

NATIONAL QUALITY FORUM

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NEUROLOGY ENDORSEMENT MAINTENANCE
STEERING COMMITTEE

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WEDNESDAY

JUNE 20, 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, Co-Chair, New Jersey Health Care Quality Institute
DAVID TIRSCHWELL, MD, MSc, Co-Chair, University of Washington
A.M. BARRETT, MD, Stroke Rehabilitation Research, Kessler Foundation

WILLIAM BARSAN, MD, University of Michigan Health System
JOCELYN BAUTISTA, MD, MBA, Cleveland Clinic
RAMON BAUTISTA, MD, MBA, University of Florida HSC/Jacksonville
GWENDOLEN BUHR, MD, Duke University
GAIL AUSTIN COONEY, MD, FAAHPM, Hospice of

Palm Beach County/Spectrum Health Inc.
JORDAN EISENSTOCK, MD, CPE, UMass Memorial Medical Center
RISHA GIDWANI, DrPH, Stanford University Medical Center
DAVID HACKNEY, MD, Beth Israel Deaconess Medical Center

GREGORY KAPINOS, MD, MS, North Shore-LIJ Health System

PRESENT(Cont'd):

MICHAEL KAPLITT, MD, PhD, Weill Cornell
Medical College

DANIEL LABOVITZ, Montefiore Medical Center

THERESE RICHMOND, PhD, CRNP, FAAN, University
of Pennsylvania, School of Medicine

JACK SCARIANO, MD, PLLC, Neurologist, Fort
Sanders Parkwest Medical Center and Tennova
West Medical Center

RAJ SHETH, MD, Nemours Children's Clinic

JOLYNN SUKO, MPH, Virginia Mason Medical
Center

JANE SULLIVAN, PT, DHS, MS, Northwestern
University Feinberg School of Medicine

FREDRIK TOLIN, MD, MBA, FACS, Humana

MARY VAN de KAMP, CCC-SLP, RehabCare, Kindred
Healthcare

SALINA WADDY, MD, National Institutes of
Health

NQF STAFF:

HELEN BURSTIN, MD, Senior Vice President,
Performance Measures

ANN HAMMERSMITH, JD, General Counsel

KAREN JOHNSON, MS, Senior Director,
Performance Measures

SUZANNE THEBERGE, MPH, Project Manager,

Performance Measures

JESSICA WEBER, MPH, Project Analyst,
Performance Measures

REVA WINKLER, MD, MPH, Senior Director,
Performance Measures

ALSO PRESENT:

MARK ANTMAN, DDS, MBA, American Medical
Association

JOSEPH DROZDA, JR., MD, AMA-PCPI*

KENDRA HANLEY, MS, AMA-PCPI

DIEDRA JOSEPH, AMA-PCPI

IRENE KATZAN, MD, MS, Cleveland Clinic

KAREN KOLBUSZ, The Joint Commission

LEE SCHWAMM, Partners HealthCare System, Inc.

DAVID SEIDENWURM, MD, AMA-PCPI

MARK STEWART, American Heart Association

SARAH TONN, American Academy of Neurology

ANN WATT, MBA, The Joint Commission

LAURA YODICE, MPH, MHA, American Medical
Association

*present by teleconference

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

2 9:39 a.m.

3 OPERATOR: Welcome to the conference.
4 Welcome to the Neurology Steering Committee
5 meeting.

6 Please note today's call is being
7 recorded.

8 Please stand by.

9 MS. JOHNSON: Okay. Good morning,
10 everybody, and welcome to the Neurology
11 Steering Committee in-person meeting.

12 So, I just wanted to say thank you very
13 much for all the work that you have done in
14 looking at our measures so far and for flying
15 in to beautiful, warm, balmy Washington, D.C.

16 I am Karen Johnson. I am the Senior
17 Director for this project. And I think I have
18 sent you a few emails along the way. So, it
19 is nice to meet you guys.

20 What we are going to do this morning
21 first thing is just go through and have brief
22 introductions from everybody. I am probably

1 supposed to introduce our two Co-Chairs Dave
2 and David, but I am going to let them do that.
3 We will just go around and do just a very
4 quick introduction.

5 And then, I think Ann will also help us
6 with the COI thing.

7 MS. HAMMERSMITH: We combine
8 introductions and COI. So, we will do it that
9 way.

10 CO-CHAIR TIRSCHWELL: Okay. So, my name
11 is David Tirschwell. I am a stroke
12 neurologist. I work at Harborview Medical
13 Center, which is part of the University of
14 Washington in Seattle, Washington.

15 As a neurologist, a clinician, I work
16 with mostly stroke patients, but I am very
17 deeply committed to quality measures. I
18 really appreciate all of you participating and
19 donating your time to this process as well.

20 Should I say something about
21 disclosures, too, now? No? Okay.

22 CO-CHAIR KNOWLTON: I am Dave Knowlton.

1 I am the other Co-Chair. I am the President
2 and CEO of the New Jersey Health Care Quality
3 Institute.

4 I also served on the first with some
5 other folks here, Mary and some other people,
6 on the first Stroke Committee that took on
7 these measures.

8 The other thing that especially
9 qualifies me for this is I am a stroke
10 survivor. So, I represent purchaser and
11 consumer interests.

12 We say nothing? I don't have anything
13 to disclose. So, I would just say that.

14 MS. HAMMERSMITH: We will get there.

15 CO-CHAIR KNOWLTON: Okay. So, Ann?

16 MS. HAMMERSMITH: Good morning,
17 everyone.

18 I am Ann Hammersmith. I am NQF's
19 General Counsel.

20 What we are going to do now is go
21 through disclosures of interest. We will have
22 you introduce yourselves at the same time.

1 If you recall some time ago, you filled
2 out a form for us where we asked you a number
3 of questions. We have reviewed those forms as
4 part of the nomination and seating process on
5 the Committee.

6 For those who are on the Committee, what
7 we like to do, once you are on the Committee,
8 in the first public meeting we like you to
9 disclose anything that you think is relevant
10 to your service before the Committee. Just
11 because you disclose does not mean that you
12 have a conflict. It is simply a disclosure.

13 I want to remind you of just a few basic
14 principles. You sit as individuals on this
15 Committee. You are individual subject matter
16 experts. That is why we chose you to serve.

17 Sometimes Committee members in many of
18 our Steering Committees, in perfectly good
19 faith and innocently, will say, "I am John Doe
20 and I am here representing the American
21 Association of...." -- fill in the blank.
22 Actually, you are not here representing

1 anybody but yourself. We are interested in
2 your expertise.

3 The other thing that I want to remind
4 you about is also related to things that I
5 have heard Committee members say, again,
6 innocently and in good faith. They will say,
7 "I have no financial conflict of interest."
8 We are, of course, interested in financial
9 conflicts of interest and financial
10 disclosures, if they are relevant.

11 But in this world that we work in, many
12 of you serve as experts on committees. You
13 are active in related activities to what we
14 are talking about before the Committee, where
15 there is no money involved at all. You do it
16 as a volunteer, as you do for us. So, to the
17 extent you have had any service like that,
18 that is relevant. We ask you to disclose
19 that.

20 We are particularly interested in
21 research funding, grant funding, and any
22 consulting that you have done, if it is

1 relevant to what is before the Committee.

2 So, what I am going to do is ask you to
3 go around the table. I am going to start with
4 the Co-Chairs. Introduce yourself. Tell us
5 who you are with and if you have anything to
6 disclose.

7 CO-CHAIR TIRSCHWELL: David Tirschwell
8 again. I participate in research that is
9 funded by both industry and NIH, although I
10 don't think it is related. I do serve on a
11 task force for the American Stroke
12 Association, but that is not involved with any
13 of the development for quality measures,
14 though I am a user of many of the stroke
15 quality measures.

16 CO-CHAIR KNOWLTON: I am Dave Knowlton,
17 as I told you, and I don't have any conflicts.

18 MEMBER BUHR: My name is Gwendolyn Buhr.
19 I usually go by Gwen. And I work at Duke
20 University. I am a geriatrician. I spend
21 most of my time working in long-term care and
22 teaching various learners at Duke. And I

1 don't have any conflicts.

2 MEMBER COONEY: I am Gail Cooney. I
3 work in hospice and palliative medicine in
4 West Palm Beach, Florida. I am, actually, a
5 reformed neurologist and have boards in pain
6 and hospice and palliative medicine, which is
7 now a subspecialty of neurology. And I don't
8 believe I have any conflicts of interest.

9 MEMBER VAN DE KAMP: I am Mary van de
10 Kamp. I am Senior Vice President of Clinical
11 Operations for Rehab Care and Kindred. And my
12 role is to oversee all the clinical education
13 within long-term care, hospitals, births, and
14 skilled nursing. I am a speech and language
15 pathologist as well, probably most
16 importantly. And I have nothing to disclose.

17 MEMBER TOLIN: Fred Tolin. I am Vice
18 President with Humanity Insurance Company. I
19 am involved with medical policy development
20 and implementation. Other than working for an
21 insurance company, I have nothing else to
22 disclose.

1 (Laughter.)

2 MEMBER LABOVITZ: I am Daniel Labovitz.
3 I am a stroke neurologist at Montefiore
4 Medical Center for the Albert Einstein College
5 of Medicine. I am a card-carrying member of
6 the American Heart Association and use the
7 quality measures, serve on a task force.

8 MEMBER SHETH: Raj Sheth, Nemours
9 Clinic, affiliated with Mayo Clinic,
10 Jacksonville. I am a pediatric neurologist,
11 do mainly epilepsy. In that context, I have
12 served both in industry and in the American
13 Academy of Neurology and the American Epilepsy
14 Society with task forces and other committees
15 such as that.

16 MEMBER R. BAUTISTA: Hello, everyone.
17 Ramon Bautista from the University of
18 Florida in Jacksonville. I am an Associate
19 Chair and Associate Professor of Neurology and
20 head the epilepsy program over there.

21 I was on the Board of Directors of
22 Shands Hospital and the University of Florida

1 in Jacksonville. Aside from that, no other
2 conflicts to disclose.

3 MEMBER SULLIVAN: Good morning.

4 I am on the faculty of the Feinberg
5 School of Medicine at Northwestern University
6 in Chicago. I am a physical therapist.

7 I have industry funding and NIDRR
8 funding for stroke-related rehabilitation
9 research, and I serve the APTA, American
10 Physical Therapy Association, on their
11 outcomes as a consultant.

12 MEMBER SUKO: Good morning.

13 I am Jolynn Suko, and I serve as the
14 Administrator for the Neuroscience Institute
15 at Virginia Mason Medical Center, which is a
16 regional medical center in Seattle,
17 Washington. My background is quality and
18 quality measurement and administration. And
19 I have nothing to disclose.

20 MEMBER RICHMOND: Hi. I am Teri
21 Richmond. I am a Professor of Nursing at the
22 University of Pennsylvania School of Nursing.

1 I am also a Professor of Nursing and Surgery
2 at the Division of Trauma at the Furman School
3 of Medicine. I have nothing relevant to
4 disclose.

5 MEMBER GIDWANI: Good morning.

6 I am Risha Gidwani from Stanford
7 University Medical Center. I am a health
8 services researcher within neurosciences over
9 there.

10 I have had past scientific consulting
11 relationships with a variety of large
12 multinational pharmaceutical companies, but
13 none related to neurology. So, I believe
14 there is no conflict of interest.

15 MEMBER BARRETT: Good morning.

16 I am Anna Barrett. You can also call me
17 "A.M." if you like. I am from Kessler
18 Foundation in New Jersey, which has been
19 involved in the development of some neuro qual
20 measures. I am the Director of Stroke
21 Research there, and I also play a role in the
22 Kessler Institute of Rehab, helping them to

1 form outcomes and assess outcomes.

2 And my conflicts of interest are, I
3 think, related to research funding from the
4 NIH, Kessler Foundation. The Kessler
5 Foundation has received research funding for
6 me from a company called O'Brien Technologies,
7 which is now defunct. And four years ago, we
8 had an investigator-initiated grant, I think,
9 from Pfizer.

10 MEMBER KAPINOS: Good morning.

11 I am Greg Kapinos. I am a neuro
12 intensivist at the North Shore-NIJ in New
13 York. Nothing to disclose.

14 MEMBER BARSAN: I am Bill Barsan. I am
15 an emergency physician at the University of
16 Michigan. I have been involved in stroke
17 research since the 1980s and am an active
18 member of the stroke team at the University of
19 Michigan.

20 As far as disclosures, I am the
21 principal investigator for the NINDS-funded
22 Neurologic Emergency Treatment Trials Network

1 and have another cooperative award from NIH
2 and FDA to look at adaptative clinical trial
3 designs.

4 MEMBER WADDY: I am Salina Waddy. I am
5 a stroke neurologist and neurogeneticist. I
6 am at the National Institutes of Health as a
7 Program Director for Health Disparities within
8 the Office of Clinical Research. I am on
9 numerous trans-NIH as well as trans-agency
10 federal groups. I don't know if you need to
11 know the names of those individually, but I
12 don't think I have anything else to disclose.

13 MEMBER EISENSTOCK: Hi, everyone.

14 I am Jordan Eisenstock. I am from UMass
15 Medical Center in Worcester, Massachusetts.
16 I am double-boarded in both neurology and
17 psychiatry. Among a few different
18 administrative titles, I am also the Director
19 of Neuro Rehabilitation for UMass's System
20 Rehab Hospital. I don't have any disclosures.

