

NATIONAL QUALITY FORUM

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NEUROLOGY PHASE II

STEERING COMMITTEE

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WEDNESDAY

OCTOBER 3, 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

GWENDOLYN 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:

HEIDI BOSSLEY, MSN, MBA

HELEN BURSTIN, MD, MPH

ANN HAMMERSMITH, JD

KAREN JOHNSON, MS

SUZANNE THEBERGE, MPH

JESSICA WEBER

ALSO PRESENT:

GREGORY BARKLEY, American Academy of  
Neurology\*

CHRISTOPHER BEVER, American Academy of  
Neurology

GINA GJORVAD, American Academy of Neurology

JULIE KUHLE, Pharmacy Quality Alliance

DAVID NAU, Pharmacy Quality Alliance\*

REBECCA SWAIN-ENG, American Academy of  
Neurology

CHRISTIE TEIGLAND, Inovalon, Inc.

JACQUELINE VANCE, American Medical  
Directors Association

\*Participating by teleconference

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

9:01 a.m.

1  
2  
3 MS. JOHNSON: Well, good morning,  
4 everybody, and welcome to NQF's Neurology  
5 Endorsement Maintenance Project, Phase II. We  
6 really appreciate all of you guys coming out  
7 and joining us today on this soupy, yet not so  
8 hot, day, as the last time when you were here  
9 in June.

10 What we are going to do today, I  
11 just want to make sure everybody is aware of  
12 the project team. I am Karen. I am the  
13 Senior Director on the project. Down to my  
14 right is Suzanne, and Jessica is roaming  
15 around the room. So, that is Jessica. And  
16 then, here on my left is Helen Burstin. She  
17 is the Director of our unit, the Performance  
18 Measures Unit. And then, also here to my  
19 right are my esteemed Co-Chairs for the  
20 project, David Tirschwell and Dave Knowlton.

21 So, thank you, guys, for joining  
22 us.



1                   As we did last time, we are going  
2 to start off the morning with introductions,  
3 welcomes. Ann, our General Counsel, is going  
4 to tell us what we need to do our  
5 introductions around the table.

6                   MS. HAMMERSMITH: Thanks, Karen.

7                   I am Ann Hammersmith. I am NQF's  
8 General Counsel.

9                   I think most of you were at the  
10 last meeting, so you are familiar with this  
11 portion of the meeting. What we are going to  
12 do is go around the table once again, have you  
13 introduce yourselves, tell us who you are  
14 with, and make any disclosure that you wish to  
15 make. Just because you make a disclosure does  
16 not mean you have a conflict of interest. It  
17 is simply a disclosure.

18                   Before we start, I want to remind  
19 you of a few things. There is no need to  
20 recount your CV. Please don't because we will  
21 be here all day and you will never talk about  
22 the measures.

1 (Laughter.)

2 What we are particularly  
3 interested in you disclosing is anything that  
4 is relevant to the topics that will be  
5 discussed today and tomorrow in the meeting.  
6 In particular, we are interested in  
7 consulting, speaking engagements, grant  
8 monies, research monies, if they are relevant  
9 to what is before the Committee at this  
10 meeting.

11 I also want to remind you that  
12 conflict of interest and disclosure is not  
13 simply financial. Many times Committee  
14 members will say, "I have no financial  
15 conflict of interest." A financial conflict  
16 of interest is part of the scenario here. But  
17 because of the kind of work that all of us do,  
18 you can also have a conflict or something that  
19 should be disclosed for an activity where you  
20 are volunteer, such as serving on a committee  
21 if it is relevant to what is before us these  
22 two days.

1                   And finally, I want to remind you  
2                   that you serve as an individual. You are not  
3                   here as a representative of your employer or  
4                   of anyone who may have nominated you.  
5                   Occasionally, Committee members will say, in  
6                   good faith, "I'm" So-and-So, "and I am here  
7                   representing the American Society of" fill in  
8                   the blank. And actually, you are not. You  
9                   are here because you are experts. So, you  
10                  serve as individuals.

11                  So, with that, I will start with  
12                  the Chairs.

13                  CO-CHAIR KNOWLTON: I am Dave  
14                  Knowlton. I am the Chief Executive Officer of  
15                  the New Jersey Health Care Quality Institute,  
16                  and I have no conflicts.

17                  CO-CHAIR TIRSCHWELL: Good  
18                  morning, everyone. Welcome back.

19                  I am David Tirschwell. I am a  
20                  stroke neurologist. I work at the University  
21                  of Washington in Harborview Medical Center in  
22                  Seattle, Washington. I do not have any

1 relevant conflicts.

2 MEMBER RICHMOND: I am Terry  
3 Richmond. I am a professor at the School of  
4 Nursing at the University of Pennsylvania.

5 Since our last meeting, I received  
6 funding from NIH and yesterday from National  
7 Science Foundation. I don't think there is  
8 any conflict. One of my studies does look at  
9 depression on psychological consequences, but  
10 it is all related to injury and not directly  
11 related to these measures.

12 MEMBER SUKO: I am Jolynn Suko  
13 from Virginia Mason Medical Center,  
14 accountable for neurosciences there. I have  
15 no conflicts of interest.

16 MEMBER LABOVITZ: I am Daniel  
17 Labovitz from Montefiore Medical Center in  
18 Bronx. I am a stroke neurologist, and have  
19 nothing to disclose.

20 MEMBER R. BAUTISTA: Ramon  
21 Bautista, University of Florida. Nothing to  
22 disclose.

1                   MEMBER J. BAUTISTA: Jocelyn  
2           Bautista. I am an epilepsy neurologist at the  
3           Cleveland Clinic. I have participated with  
4           the American Academy of Neurology in writing  
5           evidence-based guidelines for epilepsy,  
6           nothing directly related, though, to the  
7           measures today.

8                   MEMBER BARSAN: Bill Barsan. I am  
9           in emergency medicine at the University of  
10          Michigan. I have NIH funding to run the  
11          Neurological Emergency Treatment Trials  
12          Network, which does do clinical trials in  
13          seizures and other neurologic emergencies.

14                  MEMBER DUDA: I am John Duda. I a  
15          movement disorder neurologist from the  
16          Philadelphia VA Medical Center in the  
17          University of Pennsylvania. I have research  
18          support from the VA and NIH and Michael J. Fox  
19          Foundation, which I don't think is relevant to  
20          today's topics.

21                   I serve on the Scientific Advisory  
22          Board for the Lewy Body Dementia Association,

1 which may be relevant for the one cognitive  
2 issue. And I do with the national VA  
3 formulary leaders to guide use of the  
4 formulary in the VA, but I don't think that is  
5 necessarily relevant, either.

6 MEMBER VAN DE KAMP: Mary Van de  
7 Kamp. I am Senior Vice President of Clinical  
8 Operations for Kindred and RehabCare, and I  
9 have nothing to disclose.

10 MEMBER SULLIVAN: I am Jane  
11 Sullivan. I am a physical therapist. I teach  
12 in the Feinberg School of Medicine at  
13 Northwestern University in Chicago.

14 I have funding from NIDRR and the  
15 Department of Education and from industry, but  
16 it is related to stroke.

17 MEMBER BUHR: My name is Gwen  
18 Buhr. I am a geriatrician at Duke University,  
19 and I have nothing to disclose.

20 MEMBER TOLIN: Fred Tolin, Vice  
21 President at Humana. Nothing to disclose.

22 MEMBER KAPLITT: I am Mike

1 Kaplitt. I am a stereotactic and functional  
2 neurosurgeon at Well Cornell Medical College  
3 in New York, and I have nothing to disclose.

4 MEMBER SCARIANO: Jack Scariano.  
5 I am a practicing neurologist, and I will be  
6 talking about sleep studies and, also,  
7 patients who have that. And I don't read  
8 sleep studies and I don't treat sleep studies.  
9 I mean, I don't treat sleep patients.

10 MEMBER BARRETT: I am A.M. Barrett  
11 from the Kessler Foundation, where I direct  
12 the stroke rehabilitation research. I have  
13 funding from the Kessler Foundation, from NIH,  
14 and from NIDRR, and the Wallerstein Foundation  
15 for Geriatric Improvement.

16 I am a member of the American  
17 Academy of Behavioral Neurology Section, and  
18 within that, of the Clinical Practice Work  
19 Group that discusses consensus recommendations  
20 for behavioral neurology activities.

21 MEMBER EISENSTOCK: I am Jordan  
22 Eisenstock. I am a neurologist at UMass

1 Medical Center in western Massachusetts. I am  
2 also a Board-certified psychiatrist. I don't  
3 have anything to disclose, no conflicts.

4 MEMBER FAZIO: I am Sam Fazio. I  
5 am a developmental psychologist. I am from  
6 the National Office of the Alzheimer's  
7 Association in Chicago, and I have nothing to  
8 disclose.

9 MEMBER COONEY: I am Gail Cooney.  
10 I am Board-certified in neurology and hospice  
11 and palliative medicine, but practice  
12 exclusively in the field of hospice and  
13 palliative medicine. I have nothing to  
14 disclose.

15 MEMBER GIDWANI: I am Risha  
16 Gidwani from Stanford University Medical  
17 Center. I have nothing to disclose.

18 MEMBER SHETH: Raj Sheth at  
19 Nemours Mayo Clinic, Jacksonville, Florida,  
20 epileptologist. Nothing to disclose.

21 MEMBER SCHMIDT: I am Peter  
22 Schmidt from the National Parkinson



1 Foundation. I have nothing to disclose, but  
2 I would like to comment.

3 The National Parkinson Foundation  
4 is listed as a cosponsor on the Parkinson  
5 measures. That came as a surprise to us when  
6 we saw the submission. So, we are not  
7 involved in that.

8 MS. HAMMERSMITH: Okay. Thank you  
9 for those disclosures.

10 Do any of you have any questions  
11 of me or anything you would like to discuss  
12 with each other based on the disclosures this  
13 morning?

14 (No response.)

15 Okay. Thank you. Have a good  
16 meeting.

17 MS. JOHNSON: Thank you, Ann.

18 Can we go ahead and bring up this  
19 morning's slides?

20 I wanted to start out the morning  
21 with just a very brief overview, some  
22 housekeeping details. By now, you guys have

1 all figured out how to work your microphones.  
2 But, just as a reminder, once you have  
3 finished speaking, please turn your microphone  
4 off, so that it will work for the next person.

5 To signal your desire to speak, if  
6 you would raise your name tag and set it  
7 vertical, that way, our Chairs will know that,  
8 just like you all just did -- thank you.

9 (Laughter.)

10 So that we know that you would  
11 like to speak. We would appreciate that.

12 You should have been given  
13 clickers when you came in. So, hopefully,  
14 everybody has a clicker. You will use the  
15 clickers to register your votes as we go  
16 through the day.

17 Next slide, please.

18 Most of you I think remember how  
19 to do this, but, basically, you will use the  
20 keypad to register either a 1 for yes or a 2  
21 for no in the appropriate set criteria, and  
22 then 1, 2, 3, or 4 for high, moderate, low, or

1       insufficient.

2                   Who is running the voting? Is  
3       that Suzanne? Okay.

4                   Suzanne's computer is the computer  
5       that has the receiver in there. So, point  
6       your clicker at Suzanne when you get ready to  
7       vote.

8                   You will have 60 seconds to vote.  
9       If you are not sure that your clicker  
10      activated, just keep clicking your selection.  
11      It will not double-count your vote.

12                  Just a quick overview. I am sure  
13      you guys already know this. You could  
14      probably recite this in your sleep. But we  
15      will be looking at 22 measures in Phase II,  
16      twelve on dementia, three on epilepsy, six on  
17      Parkinson's, and then one-off, stenosis  
18      measurement in carotid imaging studies.

19                  Most are new measures. As a  
20      matter of fact, only the carotid imaging  
21      measure is an already-endorsed measure. So,  
22      everything else is new to us.

1                   And you will have also noticed  
2                   that most of the measures, 18 of them  
3                   actually, have not yet been tested for  
4                   reliability or validity. We have communicated  
5                   to you a couple of different times on why we  
6                   did accept those kinds of measures, that  
7                   basically they are fairly non-complex  
8                   measures. Let me think. They hit a gap area.  
9                   So, in other words, we don't already have  
10                  measures in the NQF portfolio that address the  
11                  focus of the measures.

12                  And they are also time-sensitive  
13                  in a particular way. So, in the case of the  
14                  measures for epilepsy, several of the dementia  
15                  measures, and the Parkinson's measures, those  
16                  will be used in the 2012 PQRS program. So, we  
17                  consider that as a time-sensitive -- I don't  
18                  know what the word is, but we consider it  
19                  time-sensitive. And therefore, we did want to  
20                  look at these measures.

21                  As we go through and we talk about  
22                  reliability and validity, it will be different

1 because, since they have been tested, you will  
2 not be thinking about how it was tested and  
3 was it at the measure score level or the data  
4 element level, all that kind of stuff, but you  
5 will still have to think about the  
6 specifications, particularly the precision of  
7 the specifications and, also, how those line  
8 up with the evidence. So, you will see that  
9 as we go through the day.

10 Next slide, please.

11 You have some tools to help you  
12 throughout the day. First of all is your  
13 meeting agenda. I believe that has been  
14 passed out to you.

15 We are planning to go in order of  
16 the agenda. As you know, sometimes things  
17 have to get moved around, but, in general, we  
18 are planning on sticking with the agenda.

19 We also have provided what we call  
20 our summary document. That document contains  
21 brief descriptions of the measures, comments  
22 from your preliminary evaluations, and then,

1 finally, the Work Group summaries that we came  
2 up with after participating and listening to  
3 your talks on the Work Group calls.

4           You also have our quick guide.  
5 The quick guide is a little four-pager that  
6 reminds you of all the different criteria,  
7 subcriteria, and the rating scales that you  
8 will use.

9           And then, of course, you have  
10 measure submission materials. You probably  
11 haven't printed those off, but they are  
12 available on the SharePoint site or perhaps  
13 you have already downloaded them to your  
14 computer.

15           Finally, there is one set of  
16 comparison tables for related measures, and we  
17 don't even need to talk about that until  
18 tomorrow.

19           Next slide, please.

20           Our process today is going to be  
21 pretty much the same as it was the last time  
22 around. We will discuss each subcriteria and

1 then vote. So, basically, we will talk about  
2 impact and then vote on impact, and then talk  
3 about evidence and then vote on evidence, et  
4 cetera.

5 You will notice that evidence we  
6 have numbered as subcriterion 1p. We have  
7 switched those around, so we will talk about  
8 evidence first and then talk about opportunity  
9 for improvement. Part of the reasoning there  
10 is often measures have difficulty at the  
11 evidence subcriteria. So, if something is  
12 going to die, for lack of a better word, at  
13 evidence, we won't take the time to talk first  
14 about opportunity for improvement. So, it is  
15 just a time management strategy.

16 If a measure fails a "must-pass"  
17 criterion, we will stop. Okay? So, we won't  
18 go on to the other subcriteria. That is a  
19 little different than what we ask you to do in  
20 the Work Group calls because we wanted you to  
21 think about all of the criteria for the  
22 measure. But we will not be doing that here

1 in person today. So, if something dies on  
2 impact, we won't talk about any of the other  
3 criteria.

4 For our first measure, as  
5 necessary, we will review the evaluation  
6 criteria. So, I may jump in a little bit more  
7 on the first measure as you talk through it,  
8 just to remind you of what the rating scales  
9 look like or give you pointers about how to  
10 consider and evaluate the measure. I don't  
11 think I will need to do that very much  
12 throughout the rest of the day.

13 We will have roughly about 15  
14 minutes per measure. As you know, generally,  
15 how it works is we are a little bit slower  
16 with the first measures, and then we kind of  
17 speed up throughout the day. But, on average,  
18 we are going to be looking at 15 minutes per  
19 measure.

20 Next slide, please.

21 Most of you have been assigned a  
22 role of lead discussant for measures. You



1 have pretty much had a chance to do this at  
2 least once now on the Work Group calls. But,  
3 basically, just a reminder, we want you to  
4 lead the discuss against the criteria. So,  
5 how did the measure stack up? We want you to  
6 summarize your thoughts and the thoughts of  
7 the Work Group and the discussion in the Work  
8 Group, particularly on how well the measure  
9 meets or does not meet the criteria. Okay?

10 We really hope that everybody  
11 feels free and comfortable to participate in  
12 the discussion of all the measures. Even if  
13 it is not your thing, please definitely chime  
14 in. And a reminder that the entire Committee  
15 will be voting on the measures and whether or  
16 not the measures meet the criteria.

17 Next slide, please.

18 So, let me stop there and see if  
19 there are any questions about process,  
20 housekeeping, et cetera.

21 (No response.)

22 Okay. Go to the next slide,

1 please.

2 I wanted to give just a very, very  
3 quick overview of the criteria. I know,  
4 again, you guys are old hands at this; you  
5 probably don't need this, but just in case.

6 Next slide, please.

7 Just a reminder that we have four  
8 main criteria for you to look at and evaluate  
9 measures against: importance to measure and  
10 report, scientific acceptability, usability,  
11 and feasibility. The first two are what we  
12 call "must-pass" criteria. So, again, a  
13 measure must pass importance before we go on  
14 to discuss scientific acceptability, and et  
15 cetera.

16 Next slide.

17 Under importance, we have three  
18 subcriteria: high impact, evidence, and  
19 performance gap or opportunity for  
20 improvement. And again, all three of these  
21 are "must-pass". So, we will, again, talk  
22 about these in order. But each of the three

1 subcriteria under this main criteria of  
2 importance to measure and report must pass.

3 Okay. Next slide.

4 Just a reminder in terms of  
5 thinking about evidence for the measure focus.  
6 In general, NQF does have a preference for  
7 certain measures, in particular, outcome  
8 measures. So, that is what we would love to  
9 see. But, of course, that is not always easy  
10 to do, and we don't always have a lot of  
11 outcome measures. As a matter of fact, in  
12 this phase we have no outcome measures for you  
13 to consider.

14 But, then, in order of decreasing  
15 importance or preference, we would also love  
16 to see measures that are intermediate outcomes  
17 -- often, those are kind of clinical-type  
18 outcomes -- or process or structure measures.  
19 Within those, we prefer those that are most  
20 closely linked to outcomes.

21 So, again, evidence is a very big  
22 deal here for us. I think possibly what you

1 will have seen as you look through the  
2 measures, often, if evidence is lacking or may  
3 seem to be lacking, it could be because the  
4 proximity to an outcome.

5 So, next slide.

6 This, again, is our little  
7 schematic just showing you that there are lots  
8 of different types of process measures.  
9 Again, we still have our hierarchy with  
10 preference for outcome measures and  
11 intermediate outcome measures. But, if we  
12 have process measures, the ones that we prefer  
13 are the ones that actually look at provision  
14 of intervention, and then, going backwards,  
15 actually choosing or planning interventions,  
16 identifying or diagnoses, and then assessing  
17 is even less proximal to the actual health  
18 outcome. So, this is just a reminder of that  
19 preference.

20 Next slide, please.

21 There is a difference between a  
22 low rating versus a rating of insufficient

1 evidence. So, low rating means that the  
2 evidence is there, and it didn't really  
3 demonstrate that the criteria has been met.

4           Insufficient evidence could be  
5 either that the evidence is there and  
6 presented, but still didn't answer the  
7 question, or perhaps the evidence is there,  
8 but it just didn't make it to the submission  
9 form. So, there's a couple of different ways  
10 that you could have insufficient evidence. In  
11 both cases, either low or insufficient  
12 evidence, a measure would not pass, but,  
13 again, it is for different reasons.

14           Next slide.

15           In terms of evaluating measures  
16 for the evidence subcriterion, again, we don't  
17 have any health outcomes. So, for all of the  
18 measures that you will be looking at today and  
19 tomorrow, we ask the developers to provide  
20 explicit and transparent information on the  
21 quantity, quality, and consistency of the body  
22 of evidence. So, again, body of evidence is

1 the entire body, not just selected articles.

2           What we hope that they are able to  
3 do, because it makes their life easier really,  
4 is if they can find evidence that has already  
5 been graded and collected, so that they can  
6 just report to you the summaries from those  
7 already-digested, if you will, reviews. We  
8 prefer grade or USP -- I can't even say the  
9 letters -- U.S. Preventative Services Task  
10 Force system. If they use a different system,  
11 we do ask that they describe what the  
12 different grades mean. I think the developers  
13 this time around did a great job on that part.

14           There are separate rating scales  
15 for quality, quantity, and consistency. I  
16 guess probably the final thing from this slide  
17 is just to remind you that expert opinion is  
18 not what we consider evidence. Okay? So, we  
19 are looking for empirical evidence.

20           Next slide.

21           In thinking about the opportunity  
22 for improvement, so that is subcriteria 1(b),

1 that we will do third under importance to  
2 measure and report, one of the things that we  
3 ask the developers to do, if they can, is to  
4 provide some information about disparities.  
5 Often, they are not able to do that. But  
6 today I am going to specifically ask you, as  
7 a Committee, if you have any information about  
8 whether a measure might be what we would call  
9 disparity-sensitive. This is to support kind  
10 of an ongoing process that we are getting  
11 ready to implement.

12 So, basically, I will just be  
13 asking you if you know whether or not this  
14 measure is possibly disparity-sensitive. And  
15 then, if so, do you have any sources that you  
16 could point us to for us to go and understand  
17 that literature? And you may or may not.

18 Next slide, please.

19 Just a quick reminder. We have  
20 the generic rating scale, high, moderate, low,  
21 and insufficient. Those will be used for  
22 subcriteria 1(a), 1(b), and for usability and

1 feasibility.

2 Next slide.

3 Evidence subcriteria, there are  
4 different rating scales for quantity.

5 Next slide. Quality.

6 And next slide. Consistency.

7 And then, go to the next slide.

8 This is just the decision logic, which is  
9 pointing out that pretty much you need a  
10 moderate or high on all three of those in  
11 order to pass the evidence criteria.

12 Okay. Next slide.

13 I don't think we had to talk about  
14 the potential exception in Phase I, but we do  
15 have a couple of potential exceptions to the  
16 evidence subcriterion. Actually, we did talk  
17 about the first one in terms of health  
18 outcomes.

19 If you recall, for outcome  
20 measures, we didn't ask that developers tell  
21 us about quantity, quality, and consistency of  
22 evidence. We just asked about a rationale for



1 their outcome measure.

2 But, for other types of measures,  
3 non-outcome measures, we do have room for a  
4 potential exception to the evidence  
5 subcriterion. Basically, if there is no  
6 empirical evidence at all, but there is expert  
7 opinion that has been systematically assessed,  
8 and you also feel that the benefits would  
9 outweigh the potential harms, then you could  
10 consider invoking this exception to the  
11 evidence subcriteria. Okay?

12 So, if that becomes an issue, then  
13 somebody around the table would probably want  
14 to say something about "I think we should  
15 discuss invoking the evidence exception." If  
16 there is kind of general consensus around the  
17 table, then I think we vote on actually  
18 applying that exception. Okay? Anybody have  
19 any questions on that piece?

20 (No response.)

21 Okay. Next slide.

22 This is also a reminder. Our

1 Consensus Standards Approval Committee a while  
2 back did come out with some guidance for  
3 measure construction. I wanted to share just  
4 a couple of things that they found. These are  
5 the folks that see all of the measures from  
6 all the projects. Because all the Steering  
7 Committees do their thing, and then we take  
8 things to the next level, which is CSAC.

9 So, the CSAC folks see everything  
10 and they create some guidance for us.  
11 Basically, some of the guidance that they put  
12 out for developers to reflect the evidence  
13 criterion is to avoid measures that can be met  
14 primarily through documentation. That is one  
15 of the things that they suggested doing.

16 A lot of the times we use the term  
17 "checkbox" measures. So, those generally  
18 aren't the kinds of measures that the CSAC and  
19 the NQF Board is thrilled with.

20 So, they also suggest if you are  
21 thinking about teaching or counseling kinds of  
22 measures, they should be evaluated from the

1 patient perspective. So, not necessarily so  
2 much did you teach, but perhaps did the  
3 patient really understand what you taught  
4 might be another way to think about it. And  
5 I believe in Phase I you did consider an  
6 education measure.

7 Okay. Next slide.

8 Just a reminder. Again,  
9 scientific acceptability has two major  
10 subcriteria, reliability and validity. Both  
11 reliability and validity specifications are  
12 very important. The measure specifications  
13 are what you will be thinking about. For  
14 validity, you will really be thinking about  
15 how the specifications line up with the  
16 evidence, okay, and then all these other  
17 things.

18 Next slide.

19 Evaluation of testing, again, this  
20 only comes through with four of our measures,  
21 but this is just a slide reminding you that  
22 measures can be tested at data element level

1 or the measure score level. So, when you are  
2 thinking about testing and testing results,  
3 you have to think about: what were the  
4 results themselves? What level was testing  
5 done? When testing was done, was an  
6 appropriate method used, appropriate sample  
7 sizes, that sort of thing? That is the scope  
8 of the testing. And again, finally, the  
9 results of the testing. So, there are kind of  
10 a lot of moving parts when it comes to  
11 evaluating testing results.

12 Next slide.

13 And again, this is just to show  
14 you the scales that you will be using to rate  
15 validity and reliability for measures that  
16 have been tested. Again, just a reminder to  
17 get a rating of high in both cases for  
18 reliability and validity we would expect to  
19 see testing done at both the data-element and  
20 the measure-score level. So, if the testing  
21 result is a phenomenal result, I mean it is  
22 just really pristine, that is not enough to

1 give it a high. It needs to be tested at both  
2 levels. And then, if it is pristine, then it  
3 would get a high.

4 Next slide.

5 This is just the remainder of the  
6 scale.

7 And next slide.

8 We have a decision logic table  
9 that helps figure out if something passes  
10 reliability and validity and, therefore, the  
11 scientific acceptability. So, basically,  
12 again, the measures would need to have a high  
13 or a moderate on both reliability and validity  
14 to pass scientific acceptability.

15 Okay. Next slide.

16 The CSAC also offered some  
17 guidance around testing. One of the things  
18 that they suggested is you have to think about  
19 the impact of missing data. You shouldn't  
20 just make those exclusions when you are  
21 developing a measure.

22 Exclusions should be evidence-

1 based. Measures need to have the broadest  
2 applicability possible in terms of population  
3 settings as well as some analysis. And also,  
4 avoid measures where improvement decreases the  
5 denominator. Again, we won't focus too much  
6 on that guidance because I don't think it is  
7 really relevant for today's measures.

8 Next slide.

9 Usability, that is the extent to  
10 which intended audiences can understand the  
11 results of the measure and find them useful  
12 for decisionmaking. We ask you to think about  
13 public reporting as well as internal quality  
14 improvement efforts.

15 Okay. Next slide.

16 Feasibility is the extent to which  
17 data are readily available, retrievable, and  
18 easily implemented. So, it really gets a lot  
19 to data burden and that sort of thing.

20 Next slide.

21 And we can stop here. We don't  
22 have to talk about this right now.

1 Potentially, tomorrow we may need to talk a  
2 little bit about competing and related  
3 measures.

4 So, with that very brief  
5 introduction, let me see if there are any  
6 questions about what you will be doing today.  
7 Again, you have your four-pager in front of  
8 you. So, please refer to that if you forget  
9 what the scales are, and we will try to be  
10 putting scales and that sort of thing up on  
11 the screen as well when it comes time to vote.

12 DR. BURSTIN: Just one brief  
13 addition, and this is, I think, the first time  
14 you have seen untested measures. We have a  
15 strong preference for tested measures. But  
16 when there are clear programs that are going  
17 to be using these measures in the short-term,  
18 you want to have the chance to evaluate them,  
19 even if they are not tested. They have got to  
20 get their testing results done and in within  
21 12 months and have a clear plan of how they  
22 are going to do that.

1                   But, at the same time, since you  
2                   can't really look at reliability and validity,  
3                   it is very important to still look at the  
4                   precision of the specifications. Do you  
5                   believe the specifications are precise enough  
6                   that they can logically be reliably collected,  
7                   even if you don't have that testing data?

8                   CO-CHAIR KNOWLTON: When we were  
9                   talking as we were preparing for this session,  
10                  I asked you whether we should talk about some  
11                  of the criteria, some overarching criteria  
12                  that seems to be at issue. Certainly, all of  
13                  you who have participated in the Working  
14                  Groups know that there have been issues over  
15                  evidence. And I wondered if it would be  
16                  helpful to have, which I would like you to  
17                  guide, would it be helpful to have a  
18                  discussion of how we all feel about that,  
19                  because it was very much a repetitive issue in  
20                  our discussions in the working group?

21                  But we can apply these criteria on  
22                  each individual one, but I wondered if it



1 would be helpful to talk about it first, the  
2 issue of clear and present evidence. Some of  
3 these are time-limited endorsements because  
4 the evidence isn't --

5 MS. JOHNSON: Let me make sure  
6 that everybody understands, when it comes to  
7 these untested measures, you will be  
8 considering is whether you will recommend them  
9 or not for endorsement. But, as Helen said,  
10 that would just be what we call time-limited  
11 endorsement. It would be for 12 months.  
12 During that 12-month time, the developer  
13 should be testing the measure, and then they  
14 would bring it back to us and we would  
15 evaluate the results.

16 But, basically, the non-tested  
17 measures just means, when you are doing the  
18 scientific acceptability criterion, you are  
19 not going to be looking at all those different  
20 things under reliability and validity. You  
21 will pretty much be focusing only on the  
22 measure specifications, again, the precision

1 of them and how they line up with the  
2 evidence.

3 Okay. Having no testing and being  
4 up for potential time-limited endorsement has  
5 nothing at all to do with evidence. So, they  
6 are not getting a pass, if you will, on having  
7 to show impact, high impact, having strong  
8 evidence base and having opportunity for  
9 improvement. I guess that is more to the  
10 first issues that we wanted to make sure that  
11 we clarified.

12 Does that make sense, Dave?

13 CO-CHAIR KNOWLTON: But even in a  
14 time-limited endorsement there has to be  
15 evidence, and it has to be specified. I think  
16 David actually made this point during one of  
17 our calls. There has to be very clear  
18 evidence; it has to be specified, and we have  
19 to be able to understand it --

20 MS. JOHNSON: Yes.

21 CO-CHAIR KNOWLTON: -- and how it  
22 is applied.

1 MS. JOHNSON: Yes.

2 CO-CHAIR KNOWLTON: Because that  
3 seems to have been a repetitive question.

4 DR. BURSTIN: To get to be a time-  
5 limited-endorsed measure, it has to meet every  
6 single criteria for any other measure with the  
7 exception of the fact that it has not been  
8 tested for reliability and validity. That is  
9 all. There is no separate bar. It is  
10 literally exactly the same with the exception  
11 of reliability and validity.

12 And in that case, what you are  
13 really looking at is the precision of the  
14 specifications and how comfortable you feel  
15 that, as this goes out into practice, in  
16 advance of having it tested, that that is  
17 going to be likely reliably in the 12-month  
18 period while we await testing results.

19 MEMBER COONEY: The common issue  
20 that came up during our discussion, you know,  
21 you have that slide that showed the connection  
22 between the process and the outcome and the

1 different levels of importance. That one.

2           Because a number of the measures  
3 are assessment measures. What I found lacking  
4 in many of what we reviewed was the connection  
5 to the outcome. Because it applies to so many  
6 measures, as David said, is it possible to  
7 talk a little bit about that, I mean the  
8 importance of that tie? Because the  
9 assessment seems useful, valuable. We should  
10 do it. But I didn't find the tie to the  
11 outcomes, and it seems like we are supposed to  
12 have a tie to the outcomes. So, could we  
13 discuss that aspect of it a bit?

14           DR. BURSTIN: Yes. So, in  
15 general, it is an excellent question, and this  
16 comes up a lot whenever we get a batch of  
17 assessment measures, which a lot of these are.

18           So, in general, the preference  
19 would be, if you are going to have process  
20 measures, then they have got to be as proximal  
21 to the outcome as possible. And certainly,  
22 assessment measures are usually pretty distal.

1 They are the first step in that pathway  
2 towards getting to an outcome.

3 So, I think the only time we have  
4 seen assessment measures come forward is when  
5 it is a relatively-new area, for example,  
6 where there hasn't been a lot of measurement  
7 done to date, where there is significant gaps  
8 in even doing the assessment.

9 And so, one question might be --  
10 and this is where you guys may need to invoke  
11 that exception, and it is an exception; it is  
12 not a pathway; it is truly just an exception  
13 -- where you really look at that measure and  
14 you think, boy, I know enough about this  
15 topical area to know that 70 percent of the  
16 time clinicians aren't even doing that. It is  
17 so important to get this on the sort of  
18 measurement radar screen that we still think  
19 putting it forward with an exception, the  
20 benefits would so exceed the risks, that it is  
21 not so issue, you know, in your world, Gail.

22 For example, on our Palliative

1 Care Committee there was a measure that looked  
2 at whether somebody was offered spiritual  
3 services. Again, one of those things where it  
4 sort of seemed intuitive, like, of course, we  
5 want to get on this path, even though we were  
6 really pretty far away from a lot of the  
7 outcomes we were really interested in. But  
8 the Committee felt strongly that was one place  
9 where you would potentially invoke that  
10 exception.

11 MEMBER KAPLITT: So, all I would  
12 suggest is that the recommendation that was  
13 made at the beginning that we start each  
14 criteria with evidence I think really speaks  
15 to the point, because of the fact that that  
16 clearly is the major issue.

17 My concern about having an  
18 extended general discussion right now is that  
19 we are going to wind up back doing the exact  
20 same thing because each one has their own  
21 evidence issues. There may be overarching  
22 themes, right, which is evidence important or

1 not. And there may have been confusion, I  
2 think, before the calls by some people as to  
3 how evidence fit in versus reliability and  
4 validity testing. And if that is still an  
5 issue, then that may be worth a general  
6 discussion.

7 But my concern is, if we start  
8 talking about specifics of each thing, that is  
9 the reason why I think -- because, then, if we  
10 go through evidence as the first discussion  
11 point for each thing, if it falls down there,  
12 then we have saved a lot of time. And then,  
13 you know, that's that.

14 And then, I would personally -- I  
15 think it is likely that when we discuss the  
16 first measure for a given area, if the  
17 evidence falls down, the rest of them will  
18 probably go fairly quickly, because just based  
19 on the initial view, similar themes for  
20 different measures in the same area kept  
21 coming up.

22 MEMBER SULLIVAN: I have one other

1 general question that came up on our Work  
2 Group call, and it came up several times with  
3 several measures. That is the issue, it goes  
4 to specifications. But there are a number of  
5 measures that seem to lump a lot of things  
6 into the measure. You were assessing a number  
7 of things that were related but were  
8 different.

9           And I think that is likely to come  
10 up looking at a lot of these. I just don't  
11 know how to address those. I think it would  
12 be difficult in terms of usability of a  
13 measure if you are lumping six things that a  
14 clinician is supposed to be assessing. I  
15 wonder if there is some guidance in general  
16 about how to look at those measures that  
17 assess multiple related things.

18           DR. BURSTIN: Actually, that is  
19 something we see pretty commonly. Actually,  
20 many of them become composites or all-or-none  
21 composites, but you should always do all of  
22 these. So, that is not very atypical.



1                   The key is going to be do the  
2 specifications have enough precision that you  
3 can, in fact, walk through it? Now there are  
4 also at times, when you are looking at  
5 multiple things, one could make the argument  
6 reliability may take a hit. And that is  
7 something, even though you have testing  
8 results in front of you, I think it is a fair  
9 question to invoke, you know, depending on the  
10 complexity of the data collection, is that  
11 something necessarily that you think can be  
12 reliably collected, even in advance of  
13 testing.

14                   Did you have a question?

15                   CO-CHAIR TIRSCHWELL: Yes, I just  
16 had one point that I thought was probably  
17 relevant to a lot of measures. It goes back  
18 to your slide about the two things that the  
19 CSAC doesn't like in the measures. One of  
20 them was a checkbox measure.

21                   DR. BURSTIN: Yes.

22                   CO-CHAIR TIRSCHWELL: And it seems

1       like a lot of these assessment things are  
2       literally checkboxes in your clinical  
3       evaluation. Once you check them off, you are  
4       good to know. Who knows that it leads to  
5       different treatment, let alone outcomes later  
6       that are changing things?

7                So, I mean, I have had doubts  
8       about some of the evidence for a number of the  
9       measures, as I think a lot of people did.  
10      But, then, seeing that I think is something we  
11      will probably have to keep in mind for a lot  
12      of measures.

13               And what was the second CSAC  
14      thing?

15               MS. JOHNSON: It had to do with --

16               CO-CHAIR KNOWLTON: Counseling.

17               CO-CHAIR TIRSCHWELL: Oh, right.

18               CO-CHAIR KNOWLTON: From a patient  
19      perspective.

20               CO-CHAIR TIRSCHWELL: All right.

21      You gave an example of that. So, that is it.

22      Thanks.

1 DR. BURSTIN: You know, in  
2 general, the idea of having somebody say, "I  
3 counseled the patient," and it is the measure,  
4 as opposed to understanding from the patient  
5 that that was in any way a meaningful event,  
6 is difficult.

7 CO-CHAIR KNOWLTON: Maybe it is my  
8 denseness in this, but does there need,  
9 without an exception, does there need to be a  
10 clear link between a measure and a desired  
11 outcome?

12 DR. BURSTIN: Yes, there should be  
13 a clear link, and if you think it is important  
14 enough to do anyway, then you would need to  
15 invoke the exception.

16 CO-CHAIR KNOWLTON: Got it.  
17 Anybody have any other questions?  
18 I don't see anybody else.

19 Oh, quickly, go ahead, Michael.

20 MEMBER KAPLITT: A procedural  
21 question. Based on the agenda, we are also at  
22 the end tomorrow re-explore that Phase I

1 measure. Not to make too many assumptions,  
2 but if the agenda moves along quicker than  
3 anticipated because of this evidence issue, is  
4 the developer available to do this or are we  
5 going to just be hanging around until 1:30?

6 DR. BURSTIN: We will look into  
7 that. I mean, certainly, I think they would  
8 be available tomorrow. I don't know that they  
9 planned to do it today.

10 MEMBER KAPLITT: But I kind of  
11 have a suspicion maybe that the agenda may be  
12 moving quicker than this one is.

13 DR. BURSTIN: And you guys all  
14 heard, it is only one measure now, the  
15 readmission measure. CMS has withdrawn the  
16 mortality measure due to the concerns about  
17 risk adjustment.

18 CO-CHAIR KNOWLTON: And no matter  
19 how fast we go today -- thank you for raising  
20 that, Michael -- no matter how fast we go  
21 today, we still need to do tomorrow because  
22 the measure developers will be here for those

1 scores tomorrow. So, we still have to do  
2 tomorrow.

3 MEMBER KAPLITT: Right, but --

4 CO-CHAIR KNOWLTON: But that last  
5 measure, you are right.

6 MEMBER KAPLITT: -- first thing in  
7 the morning --

8 CO-CHAIR KNOWLTON: That's right.  
9 That is a good point.

10 The other thing, on the other side  
11 of that is it is our understanding that we  
12 only have one person who has to leave before  
13 our scheduled conclusion time. If anybody's  
14 change and that changes, you need to let one  
15 of the Co-Chairs know.

16 And just a housekeeping measure,  
17 when you put your thing up so that we call on  
18 you, make sure we can see it. Some people put  
19 it so I can't see the name.

20 So, we are going to start off now,  
21 and you know the process. We are going to  
22 begin with a lead discussant on the issues.

1 We are into the first measure.

2 MS. JOHNSON: Sorry, I think we  
3 put out a final agenda. So, we are missing  
4 one little thing that we wanted to do.

5 CO-CHAIR TIRSCHWELL: A "final"  
6 final agenda.

7 MS. JOHNSON: Yes, a "final" final  
8 agenda.

9 (Laughter.)

10 CO-CHAIR KNOWLTON: I am not on  
11 the "final" final.

12 MS. JOHNSON: You have the almost-  
13 final one.

14 CO-CHAIR KNOWLTON: Almost final?

15 MS. JOHNSON: Sorry, Dave.

16 What we are going to ask our  
17 developers for the first three measures to do  
18 is we are going to give you about five minutes  
19 to just give us a general overview of your  
20 measures, just so we can get to know you a  
21 little bit.

22 So, if the folks from PQA want to

1 start, that would be great.

2 MS. KUHLE: Good morning.

3 That was loud. Okay, is that  
4 better?

5 I am not sure it is best to go  
6 first in the morning, especially with a  
7 measure. You feel like you have got all the  
8 time to really scrutinize it.

9 Let me give you a little history  
10 of PQA. It is a consensus-based, multi-  
11 stakeholder alliance focused on initiatives to  
12 improve the quality of medication use. So, it  
13 is a little bit of a different measure that  
14 you are going to look at because it really  
15 does develop just using prescription claims  
16 data and then, of course, diagnosis data.

17 The members of PQA are diverse.  
18 We have pharmacist professional associations.  
19 We have federal agencies. We have health  
20 plans. We have academic institutions. We  
21 have pharmacists and chain pharmacies and  
22 independent pharmacists and consumer advocacy

1 organizations.

2 The measure development process  
3 occurs through Work Groups, and the Work  
4 Groups are comprised of representatives from  
5 all of our member organizations. So, again,  
6 they have diverse backgrounds and expertise.

7 This measure was initiated last  
8 year, 2011, in a Work Group called the Overuse  
9 Work Group. This Work Group wanted to look at  
10 this measure because of the growing evidence  
11 of poor outcomes for patients with dementia  
12 that were using antipsychotics and our  
13 understanding, as pharmacists, that  
14 antipsychotics are often overused.

15 This year, the Mental Health Work  
16 Group looked at this measure concept and  
17 further reviewed and revised it with their  
18 expertise.

19 And then, finally, the measure  
20 concept is reviewed by a quality metrics  
21 expert panel. That is a group of individuals  
22 with really specific expertise in the area of



1 prescription claims data, but also quality  
2 measurement and outcomes research.

3 And then, finally, this expert  
4 panel did review the testing. We have some  
5 limited testing of this measure. And then,  
6 the measure was brought forward to our full  
7 membership for endorsement. And that was last  
8 June.

9 So, that is my introduction. I  
10 hope that helps you understand where this  
11 measure came from.

12 Karen, I would also ask, do we  
13 have anyone on the phone? Because my  
14 colleague, Dr. David Nau, was going to call  
15 in.

16 MS. JOHNSON: I know I heard  
17 someone on the phone.

18 Dr. Nau, are you on the phone?

19 DR. NAU: Yes, I'm here.

20 MS. JOHNSON: Okay. Great.

21 DR. NAU: All I would add to what  
22 Julie mentioned is that we did have a

1 combination of physicians, pharmacists,  
2 nurses, and others that weighed-in on the  
3 development process and also made sure to test  
4 it.

5 But the institute that it was  
6 primary designed to evaluate was Medicare  
7 clients. So, we do have that testing evidence  
8 that is in the submission form that you have  
9 all evaluated.

10 We believe this is an important  
11 area that is very relevant for patients in the  
12 Medicare program and helps to give that  
13 population-level perspective on the use of  
14 these medications in patients with dementia.

15 MS. JOHNSON: Thank you very much.

16 And how about the folks from AMDA?  
17 Would you like to give us a brief overview of  
18 your measures?

19 MS. VANCE: Hi. I'm Jackie Vance.  
20 I am with the American Medical Directors  
21 Association. Our Association represents  
22 professionals who care for frail elders in the

1 long-term care continuum. So, our patient  
2 base is mostly in the nursing home setting,  
3 where the average age of the patient is 85  
4 years old. Our measure is designed for the  
5 nursing home setting.

6 According 2012 Alzheimer's  
7 Association facts and figures data, the  
8 prevalence rate of Alzheimer's disease by the  
9 age of 85 is 47 percent. In 2011, more than  
10 5.3 million American had Alzheimer's disease,  
11 while 2 million went undiagnosed. In 2009, 68  
12 percent of nursing home patients had some form  
13 of cognitive impairment, 47 percent in the  
14 moderate-to-severe stage. Yet, in 2011, we  
15 looked at Medicare claims data from the MDS  
16 assessment, which I will explain what that is  
17 in a moment, and it showed that only 47  
18 percent of those nursing home patients had an  
19 actual documentation in the medical record of  
20 having dementia.

21 According to a U.S. Preventive  
22 Service Task Force systematic evidence review,

1 it showed that 50 percent of patients with  
2 dementia have never been diagnosed by a  
3 physician at all.

4 Then, we noticed that in 1992 HCPR  
5 convened a panel of experts to develop a  
6 guideline on screening for Alzheimer's disease  
7 and related dementias, and I will quote them,  
8 "Failure to diagnose dementia can result in  
9 needless and possible harmful treatment and  
10 needless healthcare expenditures. We put out  
11 a lot more evidence, and we put that within  
12 our submission on that.

13 According to evidence such as an  
14 HCPR Guideline Overview No. 19, the correct  
15 diagnosis of dementia can prevent costly and  
16 inappropriate treatment. It all shows that  
17 awareness of dementia allows the clinicians to  
18 provide a prognosis and expectations,  
19 realistic expectations, and allows for things  
20 like improved pain detection, weight-loss  
21 intervention, elopement prevention, and other  
22 appropriate care.

1                   This measure allows us to take  
2                   advantage of what is unique to the long-term  
3                   setting. That is several things that many of  
4                   you might not be aware of. We have something  
5                   called a minimum dataset assessment that is  
6                   done for every person that is admitted to a  
7                   nursing facility. It is licensed under  
8                   Medicare or Medicaid. The MDS assessment was  
9                   updated in 2010. It is a validated tool. I  
10                  provided that evidence as well and all those  
11                  validation studies in the submission.

12                  One of the reasons why the MDS  
13                  assessment was developed is nursing homes are  
14                  mostly staffed by LPNs or LVNs who do not  
15                  really understand or are not taught assessment  
16                  techniques. They can evaluate; they don't  
17                  assess.

18                  And also, in the nursing home  
19                  setting, unlike the hospital setting, it was  
20                  a rude awakening for me. I started out in  
21                  acute care and then moved to long-term care.  
22                  You don't have physicians living in their

1 nursing home. They come every 30 days for the  
2 first 60 days of the person's life in the  
3 nursing home. It is a federally-regulated  
4 visit they must make. And then, they come  
5 every 60 days thereafter unless they need what  
6 is called a medically-necessary visit.

7 The MDS assessment triggers things  
8 -- it is actually called a care area  
9 assessment -- that will let the nursing staff  
10 know that something is going on enough with  
11 the resident that helps trigger that they need  
12 to let the practitioner know to come in and  
13 make that medically-necessary visit.

14 So, what we look for within this  
15 measure is looking for consistence, a brief  
16 interview, mental status assessment, that will  
17 give a certain score. That is certainly going  
18 to trigger that this person will most likely  
19 have severe dementia, but there hasn't been a  
20 diagnosis of dementia because the nurse can't  
21 make that diagnosis. That diagnosis is  
22 transcribed from the medical record onto the

1 MDS once that physician has made that  
2 diagnosis.

3 And then, an appropriate care plan  
4 or treatment plan can be put in place. We  
5 have evidence. We know that you have very  
6 negative outcomes, health outcomes, on  
7 healthcare cost outcomes when you don't have  
8 that appropriate diagnosis. You don't have  
9 advanced directives in place. You have things  
10 that happen, and I have seen it in my career,  
11 just these persons being sent back and forth  
12 to the hospital with futile healthcare  
13 treatments, expenditures, and you don't have  
14 these appropriate treatments in place that  
15 help maintain function, that help maintain  
16 whatever cognition that you can maintain.

17 So, what we are looking for is an  
18 assessment at least to a process and outcomes  
19 that you know will happen by what you will see  
20 happen within the future MDS documentation.

21 Thank you.

22 CO-CHAIR KNOWLTON: Thank you.

1                   Salina, welcome. We want around  
2                   and did a disclosure. Introduce yourself and  
3                   please disclose any conflicts you have.

4                   MEMBER WADDY: Sure. I am Salina  
5                   Waddy from the National Institutes of Health,  
6                   and I have no disclosures other than my job.

7                   CO-CHAIR KNOWLTON: Okay. Now we  
8                   are back to the agenda. Am I on the right one  
9                   now?

10                  So, we are going to begin with  
11                  you, Gwen, on the Measure 2111, if you could  
12                  take the lead of the discussion, please.

13                  MEMBER BUHR: So, this measure is  
14                  an psychotic use in persons with dementia. It  
15                  is from the Pharmacy Quality Alliance. It is  
16                  measuring the percentage of individuals 65  
17                  years of age and older with dementia who are  
18                  receiving an antipsychotic medication without  
19                  evidence of a psychotic disorder or related  
20                  condition.

21                  It is defining dementia as a  
22                  diagnosis of dementia or being prescribed a



1 dementia medication. The people with  
2 psychoses are the ones with schizophrenia,  
3 bipolar, Huntington's, and Tourette's  
4 syndrome. Those are the ones that are having  
5 a psychotic-disorder-related condition where  
6 you could be on an antipsychotic.

7           And so, that is the introduction.  
8 On to the evidence, on our Work Group call we  
9 felt like there was quite a bit of evidence  
10 supporting the measure, that this was a  
11 process measure fairly proximal to the  
12 outcome, that it was prescribing a medication,  
13 and there are a lot of people with dementia.  
14 There is quite a lot of evidence that a lot of  
15 people with dementia are prescribed  
16 antipsychotic medications, and that  
17 antipsychotic medications in patients with  
18 dementia can result in negative outcomes,  
19 cardiovascular bad outcomes, and mortality.  
20 So, that was what I have to say about that.

21           CO-CHAIR TIRSCHWELL: So, I guess  
22 I had a question. I think somewhere in all of

1 this paperwork they mention that they don't  
2 expect the rate to be zero because there is  
3 some appropriate use of antipsychotics in  
4 patients with dementia.

5 But, then, my question comes down  
6 to, is dementia stage related to appropriate  
7 use? In other words, does it become more  
8 appropriate and more frequently used in  
9 patients with more severe dementia? And if  
10 that is the case, then does not this measure  
11 need to be risk-stratified, so that whatever  
12 prescription plan is being evaluated on this  
13 use is appropriately compared based on the  
14 types of dementia patients, more severe or  
15 less severe, that are in their particular  
16 plan?

17 CO-CHAIR KNOWLTON: Gail?

18 MEMBER COONEY: I deal pretty much  
19 only with patients with end-stage dementia,  
20 and I am unaware of any stratification of  
21 outcomes of the data that exists. It seems  
22 reasonable that, if you are increasing your

1 risk of stroke and death, then this risk of  
2 stroke and death should be less if you are  
3 near the end of life, but I don't believe that  
4 anyone has ever looked at that.

5 CO-CHAIR TIRSCHWELL: But that  
6 wasn't quite my question. I think, given any  
7 particular severity measure, it would be  
8 better not to be on it than on it. But if you  
9 are at a severe stage and it just becomes  
10 appropriate in 20 percent of the cases, and  
11 that is the minimum that you can get away with  
12 because it is really necessary versus mild  
13 dementia where you really can get away with 10  
14 percent of people needing antipsychotics, you  
15 can't compare the health plan that has more  
16 severe to the health plan that has less severe  
17 and think that you are judging quality on  
18 that, when they are really both sort of at an  
19 appropriate level of treatment.

20 CO-CHAIR KNOWLTON: Jocelyn?

21 MEMBER J. BAUTISTA: Yes, I am not  
22 an expert in this field, but I did do a quick

1 literature search the other day, and I thought  
2 I did see a recent paper. So, the premise is  
3 that antipsychotic use increases mortality.  
4 The paper looked at in dementia patients that  
5 increased mortality was very much related to  
6 dementia severity, which I think is exactly  
7 what you are asking, right? So, those with  
8 the higher mortality were those with the more  
9 severe dementia. And this antipsychotic use  
10 may just be sort of --

11 CO-CHAIR TIRSCHWELL: But the  
12 antipsychotic use may be even an independent  
13 predictor of severity, and it is still problem  
14 for comparing the more severe group to a less  
15 severe group overall. You want to minimize  
16 it. I am not arguing with that at all. But  
17 what the appropriate rate is won't be the same  
18 for the healthcare plan that takes care of the  
19 more severe patients, is all I am saying.

20 And so, I just wonder whether  
21 certain healthcare plans -- and this is  
22 specified for a healthcare plan level, and it

1 is hard, knowing who is covered by different  
2 insurance, it is hard to believe there is not  
3 different populations of dementia patient  
4 being cared for by these different health  
5 plans.

6 CO-CHAIR KNOWLTON: Peter?

7 DR. NAU: This is David Nau from  
8 PQA.

9 CO-CHAIR KNOWLTON: Hold on. Hold  
10 on for a minute, David.

11 Peter?

12 MEMBER SCHMIDT: So, I am  
13 interested that Parkinson's disease is not  
14 included in here. Many movement disorder  
15 neurologists will tell you that, if the phone  
16 rings in the middle night and they pick it up,  
17 they say, "Clozapine." I don't want John Duda  
18 to be accused of poor-quality care for his  
19 patients.

20 So, is there a reason that  
21 Parkinson's disease is not included in the --

22 CO-CHAIR TIRSCHWELL: So, that is

1 a good point, but it is a specification issue.  
2 So, let's revisit that later, if we get to the  
3 specifications.

4 CO-CHAIR KNOWLTON: I have a  
5 concern here as well similar to David's. If  
6 we expect the number not to be zero in a  
7 measure like this, but we don't stratify how  
8 we know that it is zero, then one group of  
9 patients could be with one provider and all  
10 meeting that criteria. And so, there is no  
11 precision to the measure at all. So, it  
12 doesn't tell you anything.

13 I mean, I don't understand that  
14 clinically perhaps as well as you actual  
15 clinicians do, but I understand it logically,  
16 that it doesn't make sense, how we could  
17 differentiate the measures. That is my  
18 problem with this measure.

19 Ramon?

20 MEMBER R. BAUTISTA: We are  
21 required in the DSM-IV diagnosis of all these  
22 side conditions before we can even prescribe

1 an antipsychotic to demented patients then?  
2 Is that the idea here? Is there the DSM-IV  
3 criteria? I mean, what percent of general  
4 doctors out there know how to use the DSM-IV  
5 criteria for that matter?

6 CO-CHAIR KNOWLTON: Gwendolyn?

7 MEMBER BUHR: Well, I think in  
8 response to that, it is based on the diagnosis  
9 codes. So, it is going to be administrative  
10 data in that way.

11 And about the evidence and the  
12 different severities of dementia, I think the  
13 bulk of the evidence is just meta-analyses of  
14 the major trials of antipsychotics. You can't  
15 break it down by severity of dementia because  
16 the individual trials themselves are not  
17 showing mortality. But once you lump them all  
18 together, you have enough power to show  
19 mortality. So, you can't break them down by  
20 severity.

21 There is going to be cohort or  
22 other kinds of studies that might be able to

1 try to break it down by severity, but I think  
2 the evidence is more lumped together in meta-  
3 analysis. And if you just have the patient  
4 population, I mean, you are going to prescribe  
5 an antipsychotic for behavioral and  
6 psychological symptoms of dementia, which are  
7 happening at various stages in various ways.

8 And so, in the mild and moderate  
9 stages, you are going to have different things  
10 that you might prescribe an antipsychotic for  
11 than in the severe stages. And so, I just  
12 think that I don't know about the utility of  
13 breaking it down and risk-stratifying.

14 CO-CHAIR TIRSCHWELL: So, in  
15 direct opposition to my role as Chairman, I  
16 have confused the issue by raising the risk  
17 adjustment when that should be part of the  
18 specifications as well.

19 (Laughter.)

20 And so, we should probably table  
21 that and just talk about the evidence, as you,  
22 I think, described, Gwen, linking excessive



1 use of these antipsychotics to the outcomes of  
2 increased mortality.

3 Jocelyn?

4 MEMBER J. BAUTISTA: But I think  
5 it is still an evidence issue. If the premise  
6 is that use of antipsychotics is an  
7 independent predictor of mortality, increases  
8 risk of mortality, completely separate from  
9 severity of disease, has that been shown  
10 clearly in the evidence?

11 MEMBER BUHR: I think so.

12 MEMBER J. BAUTISTA: Didn't you  
13 just say it hasn't been adjusted for severity?

14 MEMBER BUHR: But if you have a  
15 randomized controlled trial of an  
16 antipsychotic with a person with dementia, and  
17 you have got various stages of dementia, then  
18 you can lump all those -- I mean, it seems  
19 like that it is, I don't know --

20 CO-CHAIR KNOWLTON: It appears,  
21 though, Gwen, it appears squishy when you say  
22 that the developer says we don't expect the

1 rate ever to be zero.

2 MEMBER BUHR: Well, the reason for  
3 that is because this is a difficult problem.  
4 Patients with dementia with behavioral and  
5 psychological symptoms, there are not good  
6 treatments. A patient may have some  
7 behavioral symptoms that are putting them at  
8 a danger to themselves or others, and you have  
9 to take the risk of higher mortality because  
10 the antipsychotic is the only drug that has  
11 much evidence behind it to improve their  
12 behavioral symptoms. So, you may be able to  
13 treat their behavioral symptoms and make them  
14 not be a danger to themselves or others, but  
15 they may have a negative cardiovascular or  
16 they may die sooner.

17 And families and patients -- well,  
18 patients really can't choose at that point --  
19 but families are willing to take that risk  
20 because the patient is having such a poor  
21 quality of life, and they are a danger to  
22 themselves, a danger to others. They can't

1 live in their nursing home because they are  
2 going to hurt the staff or hurt themselves.

3 And so, you take the risk of  
4 higher mortality. And that is why it can  
5 never be zero.

6 CO-CHAIR KNOWLTON: But those,  
7 then, become extenuating circumstances and  
8 confounding variables that take a particular  
9 measure and say this measure isn't providing  
10 new, meaningful information to someone because  
11 the practitioner says, well, clinically, I had  
12 to make a tough call here.

13 MEMBER BUHR: Yes.

14 CO-CHAIR KNOWLTON: But the  
15 measure is trying to say what is the  
16 appropriate call, and we don't have evidence  
17 of the appropriate call here. I mean, you  
18 guys are the clinicians, but you are going to  
19 paint --

20 MEMBER BUHR: Isn't that really  
21 validity, though?

22 CO-CHAIR KNOWLTON: You are going

1 to paint the clinician into a box, aren't you?

2 DR. BURSTIN: Again, keep in mind  
3 it is a health-plan-level measure. So, you  
4 are not really at the clinician level as a  
5 starting point.

6 I think one of the questions that  
7 I would be curious to have David or somebody  
8 respond to this is the point you raised  
9 earlier about are there differences by types  
10 of health plans. And for example, many of the  
11 NCQA measures on the health plan level are  
12 stratified by type of health plan, Medicare,  
13 Medicaid, commercial. I mean, maybe that is  
14 one approach, but I agree that is more risk  
15 adjustment.

16 But I think, David, it is actually  
17 not that dissimilar to other measures we have  
18 had where some things just can't be zero, but  
19 we would like them to be low. One example is  
20 episiotomy after birth. I mean, it is not  
21 something that is ever going to be zero. You  
22 would like it to be low.

1                   And again, by having the  
2                   comparisons across providers, it is very  
3                   useful for people to understand and drive  
4                   improvement. But, again, getting to zero  
5                   doesn't make sense.

6                   DR. NAU: This is David.

7                   I think you said a key point  
8                   there. But, also, with regard to risk  
9                   stratification, certainly with this measure  
10                  there can be the same sort of very simple  
11                  stratification as used with many of the  
12                  claims-based measures, which are just to  
13                  segment the type of plan generally by  
14                  Medicare, Medicaid, et cetera.

15                  But, additionally, in trying to do  
16                  risk stratification based on severity of  
17                  dementia, that is just not possible to do with  
18                  claims because the ICD-9 codes don't allow for  
19                  that sort of detailed nuance to be put into  
20                  the claims. So, it is only capable of  
21                  identifying those who have been diagnosed with  
22                  dementia.

1                   But when you look across the large  
2                   or even moderate-sized health plans, you are  
3                   talking about thousands or hundreds of  
4                   thousands of patients. In general, the  
5                   distribution across different risk strata are  
6                   similar across the plans. And so, it doesn't  
7                   appear as though it would greatly bias one  
8                   plan over another from that regard. In fact,  
9                   we found fairly consistent results across a  
10                  few of the plans we did evaluate this in.

11                  However, the underlying clinical  
12                  evidence, the studies, the randomized  
13                  controlled trials that were conducted did  
14                  account in many cases for the severity of the  
15                  patient and still found a significant elevated  
16                  risk of antipsychotic use in the patients  
17                  who had dementia.

18                  CO-CHAIR KNOWLTON: Very good.

19                  A.M.?

20                  MEMBER BARRETT: So, I want to  
21                  echo the concern about the evidence linking  
22                  this process measure to outcomes, not just

1 because of my being unclear about the proper  
2 percentage of people who would appropriately  
3 receive antipsychotics for behavioral and  
4 other symptoms of dementia, chronic symptoms,  
5 I assume, but also please educate me,  
6 Committee, if I am correct, but agitated  
7 delirium also can be a risk factor both for  
8 mortality and an indication for antipsychotic  
9 drug use in dementia. I am not sure that the  
10 meta-analyses that were done took into account  
11 that influence.

12 CO-CHAIR KNOWLTON: Jordan?

13 MEMBER EISENSTOCK: I am not sure  
14 if I am out of place now. That is why my card  
15 has been up and down after what you said,  
16 David.

17 (Laughter.)

18 But I think that your point is  
19 incredibly important here. That is that, as  
20 time goes on, the big global risk versus  
21 benefit factors change for these patients.  
22 This is sort of dovetailing what A.M. just

1 said as well.

2 I am just trying to think of some  
3 way to reconcile it because I think  
4 everybody's point is really right on, but it  
5 is how to bring it all together and make it  
6 fit.

7 As these patients age and they go  
8 into more moderate or severe levels of  
9 dementia, we find that the overall global risk  
10 factors sometimes predispose to providing or  
11 prescribing the antipsychotics, and that is  
12 because they are truly psychotic and there are  
13 no other treatments.

14 I think the intent of this measure  
15 was to avoid using antipsychotics in patients  
16 that could otherwise be treated for aggression  
17 or agitation in other less risky ways. So, in  
18 playing upon that intent, one way perhaps to  
19 reconcile this would be to just another  
20 diagnosis to the numerator statement. I know  
21 we don't like "not otherwise specified" very  
22 often, but if it was psychosis or psychotic



1 disorder not otherwise specified, it might  
2 include more patients who are being treated  
3 properly with antipsychotics and help to  
4 reconcile the issues that we are discussing  
5 right now.

6 CO-CHAIR KNOWLTON: Risha?

7 MEMBER GIDWANI: I think the last  
8 speaker did a good job of summarizing that.  
9 I sort of will just build on that.

10 I think Gwen makes a good point  
11 about the patients being a risk to themselves  
12 or others, and therefore, use of  
13 antipsychotics is appropriate. In fact, on  
14 page 9 of our documentation, the guideline for  
15 the American Geriatric Society actually says  
16 the recommendation is to avoid use for  
17 behavioral problems of dementia "unless non-  
18 pharmacological options have failed and  
19 patient is a threat to self or others."

20 So, I am wondering if the  
21 developer can address why their numerator  
22 statement departs from this guideline.

1 CO-CHAIR KNOWLTON: Does the  
2 developer want to answer Risha's question?

3 MS. KUHLE: I am not sure if Dave  
4 is on the line.

5 Two things. If the idea is to  
6 make sure that patients that are a danger to  
7 others can receive this medication and not be  
8 counted in the numerator, and we can try to do  
9 that with an ICD-9 code, absolutely.

10 But it is my understanding that  
11 patients who have agitation, have behavioral  
12 symptoms that can be otherwise managed with  
13 non-pharmacological treatment, shouldn't  
14 receive antipsychotics. And that is really  
15 what this measure is trying to get at.

16 And the idea that, when there is  
17 harmful behavior, absolutely, that is when we  
18 want them to be treated with an antipsychotic  
19 if that is the last choice. But it is also my  
20 understanding that patients have acute need,  
21 and then it is not as if, once they become  
22 aggressive, they always will remain

1 aggressive. They might have outbursts where  
2 they need acute treatment and then they don't.  
3 And what we don't want to see is that patient  
4 stay on an antipsychotic forever.

5 One of the criteria for this is  
6 longer than 30 days' supply of the  
7 antipsychotic. So, we are looking for more  
8 than just an acute use.

9 I hope that helps answer your  
10 question a little bit.

11 CO-CHAIR KNOWLTON: You can follow  
12 up, Risha. Go ahead.

13 MEMBER GIDWANI: Well, I am not a  
14 clinician. So, I can't really speak to what  
15 the appropriate use of the antipsychotics is.  
16 But if the clinicians in the room are able to  
17 talk about whether a lower-than-30-day supply  
18 would be considered appropriate for treating  
19 this threat to one's self or others, and then,  
20 beyond that, we would say that, yes, this is  
21 definitively an inappropriate use of  
22 antipsychotics, that would help me in deciding

1 whether this is a valid measure.

2 CO-CHAIR KNOWLTON: I will let a  
3 clinician answer Risha's question. And then,  
4 I am going to ask if we focus on evidence and  
5 ask if you have your card up for something on  
6 other issues -- let's get to a vote on the  
7 evidence. I don't know whether, Gwen, since  
8 you did this discussion, would you want to  
9 answer?

10 MEMBER BUHR: So, I think that  
11 with respect to the evidence and the measure,  
12 and whether it is appropriate to use an  
13 antipsychotic, it is that even if the person  
14 has -- the evidence says that a person who has  
15 dementia, regardless of anything else, is at  
16 risk for mortality and cardiovascular  
17 outcomes. And so, you don't want to use an  
18 antipsychotic for anything, but sometimes you  
19 have to because non-pharmacologic measures  
20 aren't working and other safer medications  
21 aren't working. And so, then, you take the  
22 risk.

1                   And so, does that help at all with  
2 your question?

3                   MEMBER GIDWANI: I think it is  
4 just more the 30-day issue.

5                   MEMBER BUHR: Okay, the 30-day  
6 issue, yes. So, I guess that you would  
7 simultaneously, as you are using an  
8 antipsychotic, be using non-pharmacologic  
9 measures. And those may work over time or you  
10 may figure out one that does work. And then,  
11 you may simultaneously use other medications  
12 that take longer to work, and so, then, after  
13 30 days, be able to get rid of the  
14 antipsychotic.

15                   And people with dementia, you  
16 know, they wax and wane in their symptoms.  
17 And so, you prescribe one, and then the rules  
18 say that in a nursing home at least you have  
19 to reduce the dose at certain intervals  
20 anyway.

21                   CO-CHAIR KNOWLTON: John, on this  
22 issue?

1                   MEMBER DUDA: So, one disclosure I  
2 forgot to mention is I wasn't here for part  
3 one and I was on a plane for my small group's  
4 conference call. So, I really have no idea  
5 what I am doing here.

6                   (Laughter.)

7                   CO-CHAIR KNOWLTON: That is a  
8 common feeling.

9                   (Laughter.)

10                  MEMBER DUDA: Like Jordan, I keep  
11 putting it up and down because I don't know  
12 when I am supposed to talk and when I am not.

13                  But, as a clinician who takes care  
14 of patients with Parkinson's disease who get  
15 psychosis all the time, it is not at all  
16 uncommon -- so, one question, do they get a  
17 separate diagnosis of psychosis coded? Not  
18 necessarily, right? If you have PD and  
19 dementia and you put them on Seroquel for  
20 their psychosis -- I work in the VA, so coding  
21 isn't as much of a problem -- so, I don't know  
22 that we would necessarily be missing some that

1 way as well.

2 But, then, the 30-day issue, I  
3 have a patient with Parkinson's disease and  
4 dementia who is not going to get better, and  
5 he has a psychotic episode at one point. I am  
6 not likely to take him off, even if he is not  
7 psychotic because there have been good studies  
8 that show that this progresses. We will even  
9 treat people with kind of insight-retained  
10 hallucinations, because we know that it  
11 progresses to insight-unretained psychosis in  
12 the future, to try to prevent that.

13 So, my thoughts.

14 CO-CHAIR KNOWLTON: Thank you.

15 Ramon, on evidence?

16 MEMBER R. BAUTISTA: Yes. If I  
17 recall my medical school and residency  
18 training in psychiatry for a patient I had  
19 anyway, the sedative symptoms actually from  
20 Haldol, for example, work right away. But the  
21 psychosis symptoms, it takes weeks before they  
22 manifest.

1                   So, to answer the question, I am  
2                   not sure if the antipsychotic is going to cure  
3                   your psychosis. It might help sedate you, but  
4                   not take care of your psychosis. That takes  
5                   a longer period of time. So, as far as I can  
6                   remember, taking a one-month prescription of  
7                   an antipsychotic doesn't help your psychosis.

8                   CO-CHAIR KNOWLTON: Gail.

9                   MEMBER COONEY: Real quick, one of  
10                  the things I really like about this measure is  
11                  that it doesn't have all those clinical  
12                  exceptions, because I think there is very  
13                  strong evidence that in this population these  
14                  drugs should be avoided. And that is all this  
15                  measure is really seeking to say.

16                 CO-CHAIR KNOWLTON: Anything else  
17                 on evidence?

18                 (No response.)

19                 Can we vote on evidence?

20                 Okay. Can you open it up for us?

21                 MS. THEBERGE: Okay. Before you  
22                 vote, we have made a small change to how we



1 would ask you to think about the evidence.  
2 Basically, if you look at that slide, the two  
3 slides on the side, if you feel like you need  
4 to choose no for evidence, we would like you  
5 to try to distinguish for us whether it is  
6 "no" because the evidence is there but it  
7 doesn't meet the criteria or is it "no"  
8 because the evidence just didn't make it to  
9 the submission form. Does that make sense?

10 So, if it is yes, you do nothing  
11 different. You just vote yes. Okay? But if  
12 it is no, tell us again -- it is on this slide  
13 here -- evidence does not meet the guidelines  
14 or there is insufficient evidence presented  
15 for you to make that determination.

16 So, again, we are just trying to  
17 be -- and this will really come into play, I  
18 think, later on in the day -- we want to be  
19 very transparent about, if you vote things  
20 down on evidence, why exactly did that happen?  
21 Okay?

22 Any questions before we go to this

1 vote?

2 (No response.)

3 Okay.

4 CO-CHAIR KNOWLTON: Okay. Can we  
5 open it up now? We are ready to vote.

6 You should be pointing toward  
7 Suzanne. You can do it as many times as you  
8 want; it will only record once.

9 (Vote taken.)

10 MS. THEBERGE: Sixteen yes; 2, no,  
11 evidence does not meet guidance, and 5, no,  
12 insufficient information submitted on  
13 evidence.

14 CO-CHAIR KNOWLTON: Okay. It  
15 passes on evidence.

16 Back to you, Gwen, impact.

17 MEMBER BUHR: Okay. So, impact,  
18 our Work Group felt like it had a high impact  
19 because there is a lot of people with  
20 dementia, and a lot of people with dementia  
21 are being prescribed antipsychotics. So, high  
22 impact.

1 CO-CHAIR KNOWLTON: Questions?

2 (No response.)

3 We can vote.

4 (Vote taken.)

5 MS. THEBERGE: We need two more  
6 responses.

7 Twenty high, 2 moderate, 1 low.

8 CO-CHAIR KNOWLTON: Okay.

9 Opportunity for improvement is next.

10 MEMBER BUHR: Okay. So, from the  
11 information they submitted, between 14 and 16  
12 percent of the Medicare Advantage patients  
13 with dementia are receiving antipsychotics.  
14 And even if we don't want the number to be  
15 zero, we felt like there was a lot of  
16 opportunity for improvement with that.

17 CO-CHAIR KNOWLTON: Okay. Hold on  
18 for a minute.

19 MS. JOHNSON: Again, this is a  
20 little bit new, but if you have any discussion  
21 at all about performance gap, I would also  
22 ask, is there any flavor from the Committee

1       that this may reflect a disparity-sensitive  
2       issue?  And it is okay to say no.  But if you  
3       know of any disparities that might be around  
4       this measure, we would like to understand  
5       that.

6                   CO-CHAIR KNOWLTON:  Gail, are you  
7       waiting to speak?

8                   MEMBER COONEY:  No.

9                   CO-CHAIR KNOWLTON:  But A.M. is.

10                  MEMBER BARRETT:  I think that  
11       there are a number of studies showing that  
12       people from minority and racial backgrounds,  
13       cultural and racial minority backgrounds, are  
14       managed differently with dementia and perhaps  
15       with less quality.

16                  MS. JOHNSON:  Okay.  And do we  
17       have any idea at all about in terms of  
18       antipsychotic use?  It is okay to say no.

19                               (No response.)

20                               Okay.  Thank you.

21                  CO-CHAIR KNOWLTON:  Okay.

22                  MEMBER BUHR:  I think in the stuff

1 they submitted there was something about some  
2 nursing homes have a much higher rate of  
3 antipsychotic use than others, and that  
4 suggests there is some kind of a disparity,  
5 but it is not understood as to why, or  
6 whatever.

7 MS. JOHNSON: And again, just a  
8 reminder, disparities, even if overall  
9 performance was great or in this case really,  
10 really low, if it turned out that there were  
11 disparities kinds of things, like you were  
12 saying that some nursing homes maybe are not  
13 performing so well, that would be another  
14 indication to you that there is room for  
15 improvement.

16 CO-CHAIR KNOWLTON: Peter?

17 MEMBER SCHMIDT: So, in  
18 performance gap, we are talking performance  
19 gap versus the measure or performance gap  
20 versus the evidence? So, for example, does  
21 John have a performance gap versus the measure  
22 or a performance gap versus the evidence?

1 MS. JOHNSON: We would be looking  
2 at for the measure. So, in this case, they  
3 have told us that the rate of antipsychotic  
4 use is between 14 and 16 percent.

5 What would be even more  
6 interesting would be knowing what the  
7 distribution of that would be to see, is it  
8 kind of fairly low, fairly uniform or really  
9 different? So, what we really want to see  
10 here is statistics about the measure itself.

11 CO-CHAIR KNOWLTON: Anybody else?

12 (No response.)

13 Okay, Suzanne.

14 (Vote taken.)

15 MS. THEBERGE: We still need two  
16 more.

17 All right. Eleven high, 11  
18 moderate, 1 insufficient.

19 CO-CHAIR KNOWLTON: Okay. We are  
20 on to acceptability, scientific acceptability.

21 Gwen?

22 MEMBER BUHR: So, is this where

1 reliability -- okay, all right. I got it.  
2 Shall I talk about reliability separately?

3 MS. JOHNSON: Yes.

4 MEMBER BUHR: Okay. So,  
5 reliability, we thought that the measure was  
6 specified in a way that you could reliably  
7 measure the same people every time. That  
8 would be reliability. So, we didn't have  
9 concerns about reliability.

10 We did have some concerns about  
11 validity, but I shouldn't talk about that  
12 right now, right?

13 MS. JOHNSON: We will vote  
14 separately on reliability and validity. But  
15 this is where we would talk about precise  
16 specifications.

17 So, Peter's question about  
18 Parkinson's patients being included in the  
19 specifications would probably come up right  
20 about now. So, maybe we might want Peter to  
21 go ahead and just ask that again.

22 CO-CHAIR KNOWLTON: Go ahead,

1 Peter.

2 MEMBER SCHMIDT: I have a question  
3 about the reliability of the specification.  
4 And there are RCTs on antipsychotic in  
5 Parkinson's disease. You know, there is  
6 plenty of evidence.

7 I was interested to note that  
8 there is one study cited in the evidence  
9 section about Parkinson's disease, and it is  
10 about the correlation between antipsychotic  
11 use and hip fracture, which is common in  
12 Parkinson's disease anyway. But I am sure  
13 that there is a higher prevalence of hip  
14 fracture in people taking antipsychotics. I  
15 don't doubt that.

16 But that should not be imputed to  
17 indicate that antipsychotics are  
18 contraindicated in Parkinson's disease, which  
19 I think is having that be the only evidence  
20 around Parkinson's disease included in the  
21 study, is the implication, and I don't agree  
22 with that.



1                   MEMBER DUDA:  Yes, I mean, I think  
2                   that that should be a consensus statement that  
3                   is not difficult to reach consensus on.  We  
4                   obviously use antipsychotics to a great deal  
5                   in patients with Parkinson's disease.

6                   But I think it gets back to what  
7                   Jordan was saying.  If there were some way to  
8                   identify the patients who had psychosis,  
9                   instead of just agitation or whatever, you  
10                  know, something else that is less indicated,  
11                  then we could get around this.  But, like I  
12                  said, I am not sure that it is acceptable to  
13                  expect every patient with Parkinson's disease  
14                  who is put on Seroquel to have a separate code  
15                  for psychosis, NOS, or related to a separate  
16                  condition, you know.

17                  MEMBER KAPLITT:  In Huntington's  
18                  we do, though.

19                  MEMBER DUDA:  Yes, but that, I  
20                  think, is because we recognize that we don't  
21                  use it for psychosis in that case, right?  We  
22                  use it for chorea.  So, that is a different

1 reason.

2 MEMBER BUHR: So, this is a  
3 question -- maybe you guys who do Parkinson's  
4 know the answer -- but when patients have  
5 dementia from Parkinson's or Lewy body  
6 dementia, were they excluded from the trials  
7 of people with dementia and behaviors that are  
8 -- and so, there is not evidence that patients  
9 with Parkinson's disease who have dementia and  
10 take antipsychotics are at increased risk of  
11 mortality? Is there not evidence there? And  
12 so, we would want to limit or try not to use  
13 antipsychotics in patients with dementia in  
14 Parkinson's or not?

15 MEMBER DUDA: Yes. So, with the  
16 potential conflict that I have worked with the  
17 Lewy Body Dementia Association, who has  
18 advocated strongly in this matter for patients  
19 with Lewy body dementia, when these results  
20 came out, there was a big backlash thing.  
21 Yes, maybe there is increased mortality, but,  
22 obviously, the benefits outweigh the risks in

1 most of these patients.

2 As far as whether or not they were  
3 included in these studies, obviously, there  
4 were some patients with Parkinson's disease  
5 dementia because you can't clinically separate  
6 out Alzheimer's disease and Parkinson's  
7 disease with 100-percent certainty and  
8 specificity.

9 I don't know, I am not aware of  
10 any studies that specifically looked at  
11 patients with Parkinson's disease with  
12 neuroleptics and looked at mortality. I think  
13 there were some small studies in dementia with  
14 Lewy bodies, but they weren't as big as the  
15 ones in Alzheimer's, obviously.

16 CO-CHAIR KNOWLTON: Risha?

17 MEMBER GIDWANI: I had a question  
18 about the measure specifications. So, the  
19 patients, they looked at folks that had  
20 diagnosis codes for dementia and medication  
21 markers for dementia, and they saw that there  
22 were more patients identified when you have

1 both the diagnosis code for dementia and a  
2 drug marker for dementia. Therefore, one  
3 should be using both of these things to  
4 identify dementia patients. And that just  
5 doesn't sit properly with me.

6           If we are looking just at higher  
7 numbers of patients that we get from using  
8 both of these different ways of capturing  
9 them, we also have to look against their  
10 charts or some other gold standard to say,  
11 yes, these are the appropriate patients. Just  
12 we got more patients when we looked at a drug  
13 marker for dementia doesn't mean that that is  
14 the right way to capture those patients. That  
15 rests on the assumption that all of the  
16 medication use that is prescribed for dementia  
17 is appropriate, and I am wondering if there is  
18 any overprescribing of the dementia-related  
19 medications. And if that is the case, then do  
20 we need to be capturing more patients that we  
21 would be erroneously considering appropriate  
22 for inclusion in this measure?

1 CO-CHAIR KNOWLTON: Gail?

2 MEMBER COONEY: I think they  
3 addressed that somewhere in the data, that  
4 they actually looked at the underdiagnosis of  
5 dementia and using the prescribing of the  
6 cholinergics for that, cholinesterase  
7 inhibitors, whatever.

8 I also had a question because the  
9 ICD-9 codes that they include for dementia is  
10 much shorter than the ICD-9 codes used for the  
11 other dementia measures we are looking at. I  
12 don't know all my ICD-9 codes well enough to  
13 know why some are in and some aren't, but I  
14 had a question about that, too.

15 CO-CHAIR KNOWLTON: Michael?

16 MEMBER KAPLITT: So, I just think,  
17 to this point of Parkinson's disease or,  
18 frankly, anything else that could be excluded,  
19 you know, John's point is correct, which is  
20 that the reason that those specific things are  
21 being excluded is not because of the fact that  
22 psychosis doesn't matter in those diseases,

1 because the drugs are being used for a  
2 different reason.

3 I would argue with Parkinson's  
4 disease and other things -- and the other  
5 thing is that these measures are not just  
6 meant for experts, right? They are meant for  
7 the vast majority of general neurologists and  
8 internists and others who are treating the  
9 majority of these patients and probably using  
10 the majority of these medicines in these  
11 patients.

12 And so, I think the point here is  
13 that, if part of the consequence of this is it  
14 forces people to have to put in a psychosis  
15 code, if that is the rationale for giving that  
16 patient the antipsychotic, right -- if someone  
17 has Parkinson's and they believe that they  
18 have psychosis, I don't see the problem with  
19 forcing them to sort of put in a psychosis  
20 code and justify it, and maybe have to think  
21 about it for a second.

22 I mean, I understand all the

1       nuances of the issue, but, really, from the  
2       general standpoint I think, unless we can make  
3       an argument that there is something different  
4       about those patients that makes them a  
5       separate breed -- I see a lot of patients with  
6       Parkinson's disease who come from the general  
7       community, and a lot of them are on medicines  
8       that have not really been well-thought-out.  
9       So, I don't think it would be such a bad thing  
10      to require, and then that would meet the  
11      criteria here.

12                   MEMBER SCHMIDT:  So, I am actually  
13      going to kind of reverse myself.  I agree with  
14      the last comment.  There only are two  
15      antipsychotics that are generally considered  
16      safe for people with Parkinson's disease, and  
17      those aren't the ones that people with  
18      Parkinson's disease mostly get in a community  
19      setting.

20                   Often -- I mean, John can tell me  
21      whether I am right about this -- but, often,  
22      psychosis can be managed by optimizing

1 existing medications and not adding on an  
2 additional one. And so, it probably is a good  
3 idea to have a general rule that  
4 antipsychotics should not be a "go-to" drug.  
5 You know, Haldol is terrible for people with  
6 Parkinson's disease and it is quite commonly  
7 prescribed by non-experts.

8 MEMBER DUDA: So, I guess I have a  
9 question to start out with. I mean, I was  
10 kind of thinking the same things that Mike was  
11 thinking. But is the purpose -- again, I am  
12 not quite sure what we are doing here -- is  
13 the purpose of this measure to guide future  
14 behavior of clinicians or to evaluate prior --  
15 so, if we are using this, if we are saying,  
16 "Okay, Insurance Company, go out and use this  
17 to evaluate prior behavior," well, then it is  
18 not fair to expect those people to do things  
19 that we only are saying that they should be  
20 doing from this point forward.

21 CO-CHAIR KNOWLTON: Remember this  
22 is a health plan measure.



1                   MEMBER DUDA: Right, that is what  
2 I am thinking. This is not a kind of  
3 individual practitioner measure. So, I think  
4 it is tricky to do that.

5                   Not to muddy the waters any more,  
6 but he is right, there are problems with the  
7 prescribing of antipsychotics in Parkinson's  
8 disease that are systemic, and there are  
9 efforts to try to improve awareness than some  
10 are better than others. But there are also  
11 complications in Parkinson's disease. Some  
12 people use Clozapine for dyskinesia. It is a  
13 completely separate indication, and it is not  
14 an inappropriate indication. It actually has  
15 been approved by some consensus panel.

16                   So, Parkinson's disease I think  
17 probably should be on that list for that  
18 reason, because you don't know if you are  
19 treating psychosis or dyskinesia, but, then,  
20 there should be some other way to pick up  
21 these other people with dementia who have  
22 psychosis.

1 CO-CHAIR KNOWLTON: I want to go  
2 back to Gail's question real quickly. Gail  
3 asked why was the list of dementia ICD-9 codes  
4 quite a bit shorter than some of our other  
5 measures. And we are not asking you to have  
6 necessarily the same list, but it does beg the  
7 question of why did you use these particular  
8 codes and not others.

9 So, maybe one of the developers,  
10 Dr. Nau, or the folks in the room, would care  
11 to answer that.

12 DR. NAU: Well, I have not looked  
13 at the other measures' list of ICD-9 codes.  
14 So, I can't speak specifically as to why they  
15 included certain diagnosis codes.

16 We did work with quite a few  
17 different experts, and we also looked at the  
18 studies, the epidemiological studies that have  
19 studied this issue of antipsychotic use in  
20 patients with dementia and tried to be  
21 judicious in what ICD-9s we included. And so,  
22 there is a lot of work back and forth and

1 refinement of our list, but I guess we would  
2 have to talk to the other measure developers  
3 about why they chose their lists the way they  
4 did.

5 MS. JOHNSON: Okay. So, just to  
6 rephrase, you had some experts weigh-in on the  
7 ones that you thought should be used, and you  
8 are pretty comfortable with that, at least for  
9 now? Talking about comparisons of lists would  
10 be something we could potentially do later,  
11 but I think it was just a question that came  
12 up.

13 CO-CHAIR KNOWLTON: Daniel?

14 MEMBER LABOVITZ: Yes, I wanted to  
15 just go back to your original point that this  
16 is, ultimately, an incredibly squishy measure.  
17 There is no way to know, even in a population,  
18 whether the use of the drug is appropriate or  
19 not. So, one healthcare plan might have a  
20 very high rate and it would all be perfect,  
21 and another healthcare plan might have a very  
22 low rate and have it be inappropriate.

1           That said, I can say from my own  
2           observation I think the general perception is  
3           that these medications are way overused. They  
4           are used for sleep. They are used for being  
5           mean. They are used for just keeping people  
6           quiet.

7           And I think, in the end, this is  
8           not dinging an individual provider. This is  
9           not Medicare coming after you and saying,  
10          "We're taking away 2 percent." This is really  
11          a chance to look at healthcare organizations  
12          in a broad swathe and say, "How are you doing  
13          with these drugs?"

14          That makes me much less inclined  
15          to turn the thumbscrews on issues that aren't  
16          -- for lack of precision. I think, in fact,  
17          the developers were thoughtful in making this  
18          imprecise.

19                 MEMBER R. BAUTISTA: My concern  
20                 why I think this might not be a reliable  
21                 measure, though, is because, although it is  
22                 not that hard to do the math and look at all

1 your CPT codes and ICD-9 codes and do the math  
2 and look, I am concerned about the fact that  
3 we may not even be correctly coding these  
4 things. In other words, we are not just  
5 measuring psychosis; we are measuring  
6 schizophrenia. We are not just measuring a  
7 sad person; we are measuring bipolar disease.  
8 These are four criteria, and I even doubt that  
9 the actual data that you actually put in, if  
10 you are not a psychiatrist, would be correct.

11 CO-CHAIR KNOWLTON: Gail?

12 MEMBER COONEY: I agree with  
13 Daniel that I think this measure is important,  
14 outweighs the concerns that are being raised.  
15 And also, I like its lack of specificity. I  
16 like the fact that it doesn't allow a lot of  
17 exclusions.

18 Even the narrowness of the  
19 diagnoses for bipolar and schizophrenia is  
20 useful because those things get tossed around  
21 without ever being correctly analyzed. So, I  
22 think it is important that we use those

1 diagnosis codes to exclude them, to make sure  
2 that we are not including people whose  
3 diagnosis was made randomly.

4 MEMBER R. BAUTISTA: The current  
5 way it is coded, though, here, if you were  
6 actually a non-psychiatrist coding the  
7 diagnosis, I would probably doubt that your  
8 diagnosis was correct in the first place. So,  
9 if you are using that as your current evidence  
10 for showing how great this measure is, how  
11 reliable might be, that in itself is a very  
12 invalid conclusion.

13 MEMBER SUDO: So, I think a lot of  
14 what we are talking about is validity, whether  
15 we are choosing the right population. That is  
16 validity.

17 So, the reliability is, can we  
18 every time get the same set of people? So,  
19 that is one point I wanted to make.

20 And the next thing is I am not  
21 sure we want to exclude psychoses because, I  
22 mean, it may be that Parkinson's disease is a

1 special thing, but psychosis, where you may  
2 prescribe an antipsychotic and in that sense  
3 it is appropriate, but the people who have  
4 psychoses and dementia and get an  
5 antipsychotic have higher mortality. So, we  
6 are trying, even though they have psychoses,  
7 to use other measures before the  
8 antipsychotic. And so, I don't think it would  
9 be right to exclude psychoses.

10 MEMBER VAN DE KAMP: I think  
11 Michael made a really good point earlier. I  
12 think it is sometimes easy to lose it in the  
13 group of such experts. There is a lot of,  
14 living in the nursing centers as much as I do  
15 and seeing the high usage, it is really a  
16 measure that just makes an awareness and I  
17 think has an opportunity to improve the  
18 quality of care for the general practitioner.

19 And that is, I would think, one of  
20 the goals of this. It isn't for the experts  
21 who really have the subtlety and the  
22 assessment skills. It is really for that very

1 often primary care physician who is just  
2 requested by the nursing center for behavior  
3 issues without really looking at all the  
4 pieces. So, I think it has a significant  
5 value and practical application within the  
6 healthcare environment.

7 MEMBER SCHMIDT: So, my question,  
8 I have a philosophical question, and that is,  
9 are we comfortable with a measure that would  
10 mark down the experts, where the true experts  
11 would get a lower score on this or a worse  
12 score?

13 Harvard Pilgrim has got a lot of  
14 experts in it. There are a lot of these  
15 centers -- there are a lot of health plans  
16 that have systematic referrals to expert care.  
17 We have seen this in -- you see this in health  
18 plans. There are some health plans that are  
19 based around academic medical centers or  
20 conglomerations of academic medical centers.

21 MS. JOHNSON: And just a reminder,  
22 this is not specified for clinicians. So,



1 this is specified for the pharmacy benefit  
2 plans. I think that would kind of get to your  
3 question, Peter.

4 MEMBER BUHR: I don't know that we  
5 can know whether the expert, like the Harvard  
6 plan would be worse or not, because maybe they  
7 have more resources. Maybe they will refer  
8 people for the different non-pharmacologic  
9 things. Maybe they have support groups.  
10 Maybe they have lots of educators to educate  
11 the families and the caregivers, because that  
12 is really where the evidence lies, in that the  
13 best treatments are educating caregivers about  
14 how to deal with these people. So, maybe  
15 Harvard has more resources in that way than  
16 another plan. I don't know that we would know  
17 that.

18 MS. KUHLE: I don't know if I can  
19 jump in real quick, but there is an old adage  
20 -- I'm sure you have all heard it -- that what  
21 isn't measured doesn't improve. And that was  
22 really the point of this measure, was to draw

1 attention to it.

2 Remember, these are all ambulatory  
3 patients, not necessarily just in nursing  
4 homes. They are a lot of dementia patients  
5 that are living at home, treated by family  
6 practice physicians.

7 Hoping that we can have an impact  
8 to improve performance is the whole goal of  
9 this measure.

10 MEMBER KAPLITT: I just want to  
11 clarify a point you made earlier when you were  
12 saying about maybe we shouldn't be excluding  
13 psychosis. So, then, I just want to make sure  
14 I understand. The suggestion would then be  
15 that the measure just be all patients who are  
16 on antipsychotics with dementia, period?

17 MEMBER BUHR: Yes.

18 MEMBER KAPLITT: I just want to  
19 make sure I understood what you were saying.

20 MEMBER BUHR: I mean, I didn't  
21 mean to not exclude the things that are  
22 already excluded, but those are very specific

1 diagnoses, Tourette's and Huntington's, and  
2 whatever. And they are not excluding people  
3 with dementia who have psychoses. They are  
4 not excluding that currently.

5 I was saying we were having some  
6 discussion about whether it should be, and I  
7 don't think that it should be because people  
8 with psychosis and dementia, while you may  
9 have to prescribe an antipsychotic to treat  
10 it, you try to treat it in lots of other ways.  
11 Those are the people with increased mortality.

12 MEMBER KAPLITT: But, I mean, I  
13 just think the concern there is that that is  
14 an indication for antipsychotic drugs, if they  
15 have a defined diagnosis of psychosis, and I  
16 think that is kind of a slippery slope at that  
17 point, because then you are basically saying  
18 to people -- I mean, I agree with you that you  
19 should try not to use them under certain  
20 circumstances, but now we are getting into a  
21 level of micromanagement that would concern  
22 me, because now you are saying plans are going

1 to have a problem if they prescribe an  
2 antipsychotic for a patient with psychosis  
3 because it is possible they didn't try enough  
4 other things first. I mean, that would  
5 concern me because that is an approved,  
6 appropriate indication for those drugs.

7 CO-CHAIR KNOWLTON: Let me ask if  
8 we can vote on reliability, get that out of  
9 the way, so that we are not here on Sunday.

10 So, let's put up the reliability  
11 vote, and please vote.

12 (Vote taken.)

13 MS. THEBERGE: Seven high, 12  
14 moderate, 2 low, 2 insufficient.

15 CO-CHAIR KNOWLTON: So, this  
16 passes on reliability.

17 Validity, we have had that  
18 discussion.

19 John, I didn't mean to cut you off  
20 if you had another point.

21 Have we had enough discussion on  
22 validity? Okay, let's go to a vote.

1 MS. JOHNSON: Just real quick, is  
2 there any more discussion about risk  
3 adjustment or stratification?

4 DR. BURSTIN: And particularly of  
5 David Nau wants to respond to that because we  
6 never let him respond.

7 MS. JOHNSON: Oh, that's right.

8 Dr. Nau, this kind of goes back to  
9 one of the first things that we talked about  
10 with your measure. Did you have anything you  
11 wanted to add in terms of staging of dementia  
12 and stratification of the health plans?  
13 Stratification of health plans, yes.

14 (No response.)

15 MEMBER BUHR: So, could I make a  
16 comment about validity, because I did not make  
17 my validity comments earlier?

18 CO-CHAIR KNOWLTON: Sure.

19 MEMBER BUHR: Okay. So, in  
20 response to whatever Risha was saying about --  
21 we did have a lot of discussion in our Work  
22 Group about the validity, because they are

1 measuring it by a diagnosis of dementia, and  
2 we know that dementia is way underdiagnosed.  
3 And they are measuring it by use of these  
4 medications, which we know that they are used  
5 sometimes inappropriately.

6 So, I have seen patients on these  
7 medications who don't have any signs or  
8 symptoms of dementia. In the stuff the  
9 developer presented to us, they say that they  
10 are used for traumatic brain injury, and  
11 Memantine is used for another indication. But  
12 they say that it is used rarely for those  
13 reasons. I don't know that we really know how  
14 rare it is.

15 By the way that they have told us  
16 that they have gathered their patients, they  
17 got prevalences of 5.3 and 7.2 percent. So,  
18 that is a much lower prevalence of dementia  
19 than is really thought to be the prevalence of  
20 dementia.

21 So, I think that, from our Work  
22 Group calls, our main concern of this measure

1 is, are we really gathering the patients with  
2 dementia with the way that they have specified  
3 it, knowing that that is the only way that  
4 they can specify it because it is claims data  
5 and pharmacy data, and whatever? We are not  
6 going to go and interview the patients and  
7 find the undiagnosed people, but that was our  
8 main concern.

9 CO-CHAIR KNOWLTON: Anybody else?

10 Yes, go ahead, Jordan.

11 MEMBER EISENSTOCK: Just to sort  
12 of follow through with that, because that was  
13 one of my concerns in the Work Group call  
14 also. And I am going to try to be very  
15 diplomatic here because I like the intent of  
16 the measure, but I have big problems with both  
17 the numerator and the denominator in this  
18 measure.

19 And I just wanted to sort of put  
20 that out there because I do agree with what  
21 Gwen said. I think that it depends on how  
22 comfortable we are with the error that we know

1 is built in on both sides. Both the numerator  
2 and the denominator we know are not very  
3 perfect, and if we are okay with that is  
4 really what it comes down to with validity.

5 CO-CHAIR KNOWLTON: Any other  
6 comments?

7 (No response.)

8 I have one. I am concerned, as you  
9 are -- I am not the expert here; I am not the  
10 clinician here -- but, as was said earlier, if  
11 you don't measure it, the way I always said it  
12 was the only way to change something is to  
13 keep score. But you have to keep score in a  
14 way that people understand and is fair or  
15 people don't pay attention to the score. They  
16 say it doesn't matter; I can define it any way  
17 I want.

18 And that was my problem with this  
19 measure. I think that it can be really  
20 defined. It is squishy.

21 And I think I agree that we should  
22 have aspirational goals, but when they become



1 measures, we are asking people to be measured  
2 according to it, and I think that makes it  
3 difficult, from where I sit, more on the  
4 outside looking into this. But that is just  
5 my opinion.

6 Do we have any other stuff on  
7 validity?

8 Risha, I'm sorry, I didn't see it.  
9 Go ahead.

10 MEMBER GIDWANI: Just a brief  
11 comment. Yes, I have the same concerns about  
12 the sensitivity and the specificity of these  
13 codes and prescriptions to be able to capture  
14 this population.

15 Just from a measurement  
16 standpoint, this could be actually addressed  
17 by doing a chart review and getting a few  
18 hundred charts of patients that have a  
19 diagnosis of dementia and seeing what their  
20 codes were and their prescription claims, and  
21 then 200 patients that just have no diagnosis  
22 of dementia and seeing how many of them

1 actually really do have dementia that wasn't  
2 coded as such. So, there is actually a way to  
3 test the sensitivity and the specificity, but  
4 that wasn't done here.

5 CO-CHAIR KNOWLTON: Gwen?

6 MEMBER BUHR: I mean, one problem  
7 with looking for people in a chart review that  
8 don't have a diagnosis of dementia is, unless  
9 you specifically test them with different  
10 tests of dementia, you are not going to find  
11 the dementia, because there are lots of people  
12 who have dementia, but their doctor isn't  
13 really looking for it and he is just treating  
14 their hypertension, and whatever, and not  
15 asking them any memory questions, not asking  
16 them to draw a clock, or any test of dementia,  
17 and not uncovering the dementia. So, I don't  
18 know that you are going to fund the  
19 undiagnosed dementia population with a chart  
20 review.

21 MEMBER COONEY: The question about  
22 the ICD-9 codes are part of the denominator.

1 How does that enter into what I think about  
2 this measure? If I think they need to go back  
3 and standardize the ICD-9 codes, how does that  
4 affect my vote here?

5 MS. KUHLE: Can we say that we  
6 will do that? As a measure developer, we will  
7 work with the other measure developers to make  
8 sure that our codes are standard?

9 DR. BURSTIN: To me, it is a  
10 harmonization issue that we would address,  
11 depending on the dementia measures left  
12 standing, yes.

13 CO-CHAIR KNOWLTON: Risha?

14 MEMBER GIDWANI: Gwen, you make a  
15 good point. I think it would be hard to look  
16 at the correlation between patients that  
17 actually have dementia and it being documented  
18 in their chart.

19 What I am talking about is just  
20 the documentation of dementia in the chart  
21 versus the correlation with the ICD-9 billing  
22 codes. I have done some work in actually

1 looking at the correlation between what is  
2 written in clinical documentation and what the  
3 ICD-9 codes can capture, because the folks who  
4 are doing the actual billing operate within a  
5 very narrow purview and they can't interpret  
6 the clinical documentation. That is the  
7 component that I was really talking about.

8 CO-CHAIR KNOWLTON: Anybody else?

9 (No response.)

10 Okay, let's vote.

11 This is no validity.

12 (Vote taken.)

13 MS. THEBERGE: One high, 9  
14 moderate, 12 low, 1 insufficient.

15 CO-CHAIR KNOWLTON: It did not  
16 pass on validity. Does that mean we stop  
17 here? We stop here. Okay. It has to pass on  
18 validity.

19 (Whereupon, the above-entitled  
20 matter went off the record at 10:55 a.m. and  
21 resumed at 11:16 a.m.)

22 CO-CHAIR KNOWLTON: Are we back?

1       Okay, we are moving on to the next measure,  
2       which is 2091, persistent indicators of  
3       dementia with other diagnoses, and it is  
4       Jocelyn, right? No.

5                   MEMBER SUKO: No, Jolynn.

6                   CO-CHAIR KNOWLTON: Jolynn, I'm  
7       sorry.

8                   MEMBER SUKO: Thank you.

9                   CO-CHAIR KNOWLTON: That's what I  
10      say when I can't read them.

11                   (Laughter.)

12                   Go ahead. Got it. Thanks,  
13      Jolynn. Sorry.

14                   MEMBER SUKO: So, this is similar  
15      to the next measure, sponsored by the American  
16      Medical Directors Association. We heard a  
17      little bit about this this morning in our  
18      introduction.

19                   This is the percentage of the  
20      nursing home residents age 65 with persistent  
21      indicators of dementia and no diagnosis of  
22      dementia on any MDS assessment over the total

1 of all long-stay residents in the nursing  
2 facility who have at least two MDS assessments  
3 during the year.

4 This is a process measure. It is  
5 available on electronic clinical data.

6 In terms of importance to measure  
7 and report, as Work Group discussed and as we  
8 discussed in our previous measure, dementia is  
9 very much underdiagnosed, and prior to  
10 diagnosis it increases healthcare costs. So,  
11 the Work Group really saw this as important  
12 with great potential.

13 In terms of impact, high and  
14 moderate were the ratings.

15 Let me just look here. In terms  
16 of performance gap, we have discussed the  
17 performance gap, particularly in the community  
18 settings. Again, the Work Group felt like  
19 this was pretty significant.

20 Evidence, this is probably the  
21 meat of the discussion and the measure  
22 developer has commented post-Work-Group call

1 this. There are no randomized controlled  
2 trials in the long-term care setting.  
3 However, there is evidence that the failure to  
4 diagnose causes increased healthcare costs.  
5 There is evidence that not having a diagnosis  
6 of dementia leads to management that is not as  
7 effective. The linkage to say that having a  
8 diagnosis leads to effective interventions is  
9 not as much there.

10 So, I don't know, David, if we  
11 should stop there for comments, discussion.

12 CO-CHAIR KNOWLTON: Discussion on  
13 that point? Any other points? This would be  
14 under evidence, right? Importance, of which  
15 evidence is important.

16 Gail?

17 MEMBER COONEY: The biggest thing  
18 that I couldn't find in this was the linkage  
19 between making the diagnosis and decreasing  
20 healthcare costs, which seemed to be one of  
21 their mainstays for why this is important.

22 CO-CHAIR KNOWLTON: Anybody else?

1 (No response.)

2 Okay. Does the developer want to  
3 respond here?

4 MS. VANCE: We feel that is there.  
5 There is some evidence in the Singer article  
6 as well as evidence in the U.S. Preventive  
7 Services Task Force, their systematic evidence  
8 review, that shows that at least in the  
9 community, again, there are no randomized  
10 controlled trials in the nursing home setting.  
11 There is the study by Singer that does show  
12 that it leads to excessive healthcare costs  
13 due to inappropriate care when the diagnosis  
14 has not been made. So, we do feel that we  
15 have provided that evidence.

16 CO-CHAIR KNOWLTON: Anybody else  
17 on this?

18 (No response.)

19 Okay. We can vote on it. Voting  
20 on evidence.

21 (Vote taken.)

22 I can't ready the number. Are you



1 still missing some? Missing one?

2 MS. THEBERGE: We need one more.

3 All right. Fourteen yes; 8, no,  
4 evidence does not meet guidance, and 1, no,  
5 insufficient.

6 CO-CHAIR KNOWLTON: Okay. Going  
7 on to impact, please. But we are not voting  
8 yet. You present the impact.

9 MEMBER SUKO: Oh, in terms of  
10 impact, the subgroup felt that this had high  
11 impact with underdiagnosis of dementia in the  
12 community setting, as we discussed in our  
13 previous measure.

14 CO-CHAIR KNOWLTON: Comments at  
15 all?

16 Gail, you have got a comment on  
17 it?

18 MEMBER COONEY: No.

19 CO-CHAIR KNOWLTON: Okay, let's  
20 vote.

21 (Vote taken.)

22 MS. THEBERGE: We are at 19, 22.

1 We need one more vote.

2 All right. Fourteen high, 9  
3 moderate.

4 CO-CHAIR KNOWLTON: Okay. We move  
5 on to opportunity for improvement.

6 MEMBER SUKO: And on this, yes,  
7 the subgroup that there was significant  
8 opportunities for improvement in this  
9 diagnosis of dementia.

10 CO-CHAIR KNOWLTON: Comments?

11 (No response.)

12 Okay.

13 (Vote taken.)

14 MS. THEBERGE: Twenty-two  
15 responses.

16 All right. Eighteen high, 5  
17 moderate.

18 CO-CHAIR KNOWLTON: Okay.  
19 Reliability?

20 MEMBER SUKO: So, this measure, it  
21 is completely claims-based electronic with  
22 precise specifications.

1 CO-CHAIR KNOWLTON: Anybody on the  
2 issue?

3 (No response.)

4 Okay, on reliability.

5 (Vote taken.)

6 MS. THEBERGE: We have 17  
7 responses, 20. We're at 22.

8 Nine high, 12 moderate, 1 low, 1  
9 insufficient.

10 CO-CHAIR KNOWLTON: Validity?

11 MEMBER SUKO: Face validity was  
12 seen as being fairly high. It is hard to  
13 manage what you haven't assessed.

14 CO-CHAIR KNOWLTON: Any comments  
15 on validity? Okay.

16 MEMBER J. BAUTISTA: I have a  
17 question.

18 CO-CHAIR KNOWLTON: Yes, Jocelyn.

19 MEMBER J. BAUTISTA: I think I  
20 read that the specificity of the MDS is about  
21 90 percent, I think I read. So, how do we  
22 account for the other 10 percent. So, this

1 would be 10 percent of patients who score on  
2 this MDS, but really aren't the patients that  
3 we want to capture. So, how do we account for  
4 that?

5 CO-CHAIR KNOWLTON: It is hard to  
6 hear, Jocelyn. Just say it again into the  
7 microphone.

8 MEMBER J. BAUTISTA: All right.  
9 So, the MDS has a sensitivity of 90 percent,  
10 according to the measure submission. So,  
11 there is some 10 percent of patients who will  
12 score on this MDS, but who should not have a  
13 diagnosis of dementia recorded on the chart.  
14 I mean, that is sort of just my simplistic  
15 interpretation of that. All right. So, how  
16 do we account --

17 MS. VANCE: I think I can answer  
18 that. The purpose of this, the MDS, to  
19 explain that a little bit better, it will  
20 score something. It is a level of impairment,  
21 but it does not give you a diagnosis.

22 So, the purpose of that is to

1 bring in a physician that would come in and  
2 then they would say, okay, why is this scoring  
3 a level of impairment? So, then, the  
4 physician would come in and they would do  
5 basically differential diagnosis. They would  
6 rule out delirium, because you know that is  
7 that 10 percent. So, they might have  
8 delirium. They might have an infection. They  
9 might have some other causes, medical causes,  
10 severe depression, something that could lead  
11 to that type of scoring.

12 And then, let's say that they do  
13 rule out those other issues or they find that  
14 they have those other issues, then that will  
15 lead to either with them following DMS-IV  
16 criteria to a diagnosis of dementia or not.  
17 At that point, then once the diagnosis of  
18 dementia would be within the medical record,  
19 at that next MDS --

20 MEMBER J. BAUTISTA: You are  
21 basically saying the exclusions account for  
22 that remaining 10 percent?

1 MS. VANCE: Yes, because there  
2 could be medical causes for that scoring.

3 CO-CHAIR KNOWLTON: Ramon?

4 MEMBER R. BAUTISTA: Just for my  
5 education here, how hard is it to give the  
6 MDS? Do you need a doctor to do that? Can a  
7 nurse do that? And how is it compared to the  
8 Mini-Mental Status Exam?

9 MS. VANCE: A nurse does it, and  
10 it is really not that difficult. It is a  
11 level of questions that are asked. And then,  
12 how the response is, the response is scored  
13 and then it is calculated electronically. So,  
14 the nurse doesn't have to do like the math.  
15 So, it is relatively easy to do, and then the  
16 Kappa rating for that is pretty good.

17 MS. TEIGLAND: I would just say  
18 that the nurses are given extensive training  
19 on scoring this MDS. It is a science, and  
20 there are training classes they take on almost  
21 a quarterly basis to make sure that they are  
22 scoring it consistently and accurately. And

1 it just underwent a three-year validation  
2 study that was directed by the VA system and  
3 RAND corporation. And so, we are really  
4 confident that it is a good tool.

5 The BIMS tool is a validated  
6 assessment tool that has been validated  
7 against other tools like the MMSE. And so, we  
8 are confident that that scoring tool is good.

9 What you will also see in our  
10 measure is that we all want the patient, the  
11 resident, to be able to respond. That is how  
12 the BIMS is scored. But in cases where  
13 patients are too cognitively impaired to  
14 actually complete that interview, the nurse,  
15 then, does the assessment. So, there are two  
16 ways that you can actually be scored for  
17 severe cognitive impairment from the  
18 resident's perspective as well as from the  
19 nursing staff, if the resident can't respond.  
20 So, we think we have that covered pretty well.

21 CO-CHAIR KNOWLTON: Ramon?

22 MEMBER R. BAUTISTA: We are going

1 to require nursing home nurses to take the  
2 formal training for this and the  
3 recertification every "X" number of times. Is  
4 that what this measure is going to imply then?

5 MS. VANCE: No, they are not  
6 certified. It is not that difficult of an  
7 instrument. CMS runs training courses for  
8 Nurse Assessment Coordinators. I mean, this  
9 is not given by the LPN. It is given by an RN  
10 Assessment Coordinator. Every nursing home  
11 has to have one. Or it can be given by the  
12 social worker who is also trained. And so,  
13 they don't have to get recertified, but they  
14 are trained by CMS courses to do so. And  
15 then, the Association of Nurse Assessment  
16 Coordinators, also, they do have certification  
17 courses and do teach it.

18 CO-CHAIR KNOWLTON: A.M.?

19 MEMBER BARRETT: I'm sorry, I have  
20 to face this way to get to the microphone.

21 Has the method that you are  
22 describing of interview been well-validated to



1       ensure that there are not healthcare  
2       disparities affecting people with  
3       communication disorders from deafness,  
4       language difficulties, and neurogenic  
5       communication disorders?

6                   MS. TEIGLAND:  Yes, that was all  
7       part of the validation testing for that BIMS  
8       tool because, obviously, those are huge issues  
9       in nursing home patients, communication  
10      issues.  Particularly in places like New York  
11      City, where I came from, we have multiple  
12      languages, and so forth.  So, it has been  
13      validated.  They do require in cases where a  
14      language interpreter is required, and so  
15      forth, that that is provided.  So, that, yes,  
16      it is covered well with this tool.

17                   MEMBER BARRETT:  I'm sorry,  
18      deafness and neurogenic communication  
19      disorders?

20                   MS. TEIGLAND:  Yes.  Yes,  
21      absolutely.

22                   CO-CHAIR KNOWLTON:  Gwendolyn?

1                   MEMBER BUHR: So, I just wanted to  
2                   make sure everybody knew that the MDS is being  
3                   used regardless of the measure and that people  
4                   are trained for the MDS already. And so, the  
5                   measure is not going to have anything to do  
6                   with the MDS being used or not used. It is  
7                   required to be used by law.

8                   CO-CHAIR KNOWLTON: Dan?

9                   MEMBER LABOVITZ: I am a little  
10                  concerned about the notion of using this to  
11                  push for a diagnosis of dementia. Now  
12                  dementia is a degenerative disease. It means  
13                  you are declining over time. It is an  
14                  assessment that can't be performed just once.

15                  This is a measure of cognitive  
16                  impairment, but it is a measure, I think, even  
17                  though the BIMS may be very good, I think a  
18                  staff assessment for cognitive status may not  
19                  be very good. We may be picking up a lot of  
20                  patients who have static injuries, old  
21                  strokes, other things that make them perform  
22                  poorly on these things, but who are not

1 demented and where assigning a diagnosis of  
2 dementia and improving your performance on  
3 this score, on this scale, on this measure,  
4 would actually be bad practice.

5 MS. VANCE: May I address that?

6 No. 1, we look for two persistent  
7 scores on the MDS. So, that means that within  
8 90 days apart having two persistent scores.

9 Second, like I said, it is an  
10 indicator of a level of impairment, but it is  
11 not a diagnosis. The diagnosis can only  
12 happen by a validated diagnosis by a  
13 physician. Nurses are not giving a diagnosis  
14 of dementia based on this instrument.

15 So, it is requiring a physician to  
16 come in and do that medically-necessary visit  
17 and do a differential diagnosis to come to see  
18 if the patient truly does have dementia or  
19 what else might be going on that is leading to  
20 that scoring of impairment. So, that is the  
21 purpose of it. So, that a patient-centric  
22 care plan can be developed based on what the

1       scoring is.

2                   It is unfortunate. Within the  
3 MDS, when you have a certain level of scoring,  
4 let's say, on the BIMS, there is something  
5 that is triggered. It is called the Care Area  
6 Assessment, and it will trigger and we will  
7 say that there is an indicator that this  
8 person has a level of cognitive impairment.

9                   Now you are supposed to address  
10 within these Care Area Assessments and say  
11 whether you are going to a care plan on that  
12 or not. An unfortunate reality is, if the  
13 person does not have a diagnosis to go with  
14 some of that indicator, the nursing can -- and  
15 it is a sad reality, that is why CMS came up  
16 with their nursing home measures, which ours  
17 were trying to be similar to -- they can say,  
18 well, there is no diagnosis of dementia.  
19 Therefore, we are not going to create a  
20 dementia patient-centered care plan.

21                   And so, one of the major purposes  
22 of this measure is then to ensure that we are

1 raising awareness of this enough that, when a  
2 person has this scoring two MDS assessments in  
3 a row without a diagnosis of dementia, that  
4 you must get a physician in there to look at  
5 this person and see why they are scoring the  
6 way they are on this BIMS.

7 So, it is not saying we are  
8 pushing that they have a diagnosis of  
9 dementia. But if they wind up having  
10 dementia, then you want to see it and you want  
11 to see a patient-centered care plan around the  
12 dementia, the level of dementia they are in,  
13 advanced directives, appropriate care,  
14 appropriate goals for that person, and leave  
15 it that way. And if they have some type of  
16 medical issue that is leading to that scoring,  
17 you want to see that addressed.

18 MEMBER LABOVITZ: I see the point  
19 in making a diagnosis of dementia and having  
20 it done by somebody who is qualified to do it.  
21 I just wonder, though, if somebody has a  
22 static encephalopathy, they are stable. They

1 are not demented, but they are cognitively  
2 impaired. Does the doctor have to come in and  
3 say every time, "No, this patient doesn't have  
4 dementia."? When the doctor does come in and  
5 say the patient doesn't have dementia, the  
6 patient has something else, what happens? The  
7 measure still dings the providers here.

8           There is no exclusion for that.  
9 You come along and you say, no, no dementia  
10 and, boom, you get dinged next year, too. And  
11 you ask the doctor to come back. "Is there  
12 dementia?" "No. I told you last year."  
13 Well, no you have to do it again.

14           CO-CHAIR KNOWLTON: Okay.  
15 Developers?

16           MS. TEIGLAND: Yes, I was just  
17 going to say that this is another one of those  
18 measures that we don't ever expect to be zero.  
19 And it is consistent with some of the other  
20 CMS measures. One I can think of is  
21 depression without antidepressant therapy.  
22 Depression is defined by you are having some

1 symptoms of depression. You are crying. You  
2 are tearful. You are sad.

3 And it is not a definitive  
4 diagnosis of depression. These are indicators  
5 where you are going to benchmark. You are  
6 going to look at your rate compared to other  
7 nursing homes with residents like yours and  
8 say, "Gee, maybe we are underdiagnosing here."

9 And the whole point of it is that  
10 it triggers a whole different set of reactions  
11 by the nursing staff that leads to better care  
12 for these patients. And I think we have  
13 provided lots of evidence about that. It  
14 reduces falls. It reduces functional decline.  
15 It helps them better diagnose pain because  
16 that is huge. Underdiagnosed pain is a huge,  
17 huge issue in this population. It reduces  
18 hospitalizations and rehospitalizations  
19 because they send her to the hospital.

20 So, the whole plan of care is  
21 different when you properly diagnose. We  
22 fully understand that we are going to say,

1       yes, this person has two indicators of  
2       depression based on this BIMS score. They are  
3       severely cognitively impaired. The MD might  
4       come in and say, "No, they don't have  
5       dementia." But, most often, the evidence  
6       shows that they do; they will.

7               And if you look at a list, we have  
8       excluded delusions, schizophrenia, bipolar.  
9       So, we have really tried to exclude all those  
10      confounders, you know, which is really a  
11      method of risk-adjusting this measure, but it  
12      is not going to be zero.

13              MEMBER LABOVITZ: I am sorry to  
14      hold onto the table, but I see a disconnect  
15      between what we are measuring and what the  
16      intended outcome is. I completely agree that  
17      encouraging nurses and nursing homes and other  
18      providers to focus more clearly on the issues  
19      related to dementia is important. But I would  
20      suggest that what this measure really does is  
21      detect cognitive impairment, and it ought to  
22      be a cognitive impairment measure. You might



1 be severely impaired for other reasons than  
2 dementia and get no benefit from this as it is  
3 constructed. You don't get any of the stuff.  
4 This doesn't drive towards that.

5 And I see the problem, but the  
6 measure, by insisting that it lead to a  
7 dementia diagnosis, misses out on  
8 opportunities and also generates lots of extra  
9 work for people who have to be recertified  
10 constantly for not having dementia.

11 MS. TEIGLAND: I think one of the  
12 problems is that we have to work with the  
13 system that we have within long-term care.  
14 And so, with the MDS, with the BIMS, et  
15 cetera, we only have scoring for dementia.  
16 And so, our system is somewhat limited and not  
17 as exclusive as you could get in different  
18 settings.

19 And we know that dementia is a  
20 problem. We have numbers of dementia. We  
21 have been able to find evidence for numbers of  
22 dementia and Alzheimer's disease and defined

1 evidence for all types of cognitive  
2 impairment. It was also more difficult. So,  
3 we have to refine our measure to the evidence  
4 that we could get and with the systems within  
5 long-term care.

6 So, while I may agree that the  
7 perfect measure would include all cognitive  
8 impairment, it is not quite possible within  
9 the setting that we have and the limitations  
10 within our setting possibly to do that.

11 CO-CHAIR KNOWLTON: Salina?

12 MEMBER WADDY: I completely agree  
13 with Daniel. Those were actually the two  
14 points that I brought up on the work call in  
15 terms of how accurate is the diagnosis and  
16 would it be more beneficial to have something  
17 that is less specific.

18 And I completely understand the  
19 points that you are bringing up as well. And  
20 so, my major question, I guess, to Christie  
21 would be, you say you aren't going to capture  
22 100 percent, but are you closer to 99 or are

1 you closer to 10 or 50?

2 MS. TEIGLAND: I think that all we  
3 know is what the previous research has shown  
4 us and what the U.S. Preventive Task Force  
5 found, which is you anywhere from 50 to 70  
6 percent of dementia goes undiagnosed in this  
7 population. It is worse in nursing homes than  
8 where a lot of these studies have been done.

9 Let's not forget that the BIMS was  
10 just put into the most recent version of MDS,  
11 MDS 3.0, because it is a validated measure of  
12 cognitive impairment. The measure they were  
13 using before was pretty loosey-goosey. It  
14 looked at memory, short-term memory,  
15 decisionmaking ability. And so, it wasn't as  
16 precise.

17 So, I feel pretty comfortable now  
18 that this BIMS score, which has been  
19 extensively validated in every setting, is a  
20 good measure of cognitive status, but it is  
21 not a diagnosis of dementia.

22 MEMBER WADDY: Right, and that is

1 the major issue that I am having. But if you  
2 have those 50 to 70 percent that are not  
3 diagnosed, by implementing this, how much do  
4 you all anticipate possibly moving the needle?  
5 I mean, I know that you can't really answer  
6 that question until it is implemented, but  
7 that is --

8 MS. TEIGLAND: Well, that is what  
9 we want to see by implementing the measure and  
10 being able to test it. I mean, we feel that,  
11 if it is implemented and you have a physician  
12 that comes in and is going to rule out medical  
13 causes, and the evidence says that there is  
14 this huge, huge level of dementia that is  
15 going undiagnosed, that we are going to  
16 capture a lot of undiagnosed dementia.

17 And again, that is empirical. So,  
18 nobody studied this. Nobody has done it. So,  
19 I can't tell you that the evidence leads to  
20 this. I am just saying that we have the  
21 evidence that shows that you have such a large  
22 population of persons with dementia in long-

1 term care that are not being diagnosed. We  
2 know that, by looking at the data, we expect  
3 this explosion of Alzheimer's patients, and  
4 they are in our setting.

5 So, we feel that we are going to  
6 capture a great deal. But, until the measure  
7 passes and we are allowed to start testing it,  
8 I can't tell you, which is why I am glad -- I  
9 like the fact that it would be a limited  
10 measure because, if what we are trying to do  
11 doesn't work, then the measure is not worth  
12 it. But if we can test it and be able to show  
13 what we feel will happen, then we are going to  
14 have some terrific outcomes.

15 MEMBER WADDY: I can give you one  
16 example. I had a grant from the Alzheimer's  
17 Association, and it was dementia. It was  
18 based on the dementia population. And we did  
19 look at folks who scored severe cognitive  
20 impairment and whether they had a diagnosis of  
21 dementia. And so, we ended up using the  
22 severe cognitive impairment scores because we

1       only got about 40 percent of the population  
2       with a diagnosis and we added about 20 percent  
3       more when we added those severely -- and we  
4       went back to the nursing home staffs and had  
5       them validate that. They discovered those  
6       people mostly really did have dementia. So,  
7       that is a little bit anecdotal, but it was a  
8       formal grant that I had.

9                       CO-CHAIR KNOWLTON: On validity,  
10       Therese, then Mary, then John, then Michael.

11                      Therese?

12                      MEMBER RICHMOND: All right. I do  
13       share Daniel's concerns. I won't reiterate  
14       that.

15                      I would like a point of  
16       clarification. So, I realize that this is  
17       based on ICD-9 codes. You are saying only a  
18       physician can make this diagnosis. So, a  
19       nurse practitioner or nursing -- you have been  
20       saying that repeatedly. So, I would like  
21       clarification on the specificity of the  
22       provider.

1 MS. VANCE: I probably used the  
2 word "physician" because I use that  
3 generically. But in our guidelines we use the  
4 word "practitioner".

5 MEMBER RICHMOND: So, it is  
6 broader than physician?

7 MS. VANCE: But it is mostly  
8 physician -- we have practitioners as members,  
9 but we are mostly a physician-based  
10 association. So, I tend to use the word  
11 "physician," though we do have, I would have  
12 say almost 20 percent of our members are  
13 practitioners. And we use the word  
14 "practitioners" in all of our guidelines. So,  
15 a practitioner can make the diagnosis.

16 MEMBER RICHMOND: Thanks.

17 CO-CHAIR KNOWLTON: Mary?

18 MEMBER VAN DE KAMP: I was going  
19 to speak to the fact that we are limited to  
20 the MDS within the skilled nursing. I think,  
21 Daniel, I agree with you, but what this does  
22 is it really takes the lack of specificity of

1 that tools and drives it to additional  
2 assessment.

3           If you look at what we are  
4 measuring, we are measuring a process that  
5 drives more than assessment. This process  
6 drives change in patient care. So, there is  
7 a quality outcome, and it is not just  
8 physicians who are engaged when this triggers;  
9 it is the rehabilitation staff as well. So,  
10 you have speech and language pathologists and  
11 occupational therapists who are then engaged,  
12 along with the physician.

13           I think what happens maybe -- I  
14 don't know what the percentage, but we need to  
15 find out -- is how many are really with  
16 dementia and how many are cognitively impaired  
17 that would be a result from some other  
18 previous stroke, that we then can identify  
19 that, once that pool of patients is pulled  
20 together, because now the specificity isn't  
21 such that you can really determine the best  
22 plan of care for those patients.



1                   And it has been an underplanned  
2                   care, if you will, because it hasn't been to  
3                   the trigger to pull it out and have  
4                   specialists review it. So, I think what your  
5                   concerns are are all of our concerns in the  
6                   rehabilitation field, but until we can pull  
7                   them into a group that we can do more  
8                   physician, nurse practitioner, clinician,  
9                   therapist evaluation, that lump stays lumped  
10                  and doesn't really turn into the kinds of best  
11                  care that we can do.

12                  So, if I look at a process that  
13                  drives behavior, this process would do that  
14                  much more than some of the other ones we have  
15                  looked at in terms of what happens once you  
16                  pull that group together.

17                  CO-CHAIR KNOWLTON: John?

18                  MEMBER DUDA: So, while I agree  
19                  with some of Daniel's concerns, to me, they  
20                  almost seem irrelevant unless you can  
21                  demonstrate some reason to believe that this  
22                  assessment with the denominator exclusions

1 specified would systematic vary from facility  
2 to facility. I mean, no facility has zero.  
3 But unless there is some reason that some  
4 facility logically would have a lot more than  
5 another based on their patient population,  
6 then I don't think -- you know, we are looking  
7 at the exclusion rather than the rule, you  
8 know, the exception rather than the rule.  
9 Sorry.

10 CO-CHAIR KNOWLTON: Michael?

11 MEMBER KAPLITT: So, here is what  
12 I am not clear on, and maybe the developer or  
13 someone else here can clarify this for me.  
14 The denominator is patients who have had at  
15 least two -- you said this in response to one  
16 of Daniel's questions earlier -- at least two  
17 MDS assessments, correct, over a period of  
18 time?

19 So, my question is, where is the  
20 evidence to support the validity of this  
21 specific measure as it relates to the fact  
22 that what you are measuring are those patients

1 who have actually gotten MDS assessments over  
2 a period of time? So, somebody has gone to  
3 that effort. The patient has evidence of  
4 abnormality on those, and they don't carry the  
5 diagnosis. Okay?

6 So, we are not talking about  
7 capturing all these undiagnosed people who  
8 have been ignored or who are not be assessed,  
9 or whatever. The question is, where is the  
10 evidence that in that population of patients  
11 that are actually getting this assessment over  
12 periods of time and found to be abnormal, that  
13 the population that don't actually get the  
14 ICD-9 code put in properly, that that is  
15 actually going to make a difference or be  
16 valid, make a big difference in the care?  
17 That is what I am having a hard time  
18 understanding.

19 Maybe I should have raised it  
20 earlier under evidence, but since we are  
21 talking about the evidence of the validity, I  
22 think it is a reasonable time to bring it up,

1 because I am still not clear on that.

2 CO-CHAIR KNOWLTON: Hold before  
3 you answer, the developer.

4 Gwen, go ahead.

5 MEMBER BUHR: Well, I don't know  
6 if this would answer it, but everybody in the  
7 nursing home gets an MDS at prescribed  
8 intervals. So, it is not that a certain  
9 population is getting MDS and others are not.  
10 Everybody is getting the MDS.

11 And so, we already know that. And  
12 that has been happening since the 1990s. So,  
13 everybody has been getting the MDS. And yet,  
14 people are not diagnosed with dementia.

15 And so something, the doctor  
16 assessment or the nurse practitioner  
17 assessment after the MDS is what has not been  
18 happening, I guess. And also, this new MDS  
19 has the BIMS where the other one didn't. But  
20 it has always had a cognitive assessment in  
21 the MDS, and every single patient gets the  
22 MDS.

1                   MEMBER KAPLITT:  Yes, but before  
2                   the developer answers, again, it goes to the  
3                   question of why is this happening, right?  So,  
4                   you say, well, because certain things aren't  
5                   happening, I guess, right?  But, again, where  
6                   is the evidence that this is actually going to  
7                   change whatever the problem is?  If the  
8                   evidence is there -- I mean, again, I wasn't  
9                   one of the primary, you know, I wasn't on this  
10                  Work Group.  So, I may be missing it.  But the  
11                  question is, where is the evidence that this  
12                  numerator is valid at addressing this issue?

13                  MS. VANCE:  Okay.  That has a lot  
14                  to do with the regulatory guidelines.  Nursing  
15                  homes are surveyed by the federal government  
16                  under state agencies yearly and more often if  
17                  there has been a complaint.  So, if you have  
18                  an MDS that has a BIMS score that indicates  
19                  that there is a level of impairment, and you  
20                  have a diagnosis of dementia, but you don't  
21                  have a care plan in place for dementia or a  
22                  patient-centric plan for dealing with that

1 dementia, that nursing home would be receiving  
2 citations, many actually, underneath that --  
3 they are called F-Tags -- for that negligence  
4 in care. So, that is one thing. It is not  
5 just leading off the ICD-9 coding.

6 The other thing, as we know, is  
7 that with the physician visits every 60 days,  
8 and then to 90 days, that unless the nursing  
9 staff is calling in the practitioner to come  
10 in for a medically-necessary visit, they are  
11 not going to know that something is going on  
12 with their resident because that is how the  
13 nursing home lives and breathes and works.

14 So, the purpose of this is, okay,  
15 yes, sometimes you are going to have someone  
16 who doesn't transcribe something accurately.  
17 That happens. But, for the most part, because  
18 the evidence does show that that documentation  
19 is nowhere within the medical record, we know  
20 that people are not making that valid  
21 diagnosis. We feel that there is more of a  
22 chance to capture the missed diagnosis with

1 this measure than capture that someone did not  
2 do accurate transcribing.

3 I don't know if that answered your  
4 question.

5 MEMBER KAPLITT: But most of your  
6 answer related to something that has nothing  
7 to do with this measure, which is that a lot  
8 of what you said makes a lot of sense. But  
9 the numerator is not the number of patients  
10 who did not have a care plan attached after  
11 they have had abnormalities on the MDS twice.  
12 The numerator is the number of patients that  
13 don't have the ICD-9 code.

14 MS. VANCE: Well, no, not an ICD-9  
15 code, but don't have a diagnosis of dementia.

16 MEMBER KAPLITT: Based on the  
17 ICD-9 code, I mean, unless I am misreading  
18 this.

19 MS. TEIGLAND: The ICD-9 code is  
20 just one way to get there. There is also a  
21 section where --

22 MS. VANCE: Section (i).

1 MS. TEIGLAND: -- Section (i)  
2 where you can actually check a diagnosis.

3 But CMS really prescribes how  
4 nursing homes sort of operate, and it is  
5 really through this tool. If that diagnosis  
6 isn't there, it is not going to trigger that  
7 evidence-based practice, following that  
8 evidence-based practice guideline for  
9 dementia. It may trigger doing some things  
10 related to the cognitive impairment status,  
11 very different from the very much more  
12 comprehensive guideline for dementia.

13 And the sad reality is they just  
14 don't follow that evidence-based guideline  
15 unless that thing is triggered. So, that is  
16 why the care is not optimal for those patients  
17 that are underdiagnosed.

18 CO-CHAIR TIRSCHWELL: This is a  
19 little bit of a background question. So, sort  
20 of the target problem is the underuse of these  
21 evidence-based dementia care plans? And is  
22 that more expensive for a nursing home? I am



1 wondering what the disincentive to the nursing  
2 home is to using them. Do they make more  
3 money from Medicare for that? Less? It is  
4 the same? It doesn't matter?

5 MS. VANCE: It doesn't matter. It  
6 is the fact that they are looking at things  
7 like pressure ulcers and falls and urinary  
8 incontinence and things that are right in  
9 their face. And this is just kind of slipping  
10 through the cracks.

11 CO-CHAIR TIRSCHWELL: So, it is if  
12 they have had to MDS assessments over time,  
13 then they would have had to have been  
14 evaluated by a practitioner on that every 60-  
15 day cycle as well, right?

16 MS. VANCE: Well, the problem  
17 is --

18 CO-CHAIR TIRSCHWELL: So, it is  
19 really targeting the bad practitioners, I mean  
20 the ones that are not making that diagnosis  
21 that you are thinking is there. I mean, they  
22 would have to have been seen in that timeframe

1 for this long stay by a practitioner, right?  
2 No? I thought you said it is every 60 days by  
3 law.

4 MS. VANCE: Well, it depends on  
5 where they are within that time, every 60  
6 days, and then to every 90 days. And, yes,  
7 you are correct.

8 Unfortunately, if they are coming  
9 in and the resident has recently had a fall or  
10 there is incontinence to address, there is  
11 this and that to address, and there is a  
12 limited amount of time, and they kind of know  
13 that there is some kind of cognitive  
14 impairment, they don't necessarily -- it is  
15 not always right on the forefront. I mean,  
16 there has got to be some reason why in the  
17 community as well as in the nursing home  
18 dementia is underdiagnosed.

19 And what we are trying to do with  
20 this measure is make people look at it. I  
21 mean, I don't know the reason why. When you  
22 look at that United States Preventive Task

1 Force study, you know, there is some major  
2 reason why, you know, it is 50 to 70 percent  
3 within the community in the nursing home that  
4 people are not diagnosed with dementia. I  
5 don't know why, but we want to put it in their  
6 face and make people look at it.

7 CO-CHAIR KNOWLTON: Gwendolyn?

8 MEMBER BUHR: I think that one  
9 problem is that the nursing home does the MDS,  
10 whoever is designated in the nursing home.  
11 Those results are not front and center for the  
12 physicians. The physician comes in to do  
13 their visit, and they don't know anything  
14 about what the MDS said unless the nursing  
15 home makes some effort to tell them. And so,  
16 that is a real problem with the MDS and the  
17 physician visits, and maybe this measure will  
18 help to make that linkage; I don't know.

19 CO-CHAIR KNOWLTON: We are on  
20 scientific acceptability, validity.

21 Ramon, you have the final point.

22 MEMBER R. BAUTISTA: So, as a

1 practical question, though, what would happen  
2 to a patient with traumatic brain injury who  
3 does not do well on the BIMS score, but is not  
4 demented? Where would they fall in all this,  
5 though? It is not in your exclusion criteria.  
6 Where would TBI patients fall in? They are  
7 not being excluded.

8 MS. VANCE: They would obviously  
9 score poorly.

10 MEMBER R. BAUTISTA: That's right.  
11 Where would they fall in here, though?

12 MS. VANCE: But, then, that would  
13 be obviously diagnosed somewhere else. That  
14 would probably be --

15 MEMBER R. BAUTISTA: But they  
16 wouldn't be part of your denominator statement  
17 then? They would be, but not of your  
18 numerator? You would get dinged, though,  
19 wouldn't you in a situation like that?

20 MS. VANCE: Most of the persons  
21 with traumatic brain injury, though, we have  
22 exclude if the resident is comatose, but we

1 don't have traumatic brain injury. Most of  
2 the residents in nursing homes, though, with  
3 traumatic brain injury are under 65.

4 MEMBER R. BAUTISTA: Well, you  
5 could have --

6 MS. VANCE: But you might have a  
7 couple that are over 65.

8 MEMBER R. BAUTISTA: They become  
9 65 one day, you know.

10 (Laughter.)

11 MS. VANCE: Yes, I mean, that is  
12 true, but most of them are under 65 because we  
13 are actually doing a study with the younger  
14 patient in the long-term care setting. But,  
15 I mean, if that is a holdup and that is  
16 something that you feel that we need to add to  
17 the exclusion details, if that's --

18 MEMBER R. BAUTISTA: I am guessing  
19 statement that may be a catchall would be more  
20 helpful because there are many exceptions,  
21 much more than what you are listing there as  
22 an exclusion.

1 CO-CHAIR KNOWLTON: Can we move on  
2 to the vote? You see the criteria. This is  
3 validity. Voting is open.

4 (Vote taken.)

5 MS. THEBERGE: Nineteen, 21.

6 Two high, 11 moderate, 9 low, 1  
7 insufficient.

8 CO-CHAIR KNOWLTON: Okay. Yes, we  
9 keep going. It passes.

10 Who is presenting this? Jolynn?

11 MEMBER SUKO: So, on to usability,  
12 as we discussed, this is derived from  
13 electronic sources. The Work Group did  
14 discuss -- in general, felt that it was  
15 usable, and Salina's point of having a measure  
16 of cognitive impairment was brought up under  
17 usability as well.

18 CO-CHAIR KNOWLTON: Yes, Peter?

19 MEMBER SCHMIDT: So, I am always  
20 concerned when I see a measure where the  
21 optimal value is not zero or 100 percent from  
22 a usability perspective because, how can you

1 use that for quality improvement if you don't  
2 know what the target is? So, there clearly  
3 are non-random variations in the issue, your  
4 percentage of TBI patients who meet these  
5 criteria, but the exclusion we were  
6 discussing; those people are not randomly  
7 distributed. So, there won't be a random  
8 variation of these people who are pushing this  
9 measure away from zero across facilities.

10 CO-CHAIR KNOWLTON: Ramon?

11 Salina?

12 MEMBER WADDY: So, just to go back  
13 briefly to your previous point on who is  
14 diagnosing the patient, I mean, I specifically  
15 brought up that point on the call and I was  
16 told by -- were both of you on the call? I  
17 brought up that point, and I was told that it  
18 was only going to be physicians at that point.  
19 And so, I am a little bit concerned because it  
20 just seems like there are small tweaks around  
21 the edges that make me nervous about this  
22 element. More of a statement than a question.

1 CO-CHAIR KNOWLTON: Yes. Anybody  
2 else on this? Daniel?

3 MEMBER LABOVITZ: I love to talk  
4 to you about this, David. I think this is a  
5 squishy measure.

6 (Laughter.)

7 And the question, then, comes, is  
8 it so compelling that we can tolerate the  
9 squishiness? I think that is a judgment call.  
10 There is no evidence here. Is this really  
11 going to make the difference? Can we put up  
12 with the mess that is going to come in some  
13 institutions which may have a lot of TBI  
14 patients and others which don't? Can we deal  
15 with that? Is this going to hurt us or help  
16 us?

17 CO-CHAIR KNOWLTON: Gail, that was  
18 an assertive card.

19 MEMBER COONEY: It was an  
20 assertive card. Other than TBI, what makes it  
21 squishy, Daniel?

22 MEMBER LABOVITZ: Anything that



1 gives you a static encephalopathy, anything  
2 that is not dementia that gives you a poor  
3 BIMS score makes it squishy. This measure has  
4 no capacity for removing those patients from  
5 the denominator year after year after year.

6 CO-CHAIR KNOWLTON: Perhaps a way  
7 to go back to answer that question would be to  
8 say, what would make it less squishy? And it  
9 would be the inclusion of exclusionary  
10 criteria such as stroke and any of the  
11 encephalopathies that you talk about that  
12 would make it less squishy. Just another way  
13 to look at that is to just reverse it. That  
14 would answer that question.

15 Mary?

16 MEMBER VAN DE KAMP: Yes, I wanted  
17 to say, back to your things, the diagnosis is  
18 physician-driven or nurse-practitioner-driven.  
19 There is no soft edges around that. None of  
20 us in the practicing fields can -- and to  
21 Daniel's squishy comment, you know, I think it  
22 is almost the first step, if you will, to get

1 to the differentiation. I think exclusion  
2 would help. But, also, just because the  
3 dementia number, there is no dinging for this  
4 one, at least from what I can see. They are  
5 not going to say you have more patients with  
6 dementia in your nursing home because it is  
7 not like some of the other measures we looked  
8 at where -- wounds is one that is poorly done  
9 because you get a facility that has wounds and  
10 they didn't grow them, and they get dinged.

11 Dementia is one that I don't think  
12 there is a ding component. I think it is just  
13 a better care component. I really think in  
14 the practicality of looking at the broader  
15 scope of patients in our nursing centers,  
16 working to the exclusions which I think are  
17 valid but minor really in the population that  
18 we are talking about, that I am hesitant to  
19 throw out a measure that I think will improve  
20 quality down the line for the exclusions that  
21 I think would fall out from the further  
22 diagnosis by physician and by therapist.

1                   So, I am hesitant. I am sure some  
2                   of my frustration is that we don't put  
3                   something out that we don't is based on an MDS  
4                   which has a lot of validity to it from certain  
5                   pieces and we don't start to look at  
6                   additional pieces because it is not perfect  
7                   yet.

8                   I think one of the ways -- they  
9                   are going to have 12 months to come back to us  
10                  to say, "Oh, it didn't work. It didn't show  
11                  is the right answer. It isn't right." But I  
12                  am fearful that, if we don't get out in front  
13                  of this, we don't start defining dementia in  
14                  this population, it is a really undercared-for  
15                  diagnosis in our elderly population.

16                  And so, maybe my passion for  
17                  improved care is overriding my scientific  
18                  assessment of the measure. But I think there  
19                  is validity to what they have said in terms of  
20                  the volume. And there certainly is an  
21                  importance to improve the patient management  
22                  with physician and rehab staff involvement.

1 CO-CHAIR KNOWLTON: Anybody else?

2 (No response.)

3 I have one comment on Mary's  
4 point. That is, as a former regulator, do not  
5 underestimate the ability of a regulator to  
6 ding for squishiness.

7 (Laughter.)

8 The issue here is this is a  
9 facility-level measure. It could easily find  
10 its way into inspection criteria.

11 MEMBER VAN DE KAMP: Would it be  
12 dinged, David, for negativity or for patient  
13 populations? I don't know which one -- I find  
14 it --

15 CO-CHAIR KNOWLTON: Well, because  
16 it is a facility-level measure, a regulator  
17 would ding the facility.

18 MEMBER VAN DE KAMP: For what?

19 CO-CHAIR KNOWLTON: For having  
20 undiagnosed patients where the implication of  
21 this is they should be more properly  
22 diagnosed.

1 I am not arguing against your  
2 point. I am just saying don't underestimate  
3 that capacity, especially, in my view, for a  
4 facility-level measure, as a former abuser.

5 (Laughter.)

6 MS. TEIGLAND: So, I think that  
7 you are right that a high rate on this measure  
8 -- or a low rate, because you want this, this  
9 is better quality is you don't have a lot of  
10 those people, that that might cause a surveyor  
11 to come in and look at that resident --

12 CO-CHAIR KNOWLTON: That is  
13 exactly right.

14 MS. TEIGLAND: -- and see if they  
15 were, indeed, misdiagnosed. But, then, if  
16 they weren't, if they had the proper  
17 documentation in place, which they should  
18 have, they can't cite. But that is the whole  
19 point of -- and all of the CMS quality  
20 measures work like that.

21 CO-CHAIR KNOWLTON: And that is  
22 not a bad outcome.

1 MS. TEIGLAND: Right.

2 CO-CHAIR KNOWLTON: But I go back  
3 to the point that Daniel pushed back to me.  
4 That is, to the extent it is squishy, to the  
5 extent that somebody could get zapped for  
6 it --

7 MS. VANCE: But if you look at the  
8 majority of the resident population, I mean  
9 TBI is not extremely high in long-term care.  
10 It does exist. Encephalopathy, I mean, I am  
11 sure it exists, but it is not extremely high.

12 And when you were talking about  
13 the risk-versus-benefit ratio that you were  
14 asked to consider, I mean, of course, I am one  
15 of the developers. But the reason we did this  
16 is we live and breathe this stuff every day.  
17 We are there in the facilities. We see the  
18 patients suffering because they are not  
19 getting appropriate care; they are not getting  
20 diagnosed. And we just feel that the benefit  
21 of this and this measure clearly outweighs any  
22 risk of giving it a try.

1 CO-CHAIR KNOWLTON: Anybody else?  
2 Salina, I'm sorry, I didn't see  
3 your card.

4 MEMBER WADDY: Even though TBI may  
5 not be a large segment of the population in  
6 nursing homes, certainly stroke is fairly  
7 sizable. In aggregate with a bunch of  
8 additional diseases, it can be a sizable  
9 population.

10 But I would like to get back to  
11 Mary's point because that is actually what is  
12 troubling me. This is such a huge problem.  
13 It is a huge unmet need. If something isn't  
14 done by someone at some point, then it is a  
15 lot of patients that are not getting  
16 appropriate care.

17 But the big question is, is this  
18 the measure that we should use or is there  
19 some recommendation that we can make to make  
20 it a stronger or more appropriate measure? I  
21 think that is just left to everyone's best  
22 judgment.

1 CO-CHAIR KNOWLTON: Risha?

2 MEMBER GIDWANI: Yes, it seems to  
3 me like we don't want to throw out the baby  
4 with the bath water. So, can we just  
5 recommend some exclusions and then  
6 appropriate, contingent on those exclusions?

7 DR. BURSTIN: Yes.

8 MEMBER GIDWANI: Okay.

9 CO-CHAIR KNOWLTON: A.M.?

10 MEMBER BARRETT: Just relative to  
11 that issue, as a cognitive neurologist, I  
12 would remind folks that dementia is a syndrome  
13 and not a disease. And so, people can have a  
14 stroke and dementia; it doesn't mean that  
15 person is not competent to make decisions,  
16 can't be static, et cetera.

17 CO-CHAIR TIRSCHWELL: So, I guess  
18 I would suggest that the developers consider  
19 adding some fairly, I guess, non-specific  
20 exclusion which allows, if a specific other  
21 diagnosis is made that can account for the  
22 score, that they no longer be counted in the



1 numerator in future versions of the measure at  
2 that particular institution. And that would  
3 allow for, yes, everybody to get at least one  
4 additional evaluation for the possibility of  
5 dementia and, hopefully, more on an ongoing  
6 basis. Because even if the stroke patient  
7 this year doesn't have dementia, they  
8 certainly could have it next year. I mean, I  
9 guess if we throw them out permanently, we  
10 would lose that possibility as well.

11 But some additional stipulation  
12 whereby, if they have done due diligence and  
13 ruled it out, that it no longer counts against  
14 them. If that makes people more comfortable,  
15 then that might be a way to move forward.

16 MEMBER WADDY: But how do we move  
17 forward? Do we just measure things as is  
18 or --

19 CO-CHAIR TIRSCHWELL: So, this is  
20 up for time-dependent --

21 DR. BURSTIN: No, it is tested.

22 CO-CHAIR TIRSCHWELL: It is tested

1 already.

2 DR. BURSTIN: It is tested.

3 I guess I have a question for the  
4 developers. Is there interest in potentially  
5 expanding the exclusions to address this  
6 issue? I am not sure I am completely  
7 comfortable with the idea of an open-ended  
8 exclusion, just because I think that it tends  
9 to be pretty imprecise. But I would be  
10 curious to hear the developers' response, if  
11 that is okay.

12 MS. TEIGLAND: I think we would  
13 certainly be open to adding some exclusions.  
14 Our process was that we had an expert panel of  
15 geriatricians, who have extensive experience  
16 in nursing homes with nursing home patients,  
17 come up with this list of exclusions. We  
18 thought they were being overly exclusive  
19 because they really wanted to limit those  
20 residents, those people who end up in the  
21 numerator that don't have dementia.

22 But I think TBI is a good example,

1 even though the numbers are really tiny, and  
2 there certainly may be some other things that  
3 they missed. So, I think that is not an  
4 issue.

5 We really haven't tested this  
6 measure because that is what we have been  
7 throwing out. I mean, we don't know how this  
8 would change the numbers of people who are  
9 diagnosed. We know there is a big gap, and we  
10 hope this would, as all the CMS quality  
11 indicators do, cause changes in behavior,  
12 which drives better care, better outcomes and  
13 better care.

14 Yes, we have all been hearing  
15 about this 30-day readmission rate, right,  
16 that they are just implementing? They are  
17 dinging nursing homes. But the whole point is  
18 that they don't expect that to be zero. They  
19 say higher than expected. Everything is  
20 benchmarked when we are doing quality  
21 measurement. It is all about benchmarking and  
22 trying to achieve those higher goals and do

1 better care and reduce cost, hopefully.

2 DR. BURSTIN: And just to clarify,  
3 the MDS data elements have been validated,  
4 which is why the measure is classified as  
5 tested, so at least to the moderate level.

6 MS. TEIGLAND: Right.

7 DR. BURSTIN: So, you haven't done  
8 testing at the measure score level yet. But  
9 I just want to clarify, since you contradicted  
10 what I said earlier; it is a tested measure.

11 MS. VANCE: But, as Christie said,  
12 we would not have an issue with expanding the  
13 exclusion criteria because we honestly didn't  
14 think about TBI. We were looking at what  
15 large numbers were. But we certainly can add  
16 that or add that somewhat statement about, if  
17 the physician rules out for a medical cause or  
18 a cause, that it doesn't have to be  
19 accountable. Maybe we could put doing it  
20 yearly or something like that, because a  
21 person could get dementia. But we could work  
22 with them, a certain type of language that

1 everybody would be comfortable with.

2 CO-CHAIR KNOWLTON: So, how do we  
3 proceed with that recommendation, Helen?

4 DR. BURSTIN: It is fine to  
5 consider it as part of your voting. It sounds  
6 like they are agreeable to add the exclusions;  
7 they will work with us.

8 CO-CHAIR KNOWLTON: Okay.

9 DR. BURSTIN: And you will get a  
10 chance to see those final specs before they go  
11 forward.

12 CO-CHAIR KNOWLTON: Okay. So, in  
13 the context of that, can we vote on usability?

14 MEMBER J. BAUTISTA: So, just to  
15 clarify, you mean, if we vote yes, we are  
16 assuming they are going to make all those  
17 changes?

18 DR. BURSTIN: Yes, it is  
19 contingent on that.

20 CO-CHAIR KNOWLTON: Okay?

21 (Vote taken.)

22 MS. THEBERGE: We need one more.

1 Six high, 15 moderate, 2 low.

2 CO-CHAIR KNOWLTON: Okay.

3 Feasibility?

4 MEMBER SUKO: So, feasibility,  
5 these are generated from electronic data  
6 sources and, in general, this is the group  
7 able to do this, fairly feasible.

8 CO-CHAIR KNOWLTON: Anybody need  
9 to comment on this?

10 (No response.)

11 Okay. Let's vote.

12 (Vote taken.)

13 MS. THEBERGE: Twenty-one.

14 All right. Fourteen high, 8  
15 moderate, 1 low.

16 CO-CHAIR KNOWLTON: Okay. The  
17 overall suitability. So, we are at overall  
18 suitability for endorsement. Does it meet NQF  
19 criteria?

20 Vote?

21 (Vote taken.)

22 MS. THEBERGE: We need one more.

1                   Twenty yes, 3 no.

2                   CO-CHAIR KNOWLTON: Okay. The  
3 next is like unto it, and it is Salina  
4 presenting on 2092, persistent indicators of  
5 dementia without a diagnosis, a short stay.

6                   MEMBER WADDY: So, this measure is  
7 very similar, obviously, to the previous  
8 measure regarding the underdiagnosis of  
9 dementia in patients who have short stay.  
10 That is really the major change. It still is  
11 a facility measure.

12                   There is a significant amount of  
13 data, but, largely, the data wasn't really  
14 divided for us between the short-stay versus  
15 the long-stay elements. But the group overall  
16 thought that there was a significant -- I am  
17 trying to find my sheet. The group overall  
18 thought that it was an important measure.

19                   CO-CHAIR KNOWLTON: Can I ask a  
20 question? It was the same group that  
21 considered this? Yes, I am addressing you.

22                   MEMBER WADDY: Yes, it was the

1 same.

2 CO-CHAIR KNOWLTON: The same group  
3 that considered this. So, it is the same  
4 issues?

5 MEMBER WADDY: So, the comments  
6 were pretty -- yes, the exact same.

7 CO-CHAIR KNOWLTON: Okay. That is  
8 what I was trying to find out.

9 MEMBER WADDY: I didn't think it  
10 was necessary to go through it.

11 CO-CHAIR KNOWLTON: Yes, I agree.

12 CO-CHAIR TIRSCHWELL: Do the  
13 short-stay and the long-stay, then, represent  
14 all?

15 MS. VANCE: It is exactly the  
16 same, except for the length of time that you  
17 do the MDS assessment. We made ours  
18 consistent, harmonized it with the CMS nursing  
19 home measures. So, you will see that the CMS  
20 nursing home measures are broken up into  
21 short-stay and long-stay because their MDS  
22 assessments are done with different timing.



1 CO-CHAIR TIRSCHWELL: I see.

2 MS. VANCE: And so, to save time,  
3 we would agree to do the same exact expansion  
4 of exclusion criteria that we agreed to do  
5 with the long-stay measure, because everything  
6 within this measure is exactly the same except  
7 the timing of the MDS assessments.

8 MEMBER WADDY: Yes, and they  
9 convinced us it was necessary to divide those  
10 two things out.

11 CO-CHAIR KNOWLTON: So, without  
12 objection, let's just go right through the  
13 voting.

14 Oh, Ramon, I'm sorry.

15 MEMBER R. BAUTISTA: So, what is  
16 short-stay? On this, what is short-stay?

17 CO-CHAIR KNOWLTON: They are  
18 looking it up, Ramon, and they can tell you  
19 offline. I think the issue is it is not  
20 defined by the measure; it is defined by --

21 MEMBER R. BAUTISTA: It is not  
22 going to impact, though, on the need for this

1 measure?

2 MS. VANCE: No, it is defined by  
3 CMS. It is a payment issue. They are being  
4 paid by Medicare Part A.

5 MS. TEIGLAND: Yes, it is 100  
6 days. It is you expect to discharge within  
7 100 days. So, yes, these are paid by Medicare  
8 as Part A instead of Part B, yes.

9 CO-CHAIR KNOWLTON: Okay. Can we  
10 move on to the voting?

11 The first will be on evidence,  
12 structure, process, and immediate. Vote.

13 (Vote taken.)

14 MS. THEBERGE: Seventeen yes; 4,  
15 no, evidence does not meet guidance, and 2  
16 insufficient.

17 CO-CHAIR KNOWLTON: Okay. Impact.

18 (Vote taken.)

19 MS. THEBERGE: We need one more  
20 response.

21 Fifteen high, 7 moderate, 1 low.

22 CO-CHAIR KNOWLTON: And we are on

1 now -- what are we on, performance gap?

2 Performance gap.

3 (Vote taken.)

4 MS. THEBERGE: Eleven high, 12

5 moderate.

6 CO-CHAIR KNOWLTON: Yes?

7 MEMBER WADDY: So, as we go

8 through these, are we also considering the

9 same exception?

10 CO-CHAIR TIRSCHWELL: The

11 additional --

12 MEMBER WADDY: Yes, the additional

13 information?

14 CO-CHAIR TIRSCHWELL: Yes.

15 MEMBER WADDY: Okay. Great.

16 CO-CHAIR KNOWLTON: The

17 exclusionary information is you are talking

18 about?

19 MEMBER WADDY: Yes.

20 CO-CHAIR TIRSCHWELL: Additional,

21 yes.

22 CO-CHAIR KNOWLTON: So, what are

1 we up to? Scientific acceptability, starting  
2 with reliability.

3 (Vote taken.)

4 MS. THEBERGE: We need one more  
5 Four high, 17 moderate, 2 low.

6 CO-CHAIR KNOWLTON: Okay. On to  
7 validity.

8 (Vote taken.)

9 MS. THEBERGE: One more.  
10 Three high, 17 moderate, 3 low.

11 CO-CHAIR KNOWLTON: Usability.

12 (Vote taken.)

13 MS. THEBERGE: Two more.  
14 Eight high, 13 moderate, 2 low.

15 CO-CHAIR KNOWLTON: Feasibility.

16 (Vote taken.)

17 MS. THEBERGE: One more.  
18 Ten high, 13 moderate.

19 CO-CHAIR KNOWLTON: Overall  
20 suitability.

21 (Vote taken.)

22 MS. THEBERGE: Twenty yes, 3 no.

1 CO-CHAIR KNOWLTON: Okay.

2 MS. JOHNSON: Okay. Great. You  
3 guys have done a lot of work, three measures  
4 by 12:30. Yay!

5 (Laughter.)

6 Who said we might get out early?

7 CO-CHAIR TIRSCHWELL: I think you  
8 jinxed us, Michael.

9 (Laughter.)

10 MEMBER KAPLITT: I would like to  
11 withdraw my statement from this morning.

12 (Laughter.)

13 MS. JOHNSON: Before we break for  
14 lunch, I did want to ask very quickly, going  
15 back to the measure that just passed,  
16 particularly the diagnosis of dementia, do we  
17 have any flavor that that would be a  
18 disparity-sensitive issue?

19 I know, A.M., you have already  
20 told us that dementia in general is. Can we  
21 also say that diagnosis of dementia may also  
22 be disparities-related? Again, it is okay to

1 say no, but you think it is? Okay.

2 Okay. I might get with you a  
3 little bit later and just see if you can point  
4 me to a particular source or something. We  
5 are doing some background look at some of  
6 these things internally. So, that would be  
7 super.

8 Okay. Great.

9 CO-CHAIR KNOWLTON: Before we do a  
10 break, we want to see if the public has any  
11 comment.

12 MS. JOHNSON: Oh, great. Yes.

13 CO-CHAIR KNOWLTON: Suzanne gets  
14 the credit. She tapped my shoulder.

15 Any members of the public wish to  
16 comment?

17 (No response.)

18 Anybody on the phone like to  
19 comment?

20 MS. THEBERGE: Operator, can you  
21 open the line?

22 THE OPERATOR: Again, to ask a

1 question, press \*, then the number 1 on your  
2 telephone keypad.

3 (No response.)

4 At this time, there are no  
5 questions.

6 CO-CHAIR KNOWLTON: Okay. Then,  
7 we will be taking a break for lunch.

8 MS. JOHNSON: Yes. So, since we  
9 are running a little bit behind, we are going  
10 to try to come back in a half-hour. So, let's  
11 plan to start up again at 1:00.

12 (Whereupon, the above-entitled  
13 matter went off the record at 12:26 p.m. and  
14 resumed at 12:59 p.m.)

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

2 1:59 p.m.

3 CO-CHAIR TIRSCHWELL: All right.

4 Sorry about the short lunch, but we are going  
5 to jump right back in, so we can try to get  
6 done before the debate starts.

7 Before we start, Michael, we need  
8 to give the developer a few minutes, the AAN  
9 I guess, to describe their measures.

10 MS. SWAIN-ENG: Well, good  
11 morning, or afternoon actually, since we are  
12 in the afternoon.

13 My name is Rebecca Swain-Eng. I  
14 am the Senior Manager of Performance  
15 Measurement Implementation at the AAN.

16 I also have with me today my  
17 colleague Gina Gjorvad, who works with me on  
18 performance measurement development, as well  
19 as Dr. Christopher Bever, who is the lead and  
20 the Chair of our Quality Measurement Reporting  
21 Subcommittee.

22 I am just going to give you a very



1 brief overview. I know we are trying to get  
2 back on time here. So, I will keep it short  
3 and sweet. I will give Dr. Bever an  
4 opportunity to add any additional comments  
5 that he may have.

6 So, just a brief history of the  
7 AAN. It was established in 1948 as an  
8 international professional association. We  
9 currently have more than 25,000 members who  
10 are neurologists and neuroscience  
11 professionals who are dedicated to providing  
12 the highest-quality patient-centered  
13 neurological care.

14 The AAN has a long history of  
15 working jointly with the AMA-PCPI on the  
16 development of performance measures. We  
17 worked with them most recently on the update  
18 to the stroke and the stroke rehabilitation  
19 measurement set, many of which you reviewed  
20 during the Phase I of this Steering Committee  
21 project. We have also worked with them on  
22 CPAP eMeasures, imaging measures, and dementia

1 measures, which you will all be reviewing  
2 tomorrow.

3 Additional measures that the  
4 Academy has developed include the epilepsy and  
5 Parkinson's disease measures that you will be  
6 reviewing today, distal symmetric  
7 polyneuropathy measures, and ALS measures. We  
8 also have measures in process for headache,  
9 muscular dystrophy, multiple sclerosis, and so  
10 on.

11 So, the AAN follows the PCPI  
12 measure development process. The measures are  
13 developed through a cross-specialty,  
14 multidisciplinary work group. The measures  
15 are publicly vetted during a 30-day public  
16 comment period. Once the measures are  
17 approved in the peer review, they are then  
18 published in the peer-reviewed journal  
19 Neurology.

20 The AAN began developing measures  
21 with minimal assistance from the PCPI in 2008.  
22 Our Association was actually the first group

1 to use independent the measure development  
2 process with the PCPI. What that means is the  
3 PCPI gives us a little bit of staff support,  
4 but the whole process is run by our  
5 Association staff. They also help us with the  
6 vetting of the measures through the PCPI and  
7 the measures are actually approved by the PCPI  
8 membership and their Board.

9 The AAN formed the epilepsy and  
10 Parkinson's disease measures work groups in  
11 2008 and 2009, respectively. They were  
12 developed to fill a gap in the lack of  
13 measures that were available for neurological  
14 conditions, to focus on epilepsy and  
15 Parkinson's disease specifically.

16 The measures were designed to  
17 identify and define quality measures towards  
18 managing and improving outcomes for  
19 individuals with epilepsy and individuals with  
20 Parkinson's disease. The Epilepsy Measure  
21 Development Work Group was chaired by Nathan  
22 Fountain and Paul Van Ness.

1                   Joining us on the phone today,  
2                   hopefully, will be one of our work group  
3                   members, Dr. Gregory Barkley.

4                   The group actually developed eight  
5                   epilepsy measures, three of which will be  
6                   reviewed today. These are the three measures  
7                   that are in the 2012 PQRS program.

8                   The Parkinson's disease measures  
9                   were co-chaired by William Weiner and Stewart  
10                  Factor. Hopefully, joining us on the phone  
11                  today will be Dr. Weiner. He is currently in  
12                  an emergency. So, we are hoping he will be  
13                  able to call in with the change in the time  
14                  today.

15                  The original measurements that had  
16                  10 Parkinson's measures, we will be reviewing  
17                  six of those today, which are in the 2012 PQRS  
18                  program.

19                  So, there are a lot of additional  
20                  things that I could say about how we develop  
21                  our work group, who is involved. It is a  
22                  multi-specialty group. But I will just leave

1 that. If you have any questions, I would be  
2 happy to answer any additional questions about  
3 the work group compensation.

4 One thing I will mention is that  
5 we would ask that the Steering Committee  
6 consider the importance of these measures and  
7 the significant performance gaps for each  
8 measure. Although the evidence that leads the  
9 process measures directly to the expected  
10 patient outcomes and improvements is somewhat  
11 limited, these measures have the potential to  
12 significantly benefit individuals with  
13 epilepsy or Parkinson's disease. The benefits  
14 significantly outweigh the risk. So, we ask  
15 that the Steering Committee consider invoking  
16 an exception to the evidence for the measures,  
17 as appropriate.

18 As I mentioned, these measures are  
19 in the PQRS 2012 program. They are also in a  
20 neuro PI program which is designed and  
21 approved by the American Board of Medical  
22 Specialties to meet the requirements for

1 performance and practice, maintenance and  
2 certification, the Part 4 requirement. They  
3 are currently in use in that program, and we  
4 have not seen any issues with implementation  
5 or usability of these measures in that  
6 program.

7 So, on behalf of the American  
8 Academy of Neurology and our epilepsy and  
9 Parkinson's disease measure development work  
10 groups, we would like to thank you for the  
11 opportunity to present these measures.

12 Dr. Bever, do you have anything  
13 else to add?

14 DR. BEVER: Good afternoon,  
15 everybody, and thank you for letting us  
16 present.

17 I guess, as I know you have a Work  
18 Group that has already looked through these  
19 measures, and they are not based on the  
20 highest level of evidence. You might wonder  
21 why we didn't just stop working when we  
22 discovered that there weren't A-level

1 recommendations to base our measures on.  
2 There really were a couple of reasons at  
3 least.

4           One is that many of the most  
5 important aspects of care, based on  
6 clinicians' understanding, are not things on  
7 which there have been randomized controlled  
8 trials and there is A-level evidence. So,  
9 oftentimes, we have to make decisions based on  
10 lower levels of evidence. So, we think that  
11 measures in those areas are important.

12           The second is an experience that a  
13 number of us had in the Department of  
14 Veterans' Affairs system back in the 1990s.  
15 I think some of you are aware that the VA went  
16 through a transformation under Ken Kizer and  
17 others in which measurement played a major  
18 part. It was credited with both protecting  
19 patients from unexpected or unplanned side  
20 effects of the transformation and, also, it  
21 enabled the VA system to show that in large  
22 populations, diabetes, congestive heart

1 failure, and other areas, that they really did  
2 an excellent job and were at least comparable  
3 with the private sector.

4 I was a neurology service chief  
5 during that time, and there were no measures  
6 for neurologic illness. So, I believe that we  
7 took excellent care of our patients with  
8 neurologic diseases, but I certainly had no  
9 measures to document that. The fact that the  
10 planners in the regional offices, the VISNs,  
11 which are the VA's Accountable Care  
12 Organizations, had no measures for neurologic  
13 diseases meant that they really did not  
14 neglect neurology at all, but that certainly  
15 was not in the forefront of their  
16 consideration.

17 So, I think the American Academy  
18 of Neurology together with patient  
19 organizations for neurologic illnesses have  
20 worked hard to develop measures for neurologic  
21 illness, because we think that it is important  
22 in the healthcare reform setting to have



1 measures related to neurologic diseases.

2 So, thank you.

3 CO-CHAIR TIRSCHWELL: Thank you.

4 So, let's go ahead and start with  
5 the first Parkinson's disease measure, annual  
6 Parkinson's disease diagnosis review, 1973.

7 Michael?

8 MEMBER KAPLITT: Okay. So, this  
9 is a measure that is designed to capture  
10 patients, the percentage or number of patients  
11 with a diagnosis of Parkinson's disease in the  
12 denominator who have had their Parkinson's  
13 disease annually assessed. So, the measure is  
14 whether or not people are doing an annual  
15 reassessment of the diagnosis and specifically  
16 looking at medication use and looking at the  
17 presence of any atypical features.

18 The rationale behind it is that  
19 Parkinson's disease is essentially a clinical  
20 diagnosis. There are other things that could  
21 be used adjunctively, but none of them are  
22 considered standard or accepted by the general

1 community. So, it is still a clinical  
2 diagnosis. And therefore, there is a  
3 reasonable rate of misdiagnosis in Parkinson's  
4 disease. Measures that could improve the  
5 diagnosis rate would, presumably, improve  
6 care, making sure that patients get the  
7 therapies that they need, on the one hand,  
8 but, on the other hand, patients who are  
9 misdiagnosed don't get therapies that are  
10 either ineffective or might actually be  
11 harmful to them if they have another type of  
12 Parkinsonism or something like that. So, that  
13 is the general rationale.

14 To get to the evidence point,  
15 because we said we were going to start with  
16 that, the Work Group reviewed this and, then,  
17 the subsequent ones after this. You heard a  
18 little bit from the developer just now  
19 telegraphing their response to some of the  
20 issues that were raised on the call.

21 While we understood, I think,  
22 those points, the major concern with the

1 evidence that seemed to be fairly universal  
2 among the Work Group was that there was none  
3 with relation to this point. It wasn't that  
4 the evidence was just weak. There really was  
5 none that specifically relates to this  
6 measure.

7 So, evidence is provided as to the  
8 rate of diagnostic inaccuracy in Parkinson's  
9 disease, and that, I think, most people do not  
10 dispute, that there is a reasonable rate of  
11 diagnostic inaccuracy.

12 And there was some evidence  
13 provided as to how better diagnostic accuracy  
14 might be useful. The problem is that there  
15 was no evidence provided that any of us could  
16 find that suggests that annual review improves  
17 the rate of diagnostic accuracy. It is true  
18 that atypical features that can develop and  
19 question the diagnosis may not be readily  
20 apparent in the initial diagnosis, and those  
21 things could develop over time. But there was  
22 no evidence provided that annual re-review

1 actually changes the diagnostic accuracy rate  
2 or would change practice at all. That is what  
3 this measure is about.

4 And so, while many of us,  
5 particularly those us who treat Parkinson's  
6 patients specifically, are extremely  
7 sympathetic to this and the other measures  
8 that might help improve the care of these  
9 patients, there was no evidence provided on  
10 this point. It is not just that, well, you  
11 know, there is little evidence and we should  
12 -- but we are trying.

13 There are real concerns because  
14 there was no evidence provided, for example,  
15 that a general practitioner or a medical  
16 doctor or a neurologist who doesn't have much  
17 expertise in Parkinson's, there was no  
18 evidence that, if they misdiagnose initially,  
19 that that would in any way change by an annual  
20 reassessment by someone who may not  
21 necessarily be as qualified. In fact, as  
22 another member of the Work Group

1 raised/mentioned in the call, the main study  
2 was used in support of this measure, the NICE  
3 study, which was a study in Great Britain that  
4 relied largely on British data that may not be  
5 relevant to the U.S., but also did review some  
6 U.S. studies, while that talked about  
7 inaccuracies in diagnosis, et cetera, that  
8 study actually specifically stated that there  
9 was no specific evidence regarding what the  
10 optimal re-review rate should be, and that  
11 patients should generally be referred to a  
12 specialist for this purpose, which has nothing  
13 to do with this measure.

14 So, that was the general view of  
15 the people on the call. As I recall, I don't  
16 think there was a huge amount of disagreement  
17 on this point, and this was our major concern.

18 CO-CHAIR TIRSCHWELL: Great. Does  
19 anybody want to comment on this issue, this  
20 seemingly lack of evidence, I guess?

21 John?

22 MEMBER DUDA: Obviously, you can't

1 debate that, but I think, getting to this  
2 exception thing, there is never going to be  
3 any evidence. You know, nobody is ever going  
4 to do a study that takes -- well, for this one  
5 maybe I guess you could do a study and take  
6 half the people.

7 But the other point, and I don't  
8 know if it is the right time to talk about  
9 this, but it is kind of a checkbox thing. A  
10 doctor says, "Oh, yeah, I reviewed my  
11 diagnosis." That doesn't really mean anything  
12 other than they have checked off this box.

13 CO-CHAIR TIRSCHWELL: So, the  
14 connection between this and then some improved  
15 clinical outcome doesn't seem like it is  
16 there?

17 MEMBER DUDA: Well, that is even a  
18 separate issue. A connection between this  
19 assessment and whether or not anything was  
20 actually done isn't even there, right?

21 CO-CHAIR TIRSCHWELL: Right.  
22 Well, I think speaks to evidence also.

1                   MEMBER KAPLITT: Right. I mean,  
2                   if it is just a checkbox, but the point here  
3                   is not that, "Well, what's the big deal?" The  
4                   point here is that this is a standard that  
5                   people are going to be held to that we are  
6                   going to say this is actually a quality-of-  
7                   care issue. Well, there is no evidence that  
8                   it is. And so, that is the concern.

9                   And if there is never going to be  
10                  any data -- first of all, I disagree. I mean,  
11                  as you suggest, one could do studies on this;  
12                  it just might take some time. But, you know,  
13                  that is not our issue here.

14                  I mean, I am very sympathetic to  
15                  these, I believe. I see patients all the time  
16                  who are sent to me for surgery who don't have  
17                  Parkinson's, and I said, "Why are you here?"  
18                  And so, I am extremely sympathetic to this,  
19                  but the evidence isn't there. It is not even  
20                  close. There is nothing.

21                  MEMBER SCHMIDT: I just wanted to  
22                  say, John, I am currently running, I am in the

1 third year of a study where part of the study  
2 is expert review of diagnosis annually. And  
3 so, you can actually get evidence for this and  
4 you can get it funded, because I am writing  
5 a --

6 MEMBER DUDA: And extrapolating  
7 that to primary care providers and  
8 everything --

9 MEMBER SCHMIDT: No, no,  
10 absolutely. No, it is only expert centers and  
11 it is only confirming the diagnosis. But  
12 there is evidence, and we do get a couple of  
13 people -- and this goes to the annual aspect  
14 of this -- we get a couple of people sort of  
15 in their first four or five years of  
16 Parkinson's disease who get re-diagnosed, who  
17 get a new diagnosis. But if a patient lives  
18 with Parkinson's disease for ten years, do you  
19 reassess it at nine or ten? You know, there  
20 is not going to be any evidence to support  
21 that, even in the experts, even for people who  
22 are referred late to an expert center.



1 CO-CHAIR TIRSCHWELL: Daniel?

2 MEMBER LABOVITZ: This measure  
3 would apply to every physician who takes care  
4 of the patient and writes down that the  
5 patient has Parkinson's disease. So, the  
6 urologist is on the hook. The primary care  
7 doctor is on the hook. And maybe there is a  
8 really good movement specialist taking care of  
9 the patient, assessing, adjusting meds. There  
10 is no way for these doctors necessarily to  
11 have -- they can't say that they did it. Can  
12 they attest to the fact that somebody else did  
13 it, they think?

14 I am worried that the patient may  
15 be getting exactly what is recommended by the  
16 NICE criteria and still generate a ding.

17 CO-CHAIR TIRSCHWELL: Saline?

18 MEMBER WADDY: So, back to your  
19 point regarding whether or not people would be  
20 able to do studies or interested in doing  
21 studies, this has come up several times,  
22 including the last time we were here. I think

1 it would be helpful if there was a way that  
2 the NQF could inform some of the funding  
3 agencies of important gaps that need to be  
4 filled, either through NIH, NINDS  
5 specifically, or AHRQ or PCORI. And  
6 particularly since PCORI is going through  
7 their decisionmaking process right now for  
8 what to fund, that could be an important  
9 opportunity.

10 But I don't know what your  
11 processes are, and certainly this isn't time  
12 to expound upon that. But I think it is  
13 really important for us, as a federal agency,  
14 to get feedback on major gaps that we can  
15 potentially provide some answers.

16 CO-CHAIR TIRSCHWELL: Jack, go  
17 ahead.

18 MEMBER SCARIANO: Yes, on the  
19 patients who I see who likely have Parkinson's  
20 disease or actually who I diagnose as having  
21 Parkinson's disease, it is usually their  
22 initial diagnosis. Oftentimes, I have seen

1 that on those patients within six months or a  
2 year they will come back, and they are either  
3 totally better or they are doing a whole lot  
4 worse. And because I am not their primary  
5 care doctor, oftentimes, there is a lapse in  
6 between when I see them and actually diagnose  
7 them and then when I see them back. The  
8 primary care doctors, they just keep on giving  
9 them all the same meds. So, I would think  
10 that, at least in an early-on diagnosis of  
11 patients, that probably seeing them back every  
12 year actually would be a good idea.

13 CO-CHAIR TIRSCHWELL: Okay. Thank  
14 you.

15 If there are no other comments  
16 from our Committee, do the developers want to  
17 respond to the assertion of a lack of  
18 evidence?

19 DR. BEVER: So, I mean, I agree  
20 with the comments that have been made about  
21 the evidence base for this. In the evidence-  
22 based medicine world, it is not that there are

1 double-blind, placebo-controlled trials, and  
2 then nothing else matters. There are lower  
3 levels of evidence for things, including  
4 consensus and expert opinion. And so, I don't  
5 think those can be totally ignored, although  
6 they are certainly lower.

7 CO-CHAIR TIRSCHWELL: Gail? And  
8 then, Peter.

9 MEMBER COONEY: What I am hearing  
10 is more the question of whether an annual  
11 review will improve diagnosis. It seems like  
12 we should be able to know that.

13 CO-CHAIR TIRSCHWELL: And that we  
14 don't, apparently.

15 Peter?

16 MEMBER SCHMIDT: Yes, so some of  
17 these things that are addressed in here are  
18 not things you would check annually, like  
19 responsiveness to levodopa. You give the  
20 patient a levodopa challenge and you don't  
21 want a year to see whether it worked.

22 And then, a number of the other

1 things are at presentation. So, a number of  
2 these things are things that I am not sure  
3 that saying this should be done annually is --  
4 there is evidence to indicate that annually is  
5 not the right frequency or it is not the right  
6 time to assess these things.

7 CO-CHAIR TIRSCHWELL: And I just  
8 want to go back to the AAN for one second.  
9 Some of these measures are being used in the  
10 -- what is it called again? Well, the PQRS,  
11 but, no, the AAN maintenance of certification.  
12 So, theoretically, there will be a lot more  
13 data coming sometime soon that might inform  
14 some of these current gaps?

15 MS. SWAIN-ENG: Yes, we will have  
16 more data. Unfortunately, we have had some  
17 technical issues where we haven't been able to  
18 pull the queries yet. We had a lot of our  
19 technical staff, unfortunately, leave in the  
20 last six months. So, we will have that  
21 availability later this fall to be able to  
22 pull more data from that.

1                   We haven't encountered, as I think  
2                   I mentioned in my introduction, any usability  
3                   issues. We get feedback, though, from the  
4                   diplomats that are participating in the  
5                   program that the physicians that are using  
6                   this measure and other measures really like  
7                   the measure, really feel like it is a valuable  
8                   use of their time. They can see, once we have  
9                   completed a program, that they have actually  
10                  improved the care, according to what they are  
11                  reporting, based upon using this measure.  
12                  They are reporting a higher level of  
13                  accordance with this measure at the end of the  
14                  period.

15                         And we are providing additional  
16                         resources for them with case control studies,  
17                         with other articles, to further inform any  
18                         gaps that they may have in their knowledge.  
19                         And then, they are coming back and  
20                         reevaluating this with this measure again, and  
21                         they are doing very well.

22                                 CO-CHAIR TIRSCHWELL: Okay. Thank

1       you.

2                       Ramon?

3                       MEMBER R. BAUTISTA: I guess the  
4       operative word here is "annual". In fact, if  
5       you look at the next seven measures, they are  
6       all about annual evaluations for something or  
7       annual documentations for something.

8                       The difficulty I have is, well,  
9       the last epilepsy measure actually listed  
10      documentation. But the question I have is, I  
11      mean, how do we know that annual things  
12      improve care? Is there data that actually  
13      even shows that? I mean, nobody is doubting  
14      that there are some undiagnosed epilepsy  
15      patients or Parkinson's patients there, but  
16      how do we know that annual documentation will  
17      improve care?

18                      CO-CHAIR TIRSCHWELL: Okay, John,  
19      you had your card up there?

20                      MEMBER DUDA: I mean, I think we  
21      have addressed that; we don't have any firm  
22      evidence for that. These were developed by

1 the thought leaders in the field, and that is  
2 the best we have.

3 I do want to point out, though,  
4 that like this one says at least annually.  
5 So, if they do it every three months, they are  
6 not going to get dinged for that, and I think  
7 some of the others are the same way.

8 CO-CHAIR TIRSCHWELL: Gail, do you  
9 have a comment?

10 MEMBER COONEY: The AAN is looking  
11 at it from a neurologist's point of view.  
12 There it is probably useful. I am not sure  
13 that it is broadly applicable to non-neurology  
14 practitioners.

15 CO-CHAIR TIRSCHWELL: Okay. Yes,  
16 AAN.

17 MS. SWAIN-ENG: So, I will just  
18 address that first question with the annual  
19 time period. It is not that it needs to be  
20 done in an annual time period. When we are  
21 developing a measure, you have to set a time  
22 period for the measure. Typically, the time



1 period, for example, with PQRS is a 12-month  
2 period. So, the annually is just saying it  
3 has to be done once during that time period.  
4 It is not that we can prove annual is better  
5 than triannual or quarterly or whatnot. We  
6 just have to set a time period when we are  
7 developing the measure. It is just a process  
8 issue.

9 CO-CHAIR TIRSCHWELL: Okay. Well,  
10 go ahead, Michael.

11 MEMBER KAPLITT: I just want to  
12 make sure that there is no wrong impression  
13 left here, because there are two things. I  
14 don't want to get sidetracked.

15 No. 1, while the annual issue may  
16 be an issue, that was not the major problem  
17 that the Work Group had. Because we agree, I  
18 mean, you could always say any measure that  
19 has a time period attached to it, you could  
20 say, well, is that the right time period  
21 versus a month earlier, versus a week longer,  
22 versus whatever.

1                   So, I don't want to leave the  
2                   impression that that is the major crux of the  
3                   problem we had here.  If there was good  
4                   evidence that at six months or every two years  
5                   or something made a difference to diagnostic  
6                   accuracy, I think we would have been more  
7                   sympathetic to the vagaries of time.

8                   And secondly, to the comment that  
9                   not everything has to be randomized,  
10                  controlled trials, again, that was not the  
11                  issue.  It was not that there weren't three  
12                  randomized, double-blind studies.  There was  
13                  zero evidence presented at all, nor any  
14                  evidence that any of us could find beyond  
15                  simply the expert consensus, which is fine for  
16                  a societal guideline, you know, for a society  
17                  guideline, but it is not necessarily fine for  
18                  the NQF standard, based on our understanding  
19                  of the NQF standard.

20                  So, I don't want to leave the  
21                  wrong impression that we are arguing over  
22                  trivialities here.

1 CO-CHAIR TIRSCHWELL: Thank you.

2 Mary?

3 MEMBER VAN DE KAMP: Yes, just  
4 being on the Work Group, I think that our  
5 challenge was that just by doing it didn't  
6 necessarily improve better diagnosis. Again,  
7 if the neurologists are doing it, that  
8 probably would be valuable. But if you are  
9 looking at an overall population, if someone  
10 doesn't see it the first time because of what  
11 they do or do not know, are they going to see  
12 it the second or the third time?

13 So, it wasn't, again, as we looked  
14 at the broader population of assessment; it  
15 was that we felt that we didn't improve the  
16 skills of the evaluation just by doing it  
17 multiple times without evidence that would  
18 show why that would change.

19 CO-CHAIR TIRSCHWELL: Okay. I am  
20 going to suggest we go ahead and vote on the  
21 evidence at this point. One is yes, and then  
22 2 and 3 are varieties of no.

1 (Vote taken.)

2 MS. THEBERGE: Three yes; 8, no,  
3 evidence does not meet guidance, and 13, no,  
4 insufficient information.

5 CO-CHAIR TIRSCHWELL: All right.  
6 We are moving on to the next measure then  
7 because it did not pass on that first evidence  
8 criteria.

9 So, the second Parkinson's disease  
10 measure, No. 1982, Parkinson's disease  
11 psychiatric disorders or disturbance  
12 assessment.

13 Jane?

14 MEMBER SULLIVAN: I think there  
15 are going to be similarities here with the  
16 previous measure. This is a measure that  
17 looks at all people with the diagnosis of  
18 Parkinson's who at least annually were  
19 assessed for the presence of psychiatric  
20 disorders or disturbances.

21 And I think I will echo what the  
22 concerns the Work Group had with this one,

1 which were similar to the prior one, which was  
2 that, while conceptually people felt like  
3 there was evidence that this is an important  
4 issue, that psychiatric disorders are  
5 relatively prevalent in this population, the  
6 connection between the annual assessment and  
7 impact on patient care was not there.

8 CO-CHAIR TIRSCHWELL: Okay. Thank  
9 you, Jane.

10 So, yes, I think there is a  
11 tremendous amount of overlap. Does anybody  
12 have any additional comments that are specific  
13 to this measure.

14 Peter?

15 MEMBER SCHMIDT: So, just a nuance  
16 to this one, there is evidence that, for  
17 example, depression is difficult to diagnose  
18 in a Parkinson's patient. And the measure  
19 didn't include diagnosis using validated tools  
20 in Parkinson's disease.

21 CO-CHAIR TIRSCHWELL: Okay. And  
22 does the AAN have any additional response that

1 is specific to this measure, as opposed to the  
2 other ones?

3 DR. BEVER: No.

4 CO-CHAIR TIRSCHWELL: Thank you  
5 for your brevity.

6 (Laughter.)

7 Over here, Jane and then John.

8 MEMBER SULLIVAN: Yes, and I want  
9 to just add to what Peter said. There was  
10 some concern in the Work Group that, despite  
11 the acknowledgment that depression is  
12 difficult to diagnose, that was the numerator  
13 of the measure. So, it was sort of it was  
14 difficult, but, yet, those were the numbers  
15 with which this measure was presented.

16 MEMBER DUDA: So, I guess related  
17 to this one, but the last one, too, to my  
18 mind, we haven't really discussed whether or  
19 not any of these apply to this potential  
20 exemption to empirical body of evidence.

21 CO-CHAIR TIRSCHWELL: Now would be  
22 the time to bring it up if you think it is

1 relevant to use the exemption. Do we want to  
2 review that criteria again? Do we have that,  
3 Suzanne?

4 MEMBER DUDA: If it is judged that  
5 the potential benefits to patients clearly  
6 outweigh the potential harms.

7 CO-CHAIR TIRSCHWELL: That is not  
8 it, though. There is no empirical evidence,  
9 expert opinion, and systematically assessed  
10 with agreement that the benefits greatly  
11 outweigh the potential harms. Pass? Yes, but  
12 only if it is judged benefits clearly  
13 outweighed harms; otherwise, no.

14 So, I guess, what are the  
15 benefits? I get that there doesn't seem like  
16 there could be much harm from this, but I  
17 guess I am not seeing any clear information --  
18 I guess I am trying to avoid the word  
19 "evidence" -- of benefit. Quite honestly, I  
20 don't know how you can establish that benefit  
21 outweighs harms without any evidence. So, it  
22 seems a little redundant or circular in some

1 ways.

2 Okay. All right. So, John, do  
3 you want to invoke it?

4 Gail?

5 MEMBER COONEY: Well, I mean, you  
6 were asking about benefits outweighing harms.  
7 It seems that, without assessment of these  
8 issues, there can't be treatment of them, and  
9 treatment of them would be expected to be  
10 beneficial. So, I think that is the link to  
11 outcomes.

12 CO-CHAIR TIRSCHWELL: Okay.  
13 Peter?

14 MEMBER SCHMIDT: So, this seemed  
15 to me to be a measure that could be easily  
16 fixed, you know, with addition of -- some of  
17 the other measures specify instruments. I  
18 think that if you kind of address that a  
19 little bit, because there is evidence that it  
20 is included in the submission that some of  
21 these issues are difficult to diagnose in the  
22 Parkinsonian patient.



1                   And so, if you just drew from that  
2                   evidence what are the validated instruments,  
3                   and included something addressing that in the  
4                   definition, that could make this a really  
5                   positive measure. Because I agree with John  
6                   that diagnosing these things is really  
7                   important and can really change -- you know,  
8                   there have been numerous studies, including a  
9                   paper that I am a coauthor on that is in  
10                  submission, that have shown that depression is  
11                  one of the key drivers of quality of life in  
12                  Parkinsonian patients. So, there absolutely  
13                  is a benefit from the assessment.

14                  It is just you wouldn't want to  
15                  pass a measure that kind of said, well, if you  
16                  examine the patient's effect and you said they  
17                  seem to be fine, that you have assessed them  
18                  for depression.

19                  CO-CHAIR TIRSCHWELL: I guess my  
20                  challenge to you is how is this different  
21                  qualitatively than the previous measure, which  
22                  didn't pass? And let me let you respond to

1 that, Peter, and then Bill.

2 MEMBER SCHMIDT: So, the different  
3 there is that you could actually, in the  
4 previous measure, you could put in UK Brain  
5 Bank criteria. But some of those things get  
6 fairly complicated. With a lot of psychiatric  
7 centers, there are validated, short surveys  
8 that you can give to a patient that will  
9 diagnose these things.

10 CO-CHAIR TIRSCHWELL: Okay. Bill?

11 MEMBER BARSAN: I think the  
12 problem with both these things and some of the  
13 others that we have looked at before is it is  
14 really a two-step process. It is not just one  
15 step. It is not one thing leads to one thing.  
16 It is one thing might lead to another thing,  
17 which might lead to another thing.

18 So, one is, do you assess it? If  
19 so, how do you assess it? Do you document  
20 that you assess it? And then, there is the  
21 assumption that, if you assess it and you  
22 document, that, in fact, you do the right

1 thing. So, there are really two assumptions.

2 So, somebody could do an  
3 assessment for depression and do nothing about  
4 it or do something that was inappropriate for  
5 it. And you don't have any way of knowing  
6 that just by assessing you, in fact, get a  
7 better outcome.

8 CO-CHAIR TIRSCHWELL: Right. And  
9 this is another one of those measures that can  
10 be achieved through documentation, only a  
11 checkbox measure.

12 John?

13 MEMBER DUDA: I guess the other  
14 difference between this and the last one is  
15 that, obviously, a Parkinson's disease  
16 patient, when they come to see the doctor for  
17 their Parkinson's disease, that is going to be  
18 addressed in some shape or form. When you  
19 come to a doctor for Parkinson's disease and  
20 you don't know that anxiety is a symptom of  
21 Parkinson's disease, and your doctor doesn't  
22 know that, it is not going to be addressed.

1                   That is why there are some asleep  
2 things and these non-motor features of  
3 Parkinson's disease assessments are different  
4 than just an annual review of the actual  
5 diagnosis.

6                   Like Peter was saying, I think  
7 there is pretty clear evidence that these  
8 things are not diagnosed; they are  
9 underdiagnosed. They are undertreated.  
10 Improving that is certainly going to  
11 improve --

12                   CO-CHAIR TIRSCHWELL: Thank you.  
13 Michael?

14                   MEMBER KAPLITT: Yes, I mean, I  
15 agree with that. I do think there is actually  
16 harm potentially, and it is an issue. For  
17 example, with the last one, the harm issue,  
18 right, and why I don't think this was invoked,  
19 is that, again, if you have somebody who is  
20 not adequately qualified to do this, and then  
21 they do this every year and say, "Yeah, I've  
22 done it and everything is fine," it leaves the

1 false impression of quality that is actually  
2 not happening. That could actually harm  
3 patients because they think that they are  
4 doing better than they were before.

5 That is maybe a little different  
6 than a measure that says you should be  
7 assessing for this thing. I am not saying  
8 that I necessarily feels there is better  
9 evidence in support of this measure, for  
10 example, but I could see the argument better  
11 about the exception for something like this  
12 because you are trying to get people who are  
13 less qualified to at least think about it to  
14 some degree.

15 Now, having said that, again,  
16 there is the potential for harm because  
17 people, as you say might misdiagnose it,  
18 because now they are being forced to do  
19 something that they are not qualified to  
20 assess. That is a much vaguer and tougher  
21 problem, but it is somewhat different than I  
22 think the previous measure in that regard.

1 CO-CHAIR TIRSCHWELL: Yes. So, I  
2 mean, I guess differences and similarities,  
3 the potential harm, Michael, you are  
4 suggesting is, if somebody uses a validated  
5 instrument but is not really an expert or  
6 qualified to use it, then they could be put on  
7 antidepressant medications, or whatnot, other  
8 psychiatric medications that could really be  
9 counterproductive in that case.

10 John?

11 MEMBER DUDA: So, as with the  
12 exceptions we made for the last couple of  
13 measures, would it be possible to change the  
14 denominator statement to say something like  
15 "all patients with a diagnosis of Parkinson's  
16 disease examined by a neurologist"? And then,  
17 we would get around a lot of these issues we  
18 are talking about. Is this a standard of care  
19 that we want to apply to neurologists and not  
20 other doctors, and is it useful in that  
21 capacity?

22 CO-CHAIR TIRSCHWELL: I guess

1 maybe we are straying off of the evidence in  
2 that respect, John. So, we may need to come  
3 back to that.

4 I need to ask the NQF staff, what  
5 is the process for evaluating the exemption to  
6 empirical body of evidence? Do we have to  
7 vote on that as a group?

8 DR. BURSTIN: You decide if you  
9 want to -- I mean, basically, if somebody  
10 calls it out, it is up to you guys to decide  
11 if you want to just vote on it, vote on the  
12 exception.

13 CO-CHAIR TIRSCHWELL: So, we  
14 should vote on the evidence, and if you want  
15 to invoke the exception, you say, yes, there  
16 is adequate evidence.

17 DR. BURSTIN: Yes.

18 CO-CHAIR TIRSCHWELL: And if you  
19 don't want to invoke the exception, you would  
20 say one of the "no" responses.

21 So, if you want to say that there  
22 is an exemption to the requirement for

1 evidence or that you think there is evidence,  
2 you would say yes.

3 DR. BURSTIN: Heidi is going to  
4 explain it.

5 CO-CHAIR TIRSCHWELL: Oh, okay, I  
6 got it wrong.

7 MS. BOSSLEY: Sorry. We spent a  
8 lot of time going through these and it is very  
9 confusing.

10 So, if you think the body of  
11 evidence as it stands now supports the  
12 measure, then you vote yes, which I am  
13 generally hearing the answer is no to that.

14 Then, if the evidence does not  
15 meet the guidance, and there is no empirical  
16 evidence that exists, that is the one where  
17 then we would move you into the exception  
18 vote.

19 CO-CHAIR TIRSCHWELL: Okay.

20 MS. BOSSLEY: You will do a second  
21 vote at that point.

22 The last one is just there was



1 nothing provided in the form or in any way to  
2 let you evaluate that measure.

3 So, if you think that you want to  
4 invoke an exception, it should be No. 2 that  
5 you are going to vote on.

6 CO-CHAIR TIRSCHWELL: Okay.

7 MS. BOSSLEY: Does that make  
8 sense?

9 CO-CHAIR TIRSCHWELL: And then,  
10 only if a majority votes No. 2 will we move on  
11 to the second vote for the exemption? Is  
12 that --

13 MS. BOSSLEY: That is how we did  
14 it with the last Committee, yes.

15 CO-CHAIR TIRSCHWELL: Okay.

16 Go ahead, Salina.

17 MEMBER WADDY: So, what percentage  
18 of patients who have Parkinson's disease is  
19 their Parkinson's disease actually treated by  
20 a neurologist?

21 CO-CHAIR TIRSCHWELL: Can you give  
22 us just one number, Peter? Give us your best

1 guess.

2 MEMBER SCHMIDT: Yes. So, 40  
3 percent are not seen by a neurologist. Twenty  
4 percent are seen by a neurologist once, and 40  
5 percent get their routine treatment by a  
6 neurologist at least annually.

7 CO-CHAIR TIRSCHWELL: Of the ones  
8 who are diagnosed?

9 MEMBER SCHMIDT: Of the ones that  
10 are diagnosed, yes, yes, and misdiagnosed.

11 MEMBER KAPLITT: I just want to  
12 clarify the procedural point that was just  
13 made, though. Because, based on what you were  
14 just saying about the exception rule, to  
15 invoke the exception, we have to majority vote  
16 No. 2. Then, that means my understanding of  
17 the exception, based on that, means that  
18 insufficient evidence is not a criteria to  
19 invoke the exception. It has to be that there  
20 is evidence that just doesn't quite meet the  
21 standard, that there is evidence presented --

22 CO-CHAIR TIRSCHWELL: No, it could

1 just be expert opinion.

2 MEMBER KAPLITT: No, because you  
3 -- well, right. So, you would have to have a  
4 majority of people feeling that there is some  
5 evidence to justify that it just doesn't meet  
6 the standard, not that there is insufficient  
7 evidence, because she is saying it has got to  
8 be No. 2. That is what she just said. I just  
9 want to make sure we are understanding this  
10 right.

11 MS. BOSSLEY: So, let's look at  
12 how this vote would go if you invoked No. 2.  
13 So, this is the question that gets asked. If  
14 there is no empirical evidence, it is only  
15 expert opinion, and you think it was  
16 systematically assessed with agreement that  
17 the benefits greatly outweigh the harms, then  
18 you would vote -- that is what you would be  
19 doing if you voted No. 2 on the previous  
20 slide. We would go to this vote.

21 Suzanne, can you, then, go back  
22 one?

1                   So, the insufficient information,  
2                   No. 3, is that, in essence, there is just  
3                   nothing to support this measure. It is just  
4                   a flat-out no.

5                   MEMBER KAPLITT: Okay. So, then,  
6                   I would argue that we may be voting  
7                   incorrectly, then, on some of these because I  
8                   don't think there is a measure that we have  
9                   seen so far that doesn't have some experts  
10                  saying, "Yeah, this is a reason to do this."  
11                  Have we ever seen anything with a zero?

12                  CO-CHAIR TIRSCHWELL: Somebody has  
13                  to bring up the exemption.

14                  MEMBER KAPLITT: No, no, I  
15                  understand. I am just saying that I think  
16                  many of us were misunderstanding the  
17                  distinction between two and three.

18                  CO-CHAIR TIRSCHWELL: We hear  
19                  that.

20                  And I guess I also don't quite  
21                  understand why, if two gets a majority in the  
22                  first vote, why do we have to vote again at

1 that point?

2 CO-CHAIR KNOWLTON: Because you  
3 might be saying that, but there isn't  
4 systematically applied evidence that would  
5 allow you -- it doesn't move to the level.

6 The first vote allows you to say  
7 some people think that there is some evidence  
8 there, but they are not necessarily saying  
9 there is enough evidence systematically  
10 applied.

11 CO-CHAIR TIRSCHWELL: I see.  
12 Okay. All right. So, let's go back to the  
13 first vote, if we can. This is it right here.  
14 I am not even going to try to explain it. I  
15 hope you understood it.

16 (Laughter.)

17 One, two, or three, let's go ahead  
18 and start.

19 (Vote taken.)

20 MS. THEBERGE: We need one more.

21 Oh, there we go.

22 One yes; 18, no, evidence does not

1 meet guidance, and 5, no, insufficient.

2 CO-CHAIR TIRSCHWELL: Okay. So,  
3 now we do the second vote, and I am going to  
4 read this outloud.

5 "If there is no empirical  
6 evidence, only expert opinion, and that  
7 opinion was systematically assessed with  
8 agreement that the benefits of the measure  
9 process" in this case, "to patients greatly  
10 outweigh potential harms," we are answering  
11 the question, is there an exceptional and  
12 compelling reason that the measure should be  
13 considered further? One is yes and 2 is no.

14 David, did you want to say  
15 something before we vote? I apologize.

16 CO-CHAIR KNOWLTON: Yes, I did. I  
17 think that this is a new test that we have got  
18 to discuss. It seems to me that in this  
19 particular case there is a whole bunch of  
20 qualifying words in there: "expert opinion,"  
21 "systematically assessed," "with agreement of  
22 benefits, and "Is there an exceptional

1 underlying and compelling reason?" From where  
2 I sit -- and NQF can tell me I am wrong -- but  
3 from where I sit, this is meant to be a very  
4 high test. I don't think it is being met in  
5 this case.

6 So, I don't want us to just go, I  
7 guess because we voted on this No. 2, then I  
8 guess this is an "auto in." That is not the  
9 way I read this.

10 DR. BURSTIN: It is not, although  
11 somebody has already asked that the exception  
12 be invoked. So, you guys can just do a vote  
13 on it; that's all. But it is still an  
14 exception.

15 CO-CHAIR KNOWLTON: Right.

16 DR. BURSTIN: And I think what  
17 David said is clear. It is not something we  
18 do as a routine course, but when there is  
19 compelling evidence that really risks outweigh  
20 benefits.

21 CO-CHAIR TIRSCHWELL: And the  
22 exceptional and compelling part, I think that

1 is an excellent point, David. Thank you for  
2 bringing that up.

3 Somebody -- I can't remember who  
4 it was -- referred to the NICE guideline from  
5 the UK where maybe some of these things were  
6 talked about. I guess I don't know -- I am  
7 sure this measure was probably included in  
8 that as well.

9 But anybody have any comments  
10 about exceptional and compelling?

11 Salina, you were first.

12 MEMBER WADDY: Not on that.

13 CO-CHAIR TIRSCHWELL: Okay.

14 Peter? And then, Jane.

15 MEMBER SCHMIDT: So, I think it  
16 would be safe to characterize the process that  
17 resulted in the paper by Eric Chang as expert  
18 opinion being systematically assessed. So,  
19 unless it requires us to systematically assess  
20 it, I think that this meets that clause.

21 You know, I agree with John. I  
22 think that this is dramatically



1 underdiagnosed. It is a huge factor in  
2 quality of life for people with Parkinson's  
3 disease.

4 You know, if you look at the  
5 standardized instrument scores for people who  
6 are experiencing psychosis or depression or  
7 anxiety, it has a terrible impact on them,  
8 worse than increasing motor disability. And  
9 so, there really is a compelling reason to  
10 assess these, to endorse the assessment of  
11 psychiatric disturbances.

12 CO-CHAIR TIRSCHWELL: Okay. Jane?

13 MEMBER SULLIVAN: Peter provided  
14 the information I was looking for.

15 CO-CHAIR TIRSCHWELL: Bill? And  
16 then, Risha.

17 MEMBER BARSAN: Yes, I don't know.  
18 Again, it is one thing to measure. It is  
19 another thing to know that anything good was  
20 done by measuring it. And so, there are two  
21 -- if there were just one leap I had to make,  
22 that would be one thing, but these are two

1 leaps I have to make, and I just have a hard  
2 time making that.

3 CO-CHAIR TIRSCHWELL: Risha? And  
4 then, John.

5 MEMBER GIDWANI: I have the same  
6 concern as Bill. I also have the other  
7 concern of whether, given the fact that it was  
8 brought up that psychiatric disorders can be  
9 difficult to diagnose in Parkinson's patients,  
10 whether a neurologist, if we do limit to only  
11 neurologists, would have the tools necessary  
12 to be able to properly make this assessment or  
13 whether it would need to go to a psychiatric  
14 professional.

15 CO-CHAIR TIRSCHWELL: Let alone a  
16 primary caregiver, who is theoretically  
17 included in this measure as well.

18 John?

19 MEMBER DUDA: Remember, Boarded  
20 neurologists are boarded in psychiatry and  
21 neurology. So, we all have to have some  
22 psychiatry training and expertise.

1                   But back to Bill's comment, I  
2                   mean, I think that this and the other measures  
3                   may all fail for other reasons. But, as I  
4                   understand it now, the only thing on the table  
5                   is whether or not we are deciding that the  
6                   lack of evidence, you know, systematic  
7                   evidence that supports this is adequate to  
8                   deny it, not these other concerns that I have  
9                   for this measure and all the other measures.

10                   CO-CHAIR TIRSCHWELL: And also  
11                   that the benefits greatly outweigh potential  
12                   harms, so another criteria here.

13                   Sorry. Were there any other  
14                   comments? Risha?

15                   MEMBER GIDWANI: Just a point of  
16                   clarification. When we say "benefits," do we  
17                   mean benefits in terms of patient outcomes or  
18                   in terms of processes of care?

19                   DR. BURSTIN: It is left open, to  
20                   patients.

21                   CO-CHAIR TIRSCHWELL: Opinion of  
22                   benefits is my guess.

1 Daniel?

2 MEMBER LABOVITZ: I think my  
3 willingness to say that there is an  
4 exceptional and compelling reason to do this  
5 depends very much on who we are asking to do  
6 it. If we are asking primary care doctors to  
7 be doing this, I think we are going to cause  
8 a lot of harm. If we are asking neurologists  
9 to do this, and we are talking about 40  
10 percent of the population I guess, because  
11 there is not going to be a reassessment after  
12 the second diagnosis in the other 20 percent,  
13 I am open to that. I would be very interested  
14 in hearing further discussion on that point.

15 But I need to know before I vote  
16 on this, can this measure be modified so it is  
17 just neurologists?

18 CO-CHAIR TIRSCHWELL: Okay. Can  
19 we throw that one over to the developers?

20 DR. BURSTIN: No, it is not  
21 something we do.

22 CO-CHAIR TIRSCHWELL: It is not

1 something we do? What? What is not something  
2 we do?

3 DR. BURSTIN: In general, measures  
4 are not to specific specialties. They are at  
5 the patient level. They apply to the patient.

6 CO-CHAIR TIRSCHWELL: They can  
7 apply to facilities or clinicians --

8 DR. BURSTIN: Yes, so clinicians  
9 broadly.

10 CO-CHAIR TIRSCHWELL: -- but not  
11 subtypes of physicians?

12 DR. BURSTIN: Correct.

13 DR. BEVER: So, would it address  
14 the concern if we added to the measure  
15 validated instruments that the provider could  
16 use?

17 CO-CHAIR TIRSCHWELL: I am sure  
18 that would help, but the NQF is suggesting  
19 that we still need to leave it open to all  
20 individual providers.

21 Man, the cards keep going up.  
22 David, John, Salina, Peter.

1                   MEMBER HACKNEY: I guess I am a  
2 little less concerned, unless I have  
3 misunderstood practice patterns, but I see  
4 some value in having either a primary care doc  
5 or some other physician who is not a  
6 neurologist or psychiatrist do the evaluation,  
7 and particularly if they have a validated tool  
8 to use. And if they think it is abnormal, do  
9 they just go ahead and treat or does that  
10 spark a referral to someone who is a mental  
11 health expert? That might be the appropriate  
12 way to go. But if the concern is a PCP may  
13 think they have made a diagnosis of depression  
14 and treat them with drugs without ever  
15 checking, I agree that is an anxiety. I just  
16 don't know how many people actually do that.

17                   CO-CHAIR TIRSCHWELL: Well, then  
18 that is the second leap of faith that I think  
19 Bill has referred to and is worried about.

20                   Who was next? John, did you have  
21 another comment?

22                   Salina?

1                   MEMBER WADDY: I mean, that was  
2 actually my concern when it was previously  
3 mentioned that we limit this to neurologists.  
4 I mean, they are, hopefully, more likely to  
5 diagnose psychiatric disorders in their  
6 Parkinson's patients than the primary care.  
7 So, are you really saying that you want to  
8 apply a level of quality to the people who are  
9 more likely to make the diagnosis.

10                   So, it seems that it will be  
11 appropriate, instead, to say clinicians who  
12 are seeing Parkinson's patients for their  
13 Parkinson's, something along that line, rather  
14 than just saying a neurologist or PCP. Does  
15 that make sense?

16                   CO-CHAIR TIRSCHWELL: I don't know  
17 how you figure out whether they are seeing  
18 them for that diagnosis.

19                   MEMBER WADDY: Well, I guess if  
20 they are checking off like for the diagnosis  
21 code, but what you wouldn't want is -- and  
22 that was brought up before -- someone who was

1 seeing them for a fractured hip and then  
2 trying to go through all these permutations  
3 that they may not be qualified.

4 CO-CHAIR TIRSCHWELL: Sure.

5 MEMBER WADDY: I don't know the  
6 wording to tease it apart, but teasing apart  
7 those two types of clinicians, ones that are  
8 seeing a Parkinson's patient, but not for  
9 their Parkinson's.

10 CO-CHAIR TIRSCHWELL: Helen, can  
11 you comment?

12 DR. BEVER: So, the measure  
13 applies only when the provider is billing for  
14 Parkinson's.

15 MEMBER WADDY: That is what I  
16 would think.

17 DR. BURSTIN: It already is,  
18 though.

19 MEMBER WADDY: Okay.

20 DR. BURSTIN: Yes.

21 MEMBER WADDY: Okay.

22 CO-CHAIR TIRSCHWELL: Okay. So,



1 that is already in place.

2 Peter? And then, Daniel.

3 MEMBER SCHMIDT: So, in the UK  
4 these assessments are done by geriatricians.  
5 You will note that it is assess for  
6 psychiatric disorders, not diagnosed with a  
7 psychiatric disorder.

8 I personally think this would be a  
9 better measure if you grouped some of these  
10 together and said that is an indication to  
11 refer somebody to an expert.

12 But the assessment for psychiatric  
13 disorders is routinely by geriatricians in the  
14 UK system. That is a very strong evidence-  
15 based guideline that they have adopted there.

16 CO-CHAIR TIRSCHWELL: Okay.  
17 Daniel? And then, Gwen.

18 MEMBER LABOVITZ: It sounds to me  
19 like perhaps NQF endorsement is really a very  
20 broad brush. It is a broad stroke meant for  
21 the population of caregivers, physicians and  
22 nurses across the country, regardless of

1 discipline. It is not set up for this sort of  
2 thing.

3 The American Academy of Neurology  
4 has already put this out and is using it, and  
5 the doctors who are using it like it. I  
6 support that. I think that is terrific. I  
7 think it is not only a useful measure for  
8 those doctors, but it is also a pedagogical  
9 tool.

10 But if we expand this to an NQF  
11 endorsement, then everybody has got to do it.  
12 I just don't think the measure is ready for  
13 that or appropriate for it.

14 CO-CHAIR TIRSCHWELL: Gwen? And  
15 then, John.

16 MEMBER BUHR: So, somebody was  
17 talking about the diagnosis of depression and  
18 whether you would then refer them to a  
19 specialist. I think that most commonly not.  
20 Primary care physicians would usually treat  
21 mood disorders or psychiatric disorders  
22 regardless of Parkinson's disease. Whether

1 that is what they should be doing or not, that  
2 is what would happen, because most depression  
3 is not treated by psychiatrists or  
4 neurologists.

5 MEMBER DUDA: So, in part in  
6 answer to your question, you know, this is  
7 only the people who claim to be taking care of  
8 a patient for Parkinson's disease. The  
9 primary care provider who is taking care of  
10 the ingrown toenail isn't going to be assessed  
11 for this.

12 I think, again, you said that it  
13 is not ready for that setting. That is not  
14 the question on the table. This may fail  
15 because it is not reliable and valid, but  
16 right now are we saying that there is a  
17 compelling reason to ignore the fact that  
18 there is no empirical evidence to support this  
19 from moving forward to further evaluation, not  
20 to approval, right?

21 CO-CHAIR TIRSCHWELL: Any further  
22 comments? Gwen, yes?

1                   MEMBER BUHR:  So, my question is  
2                   to you Parkinson's experts.  So somebody  
3                   seemed to say that it was harmful, it would be  
4                   harmful.  That is my question.  Is it harmful  
5                   if a primary care physician is assessing for  
6                   psychiatric disorders and treating them?  
7                   Because you are going to assess for it and  
8                   then you are going to treat whatever you find.  
9                   Is that going to be harmful?

10                  CO-CHAIR TIRSCHWELL:  Or I guess,  
11                  theoretically, they could assess for it and  
12                  not find it inappropriately and not treat it  
13                  appropriately --

14                  MEMBER BUHR:  Right.

15                  CO-CHAIR TIRSCHWELL:  -- and that  
16                  would harm the patient as well.

17                  MEMBER BUHR:  So, what are the  
18                  harm concerns?

19                  CO-CHAIR TIRSCHWELL:  John?  And  
20                  then, Peter.

21                  MEMBER DUDA:  So, I think missing  
22                  a diagnosis is not -- I mean, it is harmful to

1 the patient, but it is not harming a patient.  
2 Making a wrong diagnosis and treating them  
3 inappropriately could be harmful. But, I  
4 mean, are we going to say that primary care  
5 providers can't assess psychiatric illness?  
6 I mean, that is part of their training, right?  
7 And we expect them to be able to do that. I  
8 don't think there is any difference because it  
9 is a Parkinson's disease patient.

10 CO-CHAIR TIRSCHWELL: Except that  
11 these disorders are notoriously hard to  
12 diagnosis in Parkinson's disease. I think we  
13 heard that as one of the first lines in this  
14 whole thing.

15 Peter?

16 MEMBER SCHMIDT: Yes, I agree with  
17 what John is saying. There is more harm in  
18 not looking than there is in looking.

19 CO-CHAIR TIRSCHWELL: A.M.?

20 MEMBER BARRETT: I would just make  
21 a little comment that depression in  
22 Parkinson's disease I believe is associated

1 with a higher risk of suicide than it is in  
2 other age-matched people.

3 CO-CHAIR TIRSCHWELL: Okay.  
4 Anybody else have any further comments prior  
5 to going ahead and voting on this exception?

6 (No response.)

7 Okay. John, can you take your  
8 card down, please?

9 (Laughter.)

10 All right. So, let's go ahead and  
11 open the voting.

12 (Vote taken.)

13 MS. THEBERGE: We need two more.  
14 One more.

15 Okay. Fourteen yes, 10 no.

16 CO-CHAIR TIRSCHWELL: All right.  
17 So, that means we continue.

18 So, then, who was doing this  
19 measure again?

20 (Laughter.)

21 Jane? Impact I think is next,  
22 right, 1(a)?

1                   MEMBER SULLIVAN: The Work Group  
2                   felt that there was evidence of high impact in  
3                   that the developer provided information that  
4                   40 to 50 percent of people with Parkinson's do  
5                   have psychiatric disorders and 50 percent may  
6                   develop psychotic symptoms, 30 percent  
7                   hallucinations in the first five years. And  
8                   48 to 80 percent of them may develop dementia.  
9                   So, the group was comfortable that the impact  
10                  was demonstrated.

11                  CO-CHAIR TIRSCHWELL: Any comments  
12                  on the impact?

13                  (No response.)

14                  Let's go ahead and vote then on  
15                  impact.

16                  (Vote taken.)

17                  MS. THEBERGE: Nineteen high, 4  
18                  moderate, 1 low.

19                  CO-CHAIR TIRSCHWELL: Okay. The  
20                  next criteria is evidence of gap, I believe,  
21                  1(b).

22                  MEMBER SULLIVAN: There was data

1 that the developers presented about the  
2 population variance in Parkinson's disease in  
3 general, but not specific to psychiatric  
4 disease in these patients.

5 CO-CHAIR TIRSCHWELL: So, there  
6 was no evidence that depression or other  
7 psychiatric diseases are underdiagnosed or  
8 there is evidence for that? I thought I heard  
9 people saying there was lots of evidence for  
10 that.

11 MEMBER SULLIVAN: There was  
12 evidence that they were difficult to diagnose.

13 CO-CHAIR TIRSCHWELL: Okay.  
14 Peter?

15 MEMBER SCHMIDT: There is evidence  
16 that it was underdiagnosed. I am not sure to  
17 the extent that it was actually included in  
18 here. But if you go through the references,  
19 the references do address the NICE guidelines,  
20 one of the references, and they address the  
21 underdiagnosis.

22 CO-CHAIR TIRSCHWELL: Okay. Any



1 other comments about evidence of a performance  
2 gap?

3 (No response.)

4 Let's go ahead and vote then.

5 (Vote taken.)

6 MS. THEBERGE: Nine high, 12  
7 moderate, 3 low.

8 CO-CHAIR TIRSCHWELL: Okay. So,  
9 then, we are moving on to scientific  
10 acceptability. I think first is reliability.

11 MEMBER SULLIVAN: The comments  
12 that have previously been made about  
13 specifications for method of assessment, the  
14 Work Group talked a lot about that, as well as  
15 specifications about which disturbances would  
16 be assessed.

17 CO-CHAIR TIRSCHWELL: And so, the  
18 Work Group was comfortable with it as it was?

19 MEMBER SULLIVAN: The Work Group  
20 was a little uncomfortable because there  
21 weren't recommendations about a particular  
22 assessment tool or modalities for which the

1 individuals will be assessed.

2 CO-CHAIR TIRSCHWELL: Okay. John?

3 MEMBER DUDA: Remind me, but I was  
4 under the impression that these new things  
5 that have never really been tested were not  
6 supposed to be assessing reliability and  
7 validity.

8 DR. BURSTIN: We are only looking,  
9 really, at -- because it is not tested -- just  
10 2(a) there, 2(a)(1), precise specifications.

11 CO-CHAIR TIRSCHWELL: So, I guess  
12 this, the lack of tools goes to the specifying  
13 how you do the assessment or the lack of  
14 specification of how you do the assessment.

15 Bill?

16 MEMBER BARSAN: I was wondering if  
17 the developers would consider putting in some  
18 assessments that should be done, recommended  
19 assessments, as opposed to -- I mean,  
20 otherwise, this could just be another checkbox  
21 where nobody really does anything but says,  
22 "Oh, yeah, I checked for it."

1 DR. BEVER: Yes, so will the NQF  
2 allow us to specify? I mean, there are  
3 assessment instruments that have been looked  
4 at. The Committee did not put them in the  
5 actual measure.

6 DR. BURSTIN: I think the only  
7 challenge is it is not just depression. It is  
8 depression, psychosis, anxiety, apathy,  
9 impulse control. So, you are getting into a  
10 whole slew of actually -- and we have already  
11 endorsed measures that, for example, use the  
12 PHQ-9 for depression or some other promised  
13 tools.

14 I guess the question would be,  
15 there are so many; perhaps one option might  
16 just be to perhaps insert the words "using a  
17 validated tool," rather than necessarily  
18 getting into listing them one by one.

19 DR. BEVER: Right. We would be  
20 more comfortable with putting it that way,  
21 rather than trying to list all the potential  
22 instruments.

1 CO-CHAIR TIRSCHWELL: Jane, go  
2 ahead.

3 MEMBER SULLIVAN: The discussion  
4 that the group had was that in some of the  
5 guidelines there were specific tools  
6 identified, and members felt that in cases  
7 where specific tools were recommended that it  
8 might be appropriate to suggest "such as," and  
9 then list the tools that have already been  
10 vetted by other guidelines.

11 CO-CHAIR TIRSCHWELL: And I would  
12 add that in some of the other measures  
13 developers have listed some tools, and they  
14 say something like "using tools such as, but  
15 not limited to," and then a whole list of  
16 possible tools to use.

17 John?

18 MEMBER DUDA: Just to clarify, we  
19 are kind of throwing clinical acumen out the  
20 window and we are saying, if you see a  
21 Parkinson's disease patient every year, you  
22 have to give them a validated tool for

1 anxiety, a validated tool for depression, a  
2 validated tool for psychosis, a validated tool  
3 for impulse control disorders. I am not sure  
4 that is really where we want to go, either.

5 CO-CHAIR TIRSCHWELL: Terry?

6 MEMBER RICHMOND: That was my  
7 point exactly. It sounds like, then, you are  
8 saying they need to undergo a full psychiatric  
9 assessment, the way this is written. So, I am  
10 not clear how that numerator statement would  
11 play itself out in specifications. I think  
12 that is a concern.

13 CO-CHAIR TIRSCHWELL: I agree. I  
14 think it is very concerning. Of course, the  
15 alternative, leaving it as it is, is that the  
16 physician saying, "Are you having any  
17 psychosis, depression, anxiety, apathy, or  
18 impulse control problems?"

19 (Laughter.)

20 "No? Okay." Check.

21 So, I agree. It sort of seems  
22 like neither seems very satisfactory, on one

1 hand, or necessarily feasible on the other  
2 hand.

3 Yes, go ahead, Helen.

4 DR. BURSTIN: It sounds like most  
5 of the discussion we have had today so far has  
6 been about depression. And I guess I am  
7 confused why the measure has all these other  
8 psychiatric conditions. Would that be one  
9 approach to potentially hone-in on the areas  
10 that are most important?

11 DR. BEVER: I think in terms of  
12 the gap in care, probably depression is the  
13 largest in terms of numbers. There are other  
14 like impulse control things which are --

15 CO-CHAIR TIRSCHWELL: Peter, go  
16 ahead. Put your microphone on.

17 MEMBER SCHMIDT: ICD is one of the  
18 things that I think is the most impactful to  
19 a patient's life. You will have people who  
20 will gamble away all their savings. And so,  
21 that is important to assess for.

22 (Laughter.)

1                   Depression, it is the most  
2                   prevalent, and it has a very high impact  
3                   because it is so prevalent. Psychosis, again,  
4                   a terrible quality-of-life problem, but lower  
5                   prevalence.

6                   CO-CHAIR TIRSCHWELL: Salina?  
7                   Then, Michael.

8                   MEMBER WADDY: Is there a brief  
9                   screening tool that combines two or three of  
10                  these together?

11                  DR. BEVER: I think that was one  
12                  of the problems, was that there wasn't a brief  
13                  screening tool. But our committee got in a  
14                  discussion like this of the various things  
15                  that happen in Parkinson's, and that is how we  
16                  ended up with this large number of things in  
17                  the measure.

18                  CO-CHAIR TIRSCHWELL: Michael, go  
19                  ahead.

20                  MEMBER KAPLITT: So, my read of  
21                  this is not that they have to do all of these  
22                  measures all the time, but they can do any one

1 of them, right? Because it says "example,"  
2 and then it gives a list, right? So, they  
3 could --

4 DR. BEVER: It is "or". You're  
5 correct, it is "or".

6 MEMBER KAPLITT: It is "or,"  
7 right.

8 So, my concern is actually the  
9 opposite, which is that I totally agree with  
10 the impulse control issue. However, I can't  
11 tell you how many times that I, as a surgeon  
12 seeing somebody after 10 years of disease, am  
13 the first one to ask them about whether they  
14 are having issues with gambling or addictions  
15 or sexual things, whatever, because nobody  
16 asks them about this stuff with their  
17 medicines. So, I agree with that.

18 The problem in my view with the  
19 breadth of this thing is that somebody could  
20 ask them every year, "How are you feeling?  
21 Are you apathetic a little? Are you okay?"  
22 And then, they can check off the apathy box



1 and that is it. And so, it hasn't achieved  
2 the goal.

3 So, I actually think that  
4 specifying the measure down to a specific  
5 thing would be a very different thing. My  
6 problem is with the breadth of this, that it  
7 is just too easy to get credit for having done  
8 good care when you haven't done good care.

9 CO-CHAIR TIRSCHWELL: Back to the  
10 check --

11 MEMBER KAPLITT: Right.

12 CO-CHAIR TIRSCHWELL: -- easily  
13 done by documentation alone.

14 Any other comments? John, do you  
15 have something else to add?

16 MEMBER DUDA: I mean, I agree, but  
17 I think, at least in my mind, the intent of  
18 this guideline, and maybe the intent the  
19 developers can say, but it was not really to  
20 assess in the formal assessment way, but  
21 assess, you know, ask, "Are you depressed?  
22 Are you gambling too much? Are you anxious?",

1 or however you want to say it to the patient.

2 But, then, you are right, you  
3 would have to specify that it would have to be  
4 "and" for each one of those. I don't know if  
5 we are developing --

6 CO-CHAIR TIRSCHWELL: Daniel,  
7 Terry, then Bill.

8 MEMBER LABOVITZ: I am concerned  
9 that we are trying to use NQF validation here  
10 for something that is really not meant for it.  
11 We are trying to make doctors better. NQF is  
12 meant, I think -- and as we go through all  
13 these processes, we have had to invoke every  
14 exception here to get to this level of  
15 conversation.

16 This measure doesn't fit in. It  
17 is not like the others. We need to be using  
18 other tools to get doctors to do better on  
19 care of patients with Parkinson's disease and  
20 depression, anxiety, et cetera.

21 There is, I think, a desperate  
22 crying need, and I suspect that there is a

1 need for better specialty availability for  
2 patients with Parkinson's disease. Maybe just  
3 being able to see a neurologist would be a  
4 good step or a geriatrician. But you may not  
5 even have access to that.

6 I am not sure that this  
7 measurement solves any of those problems. The  
8 NQF process isn't really set up to handle a  
9 sort of, "Gee, I wish we could do better kind  
10 of measure."

11 CO-CHAIR TIRSCHWELL: Terry?

12 MEMBER RICHMOND: Yes, I continue  
13 to have concerns on the specification, and  
14 that on top of the fact that we voted in an  
15 exception. The two of them are deeply  
16 concerning to me.

17 Right now, I almost feel like we  
18 are trying to redesign the measure as a group  
19 process instead of saying, what data do we  
20 have and does this meet our criteria? So,  
21 just a thought.

22 CO-CHAIR TIRSCHWELL: Yes. Bill?

1 And then, Peter.

2 MEMBER BARSAN: I don't want to  
3 beat a dead horse, but, I mean, I feel like we  
4 are really pounding very, very hard to get a  
5 square peg in a round hole, and it is not  
6 working very well.

7 CO-CHAIR TIRSCHWELL: Peter?

8 MEMBER SCHMIDT: Yes, so all the  
9 thing that we brought up in the evidence point  
10 are going to come up again as we go through  
11 the future points because they are just as big  
12 roadblocks to things like usability and the  
13 specification, you know, the use of "or"  
14 instead of "and". They are all going to come  
15 up as we go on.

16 CO-CHAIR TIRSCHWELL: Okay.

17 Anybody else have any comments?

18 (No response.)

19 Let's go ahead and vote on  
20 reliability and -- oh, wait, this is  
21 reliability and validity?

22 DR. BURSTIN: Because it is an

1       untested measure, and there is no reason to  
2       split them.

3                   CO-CHAIR TIRSCHWELL: Well, did we  
4       have the conversation on validity?

5                   Jane?

6                   MEMBER SULLIVAN: The only other  
7       thing I would add, I think I said before, that  
8       there was concern in the Work Group that the  
9       inconsistency between the numerator, which is  
10      people who have been assessed for this and the  
11      difficulties for doing the assessment, that  
12      there is data to support that it is difficult  
13      to diagnose especially depression in this  
14      population.

15                  CO-CHAIR TIRSCHWELL: Okay. That  
16      sounds like stuff, as you say, Peter, that we  
17      have already discussed to a large degree.

18                  Anybody have any additional  
19      comments before we vote on both reliability  
20      and validity, because there is no data  
21      specifically that we are using?

22                  (No response.)

1                   Okay. Let's go ahead and vote.

2                   (Vote taken.)

3                   MS. THEBERGE: We need three more.

4                   One more. Can everyone vote one more time?

5                   All right. Five yes, 19 no.

6                   CO-CHAIR TIRSCHWELL: Okay. I  
7                   think that means we are done with this measure  
8                   then.

9                   Okay. Moving on to the next, not  
10                  terribly dissimilar, Parkinson's disease,  
11                  Measure 1983, Parkinson's disease cognitive  
12                  impairment or dysfunction assessment.

13                  Risha, do you want to start us  
14                  off?

15                  MEMBER GIDWANI: Sure. This is  
16                  another AAN measure. It is also annual. So,  
17                  it is all patients with diagnosis of  
18                  Parkinson's disease who were assessed for  
19                  cognitive impairment or dysfunction at least  
20                  annually. The denominator statement is all  
21                  patients that have been diagnosed with  
22                  Parkinson's. There are no exclusions to the

1 denominator.

2 I can talk a little bit about our  
3 assessment of the evidence.

4 CO-CHAIR TIRSCHWELL: Yes.

5 MEMBER GIDWANI: So, just a caveat  
6 in terms of the numbers that I am presenting  
7 to you. It looks like one member of the Work  
8 Group voted twice. So, sometimes we have an  
9 "N" of five; sometimes we have an "N" of six.

10 CO-CHAIR TIRSCHWELL: We are not  
11 focusing on the Work Group voting numbers.

12 MEMBER GIDWANI: Okay.

13 CO-CHAIR TIRSCHWELL: So, just  
14 give us the words.

15 (Laughter.)

16 MEMBER GIDWANI: Okay. All right.  
17 So, the concerns that the Work Group raised  
18 were very similar to the ones that we have  
19 just heard for the last two measures. And  
20 that is that the evidence didn't really  
21 address the piece here that we are evaluating,  
22 and that is cognitive impairment.

1                   There was also a lack of  
2                   information about how assessing cognitive  
3                   impairment would actually result in better  
4                   patient outcomes. The evidence that was  
5                   provided by the measure developers was really  
6                   about depression rather than cognitive  
7                   impairment.

8                   In terms of the quality of the  
9                   evidence, there were some randomized  
10                  controlled trials that the developer cited,  
11                  but those were actually looking at drugs for  
12                  treating depression, not, again, for cognitive  
13                  impairment.

14                  There seemed to be sort of a lot  
15                  of conflation going on between cognitive  
16                  dysfunction and impairment and other facets of  
17                  neurologic impairment associated with  
18                  Parkinson's disease. So, for example, the  
19                  measure developers also cited a guideline, and  
20                  that guideline stated that the Mini-Mental  
21                  Status Exam and the Cambridge Cognitive Exam  
22                  should be considered as screening tools for



1 dementia in patients with Parkinson's disease.  
2 That was the evidence that was used. Evidence  
3 about this guideline for dementia was used to  
4 support their measure about cognitive  
5 impairment and dysfunction. So, I think it is  
6 really a lot of what we have discussed here  
7 earlier, is that there may be some face  
8 validity here, but the evidence the Work Group  
9 felt wasn't really presented regarding  
10 cognitive impairment.

11 CO-CHAIR TIRSCHWELL: Okay. So,  
12 again, very similar issues to the previous  
13 measures.

14 Does anybody have any comments  
15 that are particular to this one?

16 John?

17 MEMBER DUDA: I think it is a  
18 harder argument to make that diagnosing  
19 dementia in a Parkinson's disease patient  
20 affects their quality of life to the same  
21 degree that diagnosing depression or anxiety  
22 does.

1 CO-CHAIR TIRSCHWELL: Okay. Thank  
2 you.

3 Does the developer have anything  
4 to add before we vote on the evidence in this  
5 case?

6 DR. BEVER: No, I don't think we  
7 have anything.

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

10 Then, well, let's just go ahead  
11 and vote. Nobody has invoked anything that  
12 shall remain nameless.

13 (Laughter.)

14 (Vote taken.)

15 MS. THEBERGE: Four more.

16 All right. Three yes; 14, no,  
17 evidence does not meet guidance, and 7, no,  
18 insufficient evidence.

19 CO-CHAIR TIRSCHWELL: Okay. Then,  
20 I think we are done with this measure, too, as  
21 well.

22 I am sort wondering if we could

1 skip the lunch break now that is on the  
2 agenda -- (Laughter) -- and move through a  
3 couple of more maybe before we take our  
4 afternoon break. Is everybody okay with that?

5 Okay. Do you want to take it?

6 CO-CHAIR KNOWLTON: Yes, Jack,  
7 you're up, 1985, Parkinson's disease querying  
8 about sleep disturbances.

9 MEMBER SCARIANO: Yes, as you are  
10 looking at this problem, actually, what I do  
11 in my practice is that I almost function like  
12 a primary care doctor. The patient I see are  
13 usually sent in from rural areas and also  
14 nurse practitioners. So, the ones I am seeing  
15 are usually not diagnosed. So, actually, what  
16 I see and the problems that actually happen  
17 are almost always seeing people who were just  
18 initially diagnosed.

19 In actually through the actual  
20 studies of sleep disorders of patients with  
21 Parkinson's diseases, it is really a prevalent  
22 problem. If you look in the actual medical

1 literature, there numerous papers, maybe I  
2 would say probably 100 papers worldwide that  
3 actually talk about this problem.

4           The overall problem is, what do  
5 you do about it? And then, the other problem  
6 is, is the sleep disorder caused by the  
7 Parkinson's disease or does the Parkinson's  
8 disease cause the actual sleep disorder? In  
9 the medical literature, this has been looked  
10 at numerous times. They all state that the  
11 Parkinson's disease is the cause of the sleep  
12 disorder. Studies have shown that, if you  
13 have Parkinson's disease, you have a higher  
14 incidence of having a sleep disorder. And the  
15 most common one is excessive or daytime  
16 drowsiness.

17           And they have also shown that,  
18 when you compare Parkinson's patients who have  
19 sleep disorders versus people who have other  
20 chronic illnesses, say diabetes, that the  
21 incidence of having sleep disorders is a whole  
22 lot higher in the Parkinson's patients. So,

1 it is a known problem.

2           What is it caused by? Well, when  
3 they look at it, they have seen that the  
4 obstructive sleep apnea is not any higher in  
5 the Parkinson's patient than it is in the  
6 general population. As you are looking at  
7 that, you will say, "Well, it is probably an  
8 actual central problem," that it is probably  
9 a narcolepsy maybe induced by the Parkinson's  
10 disease, or actually who knows?

11           Studies have actually shown that,  
12 that there have been some experimental animal  
13 studies that have shown changes in small,  
14 little neurotransmitters. And, also, in the  
15 Parkinson's surgery group they have seen that  
16 some patients who have even had Parkinson's  
17 surgery, even though the Parkinson's disease  
18 hasn't improved very much in some cases, in  
19 the other cases the actual sleep disorder has  
20 improved. So, there is evidence all over that  
21 it is a major problem.

22           How do you diagnose this? Well,

1       there are questionnaires out there that you  
2       can do.  But I think that the questionnaires  
3       are more oriented to the Parkinson's clinics.  
4       But it is just basic medicine.  I mean, if you  
5       ask the patient, if you are a primary care  
6       doctor, "Do you snore," does he feel drowsy  
7       all day long, you know, just the basic  
8       questions that you ask to see if someone has  
9       any signs and actual symptoms of having  
10      Parkinson's disease, I think that is the  
11      easiest way to actually diagnose this.

12                    There has always been an idea --  
13      and I had this, too -- that it is the  
14      medications that are actually causing  
15      drowsiness.  But it is shown in actual  
16      numerous studies that it isn't the medication,  
17      that it is an actual primary sleep disorder.

18                    CO-CHAIR KNOWLTON:  So, what did  
19      your group do on evidence?  Did they have a  
20      recommendation on evidence?

21                    MEMBER SCARIANO:  Well, the  
22      evidence is that the studies have actually

1 shown this. There are numerous studies that  
2 actually show this.

3 CO-CHAIR TIRSCHWELL: But, Jack,  
4 like the other Parkinson's measures that we  
5 have discussed already, I think clearly you  
6 are describing lots of evidence associated  
7 with an increased risk of these sleep  
8 disorders with Parkinson's disease. But I  
9 guess the question is, is there any evidence,  
10 at least this initial question is, is there  
11 evidence looking at this measure, which is  
12 asking about sleep disturbances and any  
13 evidence that that improves patient outcomes?  
14 Or is it that same two-step leap that, if we  
15 ask about it, we will identify it; we will  
16 refer them to the right person, and then they  
17 will get the right treatment?

18 MEMBER SCARIANO: Yes, well, there  
19 is evidence of that. Again, there are  
20 numerous articles about that. I think that  
21 Dr. Miller is the worldwide leader in this,  
22 and she done a study actually worldwide. As

1 a matter of fact, she actually just finished  
2 one in improving the outcomes in Parkinson's  
3 patients in like China who have sleep  
4 disorders. So, there are numerous studies  
5 that actually show this. And I think that it  
6 is a valid problem and that it can be  
7 assessed.

8 MEMBER DUDA: Correct me if I am  
9 wrong, but I think what you are asking is, is  
10 there any evidence that this measure will  
11 work? I think you will agree that nobody has  
12 ever tested this assessment to see if it will  
13 change the diagnosis of sleep problems, just  
14 assessing them annually, actually. So, it is  
15 like the last one; you don't know it is going  
16 to work. There is no evidence to say that it  
17 is actually going to work.

18 MEMBER SCARIANO: It actually  
19 doesn't say annually. It says at least  
20 annually. So, if you see someone one time and  
21 you treat it with medication, and then they  
22 come back and say, "Well, he can walk better



1 and he is not shaking, but he is actually  
2 feeling drowsy all the time," you know, is it  
3 medication or is it an underlying sleep  
4 disorder? And that is where I see it.

5 CO-CHAIR KNOWLTON: Other comments  
6 here on evidence?

7 Gwen?

8 MEMBER BUHR: It says in here that  
9 it is Grade Level D evidence. So, that is  
10 expert opinion.

11 CO-CHAIR KNOWLTON: Peter?

12 MEMBER SCHMIDT: So, there is an  
13 interesting difference here between the  
14 recommendation here and what is in the NICE  
15 guidelines. In the NICE guidelines, the  
16 statement is that, if the patient complains  
17 about sleep disturbance, a detailed history  
18 should be taken. That is because the problem  
19 isn't so much the diagnosis of a sleep  
20 disturbance; it is the differential diagnosis  
21 of what sleep disturbance it is. So, I think  
22 that that is the major challenge here, that

1 querying about sleep disturbance is not  
2 sufficient.

3 CO-CHAIR KNOWLTON: Anybody else  
4 on evidence?

5 (No response.)

6 Let's vote on evidence.

7 (Vote taken.)

8 MS. THEBERGE: We need three more.  
9 One more.

10 One yes, 18 no, and 5 no,  
11 insufficient.

12 CO-CHAIR KNOWLTON: The next  
13 measure is Mary on Parkinson's disease  
14 rehabilitative therapy options, 1988.

15 MEMBER VAN DE KAMP: I, again,  
16 continue the concerns that the group felt  
17 around the evidence. I think that  
18 rehabilitation, obviously, is a critical  
19 component.

20 There is one concern other than  
21 the evidence. It is that the numerator  
22 would -- or, I'm sorry -- yes, the exclusions,

1 actually, would be that any patient with a  
2 medical reason, not discussing rehabilitation  
3 options with patients or caregivers, where the  
4 patient has no known physical disability to  
5 Parkinson's disease and patient is unable to  
6 respond and no informant is available.

7 I think that is a large exclusion  
8 without taking into account that if  
9 rehabilitation is needed, an assessment would  
10 be needed to determine if that is true rather  
11 than an anecdotal or lack of information. So,  
12 I think that exclusion, I feel, has  
13 significant issues.

14 But, like the rest of the  
15 measures, the evidence around this I think is  
16 that rehabilitation is a value. But a  
17 checkbox to say that they were asked about  
18 rehabilitative services is not going to change  
19 the outcome or the quality.

20 But, specifically, if we were to  
21 have feedback, it was that the exclusions may  
22 not actually be the right exclusions for a

1 true assessment of rehabilitation needs.

2 CO-CHAIR KNOWLTON: Any new  
3 arguments on this one?

4 Peter?

5 MEMBER SCHMIDT: I am not sure  
6 whether it is a new argument, but I do think  
7 that this is one of those things where there  
8 is evidence where it front of mind to the  
9 clinician results in a higher level of  
10 referrals. We have seen that. I have  
11 evidence on this that I haven't published yet.  
12 But it does make a difference.

13 And there is ample evidence that  
14 rehabilitative therapy makes a difference in  
15 patients with Parkinson's disease. So, there  
16 is a reasonable causal link.

17 CO-CHAIR KNOWLTON: But, I mean,  
18 can you speak to Mary's comment that the  
19 exclusionary problem --

20 MEMBER SCHMIDT: I totally agree  
21 with her about the problems with the  
22 exclusions.

1 CO-CHAIR KNOWLTON: Okay. That is  
2 my question.

3 MEMBER VAN DE KAMP: Yes.

4 CO-CHAIR KNOWLTON: So, that this  
5 measure doesn't do it because of the  
6 exclusions.

7 MEMBER VAN DE KAMP: And I just  
8 wanted to support Peter, because, I mean,  
9 clearly, the rehabilitative evidence or  
10 evidence for rehabilitative care is  
11 significant.

12 I guess the question that we had,  
13 as the Committee, one, obviously, the  
14 exclusions were of grave concern. But, more  
15 importantly, there wasn't evidence in here to  
16 show us that that bringing it to the referral  
17 or bringing it forward increased referrals to  
18 rehab. I think that would be great. I mean,  
19 I think that is a great thing. I just don't  
20 think we saw it.

21 CO-CHAIR TIRSCHWELL: I just want  
22 to make a comment outloud, maybe for the

1 developers. It seems like in all of these  
2 measures there would seem to be a lot more  
3 support if the measure not only included  
4 assessment but referral for appropriate care,  
5 which would, I guess, increase our confidence  
6 that that improved intervention would take  
7 place. Of course, it still wouldn't guarantee  
8 it, but I think it would get us a lot closer.

9           So, if this one, for example, were  
10 that options for rehabilitation therapy were  
11 discussed and were identified and appropriate  
12 referral was made -- now I think the hard part  
13 is that that is a lot harder to measure, and  
14 may be the reason why you are not doing that.  
15 But I think there is this conflict between  
16 what is the important measure to really drive  
17 care and what is hard to measure versus easier  
18 to measure with the EHR. So, I would just  
19 make that comment.

20           MEMBER SCHMIDT: I just want to  
21 say this is almost one that you could do  
22 without any exclusions.

1                   MEMBER SULLIVAN: I was just going  
2 to echo what David said. It seems like we  
3 looked at stroke measures that said, "Referred  
4 for rehabilitation," and then there were  
5 exclusions in there, people who, for whatever  
6 reason, weren't appropriate. But I think that  
7 would capture what really we would try to do  
8 to effect care.

9                   MEMBER WADDY: Yes, that was the  
10 comment that I was going to make, but a lot  
11 more eloquently than I would have made it.

12                   But, to me, it seems like for  
13 something that is so clear-cut in terms of  
14 making the diagnosis and then referring them  
15 for therapy, if we can't manage to put that  
16 into a single measurement, I don't know what  
17 you would be able to do for practically  
18 anything in terms of how we practice, because  
19 everything is a two-step. You have to  
20 diagnose, and then you have to make a  
21 decision. So, how can that really be captured  
22 in a single measure effectively and

1       efficiently? I think that you have described  
2       that.

3                   MS. SWAIN-ENG: So, I just wanted  
4       to respond to a couple of the comments. I  
5       know we had talked about this specific  
6       exclusion for this measure during the Work  
7       Group conference call.

8                   I just want to reiterate the  
9       reason why this exclusion was put in. During  
10      our public comment period, we received  
11      numerous comments from the public, from  
12      different physicians, not only neurologists,  
13      saying that they felt that an exclusion was  
14      appropriate, because initially we didn't have  
15      one for this measure.

16                   Because of the number of patients  
17      they see who are so early on in the disease  
18      course, they felt like it created an undue  
19      burden on these physicians to have to discuss  
20      rehabilitative therapy options if it was clear  
21      in their professional judgment that this  
22      patient did not need that discussed at that



1 time. It does not mean you cannot discuss it  
2 with them. That option is always there. But  
3 it helps to reduce that burden on those  
4 physicians that didn't feel it was merited for  
5 those patients.

6 And the additional exclusion was  
7 patients unable to respond and no informant  
8 available. Well, if the patient can't  
9 medically have a discussion with the  
10 physician, you can't discuss therapy options  
11 with that patient. That is just a simple  
12 fact.

13 Additionally, I think one of the  
14 additional issues was -- I think maybe that  
15 was it. I think that was actually it. That's  
16 it.

17 CO-CHAIR KNOWLTON: Peter?

18 MEMBER SCHMIDT: So, I know that  
19 lots of people don't like to refer, but a lot  
20 of the leading experts in Parkinson's disease  
21 based on academic medical centers will refer  
22 their early-stage patients for an

1 interdisciplinary assessment at the second  
2 visit. They confirm the diagnosis, and then  
3 the second visit they do interdisciplinary  
4 assessment. I think that is the standard of  
5 care adopted at most of the leading centers.  
6 So, I am not sure that a community physician  
7 not wanting to refer is a great way to do  
8 that, but to consider it.

9           And also, another thing is that  
10 difficulty with communication is a symptom of  
11 Parkinson's disease. Many of these people can  
12 receive information, even if they have trouble  
13 engaging in conversation. So, I would look  
14 for more than just -- you know, speech  
15 pathologists are a key component to a  
16 Parkinson's team.

17           CO-CHAIR KNOWLTON: John?

18           MEMBER DUDA: So, at the  
19 University of Pennsylvania, we have  
20 prehabilitation where patients are not  
21 debilitated and we send them to the rehab. At  
22 the Philadelphia VA Medical Center, I must not

1 be applying standard of care because we just  
2 don't do that. And I think there are a lot of  
3 centers that don't have easy access to  
4 rehabilitative services, don't refer every PD  
5 patient within the first year to  
6 prehabilitation.

7 CO-CHAIR KNOWLTON: Peter,  
8 anything else? Anything else, John? You're  
9 done?

10 Okay. Can we vote? This is on  
11 evidence.

12 (Vote taken.)

13 MS. THEBERGE: Ten yes; 13, no,  
14 evidence does not meet guidance, and 1, no,  
15 insufficient.

16 CO-CHAIR KNOWLTON: Which moves us  
17 on --

18 MEMBER KAPLITT: well, no, wait.  
19 I hate to do this.

20 (Laughter.)

21 But I think it is worthy at least  
22 of a two-minute discussion about the exception

1 rule because I do personally, even though I  
2 was pretty harsh on some of the earlier  
3 things, I think this is in a different  
4 category. I think it is worthy of discussion,  
5 particularly since the vote was this close.  
6 I think it is worthy of discussion, because I  
7 think the risk-to-benefit profile here is very  
8 different than assessments of, are you  
9 diagnosing things properly or not, or  
10 whatever, as opposed to are you having  
11 discussions about your therapeutic options.  
12 I think the harm issue is very different here  
13 and, in my view, much less.

14 I think that people should be  
15 talking about it. So, I think it is worthy of  
16 a discussion because there may be a few people  
17 in the "no" category who feel it is worthy of  
18 an exception that would change the outcome  
19 here.

20 Mary?

21 MEMBER VAN DE KAMP: Yes, I agree.

22 I think that Michael had done it, and I was

1 going to do it as well.

2 I think that, back to Peter's  
3 point, if the note gets it to the front and  
4 foremost, then I think that, whether it is  
5 great, a referral would be a much better  
6 option.

7 But, still, I would like to have  
8 the caveat, I am still concerned about the  
9 exclusions. So, now I am confused. If I vote  
10 for the -- you know, if we say it should be an  
11 exception because we believe that the good is  
12 greater than the harm, I think the exclusion  
13 concerns me around preventing some patients  
14 from access. So, I guess I am confused.

15 MS. THEBERGE: Then we can go to  
16 specifications.

17 MEMBER VAN DE KAMP: So, I am  
18 okay. I am okay with that. All right. Thank  
19 you. Sorry.

20 CO-CHAIR KNOWLTON: Other thoughts  
21 on the exception?

22 (No response.)

1 I am misreading because I am  
2 reading this document, 1988, but it looks like  
3 -- I was just asking Suzanne -- there is a  
4 cut-and-paste error because it is saying no  
5 evidence, no evidence, no evidence, and then  
6 it is talking about sleep disorders.

7 So, where are we? Is there a  
8 belief -- reminder that when we are making an  
9 exception, making an exception says there  
10 might not be empirical evidence, but there is  
11 expert evidence and that it is very clear.

12 Did the group feel that in this  
13 case it was very clear?

14 MEMBER VAN DE KAMP: I mean,  
15 again, to take the expert component to the  
16 rehabilitation advantage, the evidence is  
17 high. The risk of not providing that to a  
18 patient I think could potentially cause  
19 deterioration sooner than might otherwise  
20 occur. So, I think there is a harm component,  
21 but I am in that field.

22 MEMBER KAPLITT: I think, yes, the

1 expert evidence is good. I think the harm is  
2 low. And I think the lack of people even  
3 understanding the role of physical therapy in  
4 Parkinson's disease is a huge problem,  
5 particularly given the fact that medications  
6 do not treat well many symptoms of  
7 Parkinson's, and rehab is one of the few  
8 things that can be helpful for a lot of things  
9 like balance and walking issues, for example,  
10 and other things.

11 So, I think that the expert  
12 evidence is adequate from this in my personal  
13 view. But even though I think the evidence  
14 doesn't meet the normal standard, I think the  
15 benefit combined with the expert evidence and  
16 the lack, in my view, of harm in this one  
17 compared to some of the others to me does rise  
18 to the level of exception, just in my personal  
19 view.

20 CO-CHAIR KNOWLTON: Jordan?

21 MEMBER EISENSTOCK: I was just  
22 going to say I was itching to invoke the

1 exception, too, even beforehand, just in case.

2 But I really agree with Michael on  
3 this. I think this is a slightly different  
4 case than some of the other measures that we  
5 have examined recently. Excuse the pun, but  
6 it sort of a no-brainer. In the benefit/harm  
7 situation, I think that we prevent or minimize  
8 the use of dopaminergic medications if we stay  
9 one step ahead with the non-pharmacologic  
10 treatments like PT and OT. So, oftentimes, I  
11 will even try this in my practice if I think  
12 the patient can tolerate it and hold off on  
13 additional dopaminergic medications.

14 So, I feel pretty strongly that  
15 this is a measure we should try to work a  
16 little bit further with.

17 CO-CHAIR KNOWLTON: Anything else?

18 (No response.)

19 Okay. We are voting on the  
20 exception. Is there general agreement that  
21 the quality, quantity, and consistency of the  
22 body of evidence meets the NQF guidance?



1 I'm sorry. Is there an  
2 exceptional and compelling reason that the  
3 measure should be considered further, yes or  
4 no?

5 (Vote taken.)

6 And you are down one, Suzanne.  
7 You are down one.

8 MS. THEBERGE: Okay. So, we still  
9 need -- okay, there we go.

10 Twenty yes, 3 no.

11 CO-CHAIR KNOWLTON: A compelling  
12 argument, Michael.

13 (Laughter.)

14 All right. As they say, Mary, you  
15 are still alive.

16 We should be on impact.

17 MEMBER VAN DE KAMP: Well, I think  
18 we addressed that.

19 CO-CHAIR KNOWLTON: Yes, I think  
20 you did, too. I would ask you, however, to  
21 also, under impact, address disparities, which  
22 is where we have been putting that.

1                   MEMBER VAN DE KAMP: I think that  
2                   disparities that we discussed were around  
3                   these exclusions and it broadened the  
4                   disparities. If they have communication or  
5                   language barriers, if you are discussing it  
6                   with the patient, those would have to be  
7                   addressed as well.

8                   CO-CHAIR KNOWLTON: Okay. Can we  
9                   vote on impact?

10                  MEMBER WADDY: So, what is your  
11                  definition again for disparities? Is it just  
12                  diversity --

13                  CO-CHAIR KNOWLTON: Can we hold  
14                  it, Salina, because I put it in the wrong  
15                  place.

16                  MEMBER WADDY: Okay.

17                  CO-CHAIR KNOWLTON: We will  
18                  discuss disparities in the next round.

19                  (Vote taken.)

20                  MS. THEBERGE: I need three more.

21                  Oh, there we go.

22                  Eighteen high, 5 moderate.

1 CO-CHAIR KNOWLTON: Okay. Go back  
2 to the performance gap, Mary.

3 MEMBER VAN DE KAMP: Yes. Again,  
4 I think it speaks to the conversation of  
5 bringing it to the forefront with the  
6 physicians will, then, improve the access to  
7 rehabilitation services, hopefully sooner than  
8 later, and certainly ongoing.

9 CO-CHAIR KNOWLTON: And Salina's  
10 point on the disparities, did you hear it?

11 MEMBER VAN DE KAMP: Yes, and I  
12 think I was addressing it as well earlier.  
13 But I think this is a measure with exclusions  
14 that concern me. It is that, if there is a  
15 disparity around a language barrier or  
16 apparently not understanding, or I understand  
17 to some degree what the response was, but it  
18 concerns me that we are making a determination  
19 of whether a patient or their family member,  
20 or a patient specifically can understand  
21 before an assessment of whether they have  
22 comprehension and the skills to make that

1 determination. I mean, it is like crossing  
2 them off before we assess, I guess.

3 CO-CHAIR KNOWLTON: Go ahead.

4 MS. SWAIN-ENG: I can speak to  
5 that just very briefly. This is a medical  
6 exception. A language barrier --

7 CO-CHAIR KNOWLTON: Hold on for a  
8 minute. Just hold for a second and let Salina  
9 respond to the question, so we get the back-  
10 and-forth.

11 MEMBER WADDY: Yes. So, I just  
12 wanted to be clear in terms of how you are all  
13 defining disparities, at least across the  
14 federal agencies there are three components,  
15 both minority as well as role versus urban and  
16 socioeconomic. And certainly, if you don't  
17 have funds to be able to pay for  
18 rehabilitative services, then that is a  
19 disparity in and of itself. As well, in rural  
20 and remote places in the middle of Alaska,  
21 seriously, you are not going to find good  
22 rehabilitative services. And there are

1 various reasons why people may not.

2 And so, I just wanted to know what  
3 NQF's definition --

4 DR. BURSTIN: Much of the work  
5 that we have done to define disparity  
6 sensitivity was done on race, ethnicity, and  
7 language. I think the idea of prevalence and  
8 a performance gap and an opportunity for  
9 improvement are things that I think would work  
10 well across any of those other entities.

11 And we really just want to get a  
12 sense of, really, essentially, is this a  
13 measure that should be stratified, so you  
14 don't miss out on populations particularly at  
15 risk?

16 CO-CHAIR KNOWLTON: Rebecca, you  
17 had a point?

18 MS. SWAIN-ENG: Sorry. I am just  
19 trying to say that, if somebody did have a  
20 language barrier and that was an issue, that  
21 is not included in this measure. This is a  
22 medical reason. So, there is a medical

1 condition, problem. Perhaps somebody was  
2 late-stage dementia with Parkinson's disease  
3 and didn't have somebody there with them to  
4 either act as their caregiver or they couldn't  
5 cognitively because of a medical respond or  
6 participate in any meaningful discussion. So,  
7 language barrier wouldn't fall underneath this  
8 issue. You would get an interpreter, and that  
9 wasn't covered or intended by this exclusion.

10 CO-CHAIR KNOWLTON: Anything else?

11 (No response.)

12 Okay. We are on the performance  
13 gap, yes.

14 (Vote taken.)

15 We still need some votes.

16 MS. THEBERGE: I need four more  
17 votes.

18 All right. Nine high, 12  
19 moderate, 2 low.

20 CO-CHAIR KNOWLTON: Okay. So, we  
21 are moving on to scientific acceptability,  
22 starting with reliability.

1                   MEMBER VAN DE KAMP: This is the  
2                   area that I think I brought up too soon,  
3                   obviously, is the exclusion concerns that I  
4                   have already addressed.

5                   CO-CHAIR KNOWLTON: Jane?

6                   MEMBER SULLIVAN: This is an area  
7                   that I feel like I would like to say that  
8                   there is some burgeoning evidence of the  
9                   neuroprotective effect of exercise. So, in  
10                  addition to what has already been said, I  
11                  think that the exclusion of non-motor  
12                  symptoms, the fact that this is a progressive  
13                  disease, is compelling reason to look  
14                  seriously at removing that exclusion.

15                  CO-CHAIR KNOWLTON: Other thoughts  
16                  on this? This is reliability and validity  
17                  combined in this particular measure. Anything  
18                  else?

19                  Michael?

20                  MEMBER KAPLITT: From the  
21                  developer, whether they are willing to do this  
22                  or not, because that, I think, is going to

1 affect a lot of votes.

2 CO-CHAIR KNOWLTON: Okay.

3 DR. BEVER: So, what is the  
4 specific request?

5 MEMBER SULLIVAN: The request is  
6 to consider the exclusion of non-motor  
7 symptoms, the patient who is not presenting  
8 with a motor symptom as an exclusion, because  
9 it is currently stated that it is an exclusion  
10 and there is some concern that has been  
11 expressed that this exclusion would prevent  
12 somebody from being counseled about  
13 rehabilitation until or unless they had some  
14 frank presentation of the disease. I think  
15 prehabilitation was the term that you were  
16 using, would eliminate care for people before  
17 they maybe a year down the road were showing  
18 frank motor symptoms.

19 DR. BEVER: So, you think the  
20 measure will be used as a guideline,  
21 basically, to tell you when you have to do  
22 something? And so, the fact that the measure



1 doesn't -- you are saying the measure would  
2 lead somebody not to do rehabilitation in  
3 someone with non -- I mean, the exception  
4 wasn't meant to exclude that. The exception  
5 was only meant, as a quality issue, you are  
6 not required to counsel that person. You are  
7 saying, as a quality issue, those patients  
8 should be counseled.

9 MEMBER SULLIVAN: I guess my point  
10 was that somebody who is sensitized to the  
11 disease and the opportunities would probably  
12 do it anyway, but the primary care physician  
13 who is maybe not seeing a lot of these  
14 patients would say, "Oh, well, they are not  
15 showing motor symptoms. So, I don't need to  
16 discuss rehabilitation with them."

17 And I would like to advocate that,  
18 if they have that diagnosis, even if they are  
19 not showing symptoms, they may, and  
20 intervening early would have some benefit.  
21 So, to take the exclusion off the table.

22 DR. BEVER: Well, I mean, there is

1 some evidence, as you point out. I don't  
2 think that that is a standard of practice yet,  
3 would be my understanding. I don't know;  
4 maybe others who deal with Parkinson's  
5 patients would want to comment on that.

6 CO-CHAIR KNOWLTON: I don't  
7 understand. Well, let's take a few more  
8 comments and then we will come back to you  
9 because there is going to have to be some  
10 clarity on what the developer is willing to do  
11 to meet the exclusion issue that a number of  
12 people voting have a concern about.

13 Peter?

14 MEMBER SCHMIDT: So, although I  
15 know that lots of people like the  
16 prehabilitation model, there really isn't  
17 evidence for it. And so, the exclusions, as  
18 they stand with some nuances around difficulty  
19 with communication, I think these exclusions  
20 as they stand are in line with the evidence  
21 for health interventions.

22 CO-CHAIR KNOWLTON: Mary, John,

1       then Dan.

2                       MEMBER VAN DE KAMP: I would just  
3 say that discussing rehabilitative options  
4 doesn't mean today. And so, I think maybe  
5 that is where I am interpreting it. It goes  
6 back to, do you refer or do you just discuss?  
7 So, I think if you look at it as an  
8 opportunity to discuss the possibility of  
9 rehab might help you at a certain point, it  
10 may be of value. I think it is not saying  
11 that you must have rehabilitative services to  
12 get a quality check.

13                      I worry a little bit in this, in  
14 the exclusions, that you are leaving a lot to  
15 a prejudice maybe of the assessor on whether  
16 rehab is valuable or not generally and leaving  
17 that more to taking it to the evidence around  
18 rehabilitation over the course of care within  
19 a rehabilitation process.

20                      I don't know; I hear what you are  
21 saying about not wanting to have everyone get  
22 rehab. You know, we don't need to have a lot

1 of evaluations for rehab that aren't  
2 appropriate because that raises the cost and  
3 is of no value.

4 But this doesn't say evaluations;  
5 this says rehabilitation, right? I mean, we  
6 are talking about that. So, I don't know. I  
7 am vacillating a little, I guess, on that one.

8 CO-CHAIR KNOWLTON: John?

9 MEMBER DUDA: So, in my practice,  
10 like I said, I don't talk to people about  
11 PT/OT and speech therapy if they come in with  
12 a benign resting tremor and one extremity that  
13 is non-disabling. I don't see the point of  
14 that.

15 In every one of those patients, I  
16 do talk about physical activity or exercise.  
17 I think we are kind of blurring the  
18 distinction here, that a lot of the evidence  
19 for neuroprotection and everything is really  
20 for an active lifestyle, not for going to  
21 physical therapy and getting treatment. There  
22 is no evidence that I am aware of that

1 suggests that this has any effect on the  
2 progression of the illness. It affects the  
3 functional capacity and things. But if the  
4 physical therapist can convince you to do your  
5 exercise, sure, but that is not what we are  
6 talking about here, right? We are talking  
7 about a specific regimen of rehabilitation for  
8 a specific deficit. And a lot of PD patients  
9 don't have any deficits early on.

10 CO-CHAIR KNOWLTON: Daniel?

11 MEMBER LABOVITZ: John spoke my  
12 point. I think anybody can advocate exercise.  
13 You don't have to get it from a physical  
14 therapist.

15 MEMBER BARRETT: I would actually  
16 say that I think that your recommendation  
17 constitutes a discussion of rehabilitation  
18 options appropriate for that patient's stage  
19 of care, and fits a standard of care within  
20 neuro-rehabilitation for those kinds of  
21 patients.

22 I would say that you are doing a

1 rehabilitative option discussion when you do  
2 that. When you discuss physical fitness, I  
3 would say that that fits a standard of care  
4 within neuro-rehabilitation for those patients  
5 in general.

6 MEMBER WADDY: I would actually  
7 say you just made this a lot more difficult  
8 because separating those two out, whether or  
9 not it is just increase in exercise or some  
10 exercise regimen as opposed to rehabilitative  
11 therapy -- and those are two separate things  
12 -- and how this issue is actually addressed by  
13 practitioners, does it really reach the level  
14 of putting in rehabilitative therapy?

15 CO-CHAIR KNOWLTON: Michael?

16 MEMBER KAPLITT: I would also say  
17 that the exclusion has a documentation  
18 requirement to it. I think that that, to me,  
19 is important in giving me a comfort level with  
20 this. Because it is like, if I don't give  
21 antibiotics before a surgery, a PQRS measure  
22 requires me to document it. So, I can't just

1 choose not to do it and say, "Well, it wasn't  
2 important."

3 So, I think here the documentation  
4 requirement is going to be put a little burden  
5 on people who come in with just a tremor and  
6 every time you have got to say, "I didn't  
7 discuss rehab with them because there is no  
8 need," but it does at least require people to  
9 have documented that they thought about it and  
10 why. And so, that gives me a little bit more  
11 comfort level.

12 CO-CHAIR KNOWLTON: Peter?

13 MEMBER SCHMIDT: So, this is  
14 genuinely an area of clinical controversy.  
15 This isn't something that we can decide here  
16 ourselves.

17 There is a study ongoing in  
18 Australia where they are randomizing people  
19 into a group where it is neurologist-directed  
20 care versus a team assessment. I wrote the  
21 check for that study. So, I have seen  
22 everything about it.

1           It is established clinical  
2           controversy. People don't have an assessment.  
3           So, it is not appropriate to remove the  
4           exclusion and define as quality care to  
5           address this at presentation because there  
6           isn't the evidence for it.

7           You know, we may like that idea,  
8           and we funded that, my Foundation funded that  
9           project because we like the idea of doing this  
10          assessment. And maybe in a year this study  
11          will be published and we will have one RCT to  
12          address this issue with. But today we can't  
13          do it.

14                 CO-CHAIR KNOWLTON: So, to the  
15          developer -- oh, I'm sorry. Gwen?

16                 MEMBER BUHR: So, now you made me  
17          have a question.

18                 (Laughter.)

19                 Thinking about reliability and the  
20          exclusions, so if you have convinced me that  
21          we should keep the exclusions, are we going to  
22          be able to always get the same patients with



1 these exclusions? It seems like they can be  
2 interpreted sort of however you want to  
3 because it just says, "example". So, you  
4 could just say it wasn't appropriate for that  
5 patient, and anybody can have a different  
6 reason for why it is not appropriate. That  
7 doesn't seem very reliable.

8 There is a medical reason for not  
9 discussing rehabilitation therapy options with  
10 the patient or a caregiver, as appropriate.  
11 So, you can think of whatever medical reason  
12 you want to.

13 MEMBER KAPLITT: But that is true  
14 for a lot of these types of measures. I mean,  
15 we are giving people some element of clinical  
16 judgment. And that is why I think the  
17 documentation requirement at least forces you  
18 to give that reason. It is possible over time  
19 that that would change. I mean, we have  
20 already accepted the idea that we are making  
21 an exception and that the evidence is not  
22 there, but that we feel it is important

1 enough.

2 I think that to mandate this  
3 overall for everybody, say that you actually  
4 have to have this discussion, you know, it is  
5 probably not a big deal. But if you have  
6 people who are mute and they show up from  
7 their nursing home with somebody from the  
8 ambulette service and they don't have a family  
9 member there, and you still have to have that  
10 discussion, you know, I think that there are  
11 enough reasons that, as long as it has got to  
12 be documented by somebody, you know, yes, over  
13 time that may change, but I don't know that  
14 that is a huge harm. I mean, you are right,  
15 people could do that, but you could say that  
16 about almost any PQRS-type thing. I know that  
17 is not exactly what this is, but --

18 CO-CHAIR KNOWLTON: Other folks?

19 (No response.)

20 Developer?

21 DR. BEVER: So, do you want to  
22 vote on it as it is?

1 CO-CHAIR KNOWLTON: Well, yes, I  
2 don't know. What have we got here? What is  
3 on the table?

4 MEMBER WADDY: Well, can I just  
5 say really quickly, I mean, there is the  
6 exception issue, but I still have an issue  
7 regarding the wording of rehabilitative  
8 therapy as opposed to potentially exercise.  
9 Does it specifically need to be within PT/OT  
10 or speech?

11 CO-CHAIR KNOWLTON: Unless  
12 somebody is going to say that they want a  
13 specific exception here, I am going to leave  
14 it as it is. So, if you want the exception,  
15 speak up.

16 (No response.)

17 Okay. Then, we are voting on this  
18 as is, on reliability and validity, and you  
19 are going to take your best shot.

20 (Vote taken.)

21 MS. THEBERGE: I need one more.

22 Eleven yes, 13 no.

1 CO-CHAIR KNOWLTON: So, we are  
2 done with this measure.

3 Peter, you are up.

4 MEMBER SCHMIDT: This measure is  
5 Parkinson's disease medical and surgical  
6 options reviewed, although in the definition  
7 it also talks about non-pharmacological  
8 treatment, pharmacological treatment and  
9 surgical treatment, reviewed at least  
10 annually.

11 So, these things need to be  
12 reviewed for the patients who are seen. My  
13 first reaction to this was, if the patient is  
14 coming to the clinic and you are not reviewing  
15 their medical and therapeutic options, then  
16 what are you doing?

17 (Laughter.)

18 So, there is no evidence for this.  
19 It is at least annually. However, I think  
20 most patients, we do surveys of centers, and  
21 most people will see their average patient  
22 every three to four, maybe six months.

1                   So, this is really not very well  
2 supported. There is no real evidence around  
3 this because you would never get it past an  
4 IRB to test not reviewing medical options when  
5 the patient comes to the clinic.

6                   CO-CHAIR KNOWLTON: Don't hold  
7 back, Peter.

8                   (Laughter.)

9                   MEMBER SCHMIDT: Okay. Could I  
10 just say I appreciate that AAN submitted these  
11 guidelines, and I think it is very important,  
12 but I think this particular one being defined  
13 as a quality standard is challenging.

14                  CO-CHAIR TIRSCHWELL: I am just  
15 looking at this, and I guess although  
16 certainly the pharmacologic especially, but I  
17 am guessing that there is a good number that  
18 don't have non-pharmacologic or surgical  
19 options discussed on an annual basis --

20                  MEMBER SCHMIDT: It is "or".

21                  CO-CHAIR TIRSCHWELL: Yes, and I  
22 agree; maybe that is just a suggestion that

1 needs to go back to the developer, that maybe  
2 certain aspects of this are more relevant for  
3 a quality measure than others. I don't know.

4 MEMBER KAPLITT: Yes. No, I think  
5 the "or" is the big issue because, if people  
6 say, "Yes, your medicine seems to be working  
7 just fine," and that's it, that is the  
8 discussion, or even if it is not, and then  
9 that is it; they satisfy the criteria. So, it  
10 is the "or" that is the issue, I think.

11 And I would argue, just for the  
12 sake of maybe brevity or expediting this, that  
13 I know that we had said we were going to do  
14 evidence first. But the issue which is  
15 raised, which I think is an important one, is  
16 really more of a performance gap issue,  
17 meaning is there really evidence that there is  
18 a gap in the fact that, when patients come to  
19 their doctor to be treated for Parkinson's,  
20 they are not discussing treatment for  
21 Parkinson's, right? Is there real evidence of  
22 a gap?

1                   So, I mean, I would propose that  
2                   maybe that be the first thing we discuss  
3                   because that was the issue that was raised.

4                   MEMBER SCHMIDT: So, in fact,  
5                   there is evidence that it is being discussed  
6                   because you can see patients having escalating  
7                   doses and adjunctive therapies added on in the  
8                   community setting. And quite often, when  
9                   patients are referred to expert neurologists,  
10                  their medications are reduced, not increased,  
11                  which indicates that somebody is thinking  
12                  about their medications, just getting it  
13                  wrong.

14                  CO-CHAIR KNOWLTON: Anything else  
15                  here?

16                  (No response.)

17                  Let's stay on the evidence first.  
18                  The gap issue we could discuss, if you want  
19                  to, but -- the rule of the Chair, we will go  
20                  with evidence first. Let's vote on evidence.  
21                  Voting on evidence.

22                  (Vote taken.)

1 MS. THEBERGE: Two more responses.

2 Two yes; 16, no, evidence does not  
3 meet guidance, and 6, no, insufficient  
4 evidence submitted.

5 CO-CHAIR KNOWLTON: Okay.

6 CO-CHAIR TIRSCHWELL: So, we are  
7 back on time.

8 (Laughter.)

9 Can we take a 15-minute break? Is  
10 that okay?

11 CO-CHAIR KNOWLTON: Sure.

12 CO-CHAIR TIRSCHWELL: Yes, go  
13 ahead.

14 MEMBER WADDY: I just think that,  
15 with the previous one on rehabilitative  
16 services, to the developers, I think it is  
17 really unfortunate what happened with that  
18 one. I think it is really important that, if  
19 there was a way to somehow address the  
20 criticisms that you heard, I mean, I think it  
21 would be really of value to revisit in some  
22 subsequent time period.



1 CO-CHAIR KNOWLTON: Well, I am  
2 glad you said that, Salina. I would add to  
3 that, I am probably the least clinically  
4 knowledgeable here, but I think the developer,  
5 just looking from this side of the table,  
6 people are all saying that these are important  
7 things and requiring attention. This is the  
8 first real shot at trying to pay attention to  
9 them in a structured way. And the NQF  
10 standard is a high standard.

11 But I don't hear any of these  
12 things where people say, "Now why are we even  
13 bothering with this?" People were very  
14 supportive. It just didn't quite meet the  
15 test. So, I hope these will be things that we  
16 will continue to work on.

17 DR. BEVER: Yes, I think the  
18 challenge at the developer level is that there  
19 are different criteria at each level that we  
20 are working on these, and each group has their  
21 own thoughts about how they should be crafted  
22 and different considerations. And so,

1 navigating that has been challenging.

2 CO-CHAIR KNOWLTON: One of my  
3 comments to Suzanne during this debate was  
4 democracy is messy. You know, getting  
5 consensus through this process is a very high  
6 bar. But, at the end of the day, hopefully,  
7 it gets better.

8 I have seen these debates before.  
9 I have been on a number of these. This was a  
10 good one and a rich one, and it was a very  
11 positive one for these measures. I have  
12 watched enough measures go down in flames;  
13 that isn't what happened here. So, there is  
14 a lot of support for these measures. So, I  
15 hope you won't be disheartened. That is just  
16 an editorial comment from me. Don't be  
17 disheartened. These are good measures. They  
18 need some tweaking to get through the  
19 consensus process.

20 DR. BEVER: Thank you.

21 MEMBER WADDY: I agree with that.  
22 I mean, I just really think that that is such

1 an important one, in particular, that if there  
2 was a way to take some of our comments and  
3 tweak it, because this isn't a measure where  
4 you just have to throw it out and start  
5 completely over. I think that tweaks, small  
6 tweaks, can really change how the measure is  
7 viewed.

8 MS. JOHNSON: And just to remind  
9 everybody, like we did last time, tomorrow we  
10 will have a little bit of time for you guys to  
11 weigh-in in terms of ideas for future measure  
12 development. So, that might be something, and  
13 we always write those up and put those in our  
14 reports. So, we would encourage the  
15 developers to take a peek at that as well.

16 (Whereupon, the above-entitled  
17 matter went off the record at 3:02 p.m. and  
18 resumed at 3:20 p.m.)

19 MEMBER RICHMOND: Okay, let's go  
20 ahead and get started again.

21 Raj Sheth will be presenting the  
22 next, our third-to-last measure for the day,

1 1814. We are switching to epilepsy. This is  
2 counseling for women of childbearing potential  
3 with epilepsy.

4 Do we need to introduce the  
5 developers? It is the same developer for all  
6 three of these.

7 Did you have any different  
8 comments about the epilepsy measures as  
9 opposed to the Parkinson's ones.

10 DR. BEVER: No

11 CO-CHAIR TIRSCHWELL: Okay.  
12 Great.

13 So, Raj, go ahead and start us off  
14 with an overview and then right into the  
15 evidence.

16 MEMBER SHETH: Thank you.

17 This is a pretty big issue, and it  
18 is not one where you run into the typical  
19 challenges of is or is the patient not  
20 depressed. I mean, the numerator should be  
21 relatively easy, at least from a pregnancy  
22 perspective. You are either pregnant or not,

1 obviously. And so, from that regard, it is  
2 very important.

3 There are probably half a million  
4 women with epilepsy. The amount of  
5 controversy that exists about pregnancy,  
6 contraception, breastfeeding is huge.

7 There are also two people in this.  
8 There is the fetus and the mom. So, it really  
9 has a big impact. Teratogenic effects on the  
10 fetus really have long-term consequences and  
11 huge costs. These are going to be 30-, 40-,  
12 50-, 69-year expenses. So, the overall impact  
13 is quite significant.

14 And the rationale that is provided  
15 by the developers is that the performance gap  
16 is that only 2 to 20 percent, between 2 and 20  
17 percent of women --

18 CO-CHAIR TIRSCHWELL: We are not  
19 on performance gap. It is this --

20 MEMBER SHETH: So, that is the  
21 overall introduction.

22 CO-CHAIR TIRSCHWELL: So, I guess

1 we are looking for evidence that this measure,  
2 as crafted here, will have a positive effect  
3 on patient outcomes.

4 MEMBER SHETH: And the evidence  
5 is, like the discussions that went before, it  
6 is very scant and not really highly --

7 CO-CHAIR TIRSCHWELL: It is not a  
8 direct link. It is through a couple of  
9 intermediate assumed processes?

10 MEMBER SHETH: That is correct.

11 CO-CHAIR TIRSCHWELL: Okay. Thank  
12 you, Raj.

13 Anybody else want to comment? Dr.  
14 Barsan?

15 MEMBER BARSAN: Yes, I think the  
16 issue is that nobody doubts that this is  
17 important and nobody doubts that this is a  
18 critical issue. It is a question of, does  
19 this, as outlined, doing these things, is that  
20 going to really make a difference? Is that  
21 going to affect an outcome at all?

22 And so, trying to determine the

1 assessment with the outcome. I mean, the same  
2 problem with the other assessments. And so,  
3 I think that is really where the issue comes  
4 in.

5 The other thing that we talked  
6 about, too, is, is it sufficient to say,  
7 "Here's a website."? Is it sufficient to give  
8 handout materials? Does it have to be a half-  
9 hour discussion? I mean, you know, there is  
10 not a lot of discussion about what is adequate  
11 in terms of that. So, that is part of the  
12 issue, too.

13 CO-CHAIR TIRSCHWELL: Daniel?

14 MEMBER LABOVITZ: I am just  
15 warning you that I am going to invoke an  
16 exception on this one.

17 (Laughter.)

18 I think it is really important,  
19 and I don't need much evidence to believe that  
20 talking to patients about this issue makes a  
21 difference, both in terms of patient behavior  
22 and in terms of knowledge and the provider's

1 awareness.

2 I have screwed this up. It didn't  
3 lead to any disaster, but I failed to have the  
4 conversation. I feel bad about it. I think  
5 it is a quality measure that needs careful  
6 scrutiny.

7 CO-CHAIR TIRSCHWELL: Michael?

8 MEMBER KAPLITT: I mean, before we  
9 get to the exception point, I think that there  
10 is some evidence presented here. I mean,  
11 again, it is not randomized controlled  
12 evidence, but there is evidence here compared  
13 to some of the other measures we talked about  
14 that are directly on point. I mean, there are  
15 several surveys, for example, that they cite,  
16 large surveys, of women of childbearing age  
17 who report that they feel, you know, a large  
18 percentage feel that they are not being  
19 adequately informed. Well, I guess that is  
20 more of a performance-gap issue.

21 CO-CHAIR TIRSCHWELL: Yes.

22 MEMBER KAPLITT: But, again, here,



1 for example, if there is good evidence  
2 provided that certain epileptic medications  
3 can affect child development, et cetera, right  
4 -- so, the question is, what is the evidence  
5 we are looking for, right? If there is good  
6 evidence that there are problems if you don't  
7 fully understand how treatment of epilepsy can  
8 affect child development or can affect your  
9 health, right, that is evidence A, and there  
10 is a pool of evidence that they provide on  
11 that point.

12 And then, B, there is evidence  
13 that women are not understanding adequately  
14 enough of childbearing age what their options  
15 are. And the question is, what kind of  
16 evidence are we looking for to affect whatever  
17 healthcare in this regard?

18 CO-CHAIR TIRSCHWELL: So, you  
19 know, I think the evidence that we are looking  
20 for in this criteria, the best evidence that  
21 would be available would be if there had been  
22 a randomized trial of discussing this with

1 pregnant women and it led to less  
2 malformations as a result. That would be top  
3 of the line.

4 What is the case for all of these  
5 measures, including a number that have failed  
6 already, is that there is lots of evidence  
7 that treating sleep disorders or depression or  
8 getting rehab therapy in Parkinson's disease  
9 is beneficial, but not that that measure, as  
10 it was constructed, is going to lead to all  
11 those better outcomes. And it is that lack of  
12 linkage which has been, I think, the issue  
13 with the other measures and probably continues  
14 to be the issue to some degree with this one.

15 Salina? And then, Bill and Ramon.

16 MEMBER WADDY: It seems to me, I  
17 mean, are there other concrete measures that  
18 have been developed or is this just the very  
19 first attempt at pregnancy in women, such as  
20 use of folate or developing a requirement that  
21 they develop a strategy in case the person  
22 becomes pregnant, so that they understand it,

1       rather than your just having this open-ended,  
2       not open-ended, but sort of random  
3       conversation?

4                   CO-CHAIR TIRSCHWELL: Right. So,  
5       again, you are sort of bringing up the point  
6       that has come up in related ways. Is there a  
7       way that we can get closer to valuable actions  
8       as opposed to just the discussion with the  
9       assumption of an action down the line.

10                   Bill, were you next, I think?

11                   MEMBER BARSAN: Yes, the only  
12       other thing I was going to add to that is I  
13       think you could actually move this a lot  
14       closer from the assessment to something  
15       meaningful if it were a very simple thing.  
16       That is that evidence that once a year in any  
17       woman of childbearing potential they are asked  
18       if they plan on becoming pregnant in the next  
19       year. If you ask that question alone, you  
20       would open the whole topic of pregnancy, and  
21       whatever. If there were questions about that,  
22       I think it would at least get the discussion

1 started.

2 As it is, it is a little bit  
3 nebulous as to what the counseling is. It is  
4 not real clear how you measure it.

5 CO-CHAIR TIRSCHWELL: Ramon? And  
6 then, Peter.

7 MEMBER R. BAUTISTA: There is  
8 about a 91-90 percent chance that pregnant  
9 women with epilepsy are going to have normal  
10 pregnancies anyway, no matter what you do, as  
11 opposed to 98 percent chance of the average  
12 person without epilepsy. So, the effect size  
13 is really very small.

14 In other words, even in the best  
15 of circumstances, the difference between the  
16 morbidity rates for those with epilepsy and  
17 without epilepsy is still going to be very  
18 small, and that is where the difficulty is.

19 CO-CHAIR TIRSCHWELL: Peter?

20 MEMBER SCHMIDT: So, quickly, to  
21 your comment, if you reversed that and made it  
22 an odds ratio, it would be pretty dramatic.

1                   In the issue of RCTs, we should be  
2                   accepting things like all-or-none evidence as  
3                   valid. RCTs are only really done by  
4                   pharmacies, pharmaceutical companies and the  
5                   NIH. There are other levels of evidence that  
6                   are just as compelling.

7                   I think that we could address  
8                   this. This could be assessed as an all-or-  
9                   none-type criteria. If we are saying that  
10                  everybody who has this, if we are saying  
11                  everybody, we should be counseling everybody,  
12                  and by this measure, we are pushing people to  
13                  counsel everybody. We are defining counseling  
14                  everybody as quality care. That counseling  
15                  has evidence that it has an effect.

16                  You don't need a randomized trial.  
17                  That fits the all-or-none criteria, and so it  
18                  can be considered valid. So, you don't have  
19                  to go to an exception in a case like that.

20                  CO-CHAIR TIRSCHWELL: Raj?

21                  MEMBER SHETH: The AAN actually  
22                  has practice parameters that address this

1 issue. The question is, does the intervention  
2 that they suggest actually affect outcome?  
3 That link is the one we are debating at  
4 present.

5 But there are several levels of  
6 evidence that are below that, particularly  
7 with regards to the malformation rate that is  
8 very clearly defined. We do know, for  
9 instance, that the malformation rate with  
10 valproic acid is somewhere in the order of 15  
11 to 20 percent of all pregnancies.

12 We do know that low dose versus  
13 high dose affects the impact as well. We also  
14 know relatively sure, not proven, that  
15 administering folic acid does not reduce the  
16 risk of valproic-associated malformations.  
17 So, there are several pieces of evidence that  
18 are under the surface that are known, but they  
19 haven't really come up to the surface with the  
20 developers' recommendations here.

21 CO-CHAIR TIRSCHWELL: Any others?  
22 Salina, do you have another comment?

1                   MEMBER WADDY: Yes, the only point  
2 I wanted to add is regarding Bill's comment,  
3 if you plan to get pregnant, and I do think  
4 that that is important because that can  
5 stimulate a conversation, but I am not sure  
6 how many people who have epilepsy or on these  
7 medications have planned pregnancies versus  
8 not, if they haven't had the conversation.

9                   CO-CHAIR TIRSCHWELL: Terry?

10                  MEMBER RICHMOND: Yes, I have had  
11 trouble. The last time I had trouble about  
12 education and counseling things, and we have  
13 had that discussion here. I agree that the  
14 evidence really isn't there.

15                         However, I am more favorable to  
16 this in the sense that there is clear evidence  
17 that things can hurt the woman and fetus, you  
18 know, that piece. Just as counseling, is  
19 there evidence for counseling?

20                         And while that is not there, I am  
21 with you on the exception thing, I think, in  
22 that this is at least a very specified

1 population for a very specific thing where we  
2 know harm can be done. So, I think I look at  
3 this in a very different way that sort of a  
4 generic discharge teaching, for those reasons.

5 CO-CHAIR TIRSCHWELL: David? And  
6 then, Ramon.

7 CO-CHAIR KNOWLTON: I completely  
8 agree with you and some of the other comments.  
9 I think on this one we have a lot of measures  
10 like this that are used, required counseling  
11 that we measure people who have HIV regarding  
12 safe sex. We have smoking cessation. We have  
13 some genetic disorders where we have genetic  
14 counseling in terms of childbearing years.

15 We have seen this from the health  
16 plan side, some problem getting people covered  
17 because they need different diagnostic  
18 testing. And there is quite a bit of  
19 ignorance that surrounds epilepsy and  
20 pregnancy. And so, I agree with exactly what  
21 you said, Therese. I think that I feel  
22 differently about this measure than I do other



1 ones, and there is harm done when people don't  
2 get the type of information that they need in  
3 this.

4 CO-CHAIR TIRSCHWELL: Ramon?

5 MEMBER R. BAUTISTA: Yes, my  
6 comment wasn't meant to dissuade this measure.  
7 In fact, it was actually to just point out  
8 that it is hard to get evidence for something  
9 like this. It is very hard.

10 At this point in time, I mean,  
11 prescribing folic acid, for example, for women  
12 of childbearing age with epilepsy is actually  
13 standard of care. It is not even a question  
14 that we ask ourselves in this day and age. It  
15 is very hard to get the evidence that we  
16 really normally look for for this kind of a  
17 question.

18 CO-CHAIR TIRSCHWELL: Salina?

19 Then, Raj.

20 MEMBER WADDY: Well, my main issue  
21 is, I don't have a problem with having this  
22 type of measure. I think it should go a step

1 further where you have to have a documented  
2 plan within your chart and show that you have  
3 discussed it or given it to the patient as  
4 well, and not just check off a box that "I  
5 talked to them." You don't know so much what  
6 is involved in that conversation.

7 CO-CHAIR TIRSCHWELL: Raj? And  
8 then, David.

9 MEMBER SHETH: There are issues  
10 here that can be easily addressed. One, for  
11 instance, is what is the impact of  
12 breastfeeding on the fetus if a mother is  
13 taking medication and has epilepsy? That has  
14 a huge impact, and there is a lot of data that  
15 is out there that can be formulated into a  
16 plan of action and can affect outcome, I  
17 think.

18 I think the relationship is two  
19 ways. I think the relationship is, what  
20 happens to the pregnancy in a woman who  
21 becomes pregnant? And then, the second issue  
22 is, what happens to the epilepsy in a woman

1 that becomes pregnant? So, it is  
2 bidirectional.

3 You can have seizure control that  
4 is completely out of whack when you are  
5 pregnant because of blood volume changes or  
6 medications or the false belief that the  
7 moment the mother knows that she is pregnant,  
8 she stops the medication, when, in fact, the  
9 teratogenic effect has already occurred by the  
10 time the pregnancy test is confirmed, because  
11 it is in the early month of pregnancy.

12 So, I think this is definitely a  
13 measure that has a very defined population, as  
14 you well said, Therese, and I think it really  
15 needs rework on that.

16 CO-CHAIR TIRSCHWELL: Michael?  
17 Then, Salina.

18 MEMBER KAPLITT: Yes, I think if  
19 you look at the numerator statement, where  
20 what they are measuring here is counseling  
21 women specifically about how epilepsy and its  
22 treatment could affect contraception and

1 pregnancy.

2           If we all agree that the evidence  
3 is there, and much of it is in this document,  
4 supporting the idea that epilepsy treatment  
5 can affect contraception in pregnancy, and if  
6 there is good evidence provided here, which I  
7 think there is, that a large percentage of  
8 women feel they are not getting that  
9 information, so they don't know, then I think  
10 that, even in the absence of a randomized  
11 controlled trial, this is one of those again  
12 yes/no things, where if women don't know what  
13 this can do, and we know that this can harm  
14 pregnancies and contraception, then it  
15 absolutely has to change care.

16           Because if they don't know, and  
17 you are informing them, and we know that that  
18 information is relevant, then I think this is  
19 more than just evidence from an expert panel.  
20 I think that this rises to a different level  
21 than some of the evidence that we have  
22 considered earlier.

1                   MEMBER SCARIANO: Yes, I think  
2                   that this is actually really important. On  
3                   the patients I have who have seizures, you  
4                   know, I often look and see what medications  
5                   that they are on. I once had an OB doctor  
6                   tell me that, "I have your patient here, and  
7                   she wants to get pregnant and she is on  
8                   Depakote." I said, "Yes, but she is  
9                   controlled on Depakote." He said, "Well, she  
10                  is not going have an OB doctor."

11                  So, I mean, you have to plan ahead  
12                  and see if someone wants to have children.  
13                  You have to think about what pills that they  
14                  have to be on and actually tell them that, "As  
15                  soon as you are pregnant, tell me. If you  
16                  find out that you are pregnant, actually don't  
17                  stop the pills" -- I just think it is actually  
18                  really important.

19                  MEMBER R. BAUTISTA: I mean, it  
20                  sounds like counseling is really only a  
21                  surrogate measure here. The real measure here  
22                  is interventions for women who might become

1 pregnant. I mean, you know, not prescribing  
2 cytochrome P450, for example, if you use birth  
3 control pills or using folic acid, for  
4 example, if you intend to become pregnant.

5 The counseling thing is really a reflection of  
6 all that, I think, that really takes place as  
7 part of patient care.

8 CO-CHAIR TIRSCHWELL: David?

9 CO-CHAIR KNOWLTON: I just didn't  
10 want to miss Raj's point because, when you  
11 read the numerator again, this says the  
12 impact, the concept about epilepsy and how its  
13 treatment may affect contraception and  
14 pregnancy.

15 It also, to Raj's point, it can  
16 also affect the treatment of the epilepsy.  
17 That is a risk factor, and it is something  
18 that should be discussed with a woman.

19 To Salina's point about a plan, a  
20 plan is important, but in this particular case  
21 the patient is a real party to that plan.  
22 That plan can be blown up pretty easily by the

1 patient saying, "I want to do this anyway."

2 And so, this is a very, very  
3 complicated issue. That is why I think it is  
4 so important. Just for the note of the  
5 developer, there is an impact on the epilepsy  
6 treatment as well with the pregnancy, and that  
7 is not in the numerator statement.

8 CO-CHAIR TIRSCHWELL: Jolynn?

9 MEMBER SUKO: This may be from  
10 just a non-clinician in the room, but I think  
11 this is bigger than just pregnancy. It also  
12 affects the choices that women would make  
13 probably about the type of contraception they  
14 would use. And so, this has a huge impact,  
15 based upon what I read in the specifications.  
16 I hear everybody talking about pregnancy, but  
17 I think it is much bigger than just pregnancy.

18 CO-CHAIR TIRSCHWELL: Salina?

19 MEMBER WADDY: Yes, so I agree  
20 with all three of those points and actually  
21 think the numerator should probably be  
22 expanded to include those.

1 CO-CHAIR KNOWLTON: I don't think  
2 they would have to do that to have us vote on  
3 it. I think they are hearing the debate.

4 MEMBER KAPLITT: I mean, the  
5 discussion here is, is there evidence to  
6 support this measure with this numerator.  
7 Right now, there may be a lot of other things  
8 in the world we could do. But what I am  
9 asking is, is there a negative to this  
10 numerator as it is written, which is the  
11 discussion in hand here?

12 CO-CHAIR KNOWLTON: Right, right.  
13 Yes, that was my point. I think they are  
14 listening, and they might say nobody is going  
15 to object to expanding it; we understand it  
16 was an oversight.

17 CO-CHAIR TIRSCHWELL: Do you guys  
18 want to ask a question to the developer or  
19 not?

20 All right, Raj, maybe the last  
21 comment.

22 MEMBER SHETH: Yes, I think what



1 might be important for the developer to do is  
2 actually broaden the degree of support, bring  
3 in other organizations that might help with  
4 the development. I know that the Epilepsy  
5 Foundation is probably another critical  
6 element in this that would be very interested,  
7 has a vested interest in serving this  
8 community as well. So, it might be broadening  
9 it would be an option, too.

10 CO-CHAIR TIRSCHWELL: Yes, do  
11 ahead.

12 MS. SWAIN-ENG: That is just what  
13 I was going to say. We did have the Epilepsy  
14 Foundation of America that was involved and  
15 the American Academy of Family Physicians, the  
16 American Academy of Pediatrics, numerous  
17 different health insurers, NAAC. All those  
18 groups were involved.

19 CO-CHAIR TIRSCHWELL: We just  
20 didn't know that because it wasn't written  
21 down, I guess, right, Raj?

22 MS. SWAIN-ENG: No, it is in

1 the --

2 CO-CHAIR TIRSCHWELL: It is? Oh,  
3 it is not in the summary we got. Okay. Thank  
4 you.

5 So, let's go ahead and vote on the  
6 evidence. You could either think there is  
7 sufficient evidence -- if you want to go with  
8 the exemption, which has been brought up on a  
9 couple of occasions now, then you need to vote  
10 for No. 2, is that right? And if neither of  
11 those, then I guess three.

12 Yes, let's go.

13 (Vote taken.)

14 MS. THEBERGE: I need two more  
15 responses. One more. Is anyone missing? Can  
16 everyone vote one more time? There we go.

17 Eleven yes; 13, no, evidence does  
18 not meet guidance.

19 CO-CHAIR TIRSCHWELL: So, I think  
20 that means that we need to vote, then, on the  
21 exception rule.

22 Does anybody have any other

1       comments they want to make about the exception  
2       to empirical evidence before we vote?

3                       (No response.)

4                       Okay. Let's go ahead and vote on  
5       this then.

6                       (Vote taken.)

7                       MS. THEBERGE: I need one more  
8       response. There we go.

9                       Twenty-three yes, 1 no.

10                      CO-CHAIR TIRSCHWELL: All right.  
11       We are past that hurdle.

12                      Raj, now we want you to briefly  
13       discuss high impact.

14                      MEMBER SHETH: I think that some  
15       of the impact has already been discussed.

16                      CO-CHAIR TIRSCHWELL: Okay.

17                      MEMBER SHETH: But the impact,  
18       obviously, from a population number, this is  
19       a big impact. We are talking about half the  
20       population with epilepsy could potentially be  
21       affected, obviously excluding the younger  
22       children and those over 44 for the women.

1                   So, it is a big impact factor.  
2                   The consequences of not getting the advice,  
3                   not understanding their risks, really has an  
4                   impact on the fetus. That is one. And it may  
5                   have a lifelong impact on the patient. So,  
6                   clearly, a very high impact.

7                   CO-CHAIR TIRSCHWELL: Great. I  
8                   think, yes, let's go ahead and vote.

9                   (Vote taken.)

10                  So, no issues there. And then,  
11                  1(b), the performance gap or the opportunity  
12                  for improvement.

13                  MS. THEBERGE: I just need to read  
14                  out the numbers for the transcript.

15                  CO-CHAIR TIRSCHWELL: Sorry.

16                  MS. THEBERGE: Twenty-three high,  
17                  1 moderate.

18                  CO-CHAIR TIRSCHWELL: Just trying  
19                  to keep the train rolling.

20                  (Laughter.)

21                  Raj, performance gap.

22                  MEMBER SHETH: The performance gap

1 I think has been established. Clearly,  
2 studies vary between 2 and 20 percent of women  
3 are counseled with regards to their epilepsy  
4 risk. So, this doesn't even hit the 50-  
5 percent mark. So, clearly, there is a  
6 performance gap.

7 CO-CHAIR TIRSCHWELL: I think that  
8 is good enough.

9 (Laughter.)

10 Let's go ahead and vote.

11 (Vote taken.)

12 MS. THEBERGE: Twenty-four high.

13 CO-CHAIR TIRSCHWELL: Make a note.

14 All right. Now we are on to scientific  
15 acceptability, reliability and then validity.  
16 But they are combined here because this has  
17 not been out before, right? It has not been  
18 tested.

19 Okay. So, reading out the slide,  
20 the reliability part is for the  
21 specifications. They are unambiguous, likely  
22 to consistently identify who the population

1 is, identify the process, and compute the  
2 score, and that the specifications also  
3 reflect the quality-of-care problem and the  
4 evidence that we have ignored.

5 MEMBER SHETH: So, I think here  
6 there is very little controversy. I think on  
7 both counts the population is clearly  
8 identified. I think that the evidence that  
9 exists is quite high.

10 CO-CHAIR TIRSCHWELL: And it will  
11 identify the problem at hand?

12 MEMBER J. BAUTISTA: I would  
13 disagree.

14 CO-CHAIR TIRSCHWELL: Okay.

15 MEMBER J. BAUTISTA: Yes, I think  
16 the measure specifications are not at all  
17 precise. I mean, the scope is huge. It is  
18 impact of epilepsy on contraception and  
19 pregnancy. What is exactly meant by  
20 "counseled"? There is no operational  
21 definition.

22 CO-CHAIR TIRSCHWELL: Okay.

1 Salina?

2 MEMBER WADDY: I agree. I mean,  
3 that is the issue that I have been having with  
4 this measure. If it can be more specific or  
5 somehow, even if the AAN had some type of  
6 structured basic conversation to have that was  
7 required, that would make it much simpler.  
8 But this is very open-ended.

9 CO-CHAIR TIRSCHWELL: Terry?

10 MEMBER RICHMOND: I am usually  
11 really into preciseness here, but I am not  
12 sure how much we could micromanage this.  
13 Because how we would talk to a 12-year-old who  
14 just sort of could potentially be pregnant  
15 versus a 30-year-old versus a 40-year-old, and  
16 the issues we would counsel about I think  
17 would be really different.

18 So, in terms of really specifying  
19 at a high level, it just does not ring true to  
20 me as a clinician. So, I understand the  
21 concerns, but I am not sure how we would deal  
22 with that.

1 CO-CHAIR TIRSCHWELL: Jocelyn, do  
2 you still have more?

3 MEMBER J. BAUTISTA: Well, I think  
4 maybe, then, that speaks to whether this  
5 really meets NQF criteria. I mean, this is  
6 good standard of care. I don't argue that  
7 this is very important to do in your day-to-  
8 day work, but does it meet criteria if we are  
9 not able to have precise measure  
10 specifications?

11 CO-CHAIR TIRSCHWELL: Michael,  
12 Salina, and then Peter.

13 MEMBER KAPLITT: Yes, I mean, I am  
14 just wondering how you would capture that  
15 because there is a CPT code, right, for this,  
16 which is counseling women of childbearing, or  
17 whatever, but it is basically this thing.

18 So, I am wondering, separate from  
19 anything else, if you make this too specific,  
20 how exactly are you going to make this useful  
21 and capture it? That is my concern.

22 CO-CHAIR TIRSCHWELL: Salina?



1                   MEMBER WADDY: I agree with you,  
2 but I am not talking about developing some  
3 type of script, which I think would be  
4 completely inappropriate. But, basically,  
5 discussing the medications that have the  
6 highest fetal anomalies as well as the impact  
7 that it could have on your type of epilepsy,  
8 potential decisions regarding avoidance of  
9 pregnancy and what the options are, and the  
10 use of folate. I mean, those just very basic  
11 things, but within this, if you were talking  
12 about something like driving, it wouldn't be  
13 enough to say, you know -- I don't know how to  
14 answer that beyond that.

15                   CO-CHAIR TIRSCHWELL: Peter?

16                   MEMBER SCHMIDT: So, before coming  
17 here, I reviewed a number of clinical practice  
18 guidelines, you know, quality indicators that  
19 have been very successful elsewhere. And they  
20 are not that specific. You have to allow the  
21 clinician to make choices about how to address  
22 something.

1                   And so, with the depression in  
2                   Parkinson's disease, there was evidence that  
3                   depression is difficult to diagnose in  
4                   Parkinson's disease. So, that is something  
5                   where we have evidence to back up a request  
6                   for specificity. But if we don't have  
7                   evidence that addressing this issue is  
8                   challenging, then it is difficult for us. We  
9                   should not apply our own opinions about that  
10                  some other clinician is going to fail at doing  
11                  it, just because we don't trust them. You  
12                  know, you have to let the clinician have some  
13                  autonomy.

14                         CO-CHAIR TIRSCHWELL: Any other  
15                         comments about the reliability or validity,  
16                         really mostly related to the specifications of  
17                         this measure, before we go ahead and vote?

18                                 (No response.)

19                                 Okay, then, I think we should go  
20                                 ahead and vote.

21                                 (Vote taken.)

22                                 MS. THEBERGE: I need three more

1 responses.

2 CO-CHAIR TIRSCHWELL: There you  
3 go.

4 MS. THEBERGE: Twenty-one yes, 3  
5 no.

6 CO-CHAIR TIRSCHWELL: All right.  
7 So, we are in the relatively-unchartered  
8 territory, usability.

9 (Laughter.)

10 Raj, comments on usability?

11 Risha, could you take over his  
12 microphone, please?

13 (Laughter.)

14 MEMBER SHETH: From the general  
15 feeling of usability, the group felt that  
16 there was a high degree of usability for this.

17 MEMBER J. BAUTISTA: Again, I  
18 disagree. There is no data at all about  
19 usability. I mean, how can you judge? There  
20 is no data submitted.

21 MEMBER SHETH: The data is not  
22 submitted, but it clearly exists.

1 CO-CHAIR TIRSCHWELL: So, there is  
2 a CPT code. No data is reported, but,  
3 apparently, the AAN is using it.

4 Why don't you guys comment for a  
5 moment about the usability?

6 MS. SWAIN-ENG: So, the measure is  
7 already in use by multiple different programs.  
8 It is in use in our neuro-protective program,  
9 which, again, our maintenance and  
10 certification Part V program. The feedback  
11 that we have gotten from the clinicians, we  
12 have had 119 who have purchased the epilepsy  
13 module, which includes this measure, and have  
14 had no issues specifically with this measure.

15 This is one of the measures they  
16 find to be the most helpful, that has really  
17 helped them improve their practice, really  
18 brought a sense of awareness to them, things  
19 that they hadn't considered, that they needed  
20 to counsel a patient who was young about  
21 possible contraception issues, you know,  
22 different things that they hadn't considered

1 before. So, this has really helped them and  
2 they haven't had issues.

3 As Dr. Bever was mentioning, too,  
4 this measure is also in the PQRS 2012 program,  
5 and we have a registry through CECity that is  
6 approved. It is a CMS-approved registry where  
7 patients can report on this measure that will  
8 go directly to CECity. So, we are starting to  
9 aggregate a little bit of data from that. It  
10 did just open in August, and we have 11 people  
11 who have enrolled in this program so far.

12 So, we are definitely accumulating  
13 data and haven't heard any issues with  
14 usability at all.

15 CO-CHAIR TIRSCHWELL: And is this  
16 one up for time-limited?

17 MS. SWAIN-ENG: Yes.

18 CO-CHAIR TIRSCHWELL: So, then, we  
19 will hear back, or at least the NQF will hear  
20 back with some data in a year's time. And  
21 hopefully, you will be able to close the loop  
22 a little bit on some of these issues.

1 Any other comments on usability?

2 Salina?

3 MEMBER WADDY: Yes. So, I just  
4 want to be clear. So, physicians have told  
5 you that it has changed their practice. Has  
6 it actually improved quality of care?

7 DR. BARKLEY: May I make a  
8 comment, please?

9 CO-CHAIR TIRSCHWELL: Is somebody  
10 on the line?

11 Hold on one second, please.

12 Were you addressing that question,  
13 Salina, to the developers?

14 MS. SWAIN-ENG: He is part of us.

15 CO-CHAIR TIRSCHWELL: Okay, go  
16 ahead on the phone. Can you identify  
17 yourself, please?

18 DR. BARKLEY: My name is Gregory  
19 L. Barkley. I am a neurologist at Henry Ford  
20 Hospital in Detroit, and I am an  
21 epileptologist. I was involved with the  
22 committee that helped develop these.

1                   We have an abstract that we are  
2 going to present at the American Epilepsy  
3 Society meeting this December where we  
4 actually looked at clinical documentation of  
5 patients with epilepsy seen by neurologists at  
6 Henry Ford Hospital as well as the epilepsy  
7 specialists.

8                   For this particular question of  
9 the childbearing potential, the documentation  
10 went up dramatically in terms of our awareness  
11 of the need to do that, and the documentation  
12 of this discussion was being held with women.  
13 As others noted, this opens up a whole can of  
14 worms about will my child have epilepsy or  
15 what is the right drug, all those kinds of  
16 questions.

17                   And so, we went from about 11  
18 percent of the charts documenting this in  
19 women of childbearing age to 56 percent  
20 amongst the epileptologists, just in  
21 documentation. So, I am sure this has made an  
22 impact on the quality of care of these

1 patients.

2 CO-CHAIR TIRSCHWELL: Followup  
3 from Dr. Waddy?

4 MEMBER WADDY: Yes. So, I mean,  
5 do you have other measures like either  
6 compliance or adoption of some of the AAN  
7 practice parameters? Did it increase the  
8 number of patients who were on folate? Did it  
9 change people who were on valproic or I think  
10 Topamax? Do you have any evidence that there  
11 was actually change in the quality of care?

12 DR. BARKLEY: Actually, our  
13 abstract or our research didn't address that,  
14 but I am sure that, when you have these  
15 discussions, particularly we were involved  
16 with Kimford Meador's neonatal outcomes of  
17 anti-epileptic drug program, which showed, in  
18 particular, that valproic acid was negatively  
19 correlated not only with the presence of birth  
20 defects, but the intellectual outcome at four-  
21 and-a-half years, which is clearly lower than  
22 all of the other three anticonvulsant drugs in



1 that prospective study and independent of  
2 maternal IQ.

3 So, this is really, as opposed to  
4 what Raj -- I am not sure of your last name --  
5 said. This is a third-trimester effect, more  
6 likely than the first-trimester effect for the  
7 congenital malformation. So, I think this  
8 really has the potential to change care. Once  
9 you start to discuss this, women make big  
10 changes in their decision about what they are  
11 going to do about getting pregnant, which  
12 drugs to take, whether they should be on an  
13 IUD versus an oral contraceptive medication.

14 CO-CHAIR TIRSCHWELL: Okay. Thank  
15 you very much.

16 I just will suggest that we have  
17 strayed back into evidence when we want to be  
18 talking about usability.

19 Peter?

20 MEMBER SCHMIDT: Yes, just a  
21 similar comment. We seem to be conflating  
22 usability and feasibility. Usability is

1 defined as for public reporting and  
2 accountability. And I think that because of  
3 the concept of the time-limited endorsement,  
4 that usability is something that we assess  
5 once there is data.

6 MEMBER WADDY: Yes, but the  
7 problem is 3(b). That is the one that I have.  
8 That is what was generating my questions, is  
9 whether it is meaningful, understandable, and  
10 useful for quality improvement.

11 MS. BOSSLEY: Right. This is  
12 Heidi.

13 This is one that everyone  
14 struggles with, especially when measures are  
15 not yet tested, because there is a little  
16 blurring of evidence and validity, I think.

17 But any new measure that comes in,  
18 there, first of all, is not an expectation  
19 that it be in use when it comes into NQF.  
20 This measure actually is in use. So, they are  
21 ahead of the game in that way.

22 So, what we really are asking you

1 to look at is, based on the information you  
2 have and what you have heard from those on the  
3 phone and here at the table, do you believe it  
4 will inform through public reporting and  
5 accountability purposes and could it for  
6 quality improvement?

7 We don't expect them to come back  
8 with that data until maintenance the next  
9 time. So, again, it is, do you believe, based  
10 on what you know now, that it could be useful  
11 and usable?

12 So, it is going to be a little  
13 vague because you don't have data yet, but  
14 that is kind of where we are now with new  
15 measures.

16 CO-CHAIR TIRSCHWELL: Salina?

17 MEMBER WADDY: I mean, at least  
18 for 3(a), to me, it seems very much  
19 absolutely; that is kind of a no-brainer for  
20 me.

21 But, for 3(b), because of the way  
22 it is structured -- and I don't know really

1       what is going to go on in that conversation,  
2       if that conversation actually changes  
3       practice, and it leads to changes. That is  
4       the one that I am having trouble with.

5                   MS. BOSSLEY: And I think you  
6       should rate this criteria against that. I  
7       think that should be one of the factors, and  
8       one of the questions could be, at the time of  
9       maintenance, assuming this is endorsed, can  
10      AAN come back with some information on that?

11                   CO-CHAIR TIRSCHWELL: I just want  
12      to remind people, as I was just reminded, that  
13      this is not a "must-pass" criteria.

14                   MS. BOSSLEY: Right.

15                   CO-CHAIR TIRSCHWELL: So, even if  
16      you vote it down, the measure can still pass,  
17      and your objection would be noted.

18                   (Laughter.)

19                   We're done; let's vote.

20                   (Laughter.)

21                   (Vote taken.)

22                   MS. THEBERGE: I need three more

1 responses.

2 Ten high, 12 moderate, 1 low, 1  
3 insufficient.

4 CO-CHAIR TIRSCHWELL: Okay. Very  
5 good.

6 And then, finally, we are on to  
7 category 4, which is feasibility.

8 Raj, do you want to address that?

9 MEMBER SHETH: So, I think the  
10 issue is, how would you ascertain that this  
11 has been done? Again, this would be a  
12 checkoff box, and it would be done perhaps on  
13 a yearly basis.

14 The implementation is unclear.  
15 You know, what do you do with paper records?  
16 Are you able to abstract that aspect of it?  
17 And the general feeling of the group was that  
18 there was insufficient data that was provided  
19 to support this.

20 So, the overall feeling was that  
21 it was feasible. There is a CPT code that you  
22 can look at that that would assess whether

1 counseling of women was done, but there were  
2 some members of the group that felt that they  
3 were not quite sure how you would collect it  
4 in paper medical record terms.

5 CO-CHAIR TIRSCHWELL: So, there  
6 are some details, and in a pure EHR  
7 environment with CPT codes it might be easier  
8 to describe exactly how it would all happen,  
9 but there is a little bit of fuzziness. It is  
10 in use now. We would, hopefully, have more  
11 information in a year or so.

12 Any other comments?

13 This is also not a "must-pass"  
14 criteria. So, again, even if you vote against  
15 it, it won't necessarily affect the final  
16 outcome.

17 Other comments?

18 (No response.)

19 Okay. Let's go ahead and vote  
20 then.

21 (Vote taken.)

22 MS. THEBERGE: We need three more.

1 We need one more vote.

2 Four high, 15 moderate, 2 low, 3  
3 insufficient.

4 CO-CHAIR TIRSCHWELL: Okay. Very  
5 good. So, I think we are now on to the  
6 overall evaluation at this point.

7 Any further discussion before we  
8 vote on this overall?

9 (No response.)

10 Okay. Let's go ahead and do it.

11 (Vote taken.)

12 MS. THEBERGE: We still need one  
13 more response. There we go.

14 Twenty-four yes.

15 CO-CHAIR TIRSCHWELL: All right,  
16 then, moving right along to the next measure,  
17 Jocelyn, 1953, seizure type and current  
18 seizure frequencies.

19 MEMBER J. BAUTISTA: So, this is  
20 also a new submission from the American  
21 Academy of Neurology.

22 So, this measure captures the

1 proportion of epilepsy patients who are being  
2 seen for epilepsy for whom seizure type and  
3 current seizure frequency are documented in  
4 the medical record.

5 It excludes those patients who  
6 have a documented medical or patient reason  
7 for not recording seizure type or seizure  
8 frequency, such as the patient is unable or  
9 unwilling to communicate or provide that  
10 information.

11 And the level of analysis is at  
12 the clinician level.

13 CO-CHAIR TIRSCHWELL: And  
14 evidence?

15 MEMBER J. BAUTISTA: Evidence.  
16 So, the question is whether there is evidence  
17 that documentation of seizure type and seizure  
18 frequency leads to better outcomes. There is  
19 not such good evidence for that in terms of  
20 the documentation. But the implication is  
21 that seizure frequency is really the main  
22 outcome measure in epilepsy, right? And so,



1 if you don't even document it, you can't  
2 impact it.

3 So, the implication is you  
4 document, you ask and you document the seizure  
5 frequency, and then you are able to act on it.  
6 So, it is, again, there are multiple steps to  
7 the improved outcome.

8 So, we again run into this  
9 evidence issue.

10 CO-CHAIR TIRSCHWELL: Daniel?  
11 Then, Risha.

12 MEMBER LABOVITZ: I am a stroke  
13 doctor, but I have a deep love for dealing  
14 with epilepsy problems. I have looked at  
15 epilepsy classification. I cut my teeth on it  
16 in training.

17 It is a total quagmire.

18 (Laughter.)

19 Epileptologists are now duking it  
20 out. There is a new classification scheme  
21 that has been proposed. You may hear the  
22 roaring. Those are the dinosaurs over here

1 and people in spaceships over there. There is  
2 a huge fight going on about classification.

3 And the question is, does that  
4 affect outcome? I don't see that we can even  
5 classify epilepsy right now or at least make  
6 providers do it.

7 CO-CHAIR TIRSCHWELL: It doesn't  
8 say you have to get it right.

9 (Laughter.)

10 MEMBER LABOVITZ: Yes, you don't  
11 have to get it right, true, but, then, I think  
12 that begs the question of does it help.

13 CO-CHAIR TIRSCHWELL: Risha?

14 MEMBER GIDWANI: Yes, I had a  
15 similar concern. The NICE guideline says that  
16 "The established classification system is  
17 undergoing review. Current proposals have the  
18 status of work-in-progress," and that failure  
19 to correctly classify an epilepsy syndrome can  
20 lead to inappropriate treatment and  
21 persistence of seizures.

22 So, I think if the field as a

1 whole hasn't come to a consensus about how to  
2 categorize epilepsy properly, I wonder if some  
3 of the harms of this are just that physicians  
4 will now feel pressured to start classifying,  
5 use an incorrect classification scheme and  
6 then go down an inappropriate treatment  
7 pathway.

8 CO-CHAIR TIRSCHWELL: And any  
9 other comments?

10 Jack?

11 MEMBER SCARIANO: Yes, well, if  
12 you have an actual focal epilepsy, that always  
13 makes me look harder, and it also may make me  
14 look and get more MRI scans over a period of  
15 time. So, if you have focal epilepsy or if it  
16 is just unilateral onset, there is a  
17 possibility that even epilepsy surgery may  
18 help. So, if you have a focal epilepsy, I  
19 think it is really important to actually  
20 document that.

21 CO-CHAIR TIRSCHWELL: Yes, I mean,  
22 I would just add that, despite the fact that

1 the classification systems are under  
2 discussion, describing the types of seizures  
3 the patient is having, even just in plain  
4 English terms, and the frequency with which  
5 they are happening, seems like a pretty  
6 minimal standard of care for an evaluation,  
7 especially in a neurology clinic, for anybody  
8 that is being seen with epilepsy.

9 Ramon, and then Risha, and then we  
10 will get to you guys over there.

11 MEMBER R. BAUTISTA: Yes,  
12 actually, we are talking about seizure types  
13 right now, not epilepsy classification. That  
14 is our next discussion, actually.

15 But, going back to your comments,  
16 I agree, David, that for the most part we know  
17 how to at least think through epilepsy and  
18 think through seizures, enough for us to make  
19 any significant change in the way we manage  
20 them. So, I don't think it is a big issue.

21 CO-CHAIR TIRSCHWELL: Thank you.

22 Did somebody else have their thing

1 up? Go ahead, AAN.

2 DR. BEVER: So, the working group  
3 that came up with this measure was motivated  
4 by the fact that the drugs are tested in  
5 specific subtypes. They acknowledge the fact  
6 that in details there is a lot of controversy  
7 about the classification of different seizure  
8 types, but, broadly, there are some large  
9 groups that do relate to the appropriate  
10 anticonvulsive medication that should be used  
11 in the patient.

12 And there was felt to be a gap at  
13 least in some providers in terms of their  
14 understanding of the patient seizure type, and  
15 based on referrals to epileptologists, a lack  
16 of documentation of a seizure type that would  
17 lead to a proper selection of a medication.  
18 So, there was felt to be a gap in care, and  
19 that you could not choose proper medications  
20 without actually identifying the seizure type,  
21 at least in terms of the drugs that you were  
22 choosing among. So, that is how they came up

1 with this.

2 CO-CHAIR TIRSCHWELL: I mean, as  
3 you are describing it there, it begs the  
4 question for the next measure about overlap.  
5 We can get to that when we get to the next  
6 measure.

7 Risha, did you have something  
8 different to add?

9 MEMBER GIDWANI: No, just the same  
10 point. I think we are conflating epilepsy  
11 with a seizure. So, if we could just stay on  
12 the epilepsy component right now?

13 CO-CHAIR TIRSCHWELL: Seizure.

14 MEMBER GIDWANI: Aren't we doing  
15 epilepsy at the moment? Then, my fault. I am  
16 sorry.

17 CO-CHAIR TIRSCHWELL: It is the  
18 diagnosis of epilepsy, but it is the seizure  
19 types that they are having.

20 MEMBER R. BAUTISTA: I mean, just  
21 for education for the group, just to make sure  
22 you understand the difference --

1 CO-CHAIR TIRSCHWELL: Please.

2 MEMBER R. BAUTISTA: -- when you  
3 classify or diagnose seizure types, you refer  
4 to things like the localization of the  
5 seizure. Is it a generalized or a partial  
6 seizure? Is it a temporal lobe or frontal  
7 lobe seizure. And you also refer to the  
8 clinical semiology? Are you dealing with a  
9 generalized tonic-clonic seizure or are you  
10 dealing with a complex partial seizure, or an  
11 abson seizure?

12 Epilepsy classification, on the  
13 other hand, refers to the classification of  
14 different diseases that cause seizures. So,  
15 for example, you have something called  
16 idiopathic epilepsy, cryptogenic epilepsy,  
17 symptomatic epilepsy. That is how you  
18 distinguish between seizures and epilepsy.  
19 One is a disease-specific diagnosis; one is a  
20 characterization of what goes on during the  
21 seizure.

22 CO-CHAIR TIRSCHWELL: So, any

1 other questions?

2 Yes, Risha, go ahead.

3 MEMBER GIDWANI: Just for the  
4 record, I will withdraw my previous statement  
5 and apply it to the next measure then, when we  
6 review that.

7 (Laughter.)

8 CO-CHAIR TIRSCHWELL: Thank you  
9 for making that official.

10 Okay. So, let's go ahead and vote  
11 on the evidence for this measure.

12 (Vote taken.)

13 MS. THEBERGE: I need one more  
14 response.

15 Yes, 11; no, evidence does not  
16 meet guidance, 9, and then 4, no, insufficient  
17 information.

18 CO-CHAIR TIRSCHWELL: Okay. So,  
19 let's go back to high impact.

20 (Chorus of noes.)

21 Oh, I'm sorry, I was just looking  
22 at the size of the bars there.



1 (Laughter.)

2 Okay. There you go. So, then,  
3 moving along to the other Dr. Bautista, 1954.

4 Are you guys related, by the way?

5 MEMBER R. BAUTISTA: All right.

6 So, let's talk about 1954. So, 1954 actually  
7 documents etiology of epilepsy or epilepsy  
8 syndrome. So, the denominator is these are  
9 the patients with a diagnosis of epilepsy, and  
10 the numerator states at least documenting the  
11 actual epilepsy classification or syndrome.

12 In other words, you want to write  
13 down if they have cryptogenic epilepsy or  
14 symptomatic, and you might want to be more  
15 specific. Do they have post-traumatic  
16 epilepsy, and so forth and so on? Or do they  
17 have idiopathic epilepsy? So, try to make the  
18 orderly diagnosis of patients you see every  
19 time you see them.

20 Let me put on my schizophrenic hat  
21 here because I do have mixed feelings about  
22 the measure which I will try to explain.

1                   No. 1, the measure is supposed to  
2 be used not just by specialists, right, but  
3 also by the general doctors. Okay, good. And  
4 that is one problem I have with this measure,  
5 is that I am not sure a non-specialist or a  
6 non-neurologist would be in a position to  
7 actually make the proper classification of  
8 epilepsy syndrome or epilepsy type.

9                   Secondly, as far as the evidence  
10 is concerned, they actually point out both the  
11 SIGN and the NICE study, both of which are  
12 really, if you look at it, position papers.  
13 They don't really give details on this, on the  
14 necessity to put down the epilepsy syndrome.

15                   On the other hand, there are tons  
16 of evidence out there that link particular  
17 syndromes to different treatment options. For  
18 example, we know that mesial temporal  
19 sclerosis is linked with epilepsy surgery. We  
20 know that idiopathic generalized epilepsies  
21 have a certain select number of drugs that you  
22 can choose from. So, this is all out there.

1 It is not just documented in the literature as  
2 it is.

3 Furthermore, the actual SIGN and  
4 NICE study actually documents early on that  
5 epilepsy has to be diagnosed by a neurologist  
6 or an epileptologist. So, in a way, choosing  
7 you want to hear from the SIGN and NICE  
8 studies, but choosing to dissuade what they  
9 don't want to hear, and that is a problem I  
10 have.

11 So, my main point is that although  
12 the papers as written do not provide good  
13 enough evidence, from the literature there is  
14 tons of evidence that actually suggests the  
15 importance of proper documentation of epilepsy  
16 syndrome.

17 CO-CHAIR TIRSCHWELL: Anybody have  
18 any comments on this particular measure for  
19 the evidence base?

20 (No response.)

21 So, let's go ahead and vote on it  
22 then.

1 Oh, I'm sorry. Daniel?

2 MEMBER LABOVITZ: I was just going  
3 to say I think we heard from the lesser  
4 Bautista about the lesser measure.

5 (Laughter.)

6 This one is even more fraught than  
7 the one we heard before. Epilepsy  
8 classification, really, I would say right now  
9 hopeless. Seizure classification, bad;  
10 epilepsy classification, hopeless.

11 And it just makes it very hard.  
12 There is clearly a role, and epilepsy doctors  
13 work very hard to choose drugs appropriate to  
14 the disease. And there are some epilepsies  
15 which require specific drugs. That is the  
16 role of the specialist.

17 But I think asking the primary  
18 care doctor to get this right, and then to  
19 make the right choice, when the specialists  
20 can't agree, is a hopeless prospect.

21 CO-CHAIR TIRSCHWELL: I guess I  
22 have a question, and anybody can answer this.

1 I don't know the answer myself.

2           When a primary care doctor sees a  
3 patient for one of these neurological  
4 syndromes, do they write on their billing  
5 codes only the things that they are really  
6 steering the ship for, the hypertension and  
7 the diabetes? Or do sort of all of the  
8 patients' diagnoses get bundled in because  
9 more diseases, higher coding, better  
10 reimbursement. Who knows what the motivation  
11 for that is? Does anybody know the answer to  
12 that?

13           MEMBER WADDY: No, that is why I  
14 brought that up about Parkinson's, that they  
15 may see them for their problems with eating or  
16 something, but somehow bundle that in. How  
17 accurate really does that reflect what happens  
18 in the visit?

19           CO-CHAIR TIRSCHWELL: Yes. Yes,  
20 go ahead, Jordan.

21           MEMBER EISENSTOCK: I was just  
22 going to say I don't have any data behind

1 this. This is just an opinion.

2 But I think with the EMR and the  
3 implications of its being easier to just sort  
4 of check off all those diagnoses and they are  
5 being kept track of visit to visit and among  
6 different specialists and PCPs, that probably  
7 we would see that.

8 CO-CHAIR TIRSCHWELL: We would see  
9 more of it even with the EHR.

10 MEMBER EISENSTOCK: Exactly.

11 CO-CHAIR TIRSCHWELL: Jack, do you  
12 have a comment?

13 MEMBER SCARIANO: Yes. On the  
14 patients who I see off the primary care  
15 doctor, almost all of them who have any type  
16 of a sinigual spell may have been diagnosed as  
17 having seizures. So, yes, if they even think  
18 there is a seizure, they put it down.

19 CO-CHAIR TIRSCHWELL: Okay.  
20 First, Terry, then Salina and Ramon.

21 MEMBER RICHMOND: Yes, so the  
22 thing I got confused about this is, when

1 patient comes in, if they are coded for  
2 epilepsy -- so, if you have a primary care who  
3 is taking care of a stable epileptic who is  
4 managing their anticonvulsants, they probably  
5 will have a code generated. And yet, it seems  
6 to me like -- I am married to an epileptic, so  
7 I will speak as a consumer here -- so, it  
8 seems to me we know the source. He has scar  
9 tissue on his brain. His primary care manages  
10 his anticonvulsants. I am sure she probably  
11 checks the CPT code. But I don't think every  
12 time she sees him she needs to say he has a  
13 scar on his brain tissue and document that on  
14 the medical record. Maybe I am missing  
15 something, but --

16 CO-CHAIR TIRSCHWELL: Well,  
17 honestly, I think it should say post-traumatic  
18 epilepsy, that simple, and you have done it at  
19 that point, if that is what --

20 MEMBER RICHMOND: But every time,  
21 every six months, if you are seeing somebody  
22 every six months?

1 CO-CHAIR TIRSCHWELL: Well, yes,  
2 just that phrase is all you need.

3 MEMBER RICHMOND: I mean, I am  
4 just not clear on those.

5 CO-CHAIR TIRSCHWELL: It should be  
6 probably automatically applied, I would think.

7 But, anyway, Ramon?

8 MEMBER R. BAUTISTA: Just to  
9 answer the question about the coding, there  
10 is, I think it is an ICD-9 code for the  
11 epilepsies from 345.1 to 345.9. In the course  
12 of actually mainly a hodgepodge of epilepsies  
13 and seizures, there is a catchall code,  
14 though, 780.39, which actually is an  
15 epileptic-seizure-type code. So, in other  
16 words, to answer your question, the primary  
17 care doctor has a way of having a catchall  
18 code for all of these.

19 CO-CHAIR TIRSCHWELL: And many of  
20 these EHRs list your problems by an ICD-9  
21 code, and it is actually included in your next  
22 whatever.



1 Salina? And then, Michael.

2 MEMBER WADDY: That was one of the  
3 things that I was thinking of as well.  
4 Certainly, in a physician's office, what you  
5 don't want is for a person to go like 10 years  
6 and it hasn't been updated. And so, I think  
7 it is a little bit better if you carry those  
8 forward.

9 But my actual question is, what is  
10 this really trying to accomplish? I mean, at  
11 the end of the day, are you just trying to  
12 document how well they do this or are you  
13 trying to match are they prescribing the  
14 medication that is appropriate for that  
15 syndrome, and if so, then that really should  
16 be the measure instead of this.

17 CO-CHAIR TIRSCHWELL: So, again,  
18 Dr. Waddy brings up the point, is this too far  
19 back in the chain of events to necessarily  
20 cause the improvement in outcomes and quality  
21 that we are looking for?

22 Michael?

1                   MEMBER KAPLITT: To that point, I  
2                   mean, putting aside the poor primary care  
3                   physician that has gotten horribly brutalized  
4                   here today -- (Laughter) -- you know, the  
5                   numerator, as was said earlier, is every  
6                   single visit that this is documented and  
7                   reviewed, right, at each visit? So, the  
8                   question is, what evidence is there that that  
9                   does anything? Is there evidence that this is  
10                  something that is changing, that requires this  
11                  to be reviewed, that the diagnosis is  
12                  changing, requires it to be reviewed every  
13                  time? Is there evidence that that does  
14                  anything?

15                         And the reason that matters, on  
16                         top of everything else, is that we have all  
17                         been hearing lately now the government is  
18                         starting to go after cloned notes, right?  
19                         Well, we are promoting cloned notes here by  
20                         saying you are going to do the same thing  
21                         every time, even though it is not changing.  
22                         We are just going to be encouraging people to

1 just cut and paste the exact same thing every  
2 single time, every note for 10 years. So,  
3 what is the evidence that it is going to  
4 change anything?

5 CO-CHAIR TIRSCHWELL: And, in  
6 fact, I mean, compared to the Parkinson's  
7 disease, which progresses and changes over  
8 time, it seems like there would be even less  
9 cause here if they have seen a specialist and  
10 gotten a good diagnosis.

11 Dr. Waddy? And then, Jolynn.

12 MEMBER WADDY: Can we just ask the  
13 developers what you wanted to accomplish with  
14 this?

15 MS. SWAIN-ENG: So, they are  
16 reviewing and documenting etiology of epilepsy  
17 or epilepsy syndrome with the patient at every  
18 visit. You should have gotten this document.  
19 So, I apologize if you didn't.

20 The clinician can determine the  
21 appropriate treatment, understand the expected  
22 response to treatment, and provide appropriate

1 content for counseling the patient. The  
2 outcome for the patient is better symptom  
3 management, appropriate treatment, and  
4 improved quality of life.

5 This measure may also lead to a  
6 reduction in overuse and misuse of treatments  
7 because etiology of epilepsy will be reviewed  
8 and documented at every visit.

9 MEMBER WADDY: Right. I mean, I  
10 understand that.

11 I jumped ahead.

12 CO-CHAIR TIRSCHWELL: No, that is  
13 okay.

14 MEMBER WADDY: I understand that;  
15 I just don't understand why the measure is not  
16 measuring -- it doesn't seem like the measure  
17 is actually measuring that part of it, the  
18 quality of care that is delivered.

19 MS. SWAIN-ENG: What exactly would  
20 you have us measure?

21 (Laughter.)

22 MEMBER WADDY: Well, if they have

1 generalized epilepsy, are they taking an  
2 appropriate medication for generalized  
3 epilepsy?

4 MS. SWAIN-ENG: So, you would have  
5 us develop separate measures for every  
6 possible etiology, just so I am following you?

7 MEMBER WADDY: I am not saying how  
8 you should develop it. It is just I think it  
9 gets back to the issue of, is it closely  
10 linked to quality of care? And this isn't  
11 measuring that, I don't feel like.

12 CO-CHAIR TIRSCHWELL: Okay.  
13 Jolynn?

14 DR. BARKLEY: May I make a  
15 comment?

16 CO-CHAIR TIRSCHWELL: All right,  
17 go ahead.

18 DR. BARKLEY: This is Gregory  
19 Barkley again.

20 One of the thinkings behind this  
21 is that people have talked about having  
22 specific syndromes where you expect good

1 outcome, for example. When they come back and  
2 you ask questions about their seizure  
3 frequency and their side effects, their  
4 medication, and they are not responding, then  
5 it challenges whether you have the correct  
6 diagnosis or the right syndrome. And then,  
7 that may lead to different kinds of diagnostic  
8 testing, and then other interventions to try  
9 to improve their outcome.

10 CO-CHAIR TIRSCHWELL: That is the  
11 seizure type and frequency measure, it would  
12 seem, and now we are talking about the  
13 epilepsy etiology and syndrome, which, again,  
14 it appears that there is overlap.

15 So, let's go to the group, a  
16 couple more comments.

17 Jolynn?

18 MEMBER SUKO: This is just more a  
19 practical comment. I think from a claim's  
20 perspective, on the physician side there is  
21 not that many diagnosis codes. So, if I was  
22 going to my primary care physician, I would be

1 having to go for treatment of epilepsy, and  
2 that would have to be coded on the visit.

3 And again, I don't think this is  
4 going to change the outcome, but just from a  
5 practical perspective, there were some  
6 questions about the coding. I think that it  
7 would be seen in a single -- I would have to  
8 be going to see you for my epilepsy, not my  
9 diabetes, and it would be that visit of  
10 epilepsy that would be counted in this.

11 CO-CHAIR TIRSCHWELL: I apologize,  
12 I don't know this. Is it just the primary  
13 diagnosis code that is being used for this  
14 measure or any of the diagnoses that are  
15 recorded? It is primary? Okay. So, that  
16 probably would mostly limit it to specialty  
17 care.

18 Michael?

19 MEMBER KAPLITT: Okay. So, again,  
20 I would like anybody in this room or on the  
21 phone to answer, because we are in the  
22 evidence section, to answer the following

1 question for me: what is the evidence that  
2 reviewing -- it is nice, the idea and the  
3 concept -- what is the evidence that reviewing  
4 the epilepsy diagnosis at every single visit  
5 changes anything? Before we get into any  
6 other discussion, I would like anybody in the  
7 room or anybody on the phone to answer this  
8 before we drift into anything else.

9 DR. BARKLEY: This is Greg Barkley  
10 again.

11 What I would say is that, if you  
12 blithely assume that you have made the right  
13 diagnosis and that you have thought that this  
14 person has a focal epilepsy, and they really  
15 have a generalized epilepsy, or vice versa,  
16 that if you don't question -- if someone comes  
17 in and is doing well, there probably isn't any  
18 evidence to need to make much of a change.  
19 But if they are not doing well, then that  
20 raises the issue, do you have the right  
21 diagnosis?

22 MEMBER KAPLITT: With all due



1       respect, that is an opinion.  What is the  
2       evidence?

3                   DR. BARKLEY:  Well, there is  
4       evidence of the diagnosis of juvenile  
5       myoclonic epilepsy, which is a syndrome that  
6       comprises about 8 percent of the people with  
7       epilepsy.  It is easily diagnosed if you know  
8       the syndrome.  And if you don't, you end up  
9       putting the people on the wrong medication.  
10      So, knowing the syndrome and putting them on  
11      the right medication improves outcome.

12                   CO-CHAIR TIRSCHWELL:  Ramon?

13                   MEMBER R. BAUTISTA:  I would  
14      submit that, if you are smart enough to know  
15      how to classify epilepsies, you are probably  
16      smart enough to know what the treatment  
17      options are.  I am not sure having to document  
18      that every time is the way to go.  I think it  
19      might be more important to, I guess, show that  
20      at least you are treating them the right way.  
21      I mean, if you know how to classify  
22      epilepsies, you know what to do.  That is part

1 of why you classify epilepsies in the first  
2 place.

3 CO-CHAIR TIRSCHWELL: And I  
4 apologize for prematurely going back to the  
5 comparison with the other measure, but it  
6 seems like I am hearing from multiple people  
7 that it is most important for all of this in  
8 the patients who are not responding to  
9 therapy. And so, maybe the measure with the  
10 seizure descriptions and the frequencies would  
11 be more likely to impact quality of care than  
12 the description of the syndrome.

13 Raj, do you have a comment?

14 MEMBER SHETH: Well, I think that  
15 the measures as they stand obviously suffer  
16 from all the criticisms that have been offered  
17 here. But I think there is another aspect to  
18 it that perhaps hasn't been addressed, and  
19 that is that, if you diagnosis a patient with  
20 having temporal lobe epilepsy, for instance,  
21 and you know that the evidence suggests that  
22 they are not likely to respond to medication,

1 you would sort of move to the next step, which  
2 would be a surgical option.

3 I think there is a lot of benefit.  
4 What typically happens in practices is they  
5 document seizure disorder and give them a  
6 visit to see them in six months' time, instead  
7 of actually looking at other options that  
8 might be available.

9 So, I think it is very important  
10 -- this is one of the AAN quality measures --  
11 that you inquire of the patient as a surgical  
12 candidate, precisely because of this, because  
13 we know that the likelihood of remission with  
14 medication, with more medications, is on the  
15 order of 2 percent. The likelihood of being  
16 seizure-free with surgery is somewhere on the  
17 order of 70-80 percent.

18 So, I think if the measure were  
19 modified some, it would have value.

20 CO-CHAIR TIRSCHWELL: Any other  
21 comments?

22 Salina?

1                   MEMBER WADDY: Yes, and I agree  
2 with you that, if it is either to assess  
3 whether or not they have the correct syndrome  
4 and they are on the correct medication, then  
5 having one measure for that. Or if it really  
6 is, as the person on the phone is saying, for  
7 you to really think about those patients that  
8 have uncontrolled epilepsy, then I think it  
9 would be more valuable to put within the  
10 numerator patients who have greater than a  
11 seizure frequency of three or some basic  
12 number over "X" period of time, and then what  
13 needs to be done.

14                   DR. BARKLEY: May I make a  
15 comment?

16                   CO-CHAIR TIRSCHWELL: Yes, go  
17 ahead.

18                   DR. BARKLEY: I agree with that.  
19 Actually, for the patient, it is a very simple  
20 proposition. If you are seizure-free, you  
21 have good quality of life. If you are having  
22 any seizures, you have poor quality of life.

1 And so, the patient-centered measure is zero  
2 for seizure count since your last visit.

3 CO-CHAIR TIRSCHWELL: Okay.

4 DR. BARKLEY: There is plenty of  
5 evidence that shows and lots of quality-of-  
6 life studies that show that that is really the  
7 only thing that counts to the patient.

8 CO-CHAIR TIRSCHWELL: Okay. Yes,  
9 one more comment from the AAN.

10 MS. SWAIN-ENG: Just quickly, just  
11 to respond to Dr. Raj's comment about referral  
12 for surgery, we do have a separate measure  
13 that we will be bringing back to NQF. It is  
14 not currently in the PQRS program. But it is  
15 focused on patients with a diagnosis of  
16 intractable epilepsy and referring them for  
17 evaluation for appropriateness for surgical  
18 therapy.

19 There is evidence that shows, on  
20 average, people have a 20-year wait before  
21 they are actually referred for surgery  
22 evaluation. So, just to answer the question,

1 that doesn't relate directly to what we are  
2 talking about now, but just to let you know  
3 that we will be coming back to NQF. If you  
4 are on the Steering Committee again, you may  
5 be seeing that sometime soon.

6 CO-CHAIR TIRSCHWELL: Thank you.

7 Okay. Any other comments?

8 (No response.)

9 Let's go ahead and vote then on  
10 the evidence for this measure.

11 (Vote taken.)

12 MS. THEBERGE: I have 20, 21, 22,  
13 23. I need one more response. Could everyone  
14 vote one more time, please? Nobody has  
15 stepped out of the room, right?

16 CO-CHAIR TIRSCHWELL: Oh, there it  
17 goes.

18 MS. THEBERGE: Okay. There we go.

19 (Laughter.)

20 All right. Zero yes; 15, no,  
21 evidence does not meet guidance, and 9, no,  
22 insufficient.

1 CO-CHAIR TIRSCHWELL: So, as we  
2 did not hear the exception brought up, I think  
3 we are done with this measure, too, then.

4 And on that note, should we open  
5 it up for public comment? So, should we talk  
6 to the operator?

7 Arnika, could you please open the  
8 phones for any public comment?

9 THE OPERATOR: Yes, sir.

10 At this time, if you would like to  
11 ask a question, please press \*, then the  
12 number 1 on your telephone keypad.

13 (No response.)

14 And there are no questions at this  
15 time.

16 CO-CHAIR TIRSCHWELL: Any other  
17 comments here?

18 (No response.)

19 MS. JOHNSON: Okay. Thanks, guys.  
20 We have had a very interesting day one of our  
21 Phase II. So, thanks for all the thought and  
22 effort that you guys have put into this.

1 I am going to ask Suzanne here in  
2 just a minute to make sure I haven't forgotten  
3 anything.

4 But I think the one thing that I  
5 do want to remind you of is we will be  
6 spending some time tomorrow afternoon  
7 discussing the CMS Yale readmission measure.  
8 Again, the mortality measure was withdrawn,  
9 but the readmission measure is still on the  
10 table.

11 And to that end, I have a little  
12 bit of homework for you. I want to ask you to  
13 take a look at the comments and the responses  
14 that came in on those measures. We had  
15 already put those up on SharePoint. To make  
16 things a little easier for you, we basically  
17 put the same thing up on SharePoint, but with  
18 only the stuff relevant to the readmission  
19 measure. So, that way, you don't have to plow  
20 through. Just look at the stuff on the  
21 readmission measure and just make sure that  
22 you have had a chance to see the developer



1 responses.

2 And then, tomorrow afternoon the  
3 developers will be here and I believe are  
4 going to show you a few slides as well. We  
5 are going to allow them to do that.

6 So, if nobody has any questions or  
7 concerns, including Suzanne --

8 MS. THEBERGE: Two quick things.  
9 I just wanted to let you all know I emailed  
10 you an updated Excel sheet and Word document  
11 this afternoon that has just the comments and  
12 responses for 2027.

13 And then, on a housekeeping note,  
14 I have just been told our building is on  
15 lockdown because the Occupy protest is like a  
16 block away, and I guess they are right around  
17 here. So, if you need to leave -- (Laughter)  
18 -- just be aware of that, but you won't be  
19 able to get back in if you leave because you  
20 don't have a key. So, don't try to come back.

21 (Laughter.)

22 CO-CHAIR KNOWLTON: Including

1 through tomorrow?

2 (Laughter.)

3 MS. THEBERGE: I believe you will  
4 be able to get in tomorrow morning.

5 So, if you forget something, you  
6 will just have to probably get it tomorrow  
7 morning, since you will need a key to get into  
8 the building. And they have your name on a  
9 list. So, if there is still a lockdown  
10 tomorrow morning, it shouldn't be a problem.

11 (Whereupon, the above-entitled  
12 matter went off the record at 4:35 p.m.)

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<b>A</b>				
<b>AAN</b> 9:4,10,19	120:19,20 297:21	<b>acknowledgment</b>	297:13	<b>advanced</b> 71:9
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In the matter of: Neurology Phase II  
Steering Committee

Before: NQF

Date: 10-03-12

Place: Washington, DC

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**NEAL R. GROSS**

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