don't know if that flies with

1 me, because -- and I certainly check for
2 depression in my patients. So I am not going
3 to have to do anything better.

4 I thought the purpose of this was
5 to kind of assess whether or not people are
6 doing standard of care health care practice
7 for the benefit of these patients, and I think
8 that assessing depression in a dementia
9 patient is a no-brainer, standard of care
10 aspect of caring for those patients.

11 So people who are doing good care
12 are not going to have to do anything
13 different, and to say -- You know, we are not
14 arguing about whether this particular measure
15 is the right way to do that. I think at this
16 point, we are arguing about whether or not the
17 lack of empirical evidence to prove that this
18 should be a topic that has a measure about it
19 is worthwhile or not.

20 This may very well fall on the
21 validity/reliability issues or usability, but
22 is this an exceptional or compelling reason to

1 step past the need for a compelling empirical
2 evidence

3 CO-CHAIR TIRSCHWELL: Peter?

4 DR, SCHMIDT: There are a number
5 of cases where things that seem obvious and
6 they are important to do wind up having
7 negative consequences. So Ramon brought up
8 the severely demented patient. How are you
9 really going to assess them? But if you set
10 this as a standard, people will carve out time
11 and do something.

12 One of the complaints that I have
13 gotten as I have gone around and talked to
14 movement sort of people is that in meaningful
15 use, they said smoking cessation is required
16 for meaningful use.

17 In Parkinson's Disease, there is
18 some evidence that you shouldn't be counseling
19 people to stop smoking. It is probably not
20 what is going to kill them.

21 Some people feel that they are
22 self-medicating by smoking, and it is very

1 frustrating to these people that they are
2 required to counsel these people about smoking
3 when, in fact, a lot of these people have
4 decided that smoking is beneficial to them, to
5 their Parkinson's Disease. So that was
6 adopted as one of 10 things that was put into
7 meaningful use, and it is a negative in this
8 case.

9 To your point, are we going to
10 wind up with people who are wasting their time
11 assessing people for depressive symptoms when
12 they are severely demented and can't respond?

13 CO-CHAIR TIRSCHWELL: Salina?

14 DR. WADDY: All of those points
15 are certainly well taken, and I think I agree
16 most, though, with what Daniel was saying. Is
17 this measure really getting at the symptoms
18 that -- or the problem that we are trying to
19 go after? I think they just throw a lot of
20 things into that. I am not confident that it
21 really reaches a level for the exception.

22 The other thing: Since I have

1 been here and I have access to the Internet
2 and this has been coming up, I am a little bit
3 troubled that some of the things I am finding
4 regarding the geriatric depression scale and
5 the attempts to use that scale, because you
6 specifically listed it -- use that scale in
7 patients with dementia.

8 There have been studies that have
9 shown that it really loses its validity when
10 you try to apply it. So can you talk a little
11 bit to that?

12 MS. TIERNEY: Sure. I think the
13 overall intent of the measure is not to be
14 prescriptive in the manner in which the
15 clinician would screen for depression.

16 I think, you know, this measure is
17 unique compared to other screening for
18 depression measures in that it specifically we
19 are screening for depressive symptoms, but it
20 is actually in many ways very similar to other
21 screening for depression measures that have
22 been endorsed by NQF and that are out there,

1 in that you are not making a diagnosis of
2 depression. You are simply screening for
3 symptoms of depression, and any of the
4 validated tools potentially do that.

5 Then the next step is actually to
6 do a formal diagnostic examination. So I
7 think this measure is actually not congruent
8 with any other screening for depression
9 measures. It might be more apparent to
10 specifically use the term screening for
11 depressive symptoms, but certainly any type of
12 screening measure, you are simply doing a
13 screen and a quick check to see whether or not
14 more evaluation might be needed. Then more
15 evaluation can be done to make the formal
16 diagnosis and then ultimately some type of
17 treatment.

18 So I think that is the spirit of
19 this measure. I think it might be difficult
20 with the terminology used to answer your
21 specific question. I think, as our Work Group
22 discussed, the ideal would be that Cornell

1 scale for depression and dementia, but as we
2 hear from -- As many of you have noted about
3 the difficulty in using these in practice, if
4 you get too prescriptive, then maybe the --
5 and I am not sure how long -- Dr. Johnson
6 might be able to compare.

7 So if we were to put this in practice
8 and say we require the Cornell Scale, we would
9 hear a lot of people saying I don't have 20
10 minutes to administer the scale, but that is
11 why we do allow clinical judgment, and we have
12 listed other scales that are also available
13 for certain patients.

14 For specifically for geriatrics,
15 PH-29 is a very broadly used scale, and I
16 guess clinicians might see most appropriate
17 for patients needs and maybe the confines of
18 their practice setting.

19 DR. WADDY: Regarding the GDS and
20 that it remains valid in older patients, but
21 actually applying it to the demented patients,
22 which is a good measure.

1 CO-CHAIR TIRSCHWELL: so we should
2 probably come back to that if we get to
3 validity. Ramon?

4 DR. R. BAUTISTA: I am quite
5 concerned to actually discussing an issue or
6 a measure where the developer, as he says, the
7 quality of the body of the evidence was not
8 addressed. You know, this is going to be one
9 of many, many things we are going to require
10 physicians, clinicians to do.

11 If you have worked in compliance
12 committees before, trying to justify every
13 single clinical note, you know how it is
14 sometimes to get everything right. It sounds
15 like a good idea on face value, but the point
16 is -- I mean, I could at least ask for a case
17 series to justify whether you want this
18 measure to come about, and there is nothing
19 here at all even close to that.

20 I am just concerned, like what
21 David said. I mean, we are actually asking
22 more and more of physicians, force another

1 test on the nurse practitioner to perform on
2 patients, and for really what is the evidence
3 for that? You know, at least show me a case
4 here that this actually works, you know.

5 CO-CHAIR TIRSCHWELL: John, Risha,
6 then Gwen.

7 DR. DUDA: I guess I just wanted
8 to say again that I think a lot of this is
9 related to validity and reliability, and I
10 haven't heard any compelling reason other than
11 you just don't believe it is exceptional and
12 compelling, that they looked at the
13 literature. They said that it is not -- it
14 was systematically assessed.

15 Is there an agreement that
16 assessing depression in demented patients --
17 and don't talk about how they are assessing;
18 I don't think that is relevant here -- greatly
19 outweighs the potential benefit, greatly
20 outweighs the potential harm? I think that is
21 the question on the table. Right?

22 CO-CHAIR TIRSCHWELL: Yes.

1 Depressive symptoms, not depression. Gwen,
2 then Risha.

3 DR. COONEY: I agree with John.
4 I think that a lot of the literature on
5 depression and dementia is more about
6 depressive symptoms. So because of the
7 difficulty of making a diagnosis of major
8 depressive disorder, they don't talk about
9 that. They talk about depressive symptoms,
10 and do you have dysphoria, and then you treat
11 that, and then they get better.

12 So I really think that, in
13 contrast to the previous one, that the
14 potential benefit does greatly outweigh the
15 potential harm.

16 CO-CHAIR TIRSCHWELL: Okay. Thank
17 you. Risha, then Michael.

18 DR. GIDWANI: what I see as a
19 potential benefit is that a patient that has
20 been diagnosed with depression getting linked
21 to treatment, that that improves their
22 outcome; and I don't think we are there with

1 this measure.

2 We are looking at depressive
3 symptoms. Then there has to be a formal
4 evaluation of depression. Then we are hoping
5 that the patient is going to be linked to the
6 appropriate management, and I think we are now
7 getting really far away from the health
8 outcome of reducing depression that we are
9 interested in.

10 CO-CHAIR TIRSCHWELL: Michael and
11 Daniel.

12 DR. KAPLITT: To David's point
13 about standards, I completely agree. As much
14 as I want to support measures like this, I
15 would kind of turn the argument around and
16 say, rather than what is the compelling
17 argument not to invoke the exception, I would
18 like to know what the compelling argument was
19 why evidence was not provided here.

20 We are not talking about
21 randomized, double-blind studies. We cannot
22 generate evidence or provide evidence in this

1 document from everything that has done out
2 there in the world that says that evaluating
3 and treating patients with depression actually
4 has benefit in any reasonable form? We are
5 giving expert opinion, and then we are saying,
6 well, we don't really have access to how they
7 did their data, because they don't provide
8 that online, whatever.

9 We are lowering our standard to a
10 level here. This is not a data gathering
11 organization, and this is not sort of a think
12 tank. To the point of, well, there is really
13 no harm, and if you are doing it anyway -- for
14 every couple of minutes that I spend on each
15 of my patients, surgical patients, having to
16 document and discuss body mass index and
17 smoking, when you add that up throughout the
18 day, that is easily two or three more patients
19 that I cannot see because of those things that
20 I am doing, and those patients that I have no
21 relationship with could care less about my
22 discussion with them about their body mass or

1 their smoking, but I have to do it, because it
2 is required, even though it does nothing.

3 So there are costs to all of this
4 unless we have a real standard.

5 CO-CHAIR TIRSCHWELL: So, Michael,
6 you are sort of bringing out the point that --

7 DR. KAPLITT: I would like to know
8 why we are even invoking the inception,
9 because while I am emotionally very supportive
10 of this idea, I would like to know why we
11 don't have better evidence here; because, to
12 me, part of the reason for the exception,
13 whether it is written or unsaid, is that there
14 is just no good way to get any type of
15 compelling evidence. Forget about randomized,
16 double-blind studies.

17 CO-CHAIR TIRSCHWELL: And you
18 don't believe that is the case here?

19 DR. KAPLITT: I don't see how that
20 is not the case here.

21 CO-CHAIR TIRSCHWELL: Okay. Very
22 good. Daniel?

1 DR. LABOVITZ: I am back to
2 beating dead horses. I think part of the
3 reason that we are struggling here a bit is
4 that each one of us individually has invented
5 his own internal set of standards for what
6 exceptional and compelling is.

7 When we have evidence based
8 measures, we go through a lengthy multi-step
9 subsection 2, Part 17. It is extraordinary.
10 Here it is just like, hey, what do you think?
11 Is this big? I can see why there is
12 disagreement in the room, and I think we have
13 been asked to do something that we are not
14 prepared to do, and that developers weren't
15 set up to present.

16 I think this is really a demand.
17 The struggle we are having here is really a
18 demand for, if we are going to have the
19 capacity to have exceptions, we need to have
20 a set of standards and a set of agreed upon
21 rules for how to approach it.

22 I think John Duda and I completely

1 agree that talking about depressive symptoms
2 to patients is a fundamental part of clinical
3 practice. Where we might disagree is whether
4 or not you go through the rigmarole of
5 checking off 17 boxes in an EMR form to
6 document it, and whether you then go through
7 the rigmarole of measuring that, because you
8 know it makes a difference to do the task.

9 That is a fair disagreement, but
10 we don't even have a basis for having that
11 disagreement. All we can do is to say, ah, I
12 think it is compelling or I don't.

13 CO-CHAIR TIRSCHWELL: Salina?

14 DR. WADDY: I agree with Daniel's
15 statement, but I also agree with Gwendolen and
16 John in that this is a very important topic
17 for them to develop a measure. The issue that
18 I have is that exceptional isn't regarding
19 whether or not the topic is important. It is
20 whether or not this measure meets that level,
21 and I just don't think so.

22 CO-CHAIR TIRSCHWELL: I think that

1 also gets back to Risha's point. Is it so far
2 removed, as has come up with many other
3 measures, that it is hard to have that faith
4 that it is going to translate into better
5 outcomes?

6 Any other comments that people
7 have? Yes, Helen?

8 DR. BURSTIN: Just one brief
9 comment. When our Evidence Task Force did
10 this work about a year and a half ago or so,
11 this was really intended to be an exception.
12 They didn't spend a lot of time on it, because
13 they really focused in on the fact that they
14 wanted to see quality, quantity, and
15 consistency of evidence. But then, as the
16 discussion really emerged, there were clearly
17 areas in clinical care and health systems
18 improvement where evidence was emerging in
19 some really important topic areas that just
20 may not be there yet.

21 So this was not to be an exception
22 for when the developer couldn't cull the data

1 and put it forward. It was really an
2 exception to when the evidence just wasn't
3 there yet, but it was such an important area
4 that people thought it was important enough to
5 bring it forward for now.

6 I think your point is well taken.
7 If we are starting to see committees
8 struggling with this and trying to invoke it
9 more often, we need to go back and standardize
10 exactly what we expect of you guys, what we
11 expect of the developers. But again, it was
12 called an exception intentionally to be a rare
13 event, not something that we just reflexively
14 go to if the developer can't provide evidence.

15 CO-CHAIR TIRSCHWELL: And just as
16 a point of clarification, if the guidelines
17 that are out there don't spell out the
18 evidence in enough detail, does it then become
19 the obligation of the developer to go back and
20 look more at the primary literature to be able
21 to present it themselves?

22 DR. BURSTIN: Right, and that is

1 the intent. For those of you who didn't see
2 it, the IOM came out with a report fairly
3 recently on the quality of guidelines in
4 America. So we are sort of in a supply chain,
5 of course.

6 So if the guidelines aren't doing
7 a good job of providing transparent systematic
8 reviews on the quality, quantity, and
9 consistency -- and those are the exact words
10 in the IOM report. They said guidelines
11 should be clear as to the quality, quantity,
12 consistency of the evidence.

13 So if there is a systematic review
14 done, that's great. they can cite the
15 systematic review. But if that is not
16 transparent, it is a burden to the developers,
17 and we understand that, and a lot of the
18 developers aren't set up to certainly do their
19 own systematic reviews, but it is, I think,
20 something we will see change over time as
21 guidelines improve.

22 CO-CHAIR KNOWLTON: But, Helen, I

1 think that getting some level of feedback is
2 actually key to transparency. That is the
3 problem here. I agree with Daniel completely.
4 You know, it is everybody's kind of seat of
5 the pants judgment here.

6 I don't disagree with what John or
7 what anybody has said, Gwen or anybody is
8 saying this clinically. I am just saying that
9 we haven't got any criteria here. It is
10 Dave's criteria and Dan's criteria and John's
11 criteria. That defeats transparency.

12 So I think -- and as we said when
13 the evidence committee came up with this
14 exceptional thing, maybe they should have
15 given us an example of an extreme. We have
16 something, and we say does it rise to that
17 level, because they could, as Michael said.

18 I think the issue here is -- I
19 don't disagree with what John and Gwen are
20 saying. This is important in clinical
21 practice. As Salina said, let's go get the
22 evidence. There's got to be evidence out

1 there.

2 DR. BURSTIN: And the intent as
3 well of making it a very transparent exception
4 -- again, you guys are still early in the
5 process. When this goes out for comment, it
6 is obvious to everybody out there reading this
7 report, this measure went forward on the
8 exception, and then we get comment on that.

9 So while it is somewhat reliant on
10 the perspective of the multi-stakeholders
11 sitting at this table, it then is fully
12 transparent and goes out for broader public
13 comment to get a sense of was that exception
14 reasonable.

15 CO-CHAIR TIRSCHWELL: Jolynn, then
16 Ramon and John.

17 MS. SUKO: Well, it sounds like
18 that this is really evolving, and I am
19 thinking that there have been a number of
20 suggestions around the table, like Peter's
21 suggestions. Is it an area where it would be
22 unethical to do research?

1 I am wondering if the NQF can cull
2 some of those from the conversation at this
3 table as it matures and moves forward to
4 better define some of this.

5 CO-CHAIR TIRSCHWELL: Ramon?

6 DR. R. BAUTISTA: If there is no
7 evidence -- There is an evidence based
8 discussion. I believe it is the developer's
9 responsibility to tell us why there is no
10 evidence. I mean, they should tell us that
11 explicitly, there is no evidence because, not
12 just to leave it hanging like this.

13 CO-CHAIR TIRSCHWELL: John?

14 DR. DUDA: I agree with that, but
15 we are here now, and I think it is -- we are
16 not going to get them to change their
17 guidelines or specify exactly what they mean,
18 and I think in the interest of transparency,
19 we have to remember that yesterday we made an
20 exception to a measure evaluating depression
21 and a bunch of other things in just a squishy
22 way for Parkinson's Disease, and now we are

1 saying that dementia patients -- that it
2 doesn't meet that standard.

3 CO-CHAIR TIRSCHWELL: I think that
4 speaks to the lack of standards in making this
5 decision more than anything else, and that it
6 is probably impossible to be consistent
7 without standards. It is definitely a seat of
8 your pants thing, and some measures people,
9 people think, are more important than others.

10 Ramon, do you have a final comment
11 or can I -- So let's go ahead and vote on the
12 exception here. If you think there is an
13 exceptional and compelling reason, vote Yes;
14 if not, vote No.

15 MS. THEBERGE: Six, Yes; 18, No.

16 CO-CHAIR TIRSCHWELL: Okay. I
17 guess we are done with that measure. Which
18 one was that anyway -- 2016.

19 All right. Last one before break,
20 1990. Daniel, can you lead us through an
21 overview and the evidence, such as it exists?

22 DR. LABOVITZ: This is a measure

1 of grading severity of dementia in patients
2 with an ICD-9 code documenting the presence of
3 dementia. So the numerator is whether a
4 severity of dementia was -- whether dementia
5 was classified as mild, moderate or severe at
6 least within a 12-month period, amongst all
7 patients with a diagnosis of dementia.

8 it is strongly implied but not
9 strictly stated that one of a number of
10 available valid and reliable instruments
11 should be used to assess the dementia.

12 This is a patient level -- a
13 provider level measure, and it has exactly the
14 same amount of evidence cited as all the
15 previous measures.

16 I did take the time to look at the
17 six citations mentioned by the developers. I
18 didn't want to spend that time, but I was
19 curious to see the six reference out of the
20 556 that are in the American Psychiatry
21 Association Guidelines.

22 Each one of those references is

1 simply a reference to one of the tools that
2 one might use. It has nothing to do with
3 evidence for the measure. I would like to see
4 down the line -- a little editorial here --
5 that -- Just spare me that. I don't want to
6 have to look to see that there is nothing
7 there. I think the developers perfectly knew
8 that. We all did.

9 The question is going to revolve
10 here, as it has with all the other measures on
11 dementia, is there a compelling exception, and
12 that was a major focus in the committee
13 discussion.

14 CO-CHAIR TIRSCHWELL: Mary, then
15 Gail.

16 MS. VAN DE KAMP: I just have more
17 of an information question. It is already a
18 PQRS dementia measure. So are they already --
19 Are physicians already reporting this as part
20 of that measurement system? Does anyone know?

21 MS. TIERNEY: Yes. In 2012 not
22 all of these measures presented for you are

1 part of the dementia measurement which is
2 currently being reported.

3 MS. VAN DE KAMP: So is there data
4 then now that you are collecting in the PQRS
5 information?

6 MS. TIERNEY: Yes. CMS is
7 currently information on these measures. It
8 usually takes some time for that to make its
9 way to us so that we can get that information
10 and see how physicians are performing on the
11 measures.

12 We do receive some patient
13 comments. So if someone had a question about
14 the measure and how it is supposed to be used,
15 those often are directed to the developer, and
16 to my knowledge we haven't really received
17 anything on any issues of concern with these
18 measures.

19 They are currently being used in
20 that program, but it takes a year, if not
21 longer, in order for us to get some data from
22 CMS on these measures.

1 MS. VAN DE KAMP: So that means
2 there is a financial incentive for physicians
3 to use these outcome measures. Is that
4 correct? with the PQRS?

5 MS. TIERNEY: Yes, there is an
6 incentive payment. Yes.

7 CO-CHAIR TIRSCHWELL: You don't
8 use them.

9 MS. VAN DE KAMP: You don't get
10 money forward. You get money back? There is
11 no disincentive.

12 DR. BURSTIN: No. They take away
13 your money. Currently, it is still an
14 incentive program, but in 2015 penalties will
15 start.

16 MS. VAN DE KAMP: I guess that is
17 one of my confusions with some of these that
18 are PQRS measures and NQF measures. Is there
19 any sort of harmonization with CMS to these?
20 I mean, do they look at NQF to come back to
21 say --

22 DR. BURSTIN: Yes. The majority

1 of the measures on PQRS are NQF endorsed.
2 Some of these newer ones were put on the PQRS
3 list in advance are reviewed by NQF.
4

5 CO-CHAIR TIRSCHWELL: and I think
6 in our first round through all these dementia
7 measures, we were confused by the fact that
8 they were already in use, but there was no
9 data. Then the developer came back to us and
10 said, yes, they are starting to be used, but
11 we don't have the data yet; so we can't
12 present the data. Gail?

13 DR. COONEY: I was waiting for
14 Daniel to invoke the squishy clause on this
15 one. My problem with this one is that I could
16 find nothing anywhere in the evidence
17 submitted to support consistent division of
18 dementia into mild, moderate and severe
19 categories, and I don't see how you could
20 measure something when there is inconsistent
21 guidance on what they are.

22 CO-CHAIR TIRSCHWELL: A.M.

1 DR. BARRETT: I will just briefly
2 add to what has been said, that I have found
3 some evidence that may be of interest to the
4 group, and it was actually in service of the
5 next measure, but also applies to staging.

6 I would urge, as Daniel has said,
7 developers to be guided to produce this kind
8 of information as part of the application,
9 because that would be very helpful.

10 First of all, the data is only in
11 a research setting, and you have to make
12 several leaps to apply this data, but it can
13 be said to apply.

14 For example, the first study
15 regards the outcomes of patients taking part
16 in Alzheimer's studies who did or did not have
17 cognitive assessment. So there are many
18 confounds, obviously.

19 In a study in Australia 1900
20 patients were evaluated initially for a
21 research study, treatment research studies,
22 and 246 did not complete the evaluation to the

1 point of cognitive assessment, and those
2 patients had worse outcomes.

3 The other evidence is even softer
4 than that, unfortunately, but there are two
5 other studies of reports by caregivers, a
6 small study of benefit of participation in
7 clinical research reported by caregivers and
8 patients which stated that assessment is one
9 of the benefits that they perceive to be
10 useful and appropriate for taking part in
11 research; also a study of behaviors, physician
12 behaviors, that lead to referral for clinical
13 trial participation. So, again like 19 leaps
14 you have to make there for outcome, but
15 essentially, obviously, people are more likely
16 to be referred for a clinical trial if
17 physicians have access to diagnostic
18 instruments and apply them.

19 Lastly, I would just say that in
20 this instance, staging will help to
21 differentiate between mild cognitive
22 impairment and mild Alzheimer's Disease, and

1 there is probably both some public health and
2 individual patient benefit on that regard.

3 CO-CHAIR TIRSCHWELL: Although
4 they have to have a diagnosis of dementia to
5 even qualify for this. So you are suggesting
6 it will lead to some diagnostic
7 reclassification? I see. Sam, and then
8 Risha.

9 DR. FAZIO: I guess I would just
10 like to add some anecdotal comments. We hear
11 from families all the time that the various
12 classification systems are confusing for
13 people, because there are so many different
14 ways to classify stages.

15 A consistent way to stage people
16 or to group all these scales in similar type
17 stages can help give people sort of a system
18 to better make decisions about care and also
19 to sort of deal with what might be happening
20 in sort of that vague stage or that larger,
21 broader stage instead of very specific stages.

22 Everybody doesn't fit into these

1 little boxes sometimes that these scales sort
2 of put people into. So having these three
3 larger staged gives people a little bit more
4 variability.

5 At the same time, I think you see
6 when people are staged incorrectly how that
7 leads to all sorts of labels and inappropriate
8 care, poor quality care, and inappropriate
9 expectations of what is going to come. So I
10 think a system that sort of groups all these
11 scales that are out there into some broader
12 systems, I think, would be really helpful for
13 families and people with disease.

14 CO-CHAIR TIRSCHWELL: Does this
15 measure get to that, or not?

16 DR. FAZIO: Yes.

17 CO-CHAIR TIRSCHWELL: They do? So
18 that was a thumbs up type of comment?

19 DR. FAZIO: Yes.

20 CO-CHAIR TIRSCHWELL: Okay. Thank
21 you. Risha.

22 DR. GIDWANI: I read the cognitive

1 assessment, a functional status assessment,
2 first. Then I read the staging of dementia.
3 It wasn't clear to me from reading the
4 developer's report for staging of dementia
5 what this is going to give us in terms of
6 being able to better hone in treatment
7 practices for patients that the cognitive
8 assessment and the functional status will not
9 provide.

10 I am hoping maybe the clinician
11 experts in the room can elucidate me on this
12 regard.

13 CO-CHAIR TIRSCHWELL: Anybody want
14 to respond to Risha's request? A.M.?

15 DR. BARRETT: There are specific
16 indications for treatment, for example,
17 cholinesterase inhibitors or other treatments,
18 either recommended by research, manufacturer
19 or third parties that refer to stages rather
20 than to specific scores on cognitive
21 assessment.

22 CO-CHAIR TIRSCHWELL: Salina?

1 DR. WADDY: I don't understand
2 them on that. I completely understand that
3 there is a need to stratify degrees of
4 dementia, but has that already been agreed
5 upon like by the Alzheimer's Association or by
6 thought leaders in terms of taking all of
7 these different tests and agreeing upon what
8 is severe, mild and moderate; because
9 otherwise, it seems like that would -- If that
10 hasn't been agreed upon by those thought
11 leaders, it seems like it is a large step
12 forward, backward or sideways to come here and
13 ask us to really push that forward.

14 So I am not an Alzheimer's expert,
15 but your comment confused me a little bit.

16 DR. FAZIO: Sure. Well, we do use
17 mild, moderate, and severe at the Alzheimer's
18 Association, but we haven't looked at these
19 assessments and grouped them that way.

20 DR. WADDY: Well, that is what I
21 am saying. This is a big step. It seems like
22 this takes us --

1 DR. FAZIO: But I guess my
2 assumption was that their group of experts
3 that came up with the clinical guidelines
4 would have done that.

5 DR. WADDY: I don't know.

6 CO-CHAIR TIRSCHWELL: I think that
7 is part of everybody's problem, is that we
8 have to make all these assumptions, because a
9 lot of it is not spelled out in the
10 application set or filled out. Jane?

11 MS. SULLIVAN: I would agree with
12 Salina, and I agree with you that, when we are
13 talking the same language, it is helpful not
14 only for practitioners but certainly for
15 families.

16 The way I read this, there are six
17 or seven different scales that are suggested,
18 but I don't read that there is any consensus
19 about the way in which people would be
20 assessed and the way in which it would be
21 staged. So I don't think -- I don't read that
22 it addresses the point that you are raising,

1 which I think is a really valid point.

2 CO-CHAIR TIRSCHWELL: Any other
3 comments before we -- Yes, Ramon?

4 DR. R. BAUTISTA: Yes. I am
5 concerned about the statement that says the
6 quality of the evidence was not addressed.
7 Again, as a committee we are not really here
8 to provide the evidence. We are here to
9 assess the evidence, so we might know that it
10 might be good for this or that reason, but the
11 fact is it is not presented as an evidence to
12 review.

13 CO-CHAIR TIRSCHWELL: Okay. Thank
14 you. Before we vote on this evidence, does
15 anybody specifically want to invoke the
16 exception for this measure? I am not seeing
17 any response. So then as we are voting for
18 this, the only way to move forward is to vote:
19 1 as Yes; either 2 or 3 would be a vote to not
20 move forward with any further evaluation of
21 this measure. Let's go ahead and start the
22 voting now.

1 MS. THEBERGE: Zero, Yes; 10 No,
2 evidence does not meet guidance; and 14, No,
3 insufficient information submitted.

4 CO-CHAIR TIRSCHWELL: So we are
5 done with this measure. I think that brings
6 us to our break. We are just a little bit
7 behind schedule, not bad. so let's take a 15-
8 minute break, and reconvene at ten minutes
9 before 11. Thank you, everybody.

10 (Whereupon, the above-entitled
11 matter went off the record at 10:34 a.m. and
12 resumed at 10:52 a.m.)

13 CO-CHAIR KNOWLTON: We are going
14 on to -- let me see -- 2000 Dementia:
15 Cognitive Assessment. Dr. Barrett.

16 DR. BARRETT: Welcome back from
17 the break, everybody.

18 In this measure we have much to
19 say and issues that had come up previously.
20 In fact, as you heard, I kind of brought out
21 my little carpetbag of evidence one measure
22 early for Daniel's presentation. But as we

1 are considering the evidence, of course,
2 cognitive assessment is part of a clinical
3 practice standard in the assessment of
4 dementia.

5 I think, in the initial assessment
6 of dementia, that many people would appreciate
7 the potential for patient harm in misdiagnosis
8 of Alzheimer Disease, either positive
9 misapplication of the diagnosis to people who
10 have ALS, early PD without motor symptoms,
11 even brain tumors, of course, depression as we
12 have talked about, but even these rare
13 disorders like atypical dementias, epilepsy,
14 B12 deficiency, and once I saw someone with a
15 factitious disorder who, of course, had been
16 diagnosed with dementia previously, infectious
17 diseases like HIV and neurosyphilis.

18 Now nobody is saying that those
19 account for a large number of people, of
20 course, and then also it would be very
21 difficult ever to do any kind of a prospective
22 study on this topic, because even if we were

1 able to look and -- Well, notoriously, looking
2 at dementia, looking at the application of a
3 diagnosis correctly versus incorrectly is very
4 difficult to do.

5 So let's focus on the second
6 rationale that we talked about before of
7 targeting treatment, and I will simply present
8 that in this instance we have a different
9 situation than staging in that in cognitive
10 assessment we can identify the profile and the
11 specific symptoms.

12 I believe that the APA guidelines
13 specify four areas. I can't cite them for you
14 right now, but I think it is like visual
15 spatial function, memory, attention, etcetera,
16 and there are people who have variance in the
17 syndrome.

18 So large numbers of people with
19 dementia may, for example, have a lot of
20 behavioral symptoms, a lot of language
21 symptoms, but not much in the other areas, and
22 they do require specific treatments. It goes

1 the other way, too.

2 So somebody may have aphasia from
3 Alzheimer Disease, may have a lot of
4 behavioral disturbance, but may be able to
5 draw a beautiful correct clock, and that
6 person may, in fact, be relatively functional.
7 So the history, of course, is misleading in
8 these people.

9 Again, as we have commented, the
10 opportunity for specific evidence from, for
11 example, care records was not taken advantage
12 of in this application. So we don't have
13 presented, for example, evidence from CMS
14 records that hospitalizations or other
15 secondary visits may be less in people who
16 received cognitive assessment, and there is a
17 CPT Code for cognitive assessment, actually
18 several of them.

19 So this is disappointing that we
20 don't have that kind of information to
21 consider, because as was commented in our Work
22 Group call, given that cognitive assessment is

1 more common probably in a subspecialty setting
2 now, that in the general practice community it
3 is likely that that would potentially support
4 the benefit of applying this criterion or this
5 standard.

6 I already listed for you evidence
7 from a research setting that cognitive
8 assessment may be beneficial. You have to
9 believe, if you look at those studies, though,
10 that it was the cognitive assessment piece
11 specifically rather than other aspects of
12 research participation. The Australian study,
13 as I said, of about 2,000 patients does
14 somewhat support this, although it is
15 confounded by dropout.

16 Unfortunately, the developers only
17 presented for us consensus measures from the
18 APA, and I think they make reference to
19 another consensus measure from California. So
20 we have that.

21 Questions that would arise with
22 respect to the rationale include initial

1 versus repeated assessment of patients. So
2 it is really important to do an annual
3 evaluation? Again I would say that all three
4 of the reasons, initial diagnosis, targeted
5 treatment, and public health, would all apply.
6 The same argument would all apply but, of
7 course, it is a smaller group of people.

8 The last argument I think you can
9 make about this is that consistently there is
10 an argument about the value of the clinical
11 trial data that we have in Alzheimer Disease.
12 People always talk about how people who take
13 part in clinical trials are different from the
14 typical population.

15 Of course, they probably
16 underrepresent disadvantaged groups, but also
17 we have to consider that there may be some
18 benefit again of the cognitive assessment that
19 these people receive as part of their clinical
20 trial participation. So it may not be that
21 there is a selection bias, but it may actually
22 be a "nonspecific" treatment effect.

1 I tried to find -- There was a
2 study, I think, published in Neurology in the
3 Nineties that supported the idea that people
4 who take part in clinical trials just do
5 better, whether they are in the placebo arm or
6 whatever. Unfortunately, I couldn't find that
7 study for today.

8 Again, unfortunately, all we have
9 from the developers with respect to evidence
10 is clinical practice guideline evidence. I
11 was unable in reviewing those guidelines to
12 find specific studies that support cognitive
13 assessment, and this is also one of these PQR
14 measures, PQR measures that are being used in
15 a trial period. I believe this is up for
16 trial one year endorsement. Is that correct?

17 CO-CHAIR KNOWLTON: Questions?
18 David? Anybody? Okay.

19 CO-CHAIR TIRSCHWELL: I guess I
20 would just add that A.M. has done extra work
21 here to try to identify an evidence base,
22 which really wasn't presented by the

1 developers. In reality, it is more the same
2 as all the other measures which didn't do well
3 than different, is my perspective.

4 CO-CHAIR TIRSCHWELL: Let's vote.
5 This is on the evidence.

6 MS. THEBERGE: Zero, Yes: No,
7 evidence does not meet guidance, 9 votes; and
8 No, insufficient information, 15 votes.

9 CO-CHAIR KNOWLTON: That's it.
10 David on 2004, Functional Status Assessment.

11 CO-CHAIR TIRSCHWELL: Okay. So
12 this is another dementia measure. Just to
13 review what the measure is, the description is
14 the percentage of patients, regardless of age,
15 with a diagnosis of dementia for whom an
16 assessment of functional status is performed
17 and the results reviews at least once within
18 a 12 month period.

19 The numerator statement is those
20 for whom a functional status -- an assessment
21 of functional status is performed, and they
22 give some examples of that, including some

1 scales, and the results reviewed. The
2 denominator is all patients, regardless of
3 age, with a diagnosis of dementia.

4 There is an exclusion for a
5 documented medical reason for not assessing
6 functional status. There is no risk
7 adjustment. It is at the clinician level, and
8 again this is one of the ones that I think is
9 being used in PQRS. At this point, though, no
10 data were presented.

11 Then focusing on the evidence, the
12 quality, quantity -- excuse me. Starting with
13 the quantity, they do refer to a number of
14 articles in the consensus papers, but those
15 are just some numbers. The quality, they
16 really don't describe at all. In fact, it is
17 not in the consensus statements, and no
18 further work was done. As far as consistency,
19 that is not commented on in the guidelines
20 either.

21 I go back to a quotation from one
22 of the guidelines, which says, and I will read

1 this -- it is a little bit long: A detailed
2 assessment of functional status may also aid
3 the clinician in documenting and tracking
4 changes over time, as well as providing
5 guidance to patient and caregivers.

6 Then they describe what functional
7 status might be: These regular assessments of
8 recent cognitive and functional status provide
9 a baseline for assessing the effect of any
10 intervention, and they improve the recognition
11 and treatment of acute problems such as
12 delirium.

13 So that is sort of the rationale
14 in connecting the assessment with a hopeful
15 good outcome, but there is no real evidence to
16 support that connection, and the particular
17 guideline says that this recommendation
18 statement was not even rated, which is -- You
19 know, they have some that are rated with high
20 confidence, and I realize that is yet another
21 rating scale that we are not so familiar with,
22 but this one isn't even on their rating scale.

1 They didn't rate this thing.

2 So I think in many ways it is
3 similar to these other measures, not a lot of
4 evidence. Virtually none was presented by the
5 developers.

6 CO-CHAIR KNOWLTON: Any questions
7 for David? Okay, on the evidence, let's vote.

8 MS. THEBERGE: I need one more.

9 Zero, Yes; No, evidence does not
10 meet guidance, 11; and No, insufficient
11 information, 13.

12 CO-CHAIR KNOWLTON: We are on a
13 streak. This is 2028, counseling regarding
14 safety concerns.

15 DR. RICHMOND: All right.
16 Counseling regarding safety concerns. This is
17 actually one step closer to outcome, because
18 we are beyond assessment and now to
19 counseling.

20 It is looking at the percentage of
21 patients, regardless of age, with a diagnosis
22 of dementia or their caregiver, who are

1 counseled or referred for counseling regarding
2 safety concerns within a 12-month period.

3 So the numerator are patients who
4 are counseled or referred, and counseling is
5 defined. The denominator is all patients,
6 regardless of age, with a diagnosis of
7 dementia. There are some exclusions, which is
8 documentation for medical reasons, for
9 example, end of life or other medical reasons.

10 Jumping right to the evidence,
11 this really does have the same issues as the
12 previous, but I would say as a nurse and an
13 injury scientist, counseling is really
14 appealing to me.

15 So I looked, and there was
16 evidence, I thought, although I don't think it
17 is really true, showing dementia, increased
18 risk of falls or wandering, then injury and
19 death. But actually, the citations supporting
20 that structure process/outcome link of just
21 does this happen was actually an instrument
22 development study that was looking at

1 interrater reliability. So it really was not
2 evidence even showing that provided.

3 Then looking for either the
4 quantity, quality or consistency of evidence
5 showing, if I counsel, does that improve
6 outcomes, it has the same issues as before, as
7 the evidence really was not provided. So the
8 Work Group had significant concerns about
9 that.

10 CO-CHAIR KNOWLTON: Questions or
11 comments on the evidence? Okay, we will vote
12 on this one.

13 MS. THEBERGE: One Yes; 10, No,
14 evidence does not meet guidance; and 13, No,
15 insufficient information.

16 CO-CHAIR KNOWLTON: The next one I
17 am presenting, which is on counseling
18 regarding the risks of driving. A couple of
19 items on this one.

20 First off, I was going to say, if
21 Terri's went through, I was going to say it is
22 already contained in the one that she did. So

1 it was completely duplicative, but I believe,
2 and the Work Group felt, it has -- I won't go
3 through it all again -- exactly the same
4 concerns that Terri raised in the first one.
5 They sort of cut and pasted the same
6 presentation, the same type of information.

7 So there was no reliability or
8 validity data provided or any indication that
9 this was making a difference. Again as Terri
10 outlined, I think people intuitively felt that
11 this was something you want to do, but there
12 was just no evidence or any way to comply with
13 the measure in a statistically or a consistent
14 -- I didn't want statistic there -- consistent
15 fashion and know that you are doing it
16 consistently.

17 Questions or comments? Okay. Oh,
18 wait a minute. We do. yes?

19 DR. BARRETT: I spent a lot of
20 time thinking about whether I would want to
21 request an exception on this measure because
22 of the -- My personal feeling about how

1 compelling this measure is, is comparable, I
2 think, to risk related to pregnancy and to
3 epileptic drugs, driving with seizures for
4 example.

5 I think the reason why I came down
6 finally with a no was that it is a counseling
7 measure. So I just wanted to --

8 CO-CHAIR KNOWLTON: It is a
9 counseling measure. So you felt, if it were
10 an assessment or -- What are you saying? If
11 it were an assessment? Just finish the
12 thought.

13 DR. BARRETT: Well, I hate to make
14 recommendations to design the measure myself,
15 but if it were closer to an intervention or
16 assessment exactly, I would be more
17 enthusiastic.

18 CO-CHAIR KNOWLTON: The reason I
19 pushed you on it is because there is a
20 transcript, and so developers will listen, and
21 that is the important thing. So that is why
22 I asked you. Salina?

1 DR. WADDY: This measure and the
2 last measure are such no-brainer things to do,
3 just sincerely, it baffles me as to how there
4 cannot be evidence regarding this. Can the
5 developer -- Is there really no evidence or
6 you just couldn't find it? I mean, this
7 doesn't make any sense.

8 CO-CHAIR KNOWLTON: Before we go
9 to the developers, let's stay -- I will go
10 over to them, because I think Peter wants to
11 answer your question. Peter?

12 DR. SCHMIDT: This measure
13 actually has a major design flaw, in that if
14 you counsel somebody and are not effective,
15 then you can counsel them again; whereas, if
16 you counsel somebody and they stop driving,
17 they fall out of the measure. They fall into
18 the exception criteria.

19 So if you continually counsel your
20 panel and they continue to drive, you can get
21 a perfect score on this.

22 CO-CHAIR KNOWLTON: Works for

1 smoking, too, doesn't it? Did you have
2 another point, Ann? Okay. Fred?

3 DR. TOLIN: Looking at the prior
4 measure and this measure, 2029 -- and I know
5 that some comments were made in a separate --
6 in a Work Group discussion about this -- it is
7 a little unclear to me why this was singled
8 out as a risk factor when the other measure is
9 more globally looking at a bunch of risks, and
10 I was really curious as to why that might be
11 the case.

12 CO-CHAIR KNOWLTON: I understand,
13 and I certainly understand, A.M., the concern
14 you stated about just sort of driving in
15 general.

16 DR. TOLIN: I think we all feel,
17 too, or logically understand where this is
18 coming from, but I was just really curious s
19 to why this was singled out as a separate item
20 when it would otherwise have been inclusive in
21 2028.

22 CO-CHAIR KNOWLTON: I would just

1 be guessing, but it would seem to me that, to
2 Salina's point, there's probably many, many,
3 many more people driving than using guns or
4 handling toxic chemicals or working as
5 electricians in these circumstances. So there
6 is much bigger and a lot more people that you
7 are dealing with. So I think, in hindsight,
8 that is why they split it out, but they
9 included it in the other one. So I don't know
10 why. It seems duplicative.

11 Anything else on the measure?

12 Okay. Oh, I'm sorry, you are right. I
13 forgot.

14 MS. TIERNEY: Your question about
15 the evidence: I just say this to emphasize
16 what I said earlier. We based our measures on
17 the practice guideline. So we are limited to
18 what the practice guidelines include and their
19 summaries of the updates.

20 We do not do systematic evidence
21 reviews, similar to other measures offered,
22 and NQF's Task Force report, although they had

1 indicated a higher bar required for the
2 evidence, they do specifically state that they
3 don't expect developers to conduct primary
4 systematic evidence reviews, but rather to
5 report on those done by others.

6 So those are kind of our
7 limitations. So the guideline with AAN are
8 just on the guideline, probably many of you
9 are aware in 2010, on driving with dementia,
10 and that guideline has rich information about
11 the evidence available, but they looked at
12 specific questions we have been trying to
13 answer like what tools might be useful for
14 identifying patients at increased risk.

15 Our measure -- The evidence
16 provided to support that in that response, to
17 answer that question, doesn't necessarily
18 address -- focused on counseling, mentioning
19 alternatives to driving. It is a very patient
20 centered measure, and some of the evidence
21 that is supported by the AAN guideline,
22 research questions which don't necessarily

1 directly link to our measure, and so our
2 measure doesn't incorporate those.

3 If our measure was for assessment
4 of whether the patient was at increased risk
5 on driving, then we included them, but our
6 Work Group felt that the measure was more
7 appropriate as a counseling measure to
8 increase visibility of the issue.

9 Just to your point, someone
10 earlier was questioning kind of how this could
11 be included in both measures, I can see that
12 it does appear a bit redundant. With the
13 safety concerns measure, that measure is
14 intended to be very broad, and we contemplated
15 leaving out driving, because it is covered by
16 this measure, but we didn't want to
17 necessarily send the wrong message, that
18 driving isn't also a safety concern.

19 So since that measure was so
20 comprehensive, we felt like we should include
21 all of the various elements that are
22 appropriately of concern, and the part of the

1 reason driving -- that we didn't just entirely
2 include it all that one measure was because
3 driving, unlike the other basic concerns, has
4 a significant potential ramifications on the
5 safety of others. So we felt like it
6 warranted its own measure.

7 The little information that is
8 available in the literature related to the gap
9 in care does show that certain elements are
10 not being consistently done in clinical
11 practice.

12 CO-CHAIR KNOWLTON: Okay. Jane?

13 MS. SULLIVAN: Just to build on
14 Salina's point, do we not have data from
15 public safety about the percentage of people
16 who have dementia or who are receiving care
17 for certain things who have traffic accidents?

18 It would seem like -- I am just
19 thinking about all these safety concerns. Do
20 we not know something about the incidence in
21 this population of safety issues, and could we
22 not consider that kind of data?

1 DR. BARRETT: There is some of
2 that data.

3 CO-CHAIR KNOWLTON: Go ahead,
4 David.

5 CO-CHAIR TIRSCHWELL: I was just
6 going to comment that there may be evidence
7 out there. It is not our job to present it,
8 and the problem is that it was not presented,
9 by and large, in the applications.

10 I have to say, it goes back to the
11 Psychiatric Association's guidelines that they
12 are reviewing, which don't present the data in
13 detail either, and they didn't write those
14 guidelines as ammunition for NQF quality
15 measures either, but it is all part of this
16 environment where this is what it is being
17 used for.

18 So I think the message has to go
19 back that, as these measures are being
20 developed, that is the kind of evidence that
21 NQF is requiring, and so the care provider
22 organizations that are involved in the care of

1 all these different types of patients with
2 these different measures have to be able to
3 provide what is needed to support their
4 measures.

5 CO-CHAIR KNOWLTON: John?

6 DR. DUDA: Sorry, I am just
7 curious. If you look at 1(c)(16) where it
8 says that all patients and family should be
9 informed that --

10 CO-CHAIR KNOWLTON: I can't hear
11 you. Speak in the mic.

12 DR. DUDA: Sorry. If you look at
13 1(c)(16) from the APA guidelines, it says that
14 all patients and family should be informed
15 that even mild dementia increases risk of
16 vehicular accidents, Category 1. There is a
17 bunch of those. What does that Category 1
18 refer to, if it is not evidence based kind of
19 delineation?

20 MS. TIERNEY: The Category 1
21 refers to a recommendation based on
22 categorization here and judgment of those

1 patients, and it is included in your form what
2 that refers to.

3 CO-CHAIR TIRSCHWELL: Something
4 like they have great confidence, clinical
5 confidence. Well, you know, it is a good
6 question, and there are other grading systems
7 that are out there that are much more specific
8 about what it means in terms of trials and
9 things like that. I think that is -- This
10 conversation suggests that maybe that needs to
11 be done in a little bit different fashion
12 going forward.

13 MS. TIERNEY: If I could just add
14 -- and I agree with your point -- just a
15 little bit more about -- The guidelines
16 themselves are included at 1(c)(10) of the
17 document. They indicate that each rating
18 considers the strength of the available
19 evidence and is based on the best available
20 data. When evidence is limited, the level of
21 confidence is also incorporated.

22 I just wanted to add that.

1 CO-CHAIR TIRSCHWELL: Anyone else?

2 DR. BARRETT: Yes. I just had a
3 follow-up to one of the comments made by the
4 developer, again related to the difference
5 between the measure being a counseling versus
6 assessment measure.

7 If I can just clarify and ask the
8 developer. It was the view of the Work Group
9 that counseling would have a larger impact on
10 public awareness? Is that correct?

11 MS. TIERNEY: Yes. So the Work
12 Group felt like a counseling measure might do
13 more to potentially impact the problem. You
14 could involve caregivers in that counseling,
15 like as many as 12, to kind of highlight the
16 potential safety concern.

17 DR. BARRETT: The follow-up
18 comment I would make then related to that is
19 that, because of the requirements of the NQF
20 process, that invokes another logical step
21 that needs to be investigated. So then the
22 effect of caregiver awareness needs to be

1 evaluated with respect to its impact on
2 reduction of accidents and alterations in
3 driving behavior.

4 Although a direct assessment
5 measure of -- So a measure of assessment of
6 driving competence, let's say, may be an
7 easier measure to present to an organization
8 like NQF.

9 CO-CHAIR KNOWLTON: Peter?

10 DR. SCHMIDT: I think that we are
11 overly critical of counseling guidelines.
12 Drug prescription is also counseling. You are
13 telling the patient to go to the drugstore and
14 to get the drug and to take it, and if we are
15 not measuring compliance, then you are really
16 talking about how well does -- You know, I
17 personally am a highly noncompliant patient
18 when I am -- you know, I don't fill
19 prescriptions. I don't take them.

20 So if somebody gives me a
21 prescription, they are counseling me to take
22 it, and I often ignore them.

1 CO-CHAIR KNOWLTON: That is right.
2 Therapy can help you.

3 DR. SCHMIDT: Yes. So counseling
4 is counseling. You know, you can't just say
5 that counseling is a terrible thing and that
6 we don't know how effective it is, because I
7 can tell you that drug prescriptions are not
8 that effective with me.

9 CO-CHAIR KNOWLTON: We will have a
10 session right after this. Gail?

11 DR. COONEY: I do think, you know,
12 t his measure as opposed to some of the others
13 we looked at, does have data regarding the
14 incidence of the problem. In 1(a)(3) they
15 talk about twofold increased risk of crashes,
16 impact on driving that increases with dementia
17 severity. So there is, actually, some data
18 and some public health issues.

19 CO-CHAIR KNOWLTON: But that is
20 impact data. That is not evidence. Not
21 evidence, in the evidence that would deal with
22 the reliability of the measure or the validity

1 of the measure.

2 DR. COONEY: Correct.

3 CO-CHAIR KNOWLTON: So it is an
4 impact issue. We are going to actually get to
5 that later, but it is an impact issue.
6 Jolynn?

7 MS. SUKO: I think just another
8 comment about counseling measures. I noticed
9 that many of these are designed for
10 physicians, and I vaguely recall from 15 years
11 ago sometimes the counseling measures aren't
12 always -- such as these, they are more
13 effective when given by other caregivers such
14 as social workers or nurses.

15 So I would just challenge -- and I
16 don't know what the literature is, but when I
17 look at this, I would ask, are we adding yet
18 another burden to physicians for something
19 that they need to do, when indeed it may not
20 be the most effective use of their skill set?

21 MS. TIERNEY: If I could just add
22 that the specifications for these measures do

1 include -- they are applicable to other care
2 providers, including psychiatry, psychology
3 and social workers.

4 CO-CHAIR KNOWLTON: Any other
5 comments? Jane?

6 MS. SULLIVAN: Well, I am just
7 Google Scholaring things. If you look for
8 counseling, driving and Alzheimer's -- and I
9 haven't read all these articles, but it seems
10 to me that there's quite a few articles here
11 that at least, just on my brief review, are
12 suggestive of some interaction between
13 counseling and a safety benefit.

14 So I think there is some
15 literature here. It wasn't our job to find
16 it. Googled Scholar counseling, driving and
17 Alzheimer's.

18 CO-CHAIR KNOWLTON: But as David
19 appropriately pointed out, that is not our
20 task.

21 MS. SULLIVAN: I agree.

22 CO-CHAIR KNOWLTON: But I think

1 the same with these measures all along. One
2 of the frustrations from where I sit is,
3 speaking for myself, that these are clearly
4 important things, and when we don't treat
5 them, we don't get them to the level of an NQF
6 measure, and it is a lost opportunity for
7 dealing with something that, if it is that
8 important, we should be doing.

9 So we got to put the rigor in to
10 get it done. That is where I get frustrated
11 with these, because it is not that I don't
12 think -- A lot of people die in motor vehicle
13 accidents, because they are not competent to
14 drive, and every primary care doc knows it,
15 and everybody treating people.

16 Every ER doc assesses for it, but
17 we are not rising this to the right level is
18 what is frustrating, because it does need to
19 be risen to that level, but if it doesn't get
20 to the level, it won't get done in an orderly
21 way. That is the frustration. Mary?

22 MS. VAN DE KAMP: I think this is

1 -- If we looked going forward, this has been
2 systemic of our industry in clinical practice.
3 I think there is an assumption that clinical
4 practice is based on evidence, and so,
5 therefore, we haven't always judged the
6 evidence, and I think that speaks to many of
7 the outcome measures that we have struggled to
8 try to defend or bring forward, is that just
9 outcomes and evidence has -- We have done a
10 lot of things, because we thought that they
11 worked or were pretty sure that they worked
12 and there's evidence. So I think it is
13 definitely a part of our industry that has
14 taken on a big clinical practice about the
15 evidence, is the challenge to bring to the
16 highest level.

17 CO-CHAIR KNOWLTON: Salina?

18 DR. WADDY: This is really a
19 question, I think, for the NQF, and is there
20 an opportunity for these two measures in
21 particular for them to go back and reassess
22 and to determine whether or not there is

1 appropriate evidence outside of essentially
2 the guidelines. Is there that opportunity?

3 CO-CHAIR KNOWLTON: Helen?

4 DR. BURSTIN: That is actually
5 what I was going to say when he called on you.
6 So if you look at the why we have written out
7 the Noes, there are two noes there, and one of
8 them is intentional to sort of get at the
9 issue of there isn't evidence, and you have
10 been talking about this exception a lot today.

11 The other one is that there is
12 insufficient evidence submitted. It may be
13 out there, but it wasn't submitted. So one
14 opportunity might be, as you vote today, you
15 should feel free to invoke 3, and then we
16 would ask the developer to bring that evidence
17 forward, but then it is a judgment call,
18 relying on the expertise of the people in this
19 room.

20 CO-CHAIR KNOWLTON: We are voting
21 on evidence. Let's vote.

22 MS. THEBERGE: Zero, Yes; five,

1 No, evidence does not meet guidance; 19 No,
2 insufficient information submitted.

3 CO-CHAIR KNOWLTON: Okay. We are
4 done with this, and we saved the best for
5 last. Gail?

6 DR. COONEY: I love going last.

7 CO-CHAIR KNOWLTON: Hold on for a
8 minute, Gail. Yes, Salina?

9 DR. WADDY: I was also wondering,
10 in light of that, can you just tell us what
11 the last vote was, the split between the two
12 and three?

13 MS. THEBERGE: On 2028, it was one
14 Yes, No 10, and then insufficient evidence
15 submitted.

16 DR. BURSTIN: They are welcome to
17 submit additional evidence, but then it will
18 be up to you to decide if you want to
19 reconsider it.

20 CO-CHAIR KNOWLTON: But we do that
21 later when we see the evidence, not now.

22 DR. BURSTIN: Yes.

1 CO-CHAIR KNOWLTON: Gail?

2 DR. COONEY: This is measure 2030
3 which is also part of the AMA-PCPI project,
4 and it looks at the percentage of patients,
5 regardless of age, with a diagnosis of
6 dementia whose caregivers were provided with
7 education on dementia disease management and
8 health behavior changes, and referred to
9 additional resources for support within a 12-
10 month period.

11 The denominator has the exclusions
12 for medical reasons, including severe disease
13 or no caregiver present, and the evidence is
14 pretty much the same that has been presented
15 for the earlier measures, for the structure
16 process outcome.

17 They do have evidence that greater
18 caregiver knowledge is associated with higher
19 care quality, that intensive caregiver support
20 resulted in improved patient outcomes, such as
21 delayed nursing home placement, and that
22 providing additional resources to caregivers

1 is important, is critically important.

2 CO-CHAIR KNOWLTON: Questions for
3 Gail on the evidence? Gail, did the committee
4 have a sense on the evidence? The sense was
5 that it is not there yet, or where are you?

6 DR. COONEY: The committee's sense
7 was pretty much the same as it was on the
8 others, that the evidence was insufficient to
9 support the measure.

10 CO-CHAIR KNOWLTON: I had one
11 comment on this in that I was concerned about
12 caregivers, not that -- I agree with your
13 presentation, Gail, but I agree with the
14 importance of getting some good measures here,
15 because I think it is important.

16 Caregivers are very variable, and
17 I think there is a disparity issue here with
18 poorer patients not having access to
19 necessarily good caregivers, and where that
20 gets stratified, you can have -- I guess I am
21 just making the editorial comment for the
22 purpose of the transcript that we are not

1 doing a real good job with caregivers, and
2 trying to figure out the wide variation there.

3 That wide variation is especially
4 disparate based upon income level and race,
5 and I hope s developers listen to this and get
6 involved in this, they will pay attention to
7 caregiver is an important variable, and we owe
8 it some diligent sight, I guess is what I am
9 saying. Ann?

10 DR. BARRETT: I think I am just
11 echoing and emphasizing your comment, that
12 studies reveal that many caregivers don't even
13 understand that their love one has Alzheimer
14 Disease or dementia, much less the particular
15 activities that need to take place in order to
16 optimize that person's quality of life or
17 reduce their own burden.

18 So the public health need is very
19 great. I agree with you.

20 CO-CHAIR KNOWLTON: David?

21 CO-CHAIR TIRSCHWELL: I just had a
22 question as to -- Many patients with dementia

1 live in nursing homes, and so who are the
2 caregivers then, and who is going to be rated
3 on this? It doesn't seem like it would be the
4 family that comes in once in a while. Is it
5 the nursing home staff? Is it appropriate to
6 apply to those patients?

7 CO-CHAIR KNOWLTON: Are you being
8 responsive for that? A.M., go ahead.

9 DR. BARRETT: I am happy to be
10 corrected by those with more experience with
11 those patients, but in general, medical care
12 and counseling don't end with skilled nursing
13 placement, and the needs of caregivers
14 continue even after the point of skilled
15 nursing care.

16 In fact, some studies indicate
17 caregivers have more needs during that period
18 of time, because it is not clear to them what
19 their responsibilities and interventions could
20 be.

21 CO-CHAIR KNOWLTON: I don't know
22 if NQF has seen other measures in caregivers,

1 but this is such an important area. I hope
2 people pay attention to it. Risha.

3 DR. GIDWANI: I was a little bit
4 more comfortable with this measure, really,
5 because of the fact that, when the developers
6 were citing the guidelines, they did mention
7 that studies indicate that education and
8 support for caregivers increases the
9 likelihood that patients are adherent to
10 treatment recommendations.

11 That, to me, seems like an
12 important link that I would like to see
13 explored a little bit further. If those
14 studies do exist, I think that it would be
15 really beneficial for us to be presented with
16 information about their quality. Even if the
17 guideline developers aren't showing that, if
18 the -- I'm sorry.

19 If the developers of this measure
20 are able to actually able to go to those
21 studies themselves and give at least some sort
22 of brief overview of what are the outcomes

1 that were measured, and was it a prospective
2 or retrospective or randomized or
3 observational study? Even that basic level of
4 information would go a long way in helping us
5 to better evaluate the body of evidence.

6 CO-CHAIR KNOWLTON: Anybody else?
7 Okay, on the evidence.

8 MS. THEBERGE: Zero, Yes; six, No,
9 evidence does not meet guidance; and 18 No,
10 insufficient information submitted.

11 CO-CHAIR KNOWLTON: We now look
12 for NQF member and public comment. Arnica,
13 can you open up our phone line and see if
14 there are questions for us?

15 OPERATOR: At this time, there are
16 no questions.

17 CO-CHAIR KNOWLTON: Thank you.
18 Yes? Robert?

19 DR. PLOVNICK: Hi. I am Rob
20 Plovnick. I direct the Department of Quality
21 Improvement in Psychiatric Services at the
22 American Psychiatric Association. We were one

1 of the groups that worked on the development
2 of these measures.

3 I just wanted to comment on a few
4 things. First of all, with regard to
5 guideline development, I just want to remind
6 the group that there is a considerable time
7 that it takes to develop guidelines and
8 performance measures.

9 So there is a lag in guideline
10 development and measure development, and these
11 guidelines were actually developed several
12 years ago, and we certainly have revised our
13 guideline development process to be more aware
14 of new IOM guidelines in terms of grading the
15 strength of evidence and other factors that
16 would tie into measure development.

17 So, hopefully, these types of
18 conversations will be easier going forward.
19 That being said, for many of the
20 recommendations here, were we to have
21 explicitly graded the evidence, it would have
22 been weak.

1 There are not randomized
2 controlled trials for assessment and for
3 counseling. Dementia and Parkinson's Disease
4 are degenerative conditions that impact
5 significant segments of the population. This
6 group is aware of that. This is really why
7 this group was convened to assess measures in
8 those areas.

9 For these type of conditions, the
10 desired outcome is not resolution of the
11 disorder, but optimizing quality of life,
12 addressing new and emergent symptoms as they
13 emerge, and then treating -- providing
14 treatment that is compatible with patient and
15 family wishes.

16 Gaps in care that prevent these
17 types of outcomes are insufficient assessment
18 of symptoms and management of them over time,
19 and of counseling. It is unlikely that we are
20 ever going to have strong evidence randomized
21 controlled trials on these aspects of
22 treatment.

1 I think that would apply to these
2 disorders and other degenerative conditions.
3 So I just want to note that, if it is desired
4 to have meaningful measurement, performance
5 measurement, for these conditions, that we
6 might need to review this process in terms of
7 how evidence is considered.

8 CO-CHAIR KNOWLTON: Any other
9 comment here? Salina?

10 DR. WADDY: Even though we would
11 like to have clinical trials, we haven't
12 excluded other types of quality research, and
13 what we are asking for is quality research to
14 support the things that we are doing so that
15 we can implement in a knowledgeable way across
16 the U.S.

17 So even though a bar for high
18 quality clinical trails is important, that is
19 about the only thing that we are considering.

20 CO-CHAIR KNOWLTON: Risha. Peter,
21 did you have a point? I will piggyback on
22 what Salina said, that the issue is are we

1 reporting the same thing consistently and with
2 enough rigor of what we are trying to measure.

3 I thought Peter was comment on his
4 repeated comment earlier of randomized
5 controlled trial, while a very high bar, is
6 not the only bar. There are many other ways to
7 have reasonable and appropriate research, and
8 randomized controlled trials is just one of
9 them. David?

10 DR. HACKNEY: I think a very high
11 bar for evidence is important, because when
12 you establish a standard, you fix practice
13 into that standard that people believe they
14 are obligated to do that; and if you haven't
15 shown that not only is a reasonable thing, but
16 it is the right thing, you may be actually, at
17 least at the applied clinical level, cutting
18 off innovation and forcing people to do things
19 that no one knows whether it is really the
20 optimal method.

21 CO-CHAIR KNOWLTON: Or we would
22 still be doing bleeding and cupping. You mean

1 they stopped? Anything else? Yes, Mary?

2 MS. VAN DE KAMP: One thing. I am
3 just wondering if there would be any
4 information that comes from the PQR
5 measurement that is already in place. Does
6 that come back to help us then make evidence,
7 because some physicians are already doing some
8 of these measures, and we are tracking that
9 through CMS.

10 To me, I don't know what we look
11 at for that, but if we don't pass this, where
12 does that information go? Does it come back?
13 How does that work?

14 DR. BURSTIN: We have been trying
15 to actually work with CMS and the developers
16 to try to break that log jam and get more of
17 that PQRS data flowing to the developers. It
18 has been a challenge. But again, part of the
19 issue is also participation is somewhat low in
20 PQRS. So the numbers tend to be small.

21 It would still be helpful just in
22 terms of getting even a validity check on the

1 rates of performance.

2 MS. TIERNEY: If I could just add,
3 related to that question about PQRS. One of
4 the challenges for us as developers is that
5 that information that we get, even when we get
6 it, only speaks to the gap.

7 So we already have some data from
8 the medical literature related to the gap.
9 That would provide additional information
10 related to the gap, and maybe be more
11 nationally representative, possibly, although
12 it is a voluntary reporting program, but it
13 still won't solve the evidence problem.

14 I don't know how that can be
15 solved, to add to Robert's point, for a
16 condition like this. I think that our Work
17 Group that developed the measures tried to
18 identify those areas that they thought
19 physicians could improve upon, and that would
20 lead to improved care.

21 They selected appropriately in
22 many things dealing with assessment and

1 counseling, and I can appreciate many of the
2 comments related to the evidence bar needing
3 to be high, but then it almost seems that a
4 condition like dementia will never have any
5 NQF endorsed measures, because the evidence
6 will not be there.

7 CO-CHAIR TIRSCHWELL: Just as a
8 response to your "it would only inform the
9 gap" statement, you know, CMS has all sorts of
10 outcomes data, rehospitalizations, use of
11 resources, costs, hospitalization, mortality;
12 and if you have information about who is or
13 isn't getting these measures done, it seems
14 that observational studies are begging to be
15 done.

16 it is not your role to perform
17 those studies, but it certainly seems like
18 there would be the ability to create some
19 evidence that looks at outcomes related to
20 these process measures.

21 DR. SCHMIDT: I think that one
22 problem that we have is that PQRS has a

1 tremendous availability bias. So it is a
2 voluntary submission. It is going to have --
3 As far as evidence, I don't see that I would
4 review a paper written based on PQRS data as
5 evidence for whatever was being measured in
6 it. That is a challenge.

7 I think that one thing that we
8 identified as a group is that a number of
9 these measures that went -- A number of these
10 assessment measures were really submitted
11 backwards. Somebody should have said, once
12 this is identified, evidence supports this
13 therapy, and then that would give us
14 information that could inform -- That would
15 give that group information that they could
16 use to write an observational paper on
17 assessment.

18 So I think that we all anticipated
19 with some of the dementia measures that not
20 passing the assessment measure would bring
21 down the intervention measure, but as the
22 discussion -- I think they both went down, but

1 as the discussion unfolded, it was the
2 intervention measure that got more support.
3 I think that developers should think about
4 that.

5 Then my third comment is I think
6 that many of the developers would not have
7 anticipated the negative position that the
8 group has taken on counseling. They wouldn't
9 necessarily have thought we need to include a
10 study on the efficacy of counseling.

11 In 2004 I was reminded that I
12 offered an anecdote about my own case, but
13 there was a study done at Kaiser where they
14 randomized people into people who were given
15 a prescription for Zyprexa and people who were
16 given a prescription for Zyprexa plus
17 counseling.

18 The compliance -- The six-month
19 compliance was 37 percent for the people who
20 did not get counseling and 74 percent for the
21 people who did get counseling. So there is
22 evidence out there for efficacy of counseling,

1 and presumably in the future people should
2 include that sort of thing in their
3 submissions.

4 CO-CHAIR KNOWLTON: I think also
5 there is the concern, though, of what is
6 counseling. Is counseling -- Remember that
7 the measure has to have some stability to it.
8 So it is reliability, so that I can say that
9 what is being done over here by William is the
10 same as what is being done by Anna, that that
11 is counseling.

12 So is it counseling to say, you
13 know, you really should stop smoking? Is that
14 counseling? It doesn't even get to that.
15 Sometimes counseling is a check in a box.

16 Yet you can establish, as you
17 know, Peter -- You can establish some
18 standards for that. Go ahead. You can
19 respond.

20 DR. SCHMIDT: If I can respond,
21 your point is -- Jerry O'Connor from Dartmouth
22 with a cystic fibrosis study has shown that

1 differences in counseling about cystic
2 fibrosis and how at different centers it is
3 very difficult -- that the great centers and
4 the middle centers both do counseling. The
5 great centers do it better. That was written
6 up by Atul Gawande in his book "Better" as
7 well as the papers by Jerry.

8 So you are absolutely right on
9 that, but we also -- You know, I think we need
10 to -- We can't be too prescriptive in how
11 people practice medicine, and I think that
12 people should look at the way that drug
13 guidelines are written up.

14 So, for example, a very effective
15 one has been aspirin for CABG. The way that
16 that is written up, it doesn't say you have to
17 tell your patient that they should take one
18 aspirin every other day or a baby aspirin
19 every day. Tell your patient to take aspirin,
20 and the assumption is they are going to be
21 told to take it the right way.

22 So we need to think about, when

1 there is evidence, that it can be done wrong
2 like there was with the depression screening
3 in Parkinson's. I take that as we should be
4 prescriptive in those situations, but when
5 there is no evidence that, when this is done,
6 it is done wrong, is that our role to assess
7 that?

8 CO-CHAIR KNOWLTON: I can't resist
9 responding to you. I think that our job is to
10 be prescriptive, not to be prescriptive in
11 medicine -- I agree with you. I think our job
12 is to be prescriptive when we say we are going
13 to measure performance and publicly report it.
14 We have an obligation to be prescriptive then.
15 We have an obligation that you should know
16 that what I am measuring you on is identical
17 to what I am measuring Gail on. But in terms
18 of clinical practice, I don't want to
19 interfere with that. But if I am going to
20 measure it and I am going to say you got to do
21 it, and I am going to report whether you do or
22 not, with all the incentives or disincentives

1 that could be tied to that, that is where I
2 think the rigor is.

3 There are all kinds of things in
4 clinical practice that people make judgments
5 on that we shouldn't interfere with. I agree
6 with that. Salina.

7 DR. WADDY: I just wanted to go
8 back to David Tirschwell's previous point
9 regarding the use of CMS and regarding the use
10 of actually big data.

11 One thing that is currently going
12 on is CMS actually working more closely with
13 NIH in order to see whether or not there are
14 questions, potentially as this, that can be
15 answered and made more available to outside
16 investigators. That may be a way of getting
17 the information that you mentioned.

18 The second thing is also to engage
19 other groups, such as Kaiser Permanente and
20 other large practice organizations, in order
21 to put in place very simple interventions that
22 can then rapidly be studied.

1 Those are very simple ways you can
2 engage those types of organizations, but it is
3 not our job to develop the research projects.
4 It is to assess whether or not that has
5 reached the level of evidence that can be more
6 broadly distributed.

7 CO-CHAIR KNOWLTON: Ramon?

8 DR. R. BAUTISTA: I would tell the
9 developer potentially to study number 209,
10 which we actually passed yesterday. It is an
11 example of a study that actually did not use
12 RCT and got passed.

13 In fact, their first statement
14 says evidence does not exist, blah-blah-blah.
15 IN other words, they did not have any direct
16 evidence for their thesis here; yet had a lot
17 of what you call circumstantial studies,
18 direct studies looking at different aspects of
19 the same problem, which again is a compelling
20 argument to pass this.

21 So it is a good example to study
22 that is not directly RCT. It has very good

1 evidence, I think circumstantial evidence for
2 their study. So it is a good study to
3 actually look at and model for future
4 reference.

5 CO-CHAIR KNOWLTON: We are going
6 to move on now to measure gaps. That is,
7 through our discussions today, have we
8 elicited gaps that we think should be
9 considered for future consideration?

10 MS. JOHNSON: I think, along with
11 that -- and you guys have already started
12 doing that, but maybe go ahead and put your
13 measure developer hat on. These measures on
14 dementia went down, most of them did. What
15 wouldn't have gone down in your mind? What
16 would be a good start? Let's give the
17 developer some concrete ideas, not just
18 dementia, but maybe we can start with
19 dementia, and then we will go through and
20 segue into the other ones.

21 CO-CHAIR KNOWLTON: I was looking
22 at you, Anna, because I thought you would

1 immediately have a suggestion. Go ahead.

2 DR. BARRETT: I think that
3 previously I made the comment about assessment
4 of driving in Alzheimer Disease, but that is
5 one of a number of functional interventions or
6 assessment measures, process measures, that
7 could be evaluated in Alzheimer Disease and
8 dementia.

9 Although rehabilitation is
10 oftentimes not thought to apply to progressive
11 disorders, yesterday we acknowledged the
12 importance of rehabilitation in Parkinson
13 Disease, and in dementia there are a number of
14 different interventions from traditional
15 rehabilitative specialties that have been
16 shown to improve function.

17 So actual assessment and referral
18 for treatment and intervention may be
19 appropriate gaps.

20 CO-CHAIR KNOWLTON: Peter.

21 DR. SCHMIDT: The driving one
22 seems like one where you could create an

1 outcome measure around that, and I think an
2 outcome measure would be much more powerful.
3 I am not aware of any evidence that people
4 with a diagnosis of dementia should be
5 driving. So, actually, getting people off the
6 road would constitute an outcome.

7 Maybe I am not aware of all of the
8 evidence around that, but I think that that
9 seems like something that is sort of a no-
10 brainer.

11 CO-CHAIR KNOWLTON: Jane.

12 MS. SULLIVAN: Maybe this is a no-
13 brainer, too, but if you look -- If the
14 developers look at, instead of did the measure
15 pass or did the measure go down, but when it
16 went down, there were several cases where
17 people seemed to feel that the evidence wasn't
18 there, that there was evidence but it wasn't
19 sufficiently cited.

20 So I would hope that developers
21 would look at those measures in particular,
22 and say, you know, people around the table

1 felt like there was some evidence, but it
2 wasn't presented to the committee, and it
3 wasn't the job of the committee to develop --
4 or to find that evidence.

5 CO-CHAIR KNOWLTON: John.

6 DR. DUDA: I think we have all
7 remembered discussions where, if measures were
8 designed to be more specific with not such a
9 big umbrella covering the whole -- you know,
10 the neuropsychiatric encyclopedia. If it was
11 just depression, it probably would have had a
12 better chance of passing.

13 CO-CHAIR KNOWLTON: Dan.

14 DR. LABOVITZ: I don't have any
15 good ideas. So I am going to just offer a
16 comment. I think that what we are seeing here
17 is an ever evolving and improving general
18 process, just within the medical community.

19 We are now establishing quality
20 measures using a very strict process. It was
21 only fairly recently we started coming up with
22 consensus guidelines. Now our guidelines are

1 getting better.

2 perhaps one of the next evolutions
3 needs to be having the various developers, the
4 American Academy of Neurology being one I am
5 most familiar with, because I am neurologist
6 and I belong, looking to provide funding to
7 show that an intervention makes a difference,
8 and then using that to drive quality.

9 This group is the last stop, and
10 is being pressed to offer up suggestions for
11 measures. We need data.

12 CO-CHAIR KNOWLTON: Gail.

13 DR. COONEY: This is a little bit
14 what John was referring to, and I doubt that
15 there is evidence for this, but looking
16 specifically at advance directives being
17 written for dementia patients early in the
18 course of their illness.

19 In my work, I too often see
20 patients who missed the opportunity to have
21 that advance directive discussion before they
22 lose their cognitive abilities, and I think

1 that that would be very valuable.

2 CO-CHAIR KNOWLTON: David?

3 DR. HACKNEY: I want to second
4 Michael's point from earlier in the discussion
5 -- now I can't remember which measure it was -
6 - saying that every new thing that you mandate
7 happens during a visit is either extending the
8 length of that visit in order to incorporate
9 it or it is crowding out something else.

10 So I think, once you have declared
11 that -- If you are going to declare that
12 something is so important that this has to be
13 done, then you should have evidence not only
14 that it is useful in its use, the desired
15 purpose, but some idea of what the magnitude
16 of that impact is, because you could spend
17 literally all day with each patient if you
18 fill out every validated measure tool that
19 there exists that might be relevant, and
20 particularly when you are talking about
21 elderly patients with multiple problems.

22 There could be an infinite number.

1 Physicians make the decision of what has to be
2 done and what doesn't, but if you create a
3 long list of mandates, it better be true that
4 every one of those is important enough that it
5 has to be done the way we are specifying.

6 CO-CHAIR TIRSCHWELL: Terry.

7 DR. RICHMOND: This might be going
8 too far afield, but I am going back to the
9 safety concerns with dementia and also the
10 driving issues.

11 I think in health care we tend to
12 be a rather incestuous little group, and I
13 think that there are some really solid data
14 out there, if we would expand our horizons.
15 So NHTSA, National Highway Traffic Safety
16 Administration, has a wonderful accident
17 analysis reporting system with solid data. It
18 is a regulatory agency. They will have data
19 on causes of fatal accidents and a random
20 sampling of nonfatal accidents.

21 The same thing with one of the
22 measures that is a counseling measure, for

1 example, was referred to counseling about guns
2 in the home of demented patients. CDC has a
3 national violence reporting death system which
4 covers data from about 26 states where there
5 really are data out there.

6 So we may need to like take off
7 our blinders and look at who else should we be
8 connecting with to get the data to look at
9 things that, as health care providers, we can
10 intervene to improve outcomes for.

11 CO-CHAIR KNOWLTON: Just
12 piggybacking on that, DOT has an awful lot of
13 information on the driving issues that are at
14 question, too. Risha?

15 DR. GIDWANI: To echo what David
16 said just now and what Michael said earlier,
17 I think that the opportunity costs of adhering
18 to these measures is something that it would
19 be great to have some data on.

20 So, for example, when I was
21 reviewing the counseling regarding safety
22 concerns for the dementia measure, and it said

1 that the physician or the provider should be
2 having a discussion with the patient on a
3 number of different bullet points, I really do
4 wonder about the time that that takes.

5 I think that, for the purposes of
6 NQF evaluation, I am not sure what NQF feels
7 about this, but I would love to see some
8 information about how much time this actually
9 takes. I think that could be easily done with
10 a pilot study to say this conversation took on
11 average six minutes across a sample of 20
12 patients.

13 I think that one of the things
14 that we need to be concerned about is the fact
15 that, when we are focusing attention on
16 certain measures, that the attention that will
17 then be focused on providers on meeting these
18 measures is not inadvertently causing quality
19 of care to reduce on other conditions that
20 don't have those measures associated with
21 them.

22 CO-CHAIR KNOWLTON: I am going to

1 call on Jane. Gwen, weren't you going to say
2 something, or not? Did somebody already cover
3 it? I just made you wait too long. You gave
4 up.

5 DR. BUHR: Yes. I was going to
6 respond to Peter about -- He was saying an
7 outcome measure about driving and dementia.
8 I don't know that it is that black and white,
9 because somebody with mild dementia with no
10 impairment in their executive function may be
11 able to drive; whereas, somebody else
12 wouldn't. So it may be more complicated.

13 CO-CHAIR KNOWLTON: Jane?

14 MS. SULLIVAN: This is to build on
15 Risha's point, which build on Michael's point,
16 which was related to David's point, and it is
17 the whole -- the time issue, but I think I
18 would like to broaden that to not only who has
19 the time but who is the appropriate provider
20 to be doing some of these things.

21 The focus of much of this has been
22 the physician. I would argue that a

1 functional assessment is probably as
2 appropriate or more appropriately done by a
3 physical therapist or an occupational
4 therapist.

5 So to broaden the definitions of
6 these things to look at who is in the best
7 position to do it and who appropriately has
8 the time. I think that goes to burden of
9 care, but appropriate provision of care.

10 CO-CHAIR KNOWLTON: I want to
11 piggyback on that question for NQF, raise with
12 Helen or with Karen or with Suzanne.

13 I remember this issue being a big
14 issue in the first round stroke, which I co-
15 chaired as well, and it was particularly on
16 dysphasia screening and who was the one that
17 did the dysphasia screening. Mary is nodding,
18 because Jane and Mary remember the debate.

19 I thought the argument at the time
20 was that we didn't have to be prescriptive,
21 because the standard is open-ended. It
22 doesn't necessarily justify the physicians.

1 It applied to nurses, but this is an issue
2 carousel.

3 It keeps coming back, you know,
4 where people say we may think it is from Mount
5 Olympus NQF. We may think that this is
6 understood in the field, but it is not. So
7 some data gatherer is saying, if a physician
8 with an MD or a DO doesn't write down
9 something in a chart, if an advanced practice
10 nurse does, it doesn't count, or if a PT does
11 or an OT or a speech and hearing person does,
12 it doesn't count.

13 I just wanted to piggyback on
14 Jane's comment, because I remember this issue.
15 We spent like a day on this issue. Mary?

16 MS. VAN E KAMP: The developer
17 left for the dementia piece. I wanted to say
18 publicly, and I think it is important, that
19 the investment and the time to bring these
20 forward is really recognized.

21 I think that, while it may not
22 have all the pieces to it that we need to have

1 to get to a high standard, I think it is
2 important that the discouragement from that
3 may be work and not driven to the next level
4 is not preventing continuation; because there
5 is a lot of work that I know people put in
6 this to bring it forward, and it is the first
7 step in health care that we start to hold each
8 other accountable and determine what we should
9 spend our time on and how to do that.

10 I know that in the first phase
11 there was -- I saw some disappointment, and I
12 saw almost a stop in their continuation of
13 bringing that forward on the ASHA NOMS. I
14 think that is something we need to go back and
15 talk about, but I think it is important that
16 this isn't seen as a discouragement, although
17 I can appreciate that it is, but that really
18 a next step. What do we need to do to really
19 grow this and to hear what is needed to have
20 that done, because I do think, as I watch
21 faces in the room after you have worked so
22 hard an you feel that work just sort of fall

1 down -- and again I think we have said it
2 before. It is not that it is not important.
3 It is that we have to continue as an industry
4 to raise the bar, but I applaud the groups
5 that have brought things forward, because
6 there are many people in health care that have
7 been hesitant to bring forward some of the
8 measurements for fear of being judged by them.

9 CO-CHAIR KNOWLTON: Michael.

10 DR. KAPLITT: My thought is more
11 to NQF than to new ideas. The Neuro Committee
12 is a new committee for you guys. Right? Last
13 time was our first time meeting, and it
14 recognized, obviously, the emergence and the
15 importance and the increasing number of neuro
16 guidelines, but neuro was different than a lot
17 of other areas of medicine and can have a lot
18 of these vagaries that are not as clear when
19 you are dealing with very concrete data points
20 like blood pressure and other things.

21 I think that a lot of the problem
22 -- It is clear that there has been enormous

1 sympathy for a lot of these things among most
2 of us, because we all know that these are
3 important areas in general, but the struggle
4 has obviously been that essentially what we
5 have been asked to do for many of these or
6 most of these things is to largely rubber
7 stamp guidelines that were made --
8 organizational guidelines without really any,
9 much additional information.

10 My sense from the comments of the
11 various developers, not one in specific
12 because it seemed like a common theme, was not
13 entirely a full understanding of what the NQF
14 process or needs are, because repeated
15 statements like, well, you are never going to
16 do a randomized controlled trial on this, so
17 this is the best we can do, to me seems
18 dramatically divorced from what our process
19 really is here.

20 So if they go home with that
21 message that, well, you know, all they want is
22 randomized controlled trials and that's it,

1 that obviously is a bad message. But we can
2 sit here and say that all we want today, but
3 it seems to me like maybe there needs to be
4 more of an engagement in advance of this
5 process between the developers and NQF to
6 understand the process and what evidence means
7 and what the purpose is here and what we are
8 all trying to do, because this isn't -- I
9 don't think anybody here is playing a game of
10 gotcha like, well, you know -- because I have
11 sat on a bunch of NIH grant reviews where that
12 is what happens, where people just look for
13 like some random line -- you know, you didn't
14 do that; that's it, you are done.

15 I don't think that is what has
16 happened here today. I think there has been
17 great struggling, and that is why we have
18 spent a lot more time than I had thought we
19 were going to spend yesterday morning with my
20 initial statement, but it was well spent,
21 because we are all struggling with this,
22 because we all live out there in this world,

1 and we all want to make this better for these
2 patients.

3 On the other hand, we also live in
4 the world where we and our colleagues are
5 increasingly under the gun, and that is only
6 going to get worse. So we have both sides of
7 that in our minds when we are doing this, and
8 I think that, if the developer is engaged NQF
9 a little more, particularly on the evidence
10 side, and what we all want in advance, then
11 that might help enormously.

12 DR. BURSTIN: Those are great
13 comments, Michael, and we have actually worked
14 really closely with developers to try to make
15 this really clear, and we actually have
16 regular monthly measure webinars. We actually
17 have an in-person measure developer meeting in
18 November.

19 I think there is actually, truly a
20 bit of a disconnect of the fact that -- Again,
21 I think Daniel raised this point as well about
22 the supply chain. I think, to a certain

1 extent, the expectation that a developer is
2 going to do a systematic review is not likely,
3 and if the guideline developer hasn't done it,
4 it does put them at a disadvantage.

5 So this is something I think we
6 need to work out, although I will point out,
7 though, very interestingly, every committee,
8 by the way, thinks that their area is not as
9 clear, and there is a lot of -- So GI,
10 urology, we run through all of these. My
11 patients are sicker. The mantra continues,
12 but I hear you.

13 I think the other thing that has
14 been really hard for us is that these are gap
15 areas for us. We have almost no measures of
16 dementia or epilepsy. So I think it is very
17 heavy hearted for us as well. We want to be
18 able to bring forward something that we feel
19 like would really help move the field forward
20 without - you know, you can only measure what
21 you -- You can only improve what you can
22 measure, and we have nothing.

1 So any ideas about what you think
2 the developers could do to improve and try to
3 move some of this forward -- and Parkinson's
4 as well, obviously.

5 CO-CHAIR KNOWLTON: Salina.

6 DR. WADDY: I really want to --
7 This is really for the NQF, but I would like
8 to go back to my statement from yesterday,
9 which is there is a lot of valuable
10 information, even if some things went down in
11 flames, but there is a lot of valuable
12 information in the discussion.

13 If there are certain elements or
14 certain measures or areas where there are gaps
15 that the NQF really thinks needs to be further
16 investigated, then potentially sitting down
17 with the agencies that fund research as well
18 as bringing in other stakeholders just to
19 discuss this is identified as a major gap
20 area, and then review this valuable
21 information that you have already gotten
22 together, could be tremendously helpful.

1 DR. BURSTIN: We have had similar
2 discussions with PCORI as well. So I think
3 there is interest in seeing that. We used to
4 actually have a section of the report, I
5 think, on research recommendations. Maybe it
6 is time to kind of loop back to that, as long
7 as we are clearly having a tough time getting
8 some of this through.

9 DR. WADDY: Right, but I am
10 involved with clinical research. For example,
11 we do bring in outside groups if there was an
12 interest to talk to the entire group.

13 DR. DUDA: It seems to me that a
14 lot of the problems that were raised in the
15 small group conference calls about these
16 measures came to us for this meeting, and
17 perhaps if there is a longer delay in between
18 when they get that feedback back from the
19 small groups until this meeting, they could
20 have more chance to answer those queries or
21 respond to those criticisms.

22 CO-CHAIR KNOWLTON: Jocelyn.

1 DR. J. BAUTISTA: Getting back to
2 the original question of what might have
3 passed, in terms of epilepsy we have said
4 multiple times that NQF prefers measures that
5 are close to the outcome. So we reviewed a
6 couple of measures that asked for
7 documentation of seizure type and seizure
8 frequency.

9 So a measure -- and I think the
10 developers actually mentioned this yesterday,
11 but a measure that said for patients who are
12 not seizure free, what percent are referred to
13 an epilepsy specialist or what percent are
14 referred for surgical evaluation, something
15 that does more than the assessment, but
16 actually acts upon the assessment.

17 CO-CHAIR KNOWLTON: Peter, nothing
18 additional? Okay. Anybody else? Then I
19 suggest that we break for lunch, and then we
20 will come back for our additional discussion
21 topic Phase I follow-up, which is on the
22 Yale/CMS stroke measure.

1 DR. BURSTIN: The disparities-
2 sensitive measures would apply to those that
3 went through. So since they were few, we
4 could see if there is any specific interest in
5 any of the ones that did get through.

6 MS. JOHNSON: I think, just a
7 reminder, too. My understanding is that the
8 ones that went through were good: the two
9 dementia measures about diagnosis in nursing
10 facilities and the counseling for women of
11 childbearing potential with epilepsy, and then
12 the stenosis measurement.

13 So the first two of those, you
14 have already told us that those are
15 disparities-sensitive. So I think our
16 discussion -- That would have been our
17 discussion. I guess the other question then
18 would be for the carotid imaging studies.

19 CO-CHAIR KNOWLTON: Let's eat.

20 (Whereupon, the above-entitled
21 matter went off the record at 12:07 p.m. and
22 resumed at 12:51 p.m.)

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

(12:51 p.m.)

1
2
3 MS. JOHNSON: Everybody, let's go
4 ahead and get started back again, in the
5 interest of time and, hopefully, we can finish
6 up our discussion this afternoon.

7 To start the next section of our
8 meeting today, we are going to go back and
9 revisit the stroke readmission measure from
10 Phase I. So to start us out in our thinking
11 about that, I am going to turn it over to
12 Helen.

13 DR. BURSTIN: Hi, everybody,
14 again. The last task before you get to leave
15 us, we want to just take this opportunity to
16 thank you for, obviously, all the hard work
17 you have done the last couple of days, but
18 also to explain why we are revisiting this
19 measure, because I know some question has come
20 up.

21 So just to recap, just
22 historically, this measure was discussed by

1 you the last time you were in this room and in
2 this meeting, the first phase of the project,
3 and the measure was approved. The readmission
4 measure was approved.

5 I will also point out just to
6 remind you, the mortality measure that we
7 talked about, the 30-day mortality measure,
8 has been withdrawn by CMS, and they are now
9 investigating other approaches potentially to
10 get more clinical data like the NIH severity
11 scale, part of it, moving forward.

12 So one of the issues is, when we
13 had that follow-up call with you, you were
14 voting on the updated measure that had
15 included the expanded planned readmission
16 algorithm, as well as the expanded risk
17 adjustment age categories for the mortality
18 measure.

19 So we had you revote on that
20 measure at the time and, if you recall, much
21 of the discussion we had on that conference
22 call was really focused on the fact that the

1 Fonarow paper had come out, and a lot of the
2 discussion was heavily focused on the
3 relationship of the NIH severity scale to the
4 outcome measures, primarily focused on
5 mortality.

6 Because the measures had
7 substantive changes made to them, we are
8 required to put them back out for public
9 comment, since people didn't have an
10 opportunity to see those updated measures.
11 And since we were sending out the mortality
12 measure, we elected -- even though the vote
13 was very close, it was 10 to 12 -- to just put
14 them both out for comment, particularly since
15 it had already passed initially before that
16 conference call.

17 So at this point of the
18 discussion, we are going to have an
19 opportunity to review the public comments that
20 were submitted. We will then have Yale and
21 CMS have an opportunity to respond to any of
22 those comments, and answer any of your

1 questions.

2 One of the things I just have to
3 acknowledge is at times it is very difficult
4 for us to know exactly what constitutes
5 consensus. So votes that are that close and
6 so nearly split are ones we tend to err on the
7 side of getting more information, putting it
8 out for comment, getting as much information
9 as we can to bring it back to the committees.

10 Certainly, if that was the final
11 vote, it would not go out for voting. It
12 would stop there. So voting requires truly
13 this majority rules, and it just goes out. So
14 we actually have a Consensus Task Force now
15 that has been convened by our Board of
16 Directors to help us really kind of more
17 crisply define what we mean by consensus in
18 terms of these votes.

19 So at the conclusion of this
20 discussion of the comments and specifically,
21 again, trying to focus at this point only on
22 readmissions, and so much of our discussion on

1 that conference call was so heavily oriented
2 to the mortality measure and the NIH severity
3 scale, we are going to focus this one today
4 just on readmissions.

5 I will point out, as you saw in
6 the AHA comments as well as communication that
7 I got after presenting indirectly at the Brain
8 Attack Coalition recently that there does not
9 appear to be significant evidence that the
10 concerns about the NIH severity scale apply to
11 readmission, as best we know at this point.

12 So we are just going to focus on
13 readmissions. At the conclusion of this, you
14 will again have the opportunity, as we always
15 do for committees whenever new information
16 comes forward, to say is there anything as a
17 result of this discussion that would lead you
18 to want to revote again on a readmission
19 measure.

20 So that will be your discussion
21 point today, and at that point I will turn it
22 back over to -- who is doing this part?

1 CO-CHAIR TIRSCHWELL: I am. I
2 have one question. I guess I wasn't sure if
3 the folks that had submitted the comments
4 about the measure and might be calling in, and
5 we are starting early. Is that an issue?

6 DR. BURSTIN: We have got most of
7 the Yale and CMS folks in the room, and I know
8 Kate Goodrich was going to be calling in.
9 Kate, are you on the phone? Arnica, are you
10 with us?

11 CO-CHAIR TIRSCHWELL: We are just
12 wondering if there is anybody connected.

13 OPERATOR: Yes. There are several
14 speakers on.

15 DR. BURSTIN: Okay, could you
16 please see if Kate Goodrich is there and, if
17 so, put her on the speaker line for us.

18 OPERATOR: She is not online at
19 this time.

20 DR. BURSTIN: Okay. Please let us
21 know when she is and, if not, we will defer to
22 Lein Han from CMS as we need to. But we are

1 okay proceeding.

2 CO-CHAIR TIRSCHWELL: I guess my
3 question was, was the Heart and Stroke
4 Association planning on calling in?

5 DR. BURSTIN: Not that I am aware
6 of.

7 CO-CHAIR TIRSCHWELL: Because they
8 submitted a lot of --

9 DR. BURSTIN: Right. We have
10 their comments.

11 CO-CHAIR TIRSCHWELL: Okay. I
12 guess I am worried that, if the schedule had
13 gone out that we were going to start at 1:30
14 and people were going to call in, they don't
15 necessarily have to make a reservation, do
16 they? So those people might miss their
17 opportunity to participate.

18 DR. BURSTIN: I suspect we will
19 still be talking at 1:30. So if they called
20 in at the end, we will make sure we do public
21 comment. How about that?

22 CO-CHAIR TIRSCHWELL: I just

1 wanted to make that comment. Helen, you said
2 that we can -- this is a different process
3 than any we have done before. We have a
4 chance to review the comments, and I know the
5 Yale group has a presentation to make.

6 Are you suggesting we literally
7 walk through the comments or just ask people
8 if they have particular things?

9 DR. BURSTIN: Do you want to
10 briefly walk through briefly what we saw in
11 terms of comments or have people had a chance
12 to look at it, and people just want to make
13 comments? I don't think we need to do a point
14 by point on comments.

15 CO-CHAIR TIRSCHWELL: Yes, go
16 ahead.

17 DR. DRYE: First, I just wanted to
18 confirm if our Yale team -- I am Elizabeth
19 Drye from Yale, and my colleague, Susannah
20 Bernheim who led the measure development for
21 both mortality and readmissions should be on
22 the line. I just wanted to confirm.

1 DR. BERNHEIM: Yes, we are here,
2 Elizabeth.

3 DR. DRYE: Great. We just wanted
4 to do what makes the most sense to you. We
5 didn't prepare slides on the comments, but we
6 could -- Susannah could walk through and
7 summarize. I just prepared slides to
8 highlight a couple of points about the planned
9 readmissions and also the medical record
10 validation of the readmission measure, just
11 actually five slides, very brief.

12 CO-CHAIR TIRSCHWELL: I will make
13 a suggestion, and then people can suggest
14 alternatives, if they like. I suggest we go
15 ahead and let you go through the slides, and
16 then open it up to questions related to that
17 or any other topic that people had questions
18 on in the question and answer document, if
19 that is okay with you all. Okay. You guys
20 want to go ahead and do your slide show?

21 DR. DRYE: Hi. thanks. We just
22 decided to keep it brief. We know you have

1 had several different discussions at different
2 stages about the measure. So I just wanted to
3 highlight particular points about the
4 readmission measure since, as Helen mentioned,
5 a lot of the discussion has been focused on
6 mortality.

7 The key change since we initially
8 submitted the measure was to update the
9 planned readmission algorithm to be more
10 expansive, to identify more readmissions as
11 planned, and it is a shift in how we are doing
12 readmissions measures generally.

13 When we put the measure together,
14 the team of experts, including neurologists
15 and others expert in stroke, identified some
16 readmissions as planned, that would be
17 typically planned following an admission for
18 stroke as related follow-on care.

19 So it was a fairly narrow
20 definition and included things like carotid
21 endarterectomy or intercranial sensing, and it
22 was less than a percent of admissions that

1 were followed by planned readmission.

2 As we have continued in the
3 measurement community to work on readmission
4 measures, we wanted to identify a broader set
5 of readmissions that were planned and, I
6 think, as some of you know, we built an
7 approach to doing that in claims data for the
8 hospital-wide readmission measure.

9 This broader approach is seeking
10 to identify as planned not only readmissions
11 that are related to stroke and that are
12 follow-on care, but just planned readmissions
13 that occur in this particular population, and
14 Medicare patients is the focus at our
15 discussion, because they have a fairly high
16 number of planned readmissions for unrelated
17 things like cholecystectomy, for example, that
18 might occur from 30 days of discharge from a
19 minor stroke or other readmissions for other
20 conditions like pneumonia, and we do not want
21 to count those in a measure looking for a
22 quality signal.

1 So what we did was we built an
2 algorithm, and we prepared a report which I
3 know was distributed to you, but it is
4 complicated and lengthy. I just wanted to
5 summarize really briefly.

6 We defined planned readmissions as
7 readmissions that were for non-acute reasons.
8 It couldn't be for an infection or a second
9 stroke or a heart attack or any emergent
10 reason, and that had a scheduled -- a
11 procedure that we would call a typically
12 scheduled procedure.

13 We never want to call planned
14 admissions that are for acute illnesses or
15 complications of care, and there were some
16 kinds of admissions that could occur within 30
17 days of discharge that we have heard quite a
18 bit about from people we collaborate with,
19 from public comment, like rehabilitation,
20 admissions for cancer chemotherapy,
21 transplants, that really are planned and
22 shouldn't be counted in this type of a

1 measure. So those, we don't count as planned.

2 So we have a list that we
3 distributed earlier to potentially planned
4 procedures and a list of acute conditions, and
5 together those allow us to put readmissions in
6 the planned or unplanned category.

7 When we applied it to the stroke
8 measure, we had an expansion of the number of
9 the percent of admissions followed by a
10 planned readmission. So in the originally
11 submitted measure, the readmission rate was
12 14.8 percent, the readmissions we were
13 counting, and it dropped when we expanded the
14 number of readmissions we are counting as
15 planned to 14.3 percent.

16 That percentage of readmissions
17 that were followed by what we are now calling
18 a planned readmission within 30 days of
19 discharge went from 0.6 percent -- that was
20 the admissions following stroke that were
21 closely related to the stroke care that
22 essentially would be follow-on care for a

1 stroke admission -- and now we have a more
2 expanded definition, and I will show you what
3 it captures in a second.

4 When you apply in this cohort of
5 patients, 1.1 percent of patients who are
6 admitted come back with what we are now
7 calling a planned readmission, and we are not
8 counting it in the measure.

9 If you look, this is a little
10 small, and I apologize. I try really hard not
11 to put small words on slides. So let me just
12 read it for you. But the most common thing
13 for a stroke patient, the most common
14 procedure for which they were admitted that we
15 are counting as a planned readmission was
16 endarterectomy, which was what we would
17 expect.

18 Also, quite a few patients -- this
19 is out of a cohort of 169,000 patients. There
20 were about 800 admissions for endarterectomy,
21 about close to 200 for diagnostic cardiac
22 cath, and 180 for rehabilitation, 174 for

1 cardiac device related procedures,
2 removal/revision of a defibrillator or
3 pacemaker. It goes down from there.

4 You will see in the bottom of the
5 list -- if you can't see, again I apologize;
6 I will read it for you -- that there are some
7 planned readmissions here for what I think
8 about as essentially care that -- this is
9 Medicare 65 and older patients -- care that
10 these patients come -- they are happening
11 subsequent to an admission for stroke in the
12 30-day window from discharge, and probably
13 very or completely unrelated to that, and they
14 just needed care. We don't want to discourage
15 it. We don't want to count it in a
16 readmission measure.

17 They include procedures like a
18 colorectal resection, presumably for colon
19 cancer. That is the most common diagnosis we
20 saw with that procedure in this cohort, or a
21 cholecystectomy, etcetera.

22 So I want to just pause there,

1 because we are using, again, a list of
2 potentially planned procedures that we
3 developed in consultation with specialists
4 across the whole spectrum of providers, and we
5 are using a list of acute diagnoses. If you
6 have a potentially planned procedure but not
7 an acute diagnosis, we will call you planned.
8 That is an algorithm that isn't that easy to
9 follow in two minutes. So let me stop and see
10 if people have questions.

11 CO-CHAIR TIRSCHWELL: I have got a
12 question. So are these additional planned
13 admission procedures -- is the only change
14 that was made to the measure and, if so,
15 judging by the percentages you just gave us,
16 to me, it seems like it is a small change that
17 is probably not going to affect much of what
18 the measure does.

19 DR. DRYE: I don't think it
20 fundamentally changes the measure, if that is
21 what you are saying. I think it improves the
22 measure.

1 CO-CHAIR TIRSCHWELL: Can you
2 quantify the improvement? I mean, it is half
3 a percentage.

4 DR. DRYE: Yes. I can give you a
5 little more information that might be helpful.

6 CO-CHAIR TIRSCHWELL: Is this the
7 only change that was made, though? That was
8 my first question.

9 DR. DRYE: We also specified the
10 measure for all payer population, but that
11 didn't change the measure. That was just
12 additional testing in a California all payer
13 dataset.

14 Then I just wanted to present one
15 last slide, which is about the validation of
16 the measure, irrespective of this change. But
17 in terms of the effect, it is not conceptual.
18 I think that we really don't want in a
19 readmission measure to be capturing planned
20 readmissions, and we were looking for a way to
21 do that better.

22 We took work for a hospital-wide

1 readmission measure that looks broadly across
2 the entire hospital, and allowed us to -- you
3 know, in that context, we were able to develop
4 this algorithm. It went through several
5 rounds of public comment. Actually, it went
6 through public comment again in the context of
7 this process, and so it is just an improvement
8 to better capture the underlying quality
9 signal that we are trying to capture.

10 I think it makes it more fair, and
11 will more fairly characterize hospitals.
12 There is a small shift in how hospitals rank
13 when you apply this, because they vary. You
14 know, they look a little different when you
15 count planned readmissions this way.

16 Does that answer your question?

17 CO-CHAIR TIRSCHWELL: Yes. Go
18 ahead and finish your presentation, or did
19 anybody else have any questions about that
20 first part? Go ahead.

21 DR. DRYE: Okay. I am just going
22 to highlight quickly the validation that we

1 did of this measure of the use of claims for
2 risk adjustment for this measure.

3 It parallels what we did in the
4 stroke mortality measure. I wanted to
5 contrast, because the results are quite
6 different than they were for the stroke
7 measure.

8 We used the National Stroke
9 Project medical record data, which contains a
10 severity scale. It is correlated with NIH.
11 Of course, it is not the NIH. It us. And we
12 matched a set of patients, and we estimated --
13 Actually, we did it at the state level, not
14 the hospital level, just given the number of
15 patients that we had, and we estimated risk
16 standardized rates of readmission.

17 When you use the medical record
18 data we had for risk adjustment, and you
19 estimate rates and then you use the claims
20 data and you estimate the rates on the same
21 patients, you basically get almost the exact
22 same rates. The correlation coefficient is

1 .99, which is a lot higher than it was for the
2 mortality measure.

3 I think that this is as expected,
4 given the findings we had going into the
5 study, which is we didn't expect stroke
6 severity to really be a strong predictor of
7 readmission. In our lit review, it was not
8 identified as a predictor of readmission, and
9 I know in the public comment, the American
10 Hospital Association highlighted that they had
11 found the same thing.

12 So my understanding of the primary
13 concern about the mortality measure was the
14 adequacy of the risk adjustment and the need
15 for a stronger signal of stroke severity in
16 the risk adjustment. I just wanted to
17 contrast what we found here and what the
18 literature says underlying that.

19 CO-CHAIR TIRSCHWELL: We are going
20 to do questions one slide at a time. Is that
21 what I should interpret your pause as? Oh,
22 you are done?

1 DR. DRYE: Yes, I am done. Sorry.
2 I am being too informal.

3 CO-CHAIR TIRSCHWELL: You had
4 flashed some other slides, but maybe those --

5 DR. DRYE: No. They are just
6 showing you -- I can show you real quick, if
7 you want. Basically, they are just showing
8 the distribution of the rates. As you, I
9 think, intuited, they don't really change --
10 These are rate distributions before and after
11 we extended the plan readmissions, and this is
12 just a slide.

13 Again, if you look at the rates
14 estimated with the original plan readmission
15 algorithm and with the new one, you see that
16 there are small -- and you subtract the
17 hospital standardized rates with the old
18 algorithm and the new one, you see that the
19 rates are changing a little bit for each
20 hospital, which means the order of the ranking
21 will change, but that is what we expect. We
22 think we have a more accurate, better measure

1 that is going to characterize hospitals more
2 fairly.

3 CO-CHAIR TIRSCHWELL: So going
4 back to your correlation curve slide, those
5 two ways that you are risk adjusting, and
6 then, I guess, what is on the vertical and
7 horizontal axes is the risk adjusted
8 readmission rate. Is that what that is?

9 DR. DRYE: The risk standardized
10 rate produced by the claims based measure is
11 the X axis, and the risk standardized rate
12 produced by the National Stroke Project
13 medical record data measure -- the risk
14 adjustment was done with that chart extracted
15 data -- is on the Y axis.

16 CO-CHAIR TIRSCHWELL: You said you
17 did this at the state level, not the hospital
18 level.

19 DR. DRYE: Right.

20 CO-CHAIR TIRSCHWELL: But you are
21 not -- You think it would play out just as
22 well, if you had the data, to do it at the

1 hospital level?

2 DR. DRYE: I do, and we have done
3 it for other measures at either the hospital
4 or state level, depending -- What we really
5 want is a national representative sample, and
6 those are expensive studies, and it is hard to
7 get enough volume on those to do it at the
8 hospital level, but given these results plus
9 what is in the literature plus what we are
10 finding with the American Hospital Association
11 and we are finding in our work, we don't
12 expect -- This is what we would expect.

13 CO-CHAIR TIRSCHWELL: I think, if
14 your point here is that again showing that the
15 NIH stroke scale or a stroke severity scale
16 doesn't make a big difference in your ability
17 to risk adjust for readmissions, I am willing,
18 certainly, to admit that it seems like that is
19 fairly well demonstrated at this point.

20 I guess my question is: Because
21 the statistics in all these predictive models
22 are so low -- I am sure it is true for the

1 medical record one as well as it is for the
2 claims based one -- I am guessing that the
3 correlation of these readmission rates with
4 the totally unadjusted is over .9 or maybe you
5 have that actual number; because if these
6 adjusted rates are really no different than
7 the unadjusted, then have we really done
8 anything, and since we don't know the factors
9 that are affecting readmission, are we really
10 going to be able to treat hospitals that are
11 somehow disadvantaged equally, or will they be
12 rated as doing more poorly?

13 DR. DRYE: I'll try to touch both
14 those pieces of the question. On the second
15 part, will hospitals be rated poorly, we have
16 looked at the measure, and this is in our
17 initial application and it is true for all of
18 our readmission measures: When we identify
19 hospitals with a lot of low socioeconomic
20 status patients, for example, and very few,
21 there is a wide distribution of performance on
22 these measures, including this one.

1 So there are some very well
2 performing hospitals with a lot of low SES
3 patients, and there are some not so well
4 performing, and the same is true among those
5 who have a more affluent population.

6 So when we see a range of
7 performance, then we are accounting for the
8 way that this measure is discriminating
9 quality, and they are not those hospitals that
10 are safety net hospitals or have more poor
11 patients, more minority patients. They don't
12 routinely look worse on the measure.

13 On average, if you look at the
14 medians, they do slightly worse, but they have
15 a broad range of performance. So that is why
16 -- and I know this committee has already had
17 this discussion -- we think we are not
18 disadvantaging those hospitals.

19 To your other point, if you just
20 ran -- If you had no risk adjustment and you
21 just ran it -- I don't think we have done
22 that. It is a great thought, but I want to

1 think for a minute about the purpose of risk
2 adjustment, which is to level the playing
3 field across hospitals that take different
4 types of patients.

5 So what we are trying to do with
6 the risk adjustment is not predict readmission
7 really accurately. As you know, we are just
8 trying to be fair, and hospitals that get
9 sicker patients, who have a higher risk
10 innately of readmission, we are trying to
11 adjust for that.

12 So we are not a priori saying that
13 we need a high C statistic in this measure,
14 and we know, whether we use chart models or we
15 use claims models for readmission, patient
16 factors are not the whole story in predicting
17 readmission, as you point out.

18 If you saw that they did very
19 little, I am not sure that would change a lot.
20 It would be interesting.

21 CO-CHAIR TIRSCHWELL: I guess,
22 just as one response, and then, Risha, I would

1 be interested in your comments, even though
2 the safety net hospitals are the ones with
3 more low socioeconomic status have a range of
4 performances, your comment that on average
5 they perform worse concerns me; and if we were
6 doing a good job, theoretically, of risk
7 adjusting, then I guess I would hope that that
8 wouldn't be the case.

9 Again, I think there is a risk of
10 these hospital, on average, being rated as
11 more poorly performing, and if there are then
12 penalties associated with this, then it would
13 be specifically the most vulnerable hospitals
14 and patients that would be potentially
15 financially disincentivized to improve their
16 care. That whole scenario -- it is very
17 theoretical, but it seems quite worrisome.

18 DR. DRYE: I think that is a valid
19 question and concern, and the way that we
20 think about it in the context of public
21 reporting is, you know, I don't know what the
22 truth is right now about those safety net

1 hospitals that aren't performing well or those
2 better off, wealthier hospitals that also
3 aren't performing well on the measure.

4 What we see, after adjusting for
5 risk, there is this range of performance, and
6 at this stage where there has been no public
7 reporting, the goal is really to illuminate
8 those differences.

9 As you know, it is an NCAP
10 guideline not to adjust those things away,
11 because if we adjust them away, we can't see
12 them. I think that is the first goal. It
13 would be great if -- you know, in an ideal
14 world, safety net hospitals that aren't doing
15 well could learn from the ones are doing
16 really well.

17 That is what we want to enable, I
18 think, and I am going to defer -- How you use
19 a measure like this to drive policy is an
20 important question, but I am not concerned
21 that there are differences there now, because
22 it could reflect a reality that patients who

1 are lesser off or minorities aren't getting as
2 good a quality care. That is possibly what is
3 going on, and it is being reflected here, and
4 that is what I think probably going on. The
5 question is how can we eliminate that and do
6 something about it constructively.

7 CO-CHAIR TIRSCHWELL: Risha?

8 DR. GIDWANI: I have a number of
9 comments, which is probably not a surprise to
10 anybody in this room.

11 I think that it is nice to see a
12 high correlation between administrative data
13 and medical record data, but the correlation
14 doesn't give us a whole lot of confidence, if
15 we see that the C statistic, the
16 discriminative ability, is so low.

17 So based off of what the
18 developers showed us, they showed a C
19 statistic of .60. That means that 40 percent
20 of the time their models are not able to
21 properly discriminate or properly predict the
22 people that actually got readmitted from the

1 people that didn't get readmitted.

2 So if the medical record model is
3 also has that same sort of 40 percent
4 inability to properly predict people that got
5 readmitted versus not readmitted, then it is
6 going to have a high correlation, but it is
7 still indicating that this is not a well
8 performing model.

9 So in saying this, I don't want to
10 take the developers to task for this. I think
11 that they are doing an admirable job with a
12 very complex and sophisticated methodology,
13 which is also a relatively nascent
14 methodology.

15 A recent systematic literature
16 review published in JAMA in 2011 looking at
17 the ability of predictive models to look at
18 readmission found that most of them don't
19 perform that well. I think the highest C
20 statistic that we found was a .77. So, of
21 course, that is much higher than a .60, what
22 we are dealing with here, but I think, really,

1 a lesson learned from the field is that this
2 is a difficult thing to do right.

3 With that, these C statistics are
4 concerning to me, and the developers have
5 numerous times said that this lack of
6 predictive ability, the sort of 40 percent
7 that we are leaving on the table, is due to
8 hospital level factors, and they are correct
9 that we don't want to adjust for hospital
10 level factor.

11 We want to illuminate a hospital
12 level factors, and by addressing for them, we
13 bury them. But it seems to me that the only
14 way that you can actually reach the conclusion
15 that it is the hospital level factors that are
16 responsible for leaving the 40 percent
17 predictive ability on the table is if you
18 actually do models that include these hospital
19 level factors, and then test the models that
20 have the hospital level factors against the
21 models that don't have the hospital level
22 factors, and then you are really going to

1 understand what is the influence of these
2 hospital level factors.

3 I think, to make conclusions in
4 the absence of evidence is an exercise in
5 using anecdotes to arrive at conclusions, and
6 at this level I am very concerned about that.

7 It also becomes even more
8 concerning to me that we are now going to be
9 expanding this measure beyond Medicare to an
10 all payer population. My concerns are strong
11 when we are just looking at the Medicare
12 population. They become amplified when we
13 have a larger patient population to which this
14 measure applies.

15 DR. BERNHEIM: Could I respond?

16 CO-CHAIR TIRSCHWELL: Sure, go
17 ahead.

18 DR. BERNHEIM: Hi, sorry to not be
19 there in person. This is Susannah Bernheim,
20 and I just want to step back. I know I have
21 said these things before, but I think there is
22 a very fundamental issue that we have to come

1 back to, which is this is not a predictive
2 model.

3 We are not aiming to give somebody
4 a risk score that says, if your patient comes
5 in with these factors, this is their chance of
6 readmission. The C statistic is one and not
7 the most important measure of the performance
8 of these models. If we were attempting to
9 predict every patient's readmission risk, we
10 would not do a terrific job at it, and that is
11 not what we are trying to do.

12 We, I think, have -- and I think
13 this was probably naive -- oversimplified the
14 idea that there are, quote, "hospital level"
15 factors that affect these readmission rates,
16 and I don't think that I could sort of put in
17 teaching status and PCI status and suddenly
18 give you a measure that explained all of the
19 admissions risks.

20 What our understanding of what
21 contributes to readmission risk is that it is
22 actually pretty complex, which is why it is

1 important to use an outcome measure in this
2 case. If it was as simple as handing patients
3 discharge instructions, then the process
4 measures would be sufficient.

5 What we are learning from an
6 emerging literature, which is new, is that
7 there are, in fact, very good evidence that
8 hospitals that put systematic programs into
9 place -- you know, Komen's Care Transition
10 Project being a great example -- reduced
11 admission risks and reduced patient
12 readmission, including stroke patients.

13 So I don't think we can build you
14 a model that tries to account for all of the
15 web of things that hospitals do around patient
16 education, around communication with
17 outpatient providers, around appropriate next
18 site of care, and making sure that patients
19 have the support they do.

20 It is a complicated thing that
21 hospitals are working very hard on right, but
22 we have more and more evidence, including good

1 trials that are small and early, that there
2 are things that hospitals can do that improve
3 the outcomes for patients.

4 CO-CHAIR TIRSCHWELL: I am not
5 sure who was next. Salina, then Michael.

6 DR. WADDY: I certainly agree that
7 readmission is very complex and there are
8 multiple factors, but unless we really know
9 what percentage of readmission is actually due
10 to hospital level factors and things that they
11 can actually change versus the activities that
12 patients actually do such as --

13 CO-CHAIR TIRSCHWELL:
14 Noncompliance.

15 DR. WADDY: -- yes, noncompliance,
16 not filling their medications, not going to
17 their physician, not having a physician who
18 can see them within a 15-day period or
19 something like that, then it is really
20 difficult to understand how they are going to
21 use the information gathered from this measure
22 to ensure that there is quality, because you

1 can get -- you may be getting quality care
2 within the hospital and through the
3 transitions, but it may be even more of a
4 patient factor, and is there any way to really
5 tease at least some of that apart so that the
6 people who should be dinged for providing poor
7 care -- that that actually happens.

8 CO-CHAIR TIRSCHWELL: Michael,
9 Daniel, Risha, and Peter.

10 DR. KAPLITT: The major concern
11 with this for many of the outside groups,
12 which is what begat this re-review, was the
13 risk adjustment strategy, and that is what we
14 have been talking about a little bit.

15 American Heart, I think, put it
16 fairly clearly and, I think, somewhat
17 convincingly. The issue of the C statistic,
18 in my view, is not so much misunderstanding
19 the nature of what this measure is. We know
20 it is not supposed to be a predictive measure,
21 but it does somewhat reflect the quality of
22 the risk adjustment strategy. At least, that

1 is my understanding of the way we have
2 discussed this in the past.

3 The response about the concern
4 about all these socioeconomic factors not
5 being brought in and how important they may be
6 in emerging literature, etcetera, was -- at
7 least, the written response was, well, we
8 think the hospital factors are of primary
9 importance, but that is not necessarily
10 proven.

11 The second thing is that in the
12 answer -- and this was again stated just now
13 on the telephone -- that if the major goal of
14 this is to try to promote improvement and see
15 hospitals improve their readmission rate, that
16 is fine, but this is not a change statistic
17 that is being looked at. It is an absolute
18 number.

19 The measure is not to look at the
20 change in readmission rate over time. It is
21 an absolute number. So hospitals that are at
22 a disadvantage are going to be reported as

1 such. It is not going to be reported -- So if
2 a hospital is at a disadvantage and they wind
3 up improving dramatically, but they are still
4 below another hospital that is not at a
5 disadvantage, they will still look bad,
6 because that is not how this is going to be
7 reported.

8 Then finally, the issue about,
9 well, we are not that worried about this
10 because of the fact that there is great
11 variability among the economically
12 disadvantaged hospitals.

13 I would ask (a) is that degree of
14 variance the same as in the nondisadvantaged
15 hospitals, because if the degree of variance
16 is difference, it again would suggest
17 different factors in the different groups,
18 even if there is great variability. Great
19 variability is not necessarily a comforting
20 factor unless there is equal variability among
21 all the groups. So I would ask the developer,
22 is there equal variability?

1 Then I still think that all of
2 these concerns are valid, and I don't see that
3 they have been sort of well addressed.

4 DR. LABOVITZ: This is a redo of a
5 redo. I think the reason is that some of us
6 have played John Kerry. We were for it before
7 we were against it, and that speaks to how
8 incredibly difficult this measure is.

9 I have struggled with it. I think
10 everybody around this table has struggled with
11 it. I think what I have not yet understood in
12 all of our conversations is why we are in such
13 a rush to put an NQF stamp of approval on a
14 group of studies that are nascent in an area
15 that is evolving, in a place where we don't
16 even have the data on how hospitals in caring
17 for disadvantaged populations might be dinged
18 for the nature of the work they do, and not
19 for the quality of it.

20 I just don't see why we have to
21 rush to approve this. This is excellent work,
22 and I am not allergic to using hospital

1 readmission as a quality measure, the way I am
2 allergic to using death as a quality measure
3 in stroke.

4 I think there is real value to be
5 gotten ere, but I think we could harm
6 ourselves badly if we rush too quickly, and
7 maybe next year isn't too late, or the year
8 after that.

9 DR. KRUMHOLZ: This is Harlan
10 Krumholz. Can I just say a few words?

11 CO-CHAIR TIRSCHWELL: Yes, go
12 ahead.

13 DR. KRUMHOLZ: Thank you. So
14 here is the urgency. The rates are above 20
15 percent. For years and years in this country,
16 people have ignored the fact that one out of
17 four or one out of five patients who leave the
18 hospital have such a catastrophic event happen
19 in the next 30 days that they require an acute
20 hospitalization again, even though anyone who
21 has just been in the hospital has a natural
22 aversion to want to come back in the hospital.

1 Every time you look deeply at the
2 transition process, you realize that it is
3 extraordinarily flawed. We are so poor at
4 this. I don't know any hospital who began to
5 do a deep dive into their transition process
6 who doesn't recognize that they don't
7 reconcile the meds correctly. They do a poor
8 job on education. They are not communicating
9 well. Their discharge summaries aren't ready
10 on time. They are not getting to the right
11 people. They are having trouble making
12 appointments.

13 Anyone who has had a recent
14 relative in the hospital or has been
15 unfortunate enough themselves to be in the
16 hospital knows how baffling this process of
17 transition is and how broken the current
18 system is.

19 I understand the pain of the
20 hospitals who are concerned that they are
21 being disproportionately discriminated
22 against, because they care for vulnerable

1 populations, but the overlap in the
2 populations plus the fact that the absolute
3 differences here we are talking about are
4 minuscule compared to the overall 20 percent,
5 22 percent, 17 percent that we are seeing for
6 all these different conditions tells you that,
7 if hospitals can work together with their
8 community, can fix these systems, can reduce
9 their risk for patients, make safe passage
10 possible, have people be confident in what is
11 happening as they move from the inpatient to
12 outpatient, then there is a large -- There is
13 just no way there is not a large opportunity
14 here to make this better for patients in
15 America.

16 We can wait this year. We can
17 wait next year. We can wait five years. We
18 can wait 10 years, but God forbid that anyone
19 you know gets in the hospital and has to
20 manage this transition from inpatient to
21 outpatient.

22 Stroke patients are particularly

1 vulnerable. They are weak, tired, often with
2 disabilities, and they are in a poor position
3 to manage this transition, as we see from
4 their readmission rates.

5 By putting this up, we are going
6 to get attention on this problem, and we are
7 going to get it focused on this particular
8 vulnerable population, and I challenge the
9 hospitals to take ownership of the part that
10 they do own, because it is enormous. The gaps
11 are enormous.

12 One thing about the C statistic.
13 We purposely are profiling hospitals. Just to
14 put it in perspective what Susannah was
15 saying, if I really wanted to predict, I would
16 use all the information on hospitalization up
17 until discharge. Five times zero is
18 admission, because we are trying to say when
19 the patients come to the hospital, what are
20 they like. We are not including any
21 information from the hospitalization.

22 That by itself disables the

1 predictive model. When I look at all the
2 things that go wrong for patients as they make
3 the transition from inpatient to outpatient,
4 it is not surprise to me that the severity of
5 disease ends up not being a very important
6 predictive factor.

7 These patients are vulnerable and
8 susceptible to a wide range of things:
9 Infection, kidney problems, in addition to the
10 reason that they were initially admitted. So
11 we need hospitals to open their eyes to see a
12 holistic view of the patient.

13 If we are truly patient centered,
14 we are realizing that people are suffering
15 every day because we are waiting for the
16 perfect measure; and if you want to get those
17 patients and let people go for some other
18 areas, okay, but I am thinking that this is a
19 group that we want the nation's hospitals
20 rolling up their sleeves and saying how can we
21 make safe passage for people who are admitted
22 with stroke.

1 So that is why the urgency. You
2 asked why the urgency? Because every day
3 patients are facing a one in five chance of
4 getting back to the hospital within 30 days
5 and terrible things happening to them in the
6 30 days, which I believe, to a large extent,
7 that risks can be modifiable, if the hospitals
8 working with their community address them, and
9 if -- We may be at the margin. There are
10 things that are going to need to be addressed
11 with regard to vulnerable populations, but
12 every time we looked at STS, the differences
13 are minuscule compared with the overall risk.

14 We have been talking to MEDPAC,
15 too. The policies are likely to evolve. The
16 current -- If you are above the average, below
17 the average, yes, I don't like it either. I
18 don't think that was a good policy. But that
19 is not our job.

20 Our job is to say can we put out a
21 measure that is the best possible measure that
22 is going to draw attention to this issue, and

1 is ultimately going to help patients around
2 this country by getting people to invest in
3 having benchmarks to look at.

4 That is what I think. That is why
5 this measure is good enough to move forward,
6 and I hope that you guys will see it in that
7 perspective.

8 CO-CHAIR TIRSCHWELL: Thank you,
9 Dr. Krumholz. I guess the thought that came
10 to me during your comments there is that, if
11 we really want to spur hospitals to action, I
12 am wondering why we don't put together an
13 evidence based intervention at hospital
14 discharge that every patient has to have
15 marked off to get credit for.

16 That would be a direct connection
17 to action for every patient, and I guess the
18 answer is maybe that evidence based
19 intervention doesn't exist. But there are a
20 number of other comments around the room.

21 Risha and then Salina.

22 DR. GIDWANI: Thanks. I think,

1 sort of in response to what the developer was
2 just saying, it seems as though the developers
3 are coming back to care coordination and
4 transitions of care as important hospital
5 components, and I think it is very important
6 to reduce readmissions. I don't think that
7 you will find a lot of disagreement in the
8 room here.

9 It is just really a question of
10 whether this measure is the best way to do
11 that. If the developers strongly feel that
12 there is an evidence base regarding care
13 transitions and care coordination and the
14 like, then I would suggest that there is an
15 opportunity to develop measures in those
16 areas.

17 This measure in particular isn't
18 getting at that nor is it going to give
19 hospitals information to say care coordination
20 is important, you should focus on that. I
21 think, really, this is about saying this is a
22 valid prediction, if we are looking at better

1 than expected, worse than expected, as
2 expected. That expected is inherently a
3 predicted variable.

4 I have looked at a lot of the
5 model diagnostics, and I have read the methods
6 reports thoroughly, and there are a variety of
7 other statistics I looked at, like there is a
8 lack of fit, amongst others.

9 I keep coming back to the C
10 statistic, because it is a highly informative
11 model diagnostic, and in this case it is also
12 a worrisome diagnostic.

13 I would also like to point out to
14 the committee that, when we look at the
15 mortality model, the 30-day mortality day that
16 has now been withdrawn, that C statistic was,
17 I think, .72, .77, something in the mid to low
18 .7.

19 The Fonarow, et al., article found
20 that including the NIHSS in this model,
21 improved the C statistic by, I think, .7, and
22 that resulted in 26 percent of hospitals being

1 reclassified from better than expected to
2 expected, expected to better than expected,
3 worse than expected. Across those three
4 categories, there was a movement of 26
5 percentage of hospitals.

6 So this C statistic does actually
7 have a real impact on the categories that
8 hospitals find themselves placed in.

9 DR. WADDY: I would like to
10 support what Risha just said, that a lot of
11 what was discussed was really the transition
12 from hospital to the community, and there is
13 a huge gap there. If there were ways to
14 smooth that transition, and actually there are
15 ongoing studies, one that should be unblinded
16 in the next couple of months funded through
17 NINDS, in order to help that process.

18 As well, there is a sort of
19 intervention with the guidelines. Some
20 hospitals are actually using those to really
21 change how they perform the discharge
22 instructions.

1 So, to me, having specific
2 measures for the facility would be more
3 appropriate than something that is more of a
4 grab bag that is a bit after the fact and a
5 messy measure.

6 DR. SCHMIDT: I just want to
7 remind people, when I did the call on the
8 training for this, one of the things that the
9 NQF staff tell us is that they like outcome
10 measures, and this is a proxy outcome measure.
11 One could say that the hospitalization is
12 actually processed, but it is a proxy for a
13 bad outcome.

14 So there is some value in -- and
15 whether this is exactly right is -- I didn't
16 vote on it the first time. So I am not voting
17 on it this time, but whether there is some
18 value in it is up to you guys to discuss. But
19 it is valuable to have outcome measures in the
20 mix and to allow clinicians to come up with
21 solutions that fit their care context to
22 achieve improved outcomes.

1 MS. SUKO: I think the question --
2 What I am about to say echoes much of what you
3 are going to say -- is that we don't know what
4 those system level factors are. I think the
5 question is: In the absence of an outcome
6 measure, will we as an industry learn what
7 those measures are and, if we are to approve
8 this outcome measure, can we be comfortable
9 with the fact that we are going to learn what
10 those are. Then do those benefits outweigh
11 the risk of the potential negative
12 interpretation or the penalties of hospitals?

13 MS. VAN DE KAMP: I think I
14 brought this up the last time, but just some
15 clarification. We already have a
16 rehospitalization measure in effect today.
17 Correct? For hospitalization? Just overall,
18 right?

19 DR. BURSTIN: We have endorsed a
20 hospital-wide all-cause readmission measure.
21 It is not in use. CMS could clarify that.

22 MS. VAN DE KAMP: Okay.

1 DR. GIDWANI: There is heart
2 failure, AMI and pneumonia, though.

3 MS. VAN DE KAMP: That are in use.
4 So I guess there is already measurement, and
5 it is diagnosis driven, to some degree. Is it
6 measurably different than this measure?

7 DR. DRYE: This measure is very
8 similar to the AMI, heart failure, and
9 pneumonia readmission measures that are
10 currently publicly reported.

11 CO-CHAIR TIRSCHWELL: Have we
12 learned things from the public reporting of
13 those other measures that have led to dramatic
14 benefits for patients in terms of readmissions
15 and the processes or factors that are involved
16 in readmission?

17 MS. DRYE: Harlan may still be on
18 the line. I think we have generated a lot of
19 focus on this transition for patients, which -
20 - I appreciate the comment about outcomes
21 measures. There isn't going to be one
22 solution, that there is one size fits all.

1 There is not going to be one checklist. There
2 is not going to be one --

3 DR. KRUMHOLZ: We have hospital --
4 Virtually every hospital in the country right
5 now has now focused attention on readmission,
6 and we have yet -- I mean, this is a big
7 complex problem. If you do one fix, it is not
8 enough.

9 If you create timely discharge
10 summaries, it is not enough. You have to make
11 sure that they are addressing the right
12 information, that they are getting to the
13 right people, that the patients are seeing the
14 people who have in their hands a discharge
15 summary, and that is just one little small
16 aspect of this. But I can tell you, I mean,
17 I have spoken to hundreds and hundreds of
18 hospitals over the last two years, and people
19 are with enthusiasm recognizing their
20 deficiencies in this area and are redoubling
21 efforts to --

22 First of all, before you get into

1 fancy new innovative solutions, the blocking
2 and tackling has just not been done. I mean,
3 just the communication and do people have a
4 place to go, and they know what is going on
5 when they leave them.

6 Again, any of you who have had
7 someone -- not just caring for someone, but
8 actually having it where you are seeing
9 through the patient's or family's eyes what it
10 is like to leave the hospital, you know.

11 These are efforts in every
12 hospital that they are starting with. You
13 know that we have been public reporting for a
14 couple of years. It is going to take some
15 time to infiltrate and change the way people
16 are thinking, especially since we all train
17 just to get people out the door. But I can
18 tell you, there is a sea change in the country
19 now compared to when we first started
20 proposing these and since these have been
21 publicly reported.

22 I can't report back the results

1 yet that I am happy with, but I can tell you
2 the efforts there and around the country.
3 There is a lot of creativity being applied to
4 how best to do this.

5 The other measures are out. So,
6 really, it is a question of whether you think
7 you want stroke to be out of that group, but
8 that is what is happening.

9 CO-CHAIR TIRSCHWELL: Daniel.

10 DR. LABOVITZ: This is a response,
11 I think, mostly -- I don't know his name, but
12 the voice in the sky.

13 DR. KRUMHOLZ: Harlan Krumholz,
14 sir.

15 DR. LABOVITZ: I welcome your
16 passion on this, and I think your comments on
17 how important this is as an area to target are
18 very meaningful. I think we all see the
19 point. It really does matter, and I can
20 certainly say as a provider at the beside that
21 we do a lousy job of paying attention to this.

22 What I am questioning is whether

1 this measure should be approved by the NQF
2 because it meets the standards, and I would
3 suggest that we have rejected other measures
4 which were very meaningful to us and
5 important, and we saw the point, but the
6 measure wasn't ready.

7 I think we have heard good
8 feedback today to suggest that this measure
9 maybe isn't ready either. There are also, I
10 would suggest, alternative means to using an
11 NQF measure to drive change.

12 CMS is experimenting now with
13 developing a reimbursement system where the
14 hospital is responsible for all care, not only
15 during the index admission but for 90 days
16 afterwards or 30 days afterwards. It will be
17 rolled out to a subset of hospitals. They are
18 going to play with it.

19 That is going to drive change
20 within the hospitals. The hospitals will be
21 reimbursed based upon their performance. That
22 is going to drive change, too, and maybe we

1 need to see those things emerge before we
2 start putting an NQF stamp on a measure just
3 because it seems like it is really important.

4 CO-CHAIR TIRSCHWELL: Peter.

5 DR. SCHMIDT: I just want to point
6 out that the ones that we rejected that we all
7 cared about were all process measures, and
8 there is a separate -- you know, on the form
9 there is a separate standard, if you accept
10 that this is an outcome, which is
11 questionable. But if you accept it is an
12 outcome, there is a separate standard that is
13 very different from the way that we assessed
14 all the process measures.

15 CO-CHAIR TIRSCHWELL: Developers
16 want to respond at all to anything further?

17 DR. DRYE: I just -- I promise
18 this is the last thing I will say about the C
19 statistic, but I think it is really important
20 to say.

21 With all due respect to the
22 committee member bringing this up, the C

1 statistic is appropriate for this measure and
2 scientifically valid. It is aligned with C
3 statistics, with measures previously approved
4 by NQF, including a PCI readmission measure
5 developed off of registry data. It is
6 completely aligned with the C statistic in a
7 readmission measure we just built with the
8 Society of Thoracic Surgeons for CABG
9 readmission using their registry data.

10 You cannot -- If you follow the
11 scientific guidelines for outcomes measures,
12 which says you do not risk adjust for things
13 that happen in the hospital, only things prior
14 to the hospital, there is no way for
15 readmission you can get a C statistic that is
16 much above .6, and I have one very vocal
17 member on this committee, but this is a
18 fundamental scientific point about the
19 validity of the measure.

20 It is completely consistent with
21 prior approval and every readmission measure
22 that I have seen, whether you use registry or

1 claims data.

2 Then I just want to make a comment
3 on outcomes measures. I really like the way
4 one of the members characterized the measure
5 as messy. Outcomes measures are messy. They
6 are really, really hard, but we are being
7 called by patients and by providers to use
8 them, because they are what matter to
9 patients, and they are the end result of a lot
10 of different complex processes that people
11 point out, which we will never be able to
12 capture process measure by process measure by
13 process measure.

14 So I just appreciate the
15 committee's deep review of the outcomes
16 measures against the criteria that NQF has set
17 forth as consensus based guidelines.

18 DR. HAN: Hi. This is Lein Han
19 from CMS. I just want to share our experience
20 with you. We are -- Someone asked whether CMS
21 has a hospital-wide readmission measure. Yes,
22 we do have one, and right now we are

1 conducting a dry run. It means that we work
2 with hospitals, share the data with them, but
3 we don't publicly report their data.

4 So during the dry run, we have
5 conference calls with all hospitals in the
6 nation, and the first time we have probably
7 2,000 hospitals call in, and the second time
8 we have about 800 hospitals call in, and at
9 each time it is about 90 minutes.

10 So during the call, we heard from
11 hospitals. They want to know more about their
12 data, how are they doing. I think people are
13 -- At the hospital level, they are in the
14 field. They don't know the big picture, how
15 they are doing.

16 So they give CMS feedback: Can
17 you give us more data where a patient goes,
18 and also can you apply this measure to other
19 populations like a pediatric population?
20 After those calls, I just got a feeling.
21 Hospitals want to know how they are doing.

22 The CMS developed measure, we see

1 a health care problem here, and we use the
2 best data available to CMS and procure the
3 best team in the nation to develop a measure.
4 So our point about -- First, there are always
5 outliers, but our goal is really to move the
6 whole curve of distribution of the hospital
7 performance to a lower mean.

8 If we have the best data, even we
9 have access data, we will do it, but we can't
10 wait to have the best data and the best
11 measure to move our quality agenda forward.
12 So I just want to share this perspective with
13 you for you to understand where we come from
14 to develop these measures, to implement these
15 measures.

16 DR. GOODRICH: This is Kate
17 Goodrich from CMS. I wonder if I could maybe
18 say something as well.

19 CO-CHAIR TIRSCHWELL: Yes, go
20 ahead.

21 DR. GOODRICH: Okay. I am the
22 Acting Director of the Quality Measurement

1 Group. I work with Lein and others, I think,
2 are there. So I want to say a couple of
3 things.

4 I think, to address the point
5 about why don't we use a number of care
6 coordination related process measures, we
7 agree that those measures are important, and
8 we want to use those type of measures. But I
9 think there is often a potentially false
10 assumption that there is a direct correlation
11 between how a hospital or a provider performs
12 on a process measure, how it is directly
13 related or not directly related to how they
14 perform on the outcome measure.

15 In fact, we know from an emerging
16 literature that there often is not that
17 correlation, as one might expect there would
18 be. So the use of process measures to drive
19 improvement, we think, is nowhere near as
20 powerful as the use of these patient centered
21 outcomes measures.

22 I do feel a little bit -- I want

1 to echo what I think others have said. I feel
2 a little bit like the patient has gotten a
3 little lost in the conversation, and for us
4 that, obviously, our primary concern.

5 We know that there is really
6 nothing in terms of measurement that is going
7 to focus the country like a laser on a serious
8 quality problem like use of these outcome
9 measures. But I will say we have heard from
10 many stakeholders the concerns about the SES
11 adjustment and race adjustment, and we hear
12 those concerns loud and clear.

13 So we have started to think within
14 our programs about how we could change some of
15 our implementation policies. There is nothing
16 absolute or final I can tell you about this
17 now, but because we have been hearing this
18 concern for a long time now, we are starting
19 to think about how we can implement our
20 programs or modify the way we implement our
21 programs to address some of those concerns.

22 So i do want the panel members to

1 know that we, too, are concerned about those
2 issues, although we agree with the NQF policy
3 of not adjusting for those factors. So we are
4 trying to find other policy related ways that
5 we could address some of those issues.

6 CO-CHAIR TIRSCHWELL: Risha, do
7 you have an additional comment?

8 DR. GIDWANI: I will just start by
9 saying that I do applaud the developers for
10 their effort in this regard. I think they do
11 have a great team, and they had a
12 sophisticated approach.

13 I think, you know, they are just
14 hemmed in by the limitations of the field in
15 general, and they are correct. The C
16 statistic of this model is in line with the
17 AMI, the heart failure, the pneumonia models,
18 but that, to me, is not a reason for endorsing
19 this measure. It is more of a reason for me
20 to be concerned about those other measures.

21 I will also point out, the
22 concerns about the C statistics -- I am not

1 the only one that has them. There is
2 systematic literature of readmissions models
3 in JAMA looking at all different kinds of
4 hospital readmission models, generally 30-day,
5 came to the same conclusion about predictive
6 ability of models, and essentially said that
7 better approaches are needed to assess
8 hospital performance.

9 My concern is really that -- I
10 guess I have another point, and then I will
11 bring up my last concern. My other point is
12 that we didn't pass or I think we were neck
13 and neck and now it has been withdrawn for the
14 mortality model, and that had a much higher C
15 statistic, and people were concerned about the
16 fact that the NIHSS wasn't included in that
17 model, because when it was included, the C
18 statistic and model performance improved.

19 So as a matter of just internal
20 congruence on our own panel, I just wonder
21 about not endorsing a measure that had a
22 higher C statistic and endorsing a measure

1 that has a lower C statistic. It does worry
2 me.

3 Then really, my major point of
4 concern is what is the harm that could happen.
5 I want to make sure that the patients are
6 being given the appropriate care. My worry is
7 that, if we have a measure that doesn't
8 properly reward hospitals for good performance
9 and disincent hospitals to avoid bad
10 performance, that we could end up with a
11 situation where certain kinds of patients are
12 just refused for admission into the hospital
13 because they may be at high risk of subsequent
14 readmission.

15 CO-CHAIR TIRSCHWELL: Mary, go
16 ahead.

17 MS. VAN DE KAMP: I think Kate
18 might have alluded to this with her discussion
19 about implementation. I think the fear is not
20 that we measure or that we look at it. It is
21 that we too quickly go to payment impact from
22 that.

1 I think, if there was a way for us
2 to look at these, because I do think -- I am
3 in the field. I see what those outcome
4 measures in the other diagnosis have done to
5 the analysis of transitions of care, and it
6 has been very impactful. But what it has also
7 done, I am fearful, is that not everyone looks
8 at it that way, and there are others who
9 prevent readmissions or are concerned about
10 readmission because they don't want the rate
11 to impact their financial payment.

12 While it is two percent the first
13 year, which is significant and not
14 insignificant, I think one recommendation --
15 and, I think, a less fear factor for those of
16 us in the room -- would be if the payment
17 didn't follow so quickly on the outcome
18 measure, so that we could really look at the
19 quality outcome and then, after a certain
20 period of time, determine did it measure the
21 right thing? Did things improve and,
22 therefore, it is a requirement for payment.

1 I think the fact that we have been
2 struggling more than anything is that there is
3 a very quick correlation to either a public
4 reporting of poor outcomes -- so publicly the
5 consensus drops or, secondly, there is a
6 reimbursement change. But I absolutely see
7 what you are saying in terms of people really,
8 really looking at -- I mean, the skilled
9 nursing arena.

10 I know that hospitals are looking
11 at post-acute discharge, because they want to
12 make sure that they are going to send to a
13 quality nursing center that doesn't send their
14 patients back.

15 So I get all that, and I think it
16 is very important. I think the payment and
17 the public analysis is there.

18 CO-CHAIR TIRSCHWELL: Sure. One
19 second, Daniel. Go ahead.

20 DR. BURSTIN: This is just one
21 process point. So the endorsement process is
22 really about the measure properties of the

1 measure. It is not in the purview for us to
2 really be, at these tables, talking about
3 applicability of measures for different
4 purposes.

5 That is really what our measures
6 application partnership is about, and they
7 would likely to have an opportunity to
8 consider which accountability applications
9 might be most appropriate for additional
10 readmission measures.

11 So just a reminder. We have got
12 to stick this to the actual measure itself,
13 not the issues around payment and public
14 reporting.

15 CO-CHAIR TIRSCHWELL: Daniel.

16 DR. LABOVITZ: This is a comment
17 on or maybe a question on whether this is an
18 outcome measure. Peter Schmidt's comments
19 point out that this is a fundamentally
20 different sort of beast than a process measure
21 are very well taken, and I think the messiness
22 of it much appreciated and, I think, important

1 to consider as we move forward. But I am not
2 sure that readmission is an outcome.

3 I am not sure it should be judged
4 the same way you might judge length of life or
5 quality of life, which I think are meaningful
6 outcomes, or even reoccurrence of a dread
7 disease. Readmission has many, many factors
8 contributing to it.

9 I know that there is some data to
10 suggest for a heart failure readmission that
11 people who come in more often have a higher
12 quality of life. The higher readmission rate
13 means that they are actually being cared for
14 better.

15 So I don't feel like I understand
16 this. It is, dare I say it, squishy.

17 CO-CHAIR TIRSCHWELL: Last word,
18 huh. Any other comments? I guess a question
19 that needs to go out to you all is have you
20 seen and heard things over the phone calls and
21 today to suggest that you want to revote on
22 this measure?

1 I guess, if we don't revote, then
2 the last vote stands, which means it would not
3 be endorsed. I don't know what the process
4 point is here. I am thinking it is like the
5 exception. If any one person thinks we should
6 revote, we probably should go ahead. Does
7 anybody want to suggest that we revote on this
8 measure?

9 I am not seeing anybody suggesting
10 that. So then the last vote stands, which I
11 believe was 10 votes for and 12 votes against.

12 The next thing on our agenda is
13 member and public comment. Arnica, can you
14 open the lines to public comment.

15 OPERATOR: At this time, there are
16 no questions.

17 CO-CHAIR TIRSCHWELL: Thank you
18 very much. Then Karen, do you want to talk
19 about next steps and committee timeline?

20 MS. JOHNSON: This is where I get
21 to hand it over to Suzanne.

22 CO-CHAIR TIRSCHWELL: Okay.

1 Suzanne, thank you.

2 MS. THEBERGE: Thanks, everybody,
3 for your time today. Next steps are going to
4 be the same as after the last meeting. We
5 will write up a draft report and put that out
6 for comment.

7 Right now we are estimating that
8 is going to go out around October 31st. That
9 is a 30-day comment period. So it will close
10 right after Thanksgiving, and then we will
11 have our conference call in early December for
12 you to discuss those comments. I think that
13 call is scheduled for December 10th, but I
14 can't remember at the moment. So I will
15 follow up with you all by email about that
16 next week.

17 Then after that comment call, we
18 will do the same thing we did last time. We
19 will discuss the comments received, if you
20 need to revote on anything, and then we will
21 go to NQF member vote, CSAC and Board
22 approval.

1 So that is next steps for this
2 project.

3 CO-CHAIR TIRSCHWELL: And just so
4 I am clear, the things that will go out for
5 public comment are those that were approved?

6 DR. BURSTIN: We want to get
7 public comment on the things that are approved
8 as well as disapproved in case people want to
9 bring other evidence or information to bear.
10 We will bring it all back to you for
11 transparency.

12 DR. GIDWANI: I just have a
13 question about the time endorsed -- time
14 limited endorsed measures. I am not sure how
15 many of those we had, but if we did have any,
16 is the committee going to be seeing any data
17 about their reliability or validity or what is
18 the process for those?

19 DR. BURSTIN: Typically, the
20 process is that the measure testing results go
21 to our Consensus Standards Approval Committee.
22 So they look at all the testing results.

1 DR. GIDWANI: Then also in terms
2 of what happens from here, we have endorsed
3 certain measures. Does then the higher level
4 CSAC need to also approval those before they
5 become formally NQF endorsed?

6 DR. BURSTIN: Actually, the CSAC
7 and then the NQF Board ratifies that decision.
8 The SAC is talking about the first phase next
9 week, Monday actually. Then it will go to the
10 Board. It will be endorsed shortly.

11 DR. GIDWANI: And what are their
12 requirements for endorsement? Is there a
13 likelihood that what we endorse does not come
14 to bear?

15 DR. BURSTIN: Generally, most of
16 the decisions remain endorsed, and I think the
17 difference is that the CSAC and the Board
18 often has a very sort of high level view of
19 the entire portfolio, and at times we do get
20 different perspectives on importance of
21 measures.

22 This group is so heavily clinician

1 oriented. When you get into a group that is
2 more balanced of consumers, purchasers, and
3 all stakeholders, sometimes, particularly
4 around importance, some of those issues may
5 bubble up differently.

6 CO-CHAIR TIRSCHWELL: I would just
7 like to personally thank everybody for all the
8 time they have put in on this, and hope to see
9 you again sometime soon.

10 CO-CHAIR KNOWLTON: And before you
11 all leave, I especially wanted to acknowledge
12 the NQF team. There is so much work behind
13 what we do that these guys do. I want to
14 mention that.

15 DR. BURSTIN: We have to
16 acknowledge our Chairs who did yeoman's work,
17 I think, over two meetings. So thank you.

18 (Whereupon, the above-entitled
19 matter went off the record at 2:01 p.m.)
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21
22

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