21 MEMBER J. BAUTISTA: I am Jocelyn
22 Bautista. I am an epilepsy neurologist at the

1 Cleveland Clinic. I also serve as the Quality
2 Officer for our Neurological Institute.

3 I have participated, along with the
4 American Academy of Neurology and the American
5 Epilepsy Society, in creating evidence-based
6 guidelines for epilepsy, but nothing directly
7 related to the measures today.

8 MEMBER SCARIANO: Yes, hi. I am Jack
9 Scariano. I am a Board-certified neurologist
10 from Knoxville, Tennessee. I have been in
11 practice now, let's see, 35 years, and I have
12 had a whole lot of experience with both urban
13 and also rural patients. And I have no
14 conflicts.

15 MEMBER KAPLITT: Hi. I am Mike Kaplitt.
16 I am the Vice Chair for Research and Residency
17 Director and Director of Functional
18 Neurosurgery in the Department of Neurological
19 Surgery at Weill Cornell in our Medical
20 College in New York.

21 I have NIH and Defense Department
22 funding for my basic research lab, as well as

1 funding from a foundation called the JPB
2 Foundation for Parkinson's research. I have
3 been involved in a variety of industry-
4 sponsored clinical trials, but not in the past
5 year. And I have no other real conflicts. I
6 spent seven years on the NINDS Clinical Trial
7 Section, but, again, that ended over a year
8 ago. That's it.

9 MEMBER HACKNEY: I am David Hackney. I
10 am a neuroradiologist at Beth Israel Deaconess
11 Hospital in Boston and at Harvard Med School.

12 As a clinical neuroradiologist, I guess
13 I make money every time somebody does an
14 imaging study for a patient with strokes. So,
15 that is probably my primary conflict.

16 (Laughter.)

17 I have administrative responsibilities
18 in the Radiology Department. I have research
19 funded by NIH and DoD. I am on far too many
20 committees for radiology societies, all of
21 which in one way or another are interested in
22 imaging of neurologic disease and stroke. I

1 don't have any industry funding or industry-
2 paid consulting. I am a current and past
3 member of Study Sections for NIH and have done
4 Study Section work for DoD. And I have done
5 guidelines committee work for the American
6 Society of Neuroradiology and the American
7 College of Radiology.

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

10 Are there any Committee members on the
11 phone?

12 (No response.)

13 No? Okay.

14 Do you have any questions of me about
15 conflicts of interest? Or is there anything
16 that you want to discuss with each other,
17 based on the disclosures this morning?

18 (No response.)

19 Okay. Thank you. Have a good meeting.

20 MS. JOHNSON: Thank you, guys.

21 And let's go ahead and have the NQF
22 staff introduce themselves.

1 MS. THEBERGE: Good morning, everyone.

2 I am Suzanne Theberge. I am the Project
3 Manager on this project. I think I have
4 spoken with all of you on the phone, by email,
5 and in person. It is great to meet you all.

6 And I just wanted to add that we have
7 flash drives available with all the meeting
8 materials, if anybody is having trouble
9 getting online or needs them on a flash drive.

10 Jessica?

11 MS. WEBER: I am Jessica Weber. I am a
12 Project Analyst at NQF.

13 DR. WINKLER: Good morning.

14 I am Reva Winkler. I am a Senior
15 Director of Performance Measures at NQF.

16 DR. BURSTIN: Good morning, everybody.

17 I am Helen Burstin. I am the Senior
18 Vice President for Performance Measures at
19 NQF. I get to oversee this lovely process
20 across all disciplines and cross-cutting
21 areas.

22 So, thank you for your service. We know

1 there is a lot of work involved in reviewing
2 these measures, and I just want to thank you
3 for your time and your effort.

4 We will be here to provide support to
5 the team, if there are any questions that come
6 up, and there are always questions that come
7 up. As measures get more and more complex,
8 these decisions also get more and more
9 complex.

10 So, thanks, everybody.

11 MS. JOHNSON: Thank you.

12 So, let's go ahead and start with just
13 some real basic notes about the process that
14 we are going to go through today. Or,
15 actually, we are going to start with tools.

16 So, even though Dave has been teasing us
17 about the trees that we have cut down for the
18 materials that we have provided, we really
19 have three hard-copy sets of things that we
20 gave you.

21 One is the meeting agenda. So, that
22 will tell you the order in which we will be

1 proceeding throughout the meeting.

2 And then, the second thing is the
3 summary document. It is about a 62-page
4 document that briefly summarizes each measure,
5 gives the results of those preliminary
6 evaluations that each of you did, and then,
7 also, includes the notes and summaries that we
8 took from our Work Group meetings. So,
9 hopefully, that will be useful to you.

10 Risha is looking at me with a question.

11 MEMBER GIDWANI: Do you have any extra
12 copies of that document?

13 MS. JOHNSON: Yes, we do. So, if
14 anybody else needs any of these documents,
15 just raise your hand and Jessica can help you.

16 The third thing that I want to go over
17 very quickly is our Quick Guide. It is the
18 NQF Evaluation Quick Guide. It is a little,
19 four-page document. We are not going to read
20 it all, but really this guide, we wanted to
21 give you an hard copy that you could keep in
22 front of you just to remind you of the

1 different criteria and all the different
2 things that you will be thinking of as you go
3 through these measures.

4 So, again, there are four main criteria
5 that we will be looking at for each of the
6 measures. Importance to measure and report is
7 the first criteria. It is a must-pass.
8 Underneath that overarching criterion is three
9 subcriteria, and each of those three also are
10 must-pass criteria. And those are high
11 impact, evidence, and performance gap. And
12 notice that we did switch evidence and
13 performance gap around a little bit, and that
14 is how we will go through today in our voting
15 and such.

16 A reminder about evidence: depending on
17 whether the measure is an outcome measure or
18 a process or structure measure, it will change
19 how you think about evidence and the kinds of
20 things that you would expect to see.

21 I don't believe we have any outcome
22 measures on our agenda for today. So, for all

1 of the measures today, you will be considering
2 the quantity, quality, and consistency of
3 evidence. Okay?

4 On the second page, well, I think the
5 second and the top of the -- all of the second
6 page is just what I told you. And again, I am
7 going through these very quickly, but there
8 will be time for questions, if you have any.

9 The second major criteria is scientific
10 acceptability of measure properties. Again,
11 that is a must-pass criterion. Underneath
12 that criterion is two subcriteria that are
13 also must-pass. Those are reliability and
14 then validity.

15 So, under reliability, that is where you
16 think about things like the specifications
17 and, also, thinking about how they tested
18 measures for reliability. Was the method
19 appropriate? Were the results adequate to
20 make you believe that the measure is reliable?

21 For validity, you are thinking about
22 specifications there as well, but you are

1 thinking about it in terms of how the specs
2 link to the evidence. So, you want to think
3 about do the specifications actually reflect
4 the evidence in the literature. You will be
5 thinking about the validity testing, including
6 the method and the scope, as well as the
7 results. But you will also be thinking about
8 things like exclusions, if risk adjustment was
9 done, was that done well and was it adequate?
10 You will be thinking about meaningful
11 differences as well as comparability of data
12 sources, if that is applicable.

13 We will be asking you to vote on
14 reliability and validity separately. And
15 then, we will use decision logic to see if a
16 measure passes the scientific acceptability
17 criterion.

18 The third and fourth criterion are
19 listed on the last page of the guide.
20 Usability, which reflects whether or not you
21 believe that a measure is meaningful,
22 understandable, and useful for public

1 reporting and accountability, as well as for
2 quality improvement efforts.

3 And then, feasibility really gets to how
4 usable, or not usable, but how the burden
5 behind collecting data for a measure is, and
6 is it really implementable? So, that is what
7 you are thinking about in terms of
8 feasibility.

9 And then, finally, there will be votes
10 for overall suitability for endorsement. And
11 I will walk you through those steps as well in
12 a few minutes.

13 No. 5 on this sheet is comparison to
14 related or competing measures. That is
15 something that we will do after we go through
16 the individual measures. So, we will look and
17 evaluate each individual measure and then, if
18 necessary, think about whether there are other
19 measures out there that are either pretty much
20 head-to-head competing with those measures, in
21 which case you would have to consider if there
22 is a best-in-class measure, or if there are

1 related measures, you would want to be
2 thinking about how different are those
3 measures. You know, do they have the same
4 list of ICD-9 codes to describe a stroke, for
5 example, those kinds of things. So, you are
6 thinking about the details of the specs when
7 you are thinking about harmonization of
8 related measures.

9 So, let me stop right there and see if
10 there are any questions on this very, very
11 brief run-through of the evaluation criteria.

12 MEMBER KAPINOS: I'm sorry.

13 MS. JOHNSON: Yes?

14 MEMBER KAPINOS: I am surprised; you
15 just said today, of all the measures, there
16 are no health outcomes. I was in Work Group
17 4. So, I didn't look at all of them, but,
18 briefly, before coming here, I saw that there
19 was one that was measuring mortality. To me,
20 that it a health outcome.

21 MS. JOHNSON: Right. That will be
22 tomorrow.

1 MEMBER KAPINOS: Oh, that's tomorrow?

2 Okay.

3 MS. JOHNSON: Right, right.

4 So, what we tried to do is -- we have a
5 very packed schedule today -- what we tried to
6 do was put all the process measures together
7 and, also, all the measures from The Joint
8 Commission from the AHA-ASA and AMA-PCPI,
9 hopefully, to try to help them out, so that
10 they only have to come one day. We may not
11 get through everything. So, we may have to
12 ask them to attend again tomorrow. But we
13 will see how that goes.

14 And then, we will leave our brain space
15 for tomorrow for those outcome measures that
16 in some ways are a little bit more
17 challenging, just because of the risk-
18 adjustment issues that come up on those.

19 There are also measure submission
20 materials. You guys have seen all of those.
21 We didn't print them out for you. They are
22 available either on the SharePoint site or on

1 the flash drives that Suzanne and Jessica have
2 been passing around.

3 And then, finally, later on today, I am
4 hoping to get you some comparison tables that
5 will help as we go through the
6 related/competing discussions that we will
7 have at some point during the meeting.

8 Okay. Could we go to the next slide,
9 please? So, I have already hinted at this,
10 but, basically, the process is discuss, then
11 vote. So, for each measure, we will be having
12 eight votes. Okay? So, we will vote on all
13 of the must-pass criteria.

14 So, what we will do is we will begin and
15 talk about and discuss impact. And then, we
16 will ask you to vote on whether or not you
17 believe the measure has impact. Okay.

18 And then, we will go to evidence,
19 discuss it, and then vote on it. We will work
20 our way through.

21 If a measure fails a must-pass
22 subcriterion, we will stop at that point. So,

1 if something fails at evidence, we will not go
2 on to discuss opportunity for improvement or
3 validity, reliability, that sort of thing.
4 Okay?

5 For the first measure, what we will do
6 is go through a little more slowly than we
7 might on the other measures. As necessary, I
8 will have slides up and walk you through some
9 of the criteria. So, we are trying this,
10 instead of giving you a 15-to-20-minute kind
11 of encapsulation of that orientation tutorial
12 that we did.

13 So, we will see how this works. If you
14 think it is not working, let us know and we
15 will change it for the next time around.

16 We will have, roughly, 15 minutes per
17 measure. That is not a lot of time. So, we
18 will do our best as we go through the day.

19 You should already have in your hands
20 clickers. You will use those clickers to
21 vote. When we get ready to cast our first
22 vote, we will describe that a little bit more.

1 So, let's go to the next slide. A few
2 housekeeping details. You have already
3 managed to use your microphones. So, that is
4 great.

5 This meeting is open to the public and
6 is being recorded and transcribed as well. It
7 is pretty important to have only one
8 microphone on at a time. So, if you can
9 possibly remember when you are done speaking,
10 turn your microphone off, so that someone
11 else's microphone will come on.

12 Your name tents in front of you are your
13 signal that you would like to speak. So, if
14 you will take your name tag when you have a
15 question or a comment and just put it on its
16 end, that is the flag to the Co-Chairs that
17 you would like to speak. Yes, exactly.
18 Exactly.

19 Our Co-Chairs are going to facilitate
20 the meeting. So, NQF staff will be here to
21 help if we need to, but it will mostly be
22 facilitated by the Co-Chairs and you guys as

1 you go through the process. So, we are here
2 to help, but you guys are the ones doing the
3 evaluations.

4 We do, obviously, plan to have lunch and
5 some breaks throughout the day. We are going
6 to try to stick to those timeframes that we
7 have for those. We may have to, depending on
8 how fast we are going through, we may have to
9 say, instead of a 15-minute break, let's take
10 a 10-minute, something like that. So, we will
11 see how the day goes and see if we need to
12 swap out or not.

13 Restrooms, if you haven't already found
14 them, are out in the hall. I am told that the
15 men's room is very close to the women's room.
16 So, out in the hall.

17 And finally, internet access, "Guest"
18 and "NQF Guest" is the login and password.

19 Let's stop one more time and see if we
20 have any questions. If not, we will start
21 with our first measure.

22 Suzanne has reminded me -- I am sorry to

1 the developers -- we have asked our
2 developers, and we have three different groups
3 that are here today, we have asked each of the
4 developers to spend two to three minutes each
5 summarizing their measures that we will be
6 thinking about today and tomorrow.

7 So, we don't have a list. How about
8 AMA-PCPI?

9 MS. JOSEPH: Good morning, and thank you
10 for the opportunity to introduce the eight
11 measures submitted for consideration by the
12 Steering Committee.

13 My name is Diedre Joseph, measure
14 development staff for the AMA-PCPI. Also
15 present to speak on behalf of the measures are
16 Dr. Irene Katzan and Dr. David Seidenwurm,
17 members of our Measure Development Work Group;
18 Dr. Mark Antman, Director of Measure
19 Development Operations at the AMA-PCPI; Kendra
20 Hanley, member of the AMA-PCPI Specifications
21 Team, and Laura Yodice, member of our Testing
22 Team.

1 The American Academy of Neurology,
2 American College of Radiology, and the
3 American Medical Association convened PCPI,
4 collaborated to form a Stroke and Stroke
5 Rehabilitation Work Group in order to identify
6 and define quality measures toward managing
7 and improving outcomes for patients with
8 stroke and for patients undergoing stroke
9 rehabilitation.

10 The eight measures presented for your
11 review were developed as a part of this
12 measure development project. The measures
13 were originally approved by the PCPI
14 membership in 2006 and were recently reviewed
15 and revised per the AMA-PCPI measure
16 maintenance review and enhancement process.
17 Six of the eight measures were originally
18 endorsed by the NQF in 2007.

19 PCPI measures are developed through
20 cross-specialty, multidisciplinary work
21 groups. All medical specialties and other
22 healthcare professional disciplines

1 participating in patient care for the clinical
2 condition or topic under study must be equal
3 contributors to the measure development
4 process.

5 In addition, the PCPI strives to include
6 on its Work Groups individuals representing
7 the perspectives of patients, consumers,
8 private health plans, and employers. This
9 broad-based approach to measure development
10 ensures buy-in on the measures from all
11 stakeholders and minimizes bias toward any
12 individual specialty or stakeholder group.

13 All Work Groups have at least two Co-
14 Chairs who have relevant clinical and/or
15 measure development expertise and who are
16 responsible for ensuring that consensus is
17 achieved and that all perspectives are voiced.

18 All eight of the measures presented
19 today have been tested and shown to be
20 reliable, feasible, and valid. The testing
21 project for these measures included the
22 assessment of face validity, inter-rater

1 reliability, feasibility, and for some a
2 comparison across multiple data sources.

3 Face validity was systematically
4 assessed by a panel of experts to establish
5 the measure's ability to accurately reflect
6 quality as specified. Additionally, all PCPI
7 performance measures are assessed for content
8 validity by a panel of expert Work Group
9 members during the development process.

10 Additional input on the content validity of
11 draft measures is obtained through a 30-day
12 public comment period and by also soliciting
13 comments from a panel of consumer, purchaser,
14 and patient representatives convened by the
15 PCPI specifically for this purpose. All
16 comments received are reviewed by the expert
17 Work Group and the measures adjusted as
18 needed.

19 Inter-rater reliability was assessed
20 with a sample from several practice sites
21 representing a range of settings, geographic
22 locations, and technology infrastructure. The

1 percent agreement between trained extractors
2 was recorded, as well as kappa statistics, to
3 ensure that agreement rates are not a
4 phenomenon of chance. All of the measures
5 showed high agreement rates, and the kappas,
6 when calculable, reflect substantial or almost
7 perfect agreement beyond chance.

8 Finally, across the sites who are
9 submitting data to PCQRS, four of the measures
10 were tested for reliability across data
11 sources. This allowed us to determine a
12 percent agreement between PQRS claims
13 submissions and a manual review of the claims
14 information. The percent agreement for the
15 four measures ranged from 91 percent to 100
16 percent agreement, reflecting high reliability
17 in comparison of these data sources.

18 Now a brief review of the measures and
19 rationale. There are eight of them, so please
20 bear with me.

21 Measure 0242, Tissue Plasminogen
22 Activator, t-PA, considered, is paired with

1 Measure 2022, t-PA-initiated, and both are
2 specified at the facility level of
3 measurement.

4 CO-CHAIR TIRSCHWELL: Sorry. I
5 apologize for interrupting. But we are going
6 to go through each measure in tremendous
7 detail.

8 MS. JOSEPH: All right. So, we were
9 told --

10 CO-CHAIR TIRSCHWELL: We only have about
11 two minutes per organization.

12 MS. JOSEPH: We were told to give an
13 overview of the testing and the methodology
14 for measure development, as well as each
15 measure.

16 CO-CHAIR KNOWLTON: Well, if the
17 Committee has questions, we will direct them
18 to you, but we have got to move on.

19 MS. JOSEPH: So, you don't want me to do
20 each measure?

21 CO-CHAIR KNOWLTON: Right.

22 MS. JOSEPH: Okay.

1 CO-CHAIR TIRSCHWELL: We are going to do
2 each measure.

3 MS. JOSEPH: Okay. Thanks.

4 CO-CHAIR TIRSCHWELL: Thank you.

5 MS. JOHNSON: Can we hear now from The
6 Joint Commission developers?

7 MS. KOLBUSZ: Good morning, everyone.

8 My name is Karen Kolbusz. I am the
9 Associate Project Director in the Division of
10 Healthcare Quality Evaluation at The Joint
11 Commission.

12 To my left I have Ann Watt, Associate
13 Director, and also Dr. Lee Schwamm, who is a
14 vascular neurologist and the Stroke Director
15 and Director of Telemedicine at Massachusetts
16 General Hospital, also Professor at Harvard
17 Medical School, and Chief Consultant with Get
18 With The Guidelines. Hopefully, I got all his
19 titles correct.

20 (Laughter.)

21 To give you just a brief overview of the
22 measure set, The Joint Commission stroke core

1 measure set consists of eight core measures.

2 The measure that deals with acute
3 intervention is Stroke 04, which is
4 thrombolytic therapy. This particular measure
5 captures those patients who arrive in the
6 hospital emergency department within two hours
7 of last-known well that received IV t-PA
8 within three hours of last-known well.

9 The next two measures are early
10 management measures which involve VTE
11 prophylaxis and also antithrombotic therapy by
12 the end of day two, with day one being the
13 hospital day of arrival, day two the day after
14 arrival.

15 The remaining six measures deal really
16 with discharge planning: patients discharged
17 on antithrombotic therapy, patients with
18 atrial fibrillation who are discharged on
19 anticoagulation therapy, patients that are
20 discharged on statin medication. These are
21 all dealing with ischemic stroke patients.
22 Also, patients that receive stroke education

1 or who are assessed for rehabilitation
2 services anytime during the hospital stay.

3 The measures were originally pilot-
4 tested in 2004. There was a 12-month pilot
5 test. They have been in use since 2004. They
6 were originally endorsed by NQF in 2008.
7 Currently, they are collected by more than 900
8 certified Joint Commission primary stroke
9 centers. Data collection for all stroke
10 measures, all eight in the set, are required
11 to maintain your certification status. They
12 have also been harmonized with the Guidelines
13 in the Paul Coverdell National Acute Stroke
14 Registry.

15 They will be collected by CMS for the
16 fiscal year 2015 payment determination.
17 Therefore, data collection will begin in
18 January of 2013.

19 And finally, they are included in the 15
20 clinical quality measures for Meaningful Use.
21 That is a fiscal initiative also from the
22 government.

1 Was there a question?

2 Okay, and that concludes. Thank you
3 very much.

4 MS. JOHNSON: And now, if the folks from
5 the American Heart Association/American Stroke
6 Association would like to speak?

7 DR. SCHWAMM: Hi. I am Dr. Schwamm.
8 You just heard my illustrious introduction
9 from Karen. I am also here representing the
10 American Heart Association.

11 I am here with my colleague, Mark
12 Stewart, who is a staff member at AHA.
13 Penelope Solis, also a staff member, is on the
14 telephone. And Greg Fonarow, who is a
15 cardiologist at UCLA and also a developer of
16 measures within the American Heart Association
17 in his capacity as a volunteer, may join by
18 the telephone.

19 There are two measures before you from
20 the American Heart Association. The first is
21 timeliness of thrombolytic therapy. So, this
22 is a measure that looks at the percentage of

1 patients among those receiving thrombolytic
2 therapy who do so within 60 minutes, which is
3 the recommendations from the NIH and the
4 American Heart Association and all major
5 guideline-issuing entities, and is supported
6 by Level 1 evidence.

7 The measure has been in place since 2003
8 within Get With The Guidelines, which now has
9 1600 hospitals collecting data on this
10 measure, and over 74,000 patients have been
11 treated in the context of Get With The
12 Guidelines and had this measure assessed.

13 And the measure also reports a median
14 time to treatment. So, it supports the use of
15 feedback to hospitals for improvement and
16 helps identify hospitals that are near the
17 boundary of that measure, but don't
18 necessarily meet the 60-minute mark.

19 There is very strong data to support,
20 both in meta-analyses and in our own work,
21 that earlier treatment leads to better
22 outcomes and reduced mortality. So, a strong

1 process/outcome link.

2 The second measure is the percentage of
3 patients who receive an NIH stroke scale to
4 assess their stroke severity on arrival. That
5 measure has been assessed in over 800,000
6 patients, recorded in over 800,000, assessed
7 in over 1.5 million patients.

8 It is a very important measure to
9 identify the assessment of stroke severity at
10 onset. It has strong linkages to both the use
11 of thrombolytic therapy as well as access to
12 comprehensive stroke center resources, and is
13 strongly predictive of outcome, particularly
14 in-hospital mortality.

15 I am happy to take any questions.
16 Otherwise, thank you.

17 MS. JOHNSON: Okay. Thank you very
18 much.

19 We will now begin our day with Measure
20 0437. This is the Stroke 04 measure from The
21 Joint Commission, Thrombolytic Therapy.

22 We tried to set up this summary document

1 in the order in which we will go today. So,
2 you should see that beginning on page 3.

3 And I am now turning it over to the Co-
4 Chairs.

5 CO-CHAIR KNOWLTON: Just a reminder that
6 we talked about earlier. As we call on you,
7 just click on your microphone, please. Go
8 through the Chair. Keeping this orderly, we
9 will see that we get through it.

10 We are going to present each of the
11 measures. We are going to ask the person who
12 presented it in your Working Group to present
13 it here.

14 But we are going to target the
15 discussion, if you would, please, to the
16 issues that we will be voting on. So, we will
17 start with impact and we will work through the
18 list. You will see it on the slides where it
19 says "voting slides" in front of you. that
20 will help us keep this organized.

21 So, for our first measure, which is
22 Measure 0437, Thrombolytic Therapy, Greg, if

1 you would start off with that, please?

2 MEMBER KAPINOS: This measure was
3 proposed by The Joint Commission for
4 maintenance. We just heard the description,
5 but, again, it is measuring, out of all the
6 patients that present with an acute ischemic
7 stroke within two hours from their last-known
8 well to the ER, how many will, indeed, receive
9 t-PA within the three hours. So, it gives us
10 an hour in the ER to give t-PA.

11 So, the numerator, as we said, is the
12 patients who receive t-PA within two hours,
13 and the denominator is the ones that were
14 eligible for this, which is within two hours
15 of their stroke onset they reach the ER.

16 I think in terms of importance, the
17 group did not have any more questions after
18 the meeting over the phone. So, the impact
19 was unanimously ranked as high for 1a.

20 1b, there were no questions --

21 CO-CHAIR KNOWLTON: Greg, stop at the
22 impact. You discuss where you got an impact,

1 and then ask if there are any questions.

2 MEMBER KAPINOS: Okay.

3 CO-CHAIR KNOWLTON: And then, we will
4 vote on it.

5 MEMBER KAPINOS: So, for 1a, impact,
6 anybody?

7 CO-CHAIR TIRSCHWELL: You shared what
8 the committee did, but this will be awkward
9 until we get used to it. But this is the most
10 efficient way; trust me.

11 So, does anybody have any questions on
12 the impact that they would like to put to Greg
13 or any other member of the project team that
14 worked on this?

15 (No response.)

16 No questions?

17 Then, you are ready for a vote. I don't
18 know how these clickers work, Karen.

19 MS. JOHNSON: We are going to have
20 Suzanne or Jessica give us a little tutorial
21 on how to use our clickers.

22 MS. THEBERGE: Okay. I am going to pull

1 up the vote and just click. For your rating,
2 1 is high, 2 is moderate, 3 is low, and 4 is
3 insufficient evidence. So, just click and, as
4 people vote, it starts to show up in that
5 little box.

6 (Vote taken.)

7 We have got four responses, eight, et
8 cetera. Seventeen. We are doing good.

9 MS. JOHNSON: And just a reminder, up on
10 the screen are the two things that you would
11 be thinking about under impact.

12 MS. THEBERGE: Twenty, and we need one
13 -- oh, 22. Okay, and we are done.

14 MS. JOHNSON: Do the colors mean
15 anything on the clicker?

16 MS. THEBERGE: No, the colors don't mean
17 anything.

18 So, this has passed with 20 votes for
19 high and 2 votes for moderate on importance.

20 CO-CHAIR TIRSCHWELL: In terms of
21 impact.

22 MS. THEBERGE: Sorry. Impact.

1 CO-CHAIR TIRSCHWELL: Okay. Greg, go on
2 to your next piece.

3 You see, the reason we do this way is,
4 if we don't -- this is a must-pass -- if we
5 did do the impact and it didn't pass, we would
6 stop discussion and move on to the next
7 measure. So, that is why we are doing it in
8 order.

9 Go ahead, Greg.

10 MEMBER KAPINOS: So, for 1b, the
11 performance gap, there was --

12 CO-CHAIR TIRSCHWELL: Actually, Greg,
13 sorry to interrupt. We want you to do the
14 evidence second and then we will go to 1b.
15 So, 1c first.

16 CO-CHAIR KNOWLTON: Yes, they are in the
17 wrong order on the slide.

18 MEMBER KAPINOS: Okay. For the
19 evidence, five of us ranked it as high; two of
20 us ranked it as medium. There were no major
21 issues that were brought up during the
22 meeting.

1 CO-CHAIR TIRSCHWELL: Any questions for
2 Greg?

3 (No response.)

4 Okay. We are ready to vote.

5 MS. THEBERGE: And Jessica has just
6 reminded me to tell you all that you can click
7 more than once, and it helps to point your
8 clickers towards me because the voting
9 reception thing is over here. But it will
10 only count your vote once.

11 (Vote taken.)

12 So, we are still waiting for several
13 votes. All right, one more. All right. We
14 are waiting for one more. It seems like
15 somebody's click didn't come through.

16 CO-CHAIR KNOWLTON: Just vote again. It
17 won't count you twice.

18 Is there anybody that didn't vote?

19 One more time.

20 MS. THEBERGE: Well, we had 22 votes
21 last time.

22 CO-CHAIR TIRSCHWELL: There's 22 votes.

1 I counted them.

2 MS. THEBERGE: All right. So, the vote
3 count is 18 yes and 3 no.

4 MEMBER KAPINOS: So, what happens when
5 there are noes? It is just the majority wins?
6 So, even if it is like borderline, like 16-15,
7 you are going to make it pass?

8 CO-CHAIR TIRSCHWELL: I guess we had
9 hoped there would be discussion if it was
10 ambiguous like that.

11 I am curious why people voted no, but I
12 don't think we have time to necessarily delve
13 into it.

14 CO-CHAIR KNOWLTON: But I think what we
15 want to do is just it is okay to say, "Look,
16 I've read what is in the project sheet, and I
17 understand people disagree with me," and move
18 on. But it is also, if you feel strongly, I
19 hope you will speak out.

20 Part of our job is to keep this moving,
21 keep it going, but it is also to make sure
22 everybody gets heard. So, it is very

1 important, if you think you have a persuasive
2 argument, you should make that argument, and
3 maybe somebody will agree with you.

4 Okay, Greg, let's move on to -- what are
5 we on?

6 MEMBER KAPINOS: Performance gap, lb?
7 Right? Performance gap, lb, we didn't do it.

8 So, there were a few questions that were
9 raised there because of actually -- no,
10 actually, it was something else. Yes, for
11 this measure, the performance gap is there.
12 Not a lot of hospitals are using t-PA, even
13 for eligible patients. So, the majority of us
14 voted that there is a performance gap. There
15 are no specific questions that were raised, I
16 think.

17 Ready to vote? Or do you have any
18 questions?

19 CO-CHAIR KNOWLTON: Questions or
20 comments?

21 (No response.)

22 Okay. Let's vote.

1 (Vote taken.)

2 MS. THEBERGE: All right. We are still
3 at 21.

4 MS. JOHNSON: If everyone could go ahead
5 and vote again?

6 MS. THEBERGE: Point at me, please.

7 All right. There we go.

8 CO-CHAIR KNOWLTON: Somebody has got a
9 sticky clicker.

10 MS. THEBERGE: So, we have 21 votes for
11 high and 1 for moderate.

12 CO-CHAIR KNOWLTON: Okay.

13 MEMBER KAPINOS: So, moving on to 2a?

14 CO-CHAIR TIRSCHWELL: Yes.

15 MEMBER KAPINOS: 2a, the reliability of
16 this measure, I don't recall any specific
17 issues there. Again, the majority of us voted
18 for high quality for item 2a.

19 CO-CHAIR KNOWLTON: Any questions on
20 this?

21 (No response.)

22 Okay. We can vote.

1 Hold on.

2 CO-CHAIR TIRSCHWELL: Can I just --

3 CO-CHAIR KNOWLTON: Sure.

4 CO-CHAIR TIRSCHWELL: There were a
5 couple of things that were brought up during
6 the Work Group discussion about the numerator
7 and the denominator. The developer explained
8 that the denominator -- and this is on the
9 back of the page in the summary document. I
10 guess there was a question about that two
11 hours and the three hours, and it is just
12 clarification that it gives the hospital at
13 least 60 minutes to make the determination and
14 begin treatment. I don't know that there are
15 any questions about that.

16 And there was another question about why
17 length of stay greater than 120 days was
18 excluded. And that is just an artifact of
19 billing cycles for CMS.

20 MEMBER J. BAUTISTA: I don't really
21 understand that. What does that mean?

22 CO-CHAIR TIRSCHWELL: Which part?

1 MEMBER J. BAUTISTA: That 120-day --

2 CO-CHAIR TIRSCHWELL: The billing cycle?

3 MEMBER J. BAUTISTA: Yes.

4 CO-CHAIR TIRSCHWELL: I think it has to
5 do with quarterly reports and billings. And
6 so, if your stay extends over more than 120
7 days, and they do the previous 120 days, you
8 can sort of be out of phase with the whole
9 thing.

10 If I had a chalkboard, I could probably
11 explain it better than that. But my guess is
12 that it is just a really minor issue in
13 general, and I wouldn't worry about it too
14 much. I believe them, that it doesn't work
15 very well with their computers.

16 CO-CHAIR KNOWLTON: That question has
17 been asked a couple of times. Can I ask the
18 developer to just clarify that?

19 MS. KOLBUSZ: The issue with regard to
20 the 120?

21 CO-CHAIR KNOWLTON: Yes.

22 MS. KOLBUSZ: This is a set of measures,

1 one of many sets of measures that The Joint
2 Commission has that we share with CMS. It is
3 just a standard exclusion for all of those
4 measures, that patients who are in the
5 hospital for longer than 120 days are excluded
6 because of the CMS billing cycle. Medicare
7 requires patients to be billed every quarter.
8 And the problem is, if they stay over 120 days
9 and then are discharged in the next quarter,
10 that history from the previous 120 days gets
11 lost. So, anybody over 120 days is excluded
12 from the measure. In real-life for this
13 measure, well, as you saw in the submission
14 materials, it is negligible.

15 CO-CHAIR KNOWLTON: Okay. Thank you.

16 Did that answer your question, Jocelyn?

17 Anything else?

18 (No response.)

19 Okay. Are we ready to vote on this?

20 We are voting first on reliability.

21 There we go.

22 (Vote taken.)

1 MS. THEBERGE: We are at 19. So, we
2 need three more votes. One more vote.

3 All right. There we go.

4 CO-CHAIR KNOWLTON: Vote early, vote
5 often.

6 MS. THEBERGE: We have 15 at high, 6 at
7 moderate, and 1 at low.

8 MS. JOHNSON: Can I just jump in here
9 real quickly?

10 Can you put up slide 16? Just to remind
11 you on how you rate reliability and validity,
12 you should be thinking about levels of testing
13 that were done. So, when you think about
14 rating for reliability, for example, you are
15 not looking only at the results of the
16 reliability test, but you are looking at
17 whether or not things were done at both the
18 data element level and the measure score level
19 or only one or the other.

20 So, for example, a high rating for
21 reliability, you would expect to see precise
22 specifications as well as testing and

1 demonstration of adequate results at both the
2 data element level and the measure score level
3 in order to give the measure a high rating.
4 Moderate would be precise specifications, but
5 only seeing testing at one or the other
6 levels.

7 So, I just want to make sure everybody
8 was clear about how the ratings for
9 reliability and validity work. Validity is
10 similar. So, again, the high and moderate
11 ratings depend -- you have to be convinced
12 that the results are adequate, but, also, it
13 depends on how much testing has been done.

14 MEMBER KAPINOS: Maybe the people who
15 voted moderate are thinking -- there was issue
16 that was brought up during the call conference
17 about comparing this measure to another one
18 that had exactly the AHA guidelines inclusion
19 and exclusion criteria for t-PA versus this
20 measure, Stroke 04, by The Joint Commission is
21 actually just including in the exclusion
22 criteria a documented reason for not

1 initiating IV thrombolytic.

2 So, I don't know what is the rationale
3 for the people who are voting moderate, but
4 from that conference call I recall that people
5 were comparing to the other measure, and maybe
6 this one is actually simpler because we are
7 just saying, as soon as you document why you
8 are not giving t-PA, you are going to be
9 excluded. Therefore, you are not going to be
10 dinged by this measure.

11 So, just to open that to the discussion.
12 If people who voted moderate are thinking
13 about the fact that the exclusion criteria for
14 t-PA are not thorough enough, there is
15 actually another measure that does include all
16 those exclusion criteria and to t-PA.

17 MS. JOHNSON: And just to clarify, and
18 you may be right, but what you want to do is
19 be voting on this measure, and this measure
20 only. So, for now in this process, forget
21 that there are other measures that are similar
22 because we will be handling that a little bit

1 later in the day. That will be our
2 related/competing.

3 So, yes, you would definitely only be
4 thinking about this one, not how this one
5 maybe stacks up to another one.

6 MEMBER COONEY: Since we are taking a
7 little more care with this one, could we maybe
8 look at this one specifically with that in
9 mind, just to show us in the text of this
10 where -- I mean, I see where the data elements
11 are. I am not sure whether I see where the
12 reliability of the measure score is in this
13 one. That is just so that I can find it more
14 quickly in others.

15 CO-CHAIR KNOWLTON: Yes, I think, Karen,
16 can you walk them through that? Because I
17 think you are right; I see --

18 MEMBER COONEY: I mean, you are making
19 a point that it is important, and I am not
20 sure I --

21 CO-CHAIR KNOWLTON: Yes, people aren't
22 following it. I see Gwen nodding. So, let's

1 walk them through it.

2 MS. JOHNSON: And Suzanne is bringing up
3 that measure right now.

4 I am sorry. I had to pull out my paper
5 copy because I can't see that from here, even
6 with glasses on.

7 Okay. So, for the reliability testing,
8 if you have the measure submission in front of
9 you, it should be somewhere around page 15, it
10 looks like on that screen.

11 What they tell you, under 2a2.2, their
12 analytic method, they tell you that they
13 looked at 900 patient records from 30
14 different sites and, basically, did a re-
15 abstraction. So, they compared data. So,
16 they have the abstraction that was made for
17 the measure, and then The Joint Commission
18 abstractor also did it, and then they compared
19 the results.

20 So, under Section 2a2.3, which is page
21 -- is it 16? -- page 23, sorry, these are the
22 results of their testing between the

1 abstractors. We do know that this isn't
2 necessarily pretty, and this is not The Joint
3 Commission's fault. This is because we can't
4 accept pretty tables. So, they go in as just
5 plain, unformatted text.

6 But what they have done here is they
7 have given you several data elements, and what
8 they are showing you is the numerator. So,
9 how many records were looked at? And how many
10 met the measure? So, if you go across there,
11 clinical trial, it looks like they looked at
12 the total "N", 712. So, what they are saying
13 here is 712, of the 714 records that they
14 looked at, 712 agreed on whether or not the
15 patient was included in a clinical trial. And
16 for this measure, clinical trial was one of
17 the exclusions.

18 So, what they are showing you over to
19 the right is the 99.7 percent, that is the
20 percent agreement. So, 712 out of 714 is the
21 99 percent.

22 So, when you are doing this kind of

1 comparing between what one person says and
2 what another person says, that is generally
3 thought of as inter-rater reliability. And,
4 of course, you want that to be high.

5 What they have shown you here is the
6 statistic that is the percentage agreement.
7 And that is a fine statistic. It is probably
8 not the greatest statistic for showing you
9 because, if you take two people off the street
10 and ask them a question, often they will
11 agree, even though they might not know
12 anything of what they are talking about.

13 So, there is another statistic that they
14 could have shown you called the kappa
15 statistic, but they chose not to do that, and
16 that is fine. But the kappa statistic often
17 will be informative as well because that gets
18 rid of that -- it takes into account chance
19 agreement that could happen.

20 So, what they have done is given you
21 many of the critical data elements. So, if
22 you recall from our tutorials, if they are

1 going to give you data element reliability,
2 they need to do it for the critical data
3 elements. So, there are several elements that
4 are critical for this measure. So, the things
5 that go in the numerator, the things that are
6 in the denominator, and the denominator
7 exclusions.

8 So, as you work your way through those
9 percentage agreements there, you would look at
10 those and just ask yourself, you know, am I
11 pretty convinced that this is reliable, based
12 on this data? And you would just look at that
13 and decide if you think those percentages
14 there are good.

15 So, what you are doing is you are
16 thinking about their methodology, which is the
17 two abstractors. You are thinking about their
18 method and their sample size. They told you
19 it was roughly 900 records total over 30
20 sites. So, does that seem reasonable to you?

21 And then, you are looking at the
22 results, the percentage agreements. Any

1 difficulties with that? Anything kind of
2 raise a flag to you that you would think that
3 there might not be some reliability there?

4 So, that is how you would check and
5 think about reliability or at least the
6 reliability testing. So, does that make
7 sense?

8 MEMBER COONEY: Well, that, to me, looks
9 like we are looking at data elements, but you
10 said, also, that it had to look at measure
11 score in order to be high?

12 MS. JOHNSON: To be high, yes.

13 MEMBER COONEY: So, does this look at
14 measure score anywhere?

15 MS. JOHNSON: This does not look at
16 reliability for the measure score. So, right
17 here, what you are seeing is data element
18 reliability.

19 What they did here as well with their
20 validity, they can use these same results as
21 their validity testing at the data element
22 level as well. The reason they can do that is

1 because their second abstractor from The Joint
2 Commission they consider the authoritative
3 source.

4 So, if you agree that The Joint
5 Commission abstractor could serve as an
6 authoritative source, then we would also
7 accept this result here as data element
8 validity. So, you can check that box off,
9 again, if you like those percentages.

10 And then, we would go further in the
11 submission to see, would they also have done
12 measure score validity or not?

13 So, is that starting to -- everybody is
14 getting that?

15 MEMBER COONEY: So, sometime when they
16 show measure score validity, will you point it
17 out to us?

18 MS. JOHNSON: Yes.

19 CO-CHAIR KNOWLTON: Jocelyn?

20 MEMBER J. BAUTISTA: Would there be a
21 reason why the sample size for the data
22 element "time last-known well" would be so

1 much smaller than, for instance, clinical
2 trial? Would there be some valid reason why
3 that would be?

4 CO-CHAIR TIRSCHWELL: Well, yes. So, I
5 asked this, I think, during our Work Group
6 call. I think it has to do with the number of
7 people who would qualify. So, these aren't
8 patients that just got IV t-PA. It is a whole
9 bunch of people that didn't, for reasons. And
10 so, who gets the different elements is
11 dependent on that, I think.

12 You know, and I would just add that --
13 and I think this is true to clinical practice
14 -- the time last-known well, there was only 80
15 percent agreement. And I think we, all of
16 clinicians, can quote you cases where it gets
17 pretty murky exactly when the last time known
18 well was. And a couple of the lower agreement
19 rates were why I rated it moderate, as a
20 comment.

21 CO-CHAIR KNOWLTON: So, on that same
22 point, what I am not understanding about this

1 -- and this is true in some other things --
2 the different numbers that are being given for
3 the different data elements, I made the
4 assumption that the smaller numbers were
5 subsets of the larger number. Because there
6 is a large group of patients, and then, within
7 that, there is a smaller subset that meets
8 whatever that criteria is.

9 What I don't understand is, why, then,
10 is the larger number relevant? Let's say here
11 you have got, whatever it is, 198 patients or
12 something that meet the criteria of time from
13 last-known well, when that is essential to
14 this particular measure, right, because there
15 is, clearly, a lot of discussion about that
16 point in your group, or whatever, if that is
17 essential to it, then why is the broader
18 number that doesn't include that relevant?
19 That is what I don't understand.

20 Like, why are we seeing numbers that say
21 the overall agreement rate is 98 percent, and
22 we are seeing 99.7 percent in sort of clinical

1 trials of like whatever the overall number is.
2 But the most relevant numbers, the ones that
3 relate specifically to this measure, are lower
4 numbers. Why are we even being given those
5 broader numbers?

6 CO-CHAIR TIRSCHWELL: Let me see if I am
7 getting this right. On the top line there,
8 they say 98.1 percent. I am guessing that
9 maybe is just an average of this entire set of
10 columns.

11 CO-CHAIR KNOWLTON: Right, but I am
12 trying to understand what the relevance is of
13 all the different parts of this column.

14 CO-CHAIR TIRSCHWELL: Right.

15 CO-CHAIR KNOWLTON: Because it seems to
16 me -- and maybe I am misunderstanding this,
17 and maybe they can clarify it for us -- but it
18 seems to me that, if there are these subsets
19 -- because this relates to how we understand
20 all of the other measures going forward.

21 CO-CHAIR TIRSCHWELL: Sure.

22 CO-CHAIR KNOWLTON: That is why I think

1 it is worth understanding now.

2 CO-CHAIR TIRSCHWELL: Well, yes, and
3 specifically, The Joint Commission measures
4 because they all present the data like this.

5 CO-CHAIR KNOWLTON: They use a lot of
6 this type of thing.

7 CO-CHAIR TIRSCHWELL: So, could we ask
8 the developers to comment, please?

9 DR. SCHWAMM: So, I think maybe this
10 will help. All of the elements that are
11 listed there are part of the measure
12 construct. Because, for example, if you are
13 in a clinical trial, that is an exclusion to
14 the measure.

15 So, I think the appropriate way to
16 report the reliability is to review every
17 element that must be abstracted responsibly
18 and reliably in order for the construct to be
19 valid.

20 So, you are correct, I think, in
21 identifying that there is better agreement
22 around whether someone was in a clinical trial

1 than the precise documentation of the time
2 last seen well. But if you didn't present
3 that number at all, and people were not
4 reliably abstracting the presence of a
5 clinical trial, the measure construct could be
6 invalid and you would never know it.

7 So, you are focused on the
8 numerator/denominator statement around the
9 numerator. But if you think about the
10 denominator, you have to also accurately
11 abstract the exclusions from the denominator.
12 So, every element listed there is part of the
13 measure. And if you reviewed the measure
14 description in detail, you would see that each
15 one of those has a specified variable, and
16 that there are guidelines to the abstractors
17 for whether or not it counts as present or
18 absent.

19 Is that helpful?

20 MEMBER KAPLITT: I think that is very
21 helpful. I do think that it is a little bit
22 -- "misleading" is probably too strong a term

1 because I am not suggesting any overt intent,
2 but I think that the problem is the overall
3 statement at the top, which is a recurrent
4 theme in a lot of The Joint Commission
5 measures, about the overall reliability
6 rating, I think gives a false impression,
7 whether it is intended or not. And I assume
8 it is not.

9 But I understand your point. I mean, I
10 think maybe going forward, not that we are
11 going to change everything now, but it might
12 be more helpful in the future to sort of
13 categorize the different submeasures. Because
14 I understand your point, but they are not all
15 necessarily equal or equally-relevant. And
16 they are presented, when they are given as the
17 overall measure, as if they were all kind of
18 an average of one thing.

19 DR. SCHWAMM: Yes. And actually, as a
20 clinician, I totally agree with you, but
21 wearing kind of more of a measurement hat, I
22 think we place a lot of emphasis on what we

1 consider to be the critical data element. But
2 abstractors have to actually figure these
3 things out.

4 And let's say, for example, being on a
5 statin was an exclusion to the measure. Well,
6 if there is data that shows that the
7 abstractors don't accurately identify drugs
8 that are statins and fail to do that
9 accurately, then you need to know that.

10 So, I think it is reassuring --

11 MEMBER KAPLITT: No, I take your point,
12 clearly.

13 DR. SCHWAMM: Yes.

14 MEMBER KAPLITT: And I think most of us
15 get that at this point.

16 DR. SCHWAMM: Yes.

17 MEMBER KAPLITT: All I am saying is that
18 the flip side is also an issue, right?

19 DR. SCHWAMM: Yes.

20 MEMBER KAPLITT: So, yes, you are right.
21 It is like the way we are going through all
22 these different criteria, one, two, three,

1 right?

2 DR. SCHWAMM: Exactly.

3 MEMBER KAPLITT: You have got to pass
4 one, but --

5 DR. SCHWAMM: Exactly.

6 MEMBER KAPLITT: -- that doesn't
7 necessarily mean that that is sufficient. So,
8 being necessary is one thing, but being
9 sufficient is another thing. And I think that
10 that is where the confusion --

11 DR. SCHWAMM: Completely agree, and I
12 think that is why you get all the individual
13 variables listed there.

14 CO-CHAIR KNOWLTON: Let me ask the
15 question, since we have had deeper discussion
16 of this, do you want to re-vote this issue?

17 Okay. Can we do that, Suzanne?

18 This will be on 1b?

19 CO-CHAIR TIRSCHWELL: No.

20 CO-CHAIR KNOWLTON: What are we on?

21 CO-CHAIR TIRSCHWELL: 2a.

22 CO-CHAIR KNOWLTON: 2a.

1 She has got to open it. There you go.

2 MS. THEBERGE: Okay, it is open.

3 (Vote retaken.)

4 Nineteen. Twenty-one. We are still
5 waiting for one vote. Oh, there we go.

6 So, we have 4 high --

7 CO-CHAIR KNOWLTON: Teachable, or we are
8 all cowards.

9 (Laughter.)

10 MS. THEBERGE: Four high, 17 moderate,
11 1 low.

12 CO-CHAIR KNOWLTON: Okay, Greg, we go on
13 to validity.

14 MEMBER KAPINOS: Yes. For criteria of
15 validity, again, there were no major issues
16 and unanimously we voted that it was a valid
17 measure.

18 CO-CHAIR KNOWLTON: Any questions on
19 validity for Greg?

20 (No response.)

21 Okay. Let's vote on validity, 2b.

22 MS. THEBERGE: Sorry. There we go.

1 Oops. Sorry, we are having a little technical
2 glitch here.

3 CO-CHAIR KNOWLTON: There you go.

4 Yes, she has got to open it. Wait.

5 No, not yet.

6 MS. THEBERGE: There seems to be a
7 technical --

8 CO-CHAIR KNOWLTON: There you go.

9 MS. THEBERGE: All right. There we go.
10 Sorry about that.

11 (Vote taken.)

12 Eighteen. Nineteen. Twenty-one. All
13 right, we need one more. All right.

14 Thirteen high, 8 moderate, and 1 low.

15 CO-CHAIR KNOWLTON: Okay. Okay. We are
16 moving on to --

17 MEMBER KAPINOS: Usability.

18 CO-CHAIR KNOWLTON: I'm sorry?

19 MEMBER KAPINOS: Usability, item 3.

20 CO-CHAIR KNOWLTON: Okay.

21 MEMBER KAPINOS: The Work Group thought
22 that there was high evidence of the usability

1 of this measure. No specific question.

2 CO-CHAIR KNOWLTON: No specific
3 discussion?

4 Any specific discussion within the
5 group? Dave?

6 CO-CHAIR TIRSCHWELL: You know, it says
7 that it is used for public reporting. I guess
8 I don't know where this is publicly-reported.
9 Or is it just publicly-reported, not at the
10 hospital level? Can the developer comment on
11 that?

12 MS. KOLBUSZ: The public reporting
13 refers to CMS's use in the fiscal year 2015
14 payment determination. It was determined in
15 the IPPS final rule last year, in Quality
16 Check as well, and also in Quality Check. But
17 the data -- let me finish.

18 The data will be collected by CMS in 2013,
19 January 1st. Also, it is publicly-reported by
20 The Joint Commission and Quality Check. That
21 has been ongoing since it has been made a core
22 measure in 2009. So, it is publicly-reported

1 on The Joint Commission website and Quality
2 Check.

3 CO-CHAIR KNOWLTON: Go ahead. Risha?

4 MEMBER GIDWANI: Thank you.

5 Can the developers confirm that the CMS
6 Meaningful Use specifications are 100 percent
7 the same as their specifications?

8 MS. KOLBUSZ: Well, that is a very
9 interesting question. I can confirm that the
10 measures, the paper-based measures, are
11 exactly the same.

12 If you are asking me, is there an exact
13 one-to-one correspondence between the
14 e-measures derived from the paper-based
15 measures and the paper-based measures, the
16 answer to that is unknown. Those measures,
17 the Meaningful Use e-measures have not been
18 tested. But that is certainly the intent.

19 CO-CHAIR KNOWLTON: Risha, would you
20 comment on what is behind your question?
21 Where are you going?

22 MEMBER GIDWANI: Well, I just want to

1 make sure that, if organizations are
2 collecting these data for CMS Meaningful Use,
3 they can submit the exact same data to The
4 Joint Commission, and that it is not a
5 duplication of effort for the institution.

6 MS. KOLBUSZ: Could I comment on that,
7 please?

8 We, The Joint Commission, have developed
9 a policy whereby hospitals who wish to report
10 these measures for Meaningful Use can report
11 either the e-measures or the paper-based
12 measures. There is still a wide variation
13 across the country in terms of the adoption of
14 EHRs. Not all hospitals, in fact, the
15 majority of hospitals don't have the
16 capability yet of reporting on the e-measures.
17 So, we are accepting both. We are not
18 requiring both. I guess we are accepting
19 either and not requiring that they do both.

20 CO-CHAIR KNOWLTON: Any other questions
21 or comments on usability?

22 This is an important criteria,

1 especially as purchasers and consumers start
2 to look at this data. So, I want to be sure
3 everybody understands the criteria that is up
4 there, as you look at what is usability.

5 Do we vote on these separately, Suzanne?

6 MS. THEBERGE: No, usability by itself.

7 CO-CHAIR KNOWLTON: Usability by itself.

8 So, the two together?

9 MS. THEBERGE: Uh-hum.

10 CO-CHAIR TIRSCHWELL: A and B.

11 CO-CHAIR KNOWLTON: A and B?

12 MS. THEBERGE: Yes.

13 CO-CHAIR KNOWLTON: Any questions?

14 (No response.)

15 Okay. Yes, go ahead, Michael. I didn't
16 see you.

17 MEMBER KAPLITT: No, because I didn't do
18 it.

19 (Laughter.)

20 The one statement here, it says, since
21 2009 -- maybe the developer can answer this --
22 since 2009, it says, "Aggregate performance

1 has increased from 48 percent to nearly 72
2 percent."

3 Has the number of patients in the
4 whatever, the denominator, or the number of
5 patients being reported on been relatively-
6 flat or increased during that time? Or does
7 that percent reflect some sort of a shift in
8 who is being reported on? Do we know?

9 DR. SCHWAMM: Let me answer that wearing
10 both hats because almost all Joint Commission
11 hospitals use Get With The Guidelines to
12 report their data. I can tell you we looked
13 at this, and this is published in a paper with
14 Matt Reeves as the first author, looking at
15 whether increased improvement was due to
16 increased denominator exclusions or an actual
17 increase in the rate of treated patients. And
18 the denominator exclusions appear flat, and
19 the rate of actual treatment appears to be
20 increasing in a statistically-significant
21 manner.

22 So, I believe that in the very beginning

1 of the program, in the sort of early 2000s,
2 there was a shift with increasing denominator
3 exclusions, but that has actually been very
4 flat.

5 CO-CHAIR KNOWLTON: Any other questions?

6 (No response.)

7 So, we are looking at whether the
8 usability criteria is high, moderate, low, or
9 insufficient information. And we can vote.

10 Let's try it again.

11 MS. THEBERGE: Sorry about this.

12 (Vote taken.)

13 Nineteen. Twenty-one again. We are
14 still short one vote. Can everyone vote
15 again? All right. There we go.

16 Sixteen high, 4 moderate, 2 low.

17 CO-CHAIR KNOWLTON: Okay. Feasibility,
18 Greg.

19 MEMBER KAPINOS: Looking at feasibility,
20 we just addressed the concern about electronic
21 medical record versus paper record, but,
22 otherwise, there was an unanimous decision to

1 qualify the evidence as high for feasibility
2 for this measure.

3 CO-CHAIR KNOWLTON: Any questions?

4 (No response.)

5 I do think we discussed this. Go ahead.
6 We can vote on this.

7 CO-CHAIR TIRSCHWELL: So, it is not open
8 until you see that timer go on, I think, on
9 the bottom right there.

10 (Vote taken.)

11 MS. THEBERGE: All right. We are at 21.
12 All right.

13 It is 18 high, 3 moderate, and 1 low.

14 CO-CHAIR KNOWLTON: And then, finally,
15 the overall suitability for endorsement.

16 MS. THEBERGE: Do you want to vote now?

17 CO-CHAIR KNOWLTON: Anybody have any
18 comment on this before we vote on it, the
19 final criteria?

20 (No response.)

21 Okay. We can vote on it.

22 Wait for her to open it. That is what

1 is bouncing us out. There you go.

2 (Vote taken.)

3 MS. THEBERGE: All right. Twenty-two
4 yes, zero no.

5 CO-CHAIR KNOWLTON: Okay.

6 MEMBER KAPLITT: Sorry, I don't want to
7 be a stickler. Can I just ask one quick
8 process question? I am not trying to call
9 anybody out. But somebody repeatedly voted
10 low and then everybody said yes. I am just
11 wondering, is that like an error? Because, by
12 the criteria I heard, if there is a person who
13 felt each time that it was low -- well, I
14 guess that is possible, yes.

15 CO-CHAIR KNOWLTON: And medium is good
16 enough.

17 MEMBER KAPLITT: No, I know. I am not
18 questioning that. It is just that somebody
19 was repeatedly voting low. I assume it was
20 one person, but maybe it wasn't. I don't
21 know.

22 DR. BURSTIN: And just so you know, we

1 have actually attached your name to your
2 clicker. So, those are the kinds of things we
3 can do post-talk and see, in fact, there are
4 any strange lack of face validity there.

5 CO-CHAIR KNOWLTON: We will have a man
6 visit your home after you leave.

7 (Laughter.)

8 DR. BURSTIN: It is actually very
9 helpful.

10 CO-CHAIR KNOWLTON: We will just be
11 giving the names of the low voters to the
12 developers.

13 (Laughter.)

14 I am from New Jersey. We handle these
15 things very directly.

16 (Laughter.)

17 CO-CHAIR TIRSCHWELL: Okay. So --

18 CO-CHAIR KNOWLTON: Just one more
19 second, David.

20 Before we go on to the next one, we will
21 go very quickly, but like Michael's issue,
22 does anybody have any process issues as we

1 went through this?

2 (No response.)

3 This will move along. Debate will be
4 more intense as the day goes on, I promise
5 you. If you have been through this a few
6 times, you will see how this grows. But it is
7 a little bit mind-boggling as you start out.
8 So, you should expect a little confusion as
9 you start out.

10 Okay, David.

11 CO-CHAIR TIRSCHWELL: So, the next
12 measure is No. 0242, Tissue Plasminogen
13 Activator Considered, from the AMA-PCPI.

14 Bill, do you want to get us started?

15 MEMBER BARSAN: Great. Yes. Yes, just
16 briefly, there was a lot of discussion about
17 this at the Work Group.

18 So, the description is all patients with
19 ischemic stroke who arrive at a hospital
20 within 4.5 hours of last-known well who were
21 considered for t-PA administration. So,
22 consideration for t-PA administration is the

1 numerator. The denominator is all those
2 patients who arrive at the hospital within 4.5
3 hours or less known well.

4 Do you want me to summarize some of the
5 issues first or no? I'm sorry.

6 We will start with impact, fine. Okay.
7 Good.

8 So, impact, you know, it was pretty
9 unanimous that we felt that -- seven people
10 voted yes as far as the impact, and most of
11 those were high.

12 CO-CHAIR TIRSCHWELL: So, that is 1a.

13 Anybody, anything to discuss on 1a
14 before we go to the vote?

15 (No response.)

16 Okay.

17 MEMBER KAPINOS: The discussion that you
18 were about to go over was probably the reason
19 for maybe 1 percent voting a little bit lower
20 quality. So, we need to talk about the fact
21 that people were disturbed maybe by the fact
22 that measuring "considered" as opposed to

1 "given" is something that we need to measure.

2 MEMBER BARSAN: Well, yes, I think there
3 were a couple of issues. One was that whole
4 issue of what is "considering". Is
5 consideration, I mean is that a documentation
6 measure or is that really a process measure?
7 I mean, what is that?

8 MEMBER J. BAUTISTA: Well, it should be
9 specified. So, what does the measure specify?
10 They define "considered," don't they? So,
11 could you summarize for us how they define it?

12 MEMBER BARSAN: "Considered" means if
13 you didn't list a reason for excluding,
14 essentially.

15 CO-CHAIR TIRSCHWELL: You know, I think
16 it means you had a comment on it, basically.
17 If they came in, you had to say either why
18 they didn't get it or, if they got it,
19 obviously, you considered it.

20 MEMBER WADDY: So, can we find out why
21 the measure was developed that way instead of
22 actual?

1 CO-CHAIR TIRSCHWELL: So, the question
2 going to the developer, why consider it as
3 opposed to used?

4 DR. KATZAN: Hi. So, this was because
5 it goes out to the 4.5-hour window. So, IV
6 t-PA within three hours has been around for a
7 while. The 3-to-4.5-hour period is something
8 that is approved by the guidelines, is
9 recommended by the guidelines, but it is not
10 FDA-approved. And there are more exclusions
11 for this measure.

12 So, the thought was that we wanted to
13 make sure that people consider the use of IV
14 t-PA out to the 4.5-hour window, this 3-to-
15 4.5-hour window period. But we realize that
16 there might be some additional factors to
17 consider when making this decision out to that
18 4.5-hour period.

19 So that, this is a combined measure.
20 This should be paired. The intent was to pair
21 it with the measure that actually talks about
22 actual administration of IV t-PA out to three

1 hours, but that we want there to be some
2 quality measurements that go out to the 4.5-
3 hour period.

4 MEMBER BARSAN: David, there is a little
5 confusion on my part because I am not sure
6 where some of these concerns that I have fit
7 in terms of specifically saying this is
8 impact, this is evidence, this is whatever.

9 So, a couple of things. One is IV t-PA
10 is not FDA-approved for administration out to
11 4.5 hours. I think there's a lot of different
12 ways this has been picked up at different
13 places. Some places do it routinely; some
14 places don't. Certainly, the criteria are
15 different. That is one.

16 Two, I think the whole issue of whether
17 or not this is just -- you know, does this
18 really reflect a process or does this just
19 reflect documentation? In other words, is
20 there really any evidence that, if somebody
21 checks off a list and they are saying, "Oh,
22 yeah, I considered it and it is not good,"

1 does that really improve the process? And I
2 don't know that there is any data for that.

3 And I guess the third thing is that this
4 takes patients who arrive at the hospital
5 within 4.5 hours of last-known well. They are
6 never going to be a candidate at 4.5 hours or
7 4 hours or probably anywhere beyond 3.5 hours.
8 So, it seems kind of silly to throw in however
9 many patients may be in that indicator that
10 will never fit the criteria and just
11 automatically X'ed off because they get there
12 too late.

13 I don't know where to put those, but
14 those are, I think, the three concerns at the
15 Work Group that were brought up most
16 prominently.

17 CO-CHAIR TIRSCHWELL: Yes. Thank you.

18 And I agree, it is sometimes a little
19 ambiguous, and maybe they overlap the
20 categories.

21 I am being informed that on the back
22 side where it says, "Work Group Call Summary,"

1 the NQF staff has kind of put the things that
2 were brought up on the calls into their
3 appropriate categories. This one, the 3-to-
4 4.5-hour time window has been into the
5 scientific acceptability, which, Karen, you
6 are saying is Category 2, validity or
7 reliability?

8 MS. JOHNSON: It actually can come up on
9 both.

10 CO-CHAIR TIRSCHWELL: Okay.

11 MS. JOHNSON: It could be under
12 reliability because it would reflect the
13 specifications themselves. But it could also
14 come up under validity because it is the
15 marriage, if you will, between specifications
16 and the evidence. So, it kind of hits both of
17 those criteria.

18 CO-CHAIR TIRSCHWELL: Well, you know,
19 impact probably is simpler than all of that.
20 Is this addressing a health concern, the use
21 of t-PA, that potentially has impact? I guess
22 you could, again, undermine it a little bit by

1 saying, "Oh, what about that 3-to-4.5-hour
2 time window?"

3 MEMBER BARSAN: Well, that was my
4 confusion because impact, you know, anything
5 that could lead to an increased use of t-PA is
6 a huge impact. I mean, there is great
7 evidence that that is a good thing. It is
8 just I am not sure whether this one does it,
9 and I am not sure where the issues fit in.

10 CO-CHAIR TIRSCHWELL: And if I could
11 just ask for one more clarification, Dr.
12 Katzan, I guess you suggested by your comments
13 that it was specifically designed this way to
14 focus on the 3-to-4.5-hour time window.

15 And then, before you answer, there was
16 a question that went around that is a little
17 more general about FDA approval and the
18 ability to endorse measures that include
19 aspects that are not FDA-approved. And we got
20 a little bit of information back. Can
21 somebody clarify that?

22 MS. JOHNSON: Helen, I think that would

1 be yours.

2 DR. BURSTIN: So, in general, we
3 obviously have tried to have committees stay
4 within whatever is the evidence and whatever
5 the guidance is. And certainly, FDA offers
6 guidance in this respect.

7 The way we drafted it in our Evidence
8 Task Force Report was really more about the
9 indications. I don't think we got to this
10 level of specificity about time window, for
11 example. So, I think this is really where the
12 expert opinion of the Committee and the
13 guidelines really come into play.

14 And I do think that the issue of whether
15 "considered" is important can fit many places,
16 but I actually do see it somewhat under impact
17 as well, because you are talking about the
18 impact of this particular measure, not just
19 t-PA and stroke care. This is specific to
20 this measure. So, I think the "considered"
21 issue is fair game here. I think the time
22 window is also fair game under evidence.

1 CO-CHAIR TIRSCHWELL: Yes.

2 Dr. Katzan, do you have anything to add?

3 MS. JOSEPH: So, before Dr. Katzan
4 responds, I just wanted to clarify a couple of
5 things. Really quickly, the FDA time window
6 is approved for three hours for t-PA
7 administration. And the measure that you are
8 reviewing now, Measure 0242, is the
9 consideration. It is not the administration
10 of t-PA. The administration of t-PA is
11 actually covered in the next measure, which is
12 Measure 2022. That is within the time window
13 of three hours for administering the t-PA.

14 So, the window for 3 to 4.5 hours is
15 included in the t-PA considered measure
16 because we are aware that there are existing
17 hospitals that do administer t-PA up to 4.5
18 hours, and our measures do not encourage or
19 capture anyone that does administer t-PA up to
20 the 4.5-hour time window. The measures only
21 capture the consideration of t-PA up to the
22 4.5-hour time window. And the measure pair,

1 the Measure 2022, actually covers patients
2 that receive t-PA up to three hours. So, I
3 just wanted to make that clarification.

4 DR. KATZAN: Yes, so we wanted to
5 measure -- that actually goes out to the 4.5-
6 hour window. So, that we didn't want to stop
7 at three hours. I don't know whether focusing
8 within that time window was the purpose of
9 this measure, but we wanted to make sure to
10 include the out-to-4.5-hour time window.

11 MEMBER R. BAUTISTA: Hello.

12 Yes, the AMA actually is a quality
13 measure. Just to be considered for t-PA by
14 itself really means not very much unless you
15 have a reason for that.

16 So, in many ways, you can think that it
17 might be a copout for some centers who don't
18 give t-PA and say, "Because you were four
19 hours and 15 minutes late," you know,
20 something like that. So, in other words,
21 consideration without reason I think is a
22 less-than-perfect measure.

1 CO-CHAIR TIRSCHWELL: Right. So, I
2 think that is the point. Again, this is just
3 a documentation issue. And is this really
4 going to drive care? If a hospital has made
5 a decision not to give t-PA in that timeframe,
6 do they really need to write it on every chart
7 to fulfill this performance measure? So, I
8 think that is where some of the doubts are
9 creeping into this assessment.

10 Does anybody else have any other
11 comments on impact? I think we should go
12 ahead and vote, otherwise.

13 Bill, do you have one last one?

14 MEMBER BARSAN: The only last comment on
15 impact is that, if you look at the impact of
16 treating a patient within an hour and a half
17 compared to three hours compared to four and
18 a half hours, a huge impact in an hour and a
19 half; a big impact, three hours. If you get
20 out between 3 and 4.5 hours, statistically-
21 significant, but much, much less. So, I mean,
22 just less of an impact than just in terms of

1 the number of patients effective.

2 CO-CHAIR TIRSCHWELL: Jolynn?

3 MEMBER SUKO: This gets to the
4 documentation issue. I guess, is there any
5 evidence that creating checklists enables t-PA
6 to be -- having those forcing functions in
7 your systems or those kinds of things, does
8 that actually drive care? And do we have any
9 evidence anywhere? And has the measure
10 developer considered do we have any data
11 around that?

12 MS. JOSEPH: So, actually, the
13 literature that we have included focuses on
14 the lack of patients receiving t-PA. The
15 performance gap based on the inclusion of the
16 measure in the Physician Quality Reporting
17 System, PQRS, shows that there is a gap in
18 care of 78.8 percent, and the medical
19 literature also indicates that, while t-PA use
20 increases stroke recovery by up to 50 percent
21 with a low serious complication rate, only 3
22 to 8.5 percent of potentially-eligible

1 patients receive the t-PA. So, that is the
2 purpose of encouraging the actual
3 consideration.

4 CO-CHAIR TIRSCHWELL: So, I think the
5 answer to your question is, no, there is no
6 literature supporting it.

7 Okay. I suggest that we go ahead and
8 vote on impact. It has to be high or moderate
9 to move forward.

10 (Vote taken.)

11 MS. THEBERGE: We are at 21. All right.
12 Two high, 8 moderate, 10 low, 2
13 insufficient evidence.

14 CO-CHAIR TIRSCHWELL: Hung jury.

15 So, 12 did not reach a moderate or high
16 level; 10 did. So, at this point, further
17 consideration of this measure will not be
18 performed.

19 Okay. So, I think at this point we are
20 thinking maybe we would take our break. Or do
21 you want to push on to do one more? What do
22 you think?

1 All right. That one went pretty fast,
2 shockingly.

3 (Laughter.)

4 So, let's make Dr. Barsan do another
5 one, 2022, t-PA initiated. This was the
6 paired measure, again from the AMA-PCPI.

7 MEMBER BARSAN: Okay. Great.

8 So, this is 2022. And the numerator for
9 this is patients for whom t-PA was initiated
10 within three hours of last-known well, and the
11 denominator, diagnosis of ischemic stroke who
12 present within two hours of time last-known
13 well who are eligible for t-PA.

14 It is a little bit -- I don't know if
15 you want to compare it with the other one --
16 but that little phrase about who are eligible
17 for t-PA makes it a little bit different than
18 the previous one we discussed because there
19 were exclusions for that in there.

20 Let me just go on down.

21 So, in terms of the impact, it was not
22 unanimous in the group as far as the impact,

1 but, mostly, six voted high, one medium.

2 CO-CHAIR TIRSCHWELL: Any further
3 discussion about impact for this one? And
4 note that this one is confined to the 3-hour
5 time window.

6 CO-CHAIR KNOWLTON: I have a question.
7 Are these the only contraindications that are
8 listed that would be considered? The
9 exclusions, it says that "contraindication
10 conditions that might lead to," et cetera, et
11 cetera. They are spelled out in this measure.
12 Is that because those are the only ones that
13 they consider for this measure?

14 MEMBER BARSAN: So, we had a lot of
15 discussion about that, because some of these
16 are actual exclusions and some of those, if
17 you look at the FDA labeling, it is taken
18 right from the FDA labeling. Some of those
19 things like advanced age, severity of stroke,
20 and whatever, are things where one should give
21 more consideration. In other words, there may
22 be reasons not to treat, although there is

1 really, frankly, nothing in the NINDS t-PA
2 which suggests you shouldn't treat somebody
3 who is at an elderly age with a bad stroke.
4 But it was in the FDA warning.

5 And so, you know, supposedly, the other
6 category, or the other measure, although these
7 things weren't explicitly listed, supposedly
8 they actually are part of that measure. And
9 documentation of those items could be listed
10 as an exclusion, is what I was told, what we
11 were told.

12 But these are just listed more
13 explicitly. I guess I have an issue with that
14 because I am not sure there is evidence that
15 one shouldn't be treating patients that fit
16 some of these criteria.

17 CO-CHAIR TIRSCHWELL: Right. I think
18 these are suggested as valid reasons why you
19 might not give it. I don't think that, if you
20 gave it, it would necessarily be counted
21 against you if you don't believe in them
22 specifically.

1 They do comment that it was harmonized
2 with The Joint Commission measure
3 specifically, although if you look at The
4 Joint Commission measure that we just looked
5 at, it doesn't look exactly the same. They
6 just say that you have listed a
7 contraindication, which is simpler to think
8 about for sure. So, there are definitely some
9 differences there.

10 Any other comments about --

11 CO-CHAIR KNOWLTON: Just a further
12 comment on that. Some of the things just
13 struck me in the exclusions as, if this became
14 a checklist for providers, some of these are
15 troubling. I don't know in terms of a quality
16 measure. They may be a rational measure from
17 a payer perspective, but from a quality
18 perspective, advanced stage and some of the
19 other issues I thought were a bit much.

20 But you are the doctor; I am not. So,
21 tell me what your clinical judgment is on some
22 of these.

1 MEMBER BARSAN: Right. Well, I am a
2 doctor, and I have a problem with it.

3 (Laughter.)

4 No, my big problem is that explicitly
5 listing them I think almost gives people a
6 rationale for not using it. "Oh, yeah,
7 somebody is old. I can't use it." Or "Gee,
8 they have got an NIHSS greater than 22. So,
9 I had better not use t-PA."

10 And that really bothers me because those
11 aren't legitimate reasons for not using it.

12 CO-CHAIR TIRSCHWELL: You know, I would
13 only add that, at least in my center and
14 almost every other center I have come across,
15 checklists do exist for inclusion and
16 exclusion criteria. And even though you might
17 not agree with any one particular one, and
18 there is always room for local clinical
19 judgment, it looks a lot like this.

20 I guess my assessment of whether this
21 particular list is going to have a huge,
22 specific impact at the patient level, I am

1 pretty dubious that it would.

2 And you know, these exact lists are in
3 the AHA/ASA guidelines. There is nothing, I
4 think, that is too terribly surprising or new.

5 MEMBER WADDY: The one that I found
6 really surprising was just the diabetic
7 retinopathy. I mean, you know, if a patient
8 comes in aphasic and they don't tell you they
9 have vision problems, I mean, in the throes of
10 a t-PA call, I don't think there are many
11 people that are doing detailed fundoscopic
12 exams for that.

13 MS. JOSEPH: Excuse me. Are we able to
14 respond regarding the exceptions?

15 CO-CHAIR TIRSCHWELL: Sure. The
16 developers want to respond briefly.

17 MS. JOSEPH: Thank you.

18 So, just for clarification, the list
19 that you are looking at in the denominator
20 exclusions box are actually denominator
21 exceptions. We distinguish between the two.
22 Denominator exclusions are actually absolutely

1 never to be included in the measure.

2 Denominator exceptions allow for clinical
3 judgment by the physician.

4 And these are actually listed only as
5 examples. We always include examples in the
6 parentheses there where it says, "e.g.,
7 contraindications and conditions that might
8 lead to increased risk of bleeding or
9 unfavorable outcomes". It is not meant to be
10 an exhaustive list by any means, but we did
11 include this list of contraindications and
12 warnings because during the Work Group
13 discussion they thought that this list was
14 really important, especially since The Joint
15 Commission measure is the measure that we have
16 harmonized with, and they have also included
17 this list which comes from the FDA label.

18 So, again, these are only meant to be a
19 list of examples for medical exceptions. They
20 are not exclusions from the measure.

21 CO-CHAIR TIRSCHWELL: Ramon?

22 MEMBER R. BAUTISTA: Yes. Would it make

1 more sense, then, to risk-stratify the measure
2 rather than actually having a long exclusion
3 criteria list? In other words, if you are
4 comparing quality across different healthcare
5 organizations, it would seem to make more
6 sense to risk-stratify the measure rather than
7 to say, you know -- because someplace, for
8 example, if you take innercity folks with a
9 higher rate of stroke-related drug problems,
10 where you might not give t-PA, for example,
11 then you are actually dinged for not doing
12 that, given a measure like this.

13 But if you actually risk-stratify and
14 say, okay, we are going to compare
15 organizations across the country, basically,
16 and the individual differences that they might
17 have.

18 CO-CHAIR TIRSCHWELL: Yes, go ahead.

19 DR. BURSTIN: Just a question for the
20 developer. This is actually specified as a
21 facility-level measure, which is a bit unusual
22 for the PCPI measures. And the exception

1 reporting, my understanding, is to allow the
2 clinician to indicate that they have a
3 particular exception that may not be captured
4 otherwise in the measure, that they should be
5 excepted from the measure.

6 That doesn't sort of work. I can't
7 understand how that works for a facility to
8 have that clinical judgment. Can you explain
9 that? It is a little confusing.

10 MS. JOSEPH: So, yes, I see how that
11 could be confusing. That is a good question.

12 I think the intent here was to include
13 the exceptions, also, because the physician
14 will still be evaluating the patient. I am
15 not sure who I am speaking to. The physician
16 will still be evaluating the patient. Any
17 reason that the physician chose not to give
18 the t-PA should still be documented. And so,
19 even though it is a facility-level measure, we
20 did opt to leave the medical exceptions in the
21 measure because it was important to capture
22 the reason for not administering the t-PA.

1 CO-CHAIR TIRSCHWELL: I think they just
2 end up averaging it over all the cases at the
3 facility and allow them to have a medical
4 reason why they don't give it. I mean,
5 theoretically, this should be identical to The
6 Joint Commission measure. I guess The Joint
7 Commission measure had the good fortune of not
8 listing their specific exclusions, although
9 they are theoretically the exact same thing.

10 So, I guess, again, I am not sure how
11 much we need to get hung up on the individual
12 details when physicians still have exception
13 and discretion to give this to who they think
14 are the appropriate patients.

15 And I don't think you would be dinged,
16 by the way, if you wrote "This patient has
17 drug abuse and I think for X, Y, or Z reasons
18 there is an increased risk of hemorrhage. So,
19 I am not giving it." That won't count against
20 you.

21 Go ahead.

22 MEMBER R. BAUTISTA: All I am saying is

1 being a quality measure where you actually
2 compare organizations across the board, people
3 aren't going to know that. They are going to
4 say that in Hospital X there is less t-PA
5 being given compared to Hospital Y. And that
6 is all they know. That is all the public
7 knows without the reasons, but they won't
8 understand anyway. That becomes a problem.

9 What I am saying is, if you have a
10 measure that actually risk-stratifies the risk
11 across different centers, you are able to at
12 least ameliorate that problem.

13 CO-CHAIR TIRSCHWELL: You know, I think
14 the number that would be presented publicly is
15 the percentage of eligible patients that get
16 it. And I don't know whether the numerator
17 and the denominator presented so that they
18 could figure out what percentage of their
19 total ischemic population is getting it. But
20 that is not the relevant number.

21 MEMBER BARSAN: That is part of my
22 problem, is the way it is defined. So, it is

1 the number of potentially-eligible patients.

2 That is the denominator, right?

3 I would be okay -- I mean, so how do you
4 determine the number of potentially-eligible
5 patients? That is the confusion. I mean, it
6 seems to me like one way to do it is if you
7 just said anybody who meets those exclusions
8 from the FDA warning label, the exclusions
9 only, that they are out. So, they are
10 ineligible. Everybody else is eligible. And
11 then, the only other ones, if for some reason
12 you decided not to treat and you documented
13 why, or whatever, that was okay.

14 But I don't know. It is just unclear to
15 me.

16 Irene, can you help me with that? Do
17 you see where my issue is? I am just not
18 quite sure I understand how do you determine
19 the patients for the denominator. I mean, how
20 is this different than just saying everybody
21 who presents within less than two hours?

22 DR. KATZAN: And I actually struggle

1 with the differences between The Joint
2 Commission measure and this measure, because
3 I think, operationally, I am in stroke
4 neurology. I see patients and I treat them
5 with IV t-PA. If they have an exclusion
6 according to the guidelines or the FDA, we put
7 them as an exclusion. They are excluded from
8 the denominator. We don't actually include
9 them in the measure.

10 And so, I think this is a lot of very
11 detailed specifics, but I think the purpose
12 and the rationale for including these measures
13 was to help the people who are actually
14 administering the t-PA, the people on the
15 ground floor, to understand that these are the
16 generally-accepted reasons for not
17 administering IV t-PA in patients who come
18 within this time window.

19 I think that, operationally, what we do,
20 as stroke neurologists, they come in; we
21 evaluate them. We actually have checklists;
22 most of us do. If they fall and they don't

1 actually have an exclusion, then we administer
2 t-PA, and if they do have an exclusion, we
3 make sure that we document why or what the
4 exclusion is.

5 And we use generally a list of things,
6 and this is actually just a list that has been
7 generally-accepted. It is on the FDA label.
8 It is in the guidelines.

9 So, I actually don't see some of the
10 issues because I think, operationally, this is
11 how we practice.

12 MS. JOSEPH: I would just add briefly,
13 to answer your question with regard to how to
14 identify the patients in the denominator, the
15 denominator statement is all patients age 18
16 years and older with a diagnosis of ischemic
17 stroke who present within two hours of time
18 last-known well and who are eligible for t-PA.

19 However, we also include in the
20 denominator details, a definition for
21 eligible. Patients are eligible for t-PA if
22 they have an acute neurologic deficit, a

1 clearly-defined time of onset of less than 180
2 minutes before treatment, and a baseline CT
3 showing no evidence of intracranial
4 hemorrhage.

5 CO-CHAIR TIRSCHWELL: And also,
6 implicitly, don't have an exclusion
7 criteria --

8 MS. JOSEPH: Exactly.

9 CO-CHAIR TIRSCHWELL: -- which is, of
10 course, coming back to what we are all
11 struggling with.

12 Salina?

13 MEMBER WADDY: So, I understand how you
14 would handle the contraindications. But if
15 you have this measure as-is, how would you
16 handle the warnings and conditions? Because
17 that could be as many as 20 percent, 30
18 percent of the patients.

19 CO-CHAIR TIRSCHWELL: I think I can
20 answer that. Basically, if the physician
21 documents almost any reason why they feel it
22 is not appropriate to give it, the patient is

1 put aside and not included in the measure.

2 This and I think The Joint Commission
3 measure are both aimed at identifying
4 patients. For example, at my center we
5 goofed, and we had a good reason why we didn't
6 give it, but we didn't document it. So, it
7 reminds us that we have to document it.

8 And more importantly, at medical centers
9 which don't have as much a commitment to
10 stroke care, where somebody comes in and could
11 have been a candidate, not only do they not
12 even think about giving it and not document
13 it, but, you know, those are the types of
14 patients that we want to be called attention
15 to, so that the appropriate patients are being
16 considered.

17 So, I think if you are documenting your
18 reasons, as I think any of the vascular
19 neurologists at this table involved in
20 National Quality Measures are probably doing
21 pretty reliably, it won't be a problem for
22 you. It is this other lower-quality care

1 scenario that is relevant.

2 MEMBER WADDY: But this measure is
3 largely for documentation and not for -- I
4 mean, I think it depends on what the measure
5 is for.

6 CO-CHAIR TIRSCHWELL: I think all care
7 measures, these process measures, are
8 documentation burdens at some level because
9 the process that they are talking about is an
10 important one for standard of care.

11 MEMBER WADDY: I just think that, if it
12 is for documentation, then I would see that;
13 I would see it in a different light than if it
14 is for improving quality. I mean, those are
15 two totally different things, and you would
16 use that same information in two totally
17 different ways in this measure.

18 CO-CHAIR TIRSCHWELL: I think at high-
19 quality centers it may be more of a
20 documentation issue, and at lower-quality
21 centers it may be really a quality issue.

22 MEMBER J. BAUTISTA: So, a minor point,

1 but there are some different exclusions, I
2 think, in The Joint Commission measure
3 compared to this measure. I think The Joint
4 Commission measure excluded patients in
5 clinical trials, that whole length-of-stay
6 issue, and then patients admitted for elective
7 vascular procedures, which was 10 percent of
8 their population in The Joint Commission
9 metrics. So, those are some differences.

10 CO-CHAIR TIRSCHWELL: A couple mor
11 comments. Gail?

12 MEMBER COONEY: I just wanted to speak
13 to the documentation versus improvement.
14 Because I see this as much more focused on
15 improvement than on documentation, because the
16 numbers are so low that are being treated. I
17 think the focus of this is that those eligible
18 patients should be treated.

19 CO-CHAIR TIRSCHWELL: Daniel?

20 MEMBER LABOVITZ: Yes, this is perhaps
21 a question for the developers. And I have got
22 to say this discussion has gotten me smarter

1 than I used to be. So, I appreciate it.

2 This has to do with the diagnosis of
3 ischemic stroke. We often, a few times a year
4 anyway, see patients who had an ischemic
5 stroke; a smart stroke neurologist would say,
6 "Yes, that was a stroke," but the ED physician
7 doesn't recognize it.

8 When is the diagnosis the diagnosis? Is
9 it at discharge? Is it in those first two
10 hours, and if you miss the diagnosis, you
11 don't get a ding? How does that work?

12 CO-CHAIR TIRSCHWELL: I think it is at
13 discharge. So, it is the final diagnosis.
14 So, that would count against you if you get a
15 lot of subtle posterior circulation strokes
16 that your ED docs and even some of your
17 neurology residents might miss on occasion.
18 So, yes, you don't want to practice at that
19 medical center.

20 MEMBER SUKO: I guess two comments,
21 responding to that. From a practical
22 perspective, the way it works in our facility

1 is it is at discharge, because it is
2 abstracted by ICD-9 codes, which is what your
3 coders code. And so, from a practical
4 perspective at a facility, it really is at
5 discharge.

6 And then, putting on my administration
7 hat around quality, you know, there is the old
8 adage about, if it is documented, it is not
9 done. And the best way that we have to
10 understand what you are thinking of as
11 physicians as you are going through care is
12 what you have documented.

13 And so, if there were a way that we
14 could read your mind, other than your
15 documentation, we could make those quality
16 judgments. But, without that, we can't do
17 that.

18 CO-CHAIR TIRSCHWELL: Okay. I am going
19 to suggest we vote on impact.

20 (Laughter.)

21 I think our discussion has extended
22 beyond impact.

1 Daniel, do you have another comment or
2 you just left your name tag up? Thank you.

3 Okay. So, high impact?

4 (Vote taken.)

5 MS. THEBERGE: Fourteen high, 6
6 moderate, 2 low.

7 CO-CHAIR TIRSCHWELL: Okay. Moving on
8 to 1c, evidence, Bill. This is still your
9 measure.

10 MEMBER BARSAN: Yes, I think that we,
11 again, six voting yes, one voting no on this.
12 I think there was pretty good agreement with
13 that.

14 CO-CHAIR TIRSCHWELL: The use of t-PA,
15 that is measured here. We are voting.

16 (Vote taken.)

17 MS. THEBERGE: All right. Twenty
18 responses. The clock is frozen. There we go,
19 yes.

20 Eighteen yes, 4 no.

21 CO-CHAIR TIRSCHWELL: Okay. And then,
22 moving on to 1b, performance gap.

1 MEMBER BARSAN: I think there is pretty
2 good evidence that at least most people felt
3 there was evidence that there was a
4 performance gap here.

5 CO-CHAIR TIRSCHWELL: Okay.

6 (Vote taken.)

7 MS. THEBERGE: Twenty-one high, 1
8 moderate.

9 CO-CHAIR TIRSCHWELL: So, next is any
10 comments on reliability. Bill?

11 MEMBER BARSAN: No, I don't think so.

12 MEMBER WADDY: Actually, can I make a
13 comment regarding 1c really quickly for the
14 evidence?

15 So, I just want it to be clear for
16 future discussions and everything, this isn't
17 evidence of utilization of t-PA. It is really
18 what is the evidence for the information in
19 this measure, right, which is different?

20 CO-CHAIR TIRSCHWELL: So, I think the
21 evidence needs to be connected to the measure,
22 but you don't have to prove that your measure

1 is improving outcomes. So, the evidence they
2 give I think is mostly related to the benefit
3 of t-PA, and you are asking whether that is
4 appropriate or not?

5 MEMBER WADDY: I am really asking, the
6 reason why I didn't put high for that one is
7 because there are theoretical issues regarding
8 the increased bleeding risks and the inclusion
9 of the warnings and conditions. And so, that
10 is why I didn't think it was as high. But if
11 they had not put that section, then, of
12 course, I mean, there is evidence for t-PA.

13 CO-CHAIR TIRSCHWELL: Yes, and I guess
14 I would ask that NQF could qualify which area
15 of evidence are we looking for here.

16 DR. WINKLER: When we are looking at the
17 section under evidence, we are talking about
18 that process of care. So, you are talking
19 about in this particular case the use of t-PA.
20 So, that is the evidence we are going to be
21 judging the measure against. Once you get to
22 scientific acceptability, you look at how the

1 measure is constructed and say, does it match
2 that evidence that we know exists?

3 But the evidence is around the process
4 of care that you are measuring. And we have
5 got several measures that have tried to
6 measure that process of care. The evidence
7 should have been pretty much the same for all
8 of them. It is how the measure works to
9 reflect that.

10 MEMBER BARSAN: Yes. So, if we had
11 issues with some of these things like we
12 talked about with how these things are used
13 and the warnings are listed, or whatever,
14 would that come under this category? Any
15 concerns about that? Yes? Okay.

16 DR. WINKLER: Yes, because you are
17 talking about the measure specifications --

18 MEMBER BARSAN: Okay.

19 DR. WINKLER: -- under scientific
20 acceptability of this measure's properties.

21 CO-CHAIR TIRSCHWELL: So, specifically,
22 we are about to vote on reliability. You can

1 see up there it says precise specifications.

2 I think the inclusion and exclusion criteria
3 certainly are part of the specifications of
4 the measure. So, that might be where you --

5 MEMBER BARSAN: So, I guess this is
6 where people had issues, right.

7 CO-CHAIR TIRSCHWELL: Right. This might
8 be where you want to put that emotion.

9 MEMBER GIDWANI: Perhaps I
10 misunderstood, but I would assume that if
11 there were issues with the denominator
12 exclusions, that would be a validity issue
13 rather than reliability. Okay. So, this is
14 more about if different people assess the same
15 dataset, do they come to the same conclusion?
16 The validity would be the part at which we
17 decide whether the denominator exclusions are
18 appropriate.

19 DR. BURSTIN: Right, other than I think
20 the fact that precision of specifications is
21 still considered under reliability. So, if
22 you don't believe some of the way it is even

1 written out as precise enough -- some of that
2 will get picked up, I think, under validity.
3 But I think it is a bit of splitting hairs.

4 MEMBER GIDWANI: Okay.

5 DR. WINKLER: One question on
6 reliability?

7 CO-CHAIR TIRSCHWELL: Yes.

8 DR. WINKLER: In terms of the testing
9 information that is presented, this is a
10 facility-level measure, but the testing
11 information says that it comes from four
12 practice sites, large-group practice, a
13 hospital-based neurology practice, a small-
14 sized group practice, large-group practice.

15 So, I am having trouble understanding if
16 we have tested the measure at the level of
17 specification at the facility. And I would
18 ask for some clarification.

19 DR. KATZAN: Yes, this was tested at a
20 facility level. It was aggregated. Due to
21 sample-size limitations for the most part, we
22 don't test across physicians. So,

1 specifically, it would be aggregated across
2 all facilities.

3 CO-CHAIR TIRSCHWELL: I think what Reva
4 was asking, if it is a group practice, that
5 doesn't sound like a facility. I don't know.
6 Is that --

7 DR. WINKLER: That is what I was
8 wondering.

9 DR. KATZAN: I mean, all I will say is
10 we aggregated across facilities. We don't do
11 by individual physicians.

12 DR. WINKLER: I guess if this measure is
13 meant to measure at the level of the facility,
14 the typical facility is a hospital. So, how
15 does this measure give you results of one
16 hospital that you would compare to other
17 hospitals, and yet, when you have tested it
18 and used it in practices? That is where I am
19 confused.

20 CO-CHAIR TIRSCHWELL: Any further
21 comments from the developer? So, I guess we
22 are suggesting that reliability data that is

1 presented doesn't quite match up with the
2 facility-level testing that is proposed.

3 MS. YODICE: Well, I mean, I will say
4 that there was 100 percent agreement if you
5 look at the sample size of 148 in our inter-
6 rater reliability.

7 CO-CHAIR KNOWLTON: I think the question
8 that is being put is that this is being
9 described as a facility measure.

10 MS. YODICE: Right.

11 CO-CHAIR KNOWLTON: So, then, you would
12 have to standardize your reliability on a
13 facility level. And if I understand the data
14 correctly, you looked at reliability, inter-
15 rater reliability, and so forth, at a
16 physician level and/or at a physician-practice
17 level, not at a facility level, which is
18 usually a hospital. Is that correct? Or do
19 we misunderstand? I think that is the
20 question.

21 MS. YODICE: Right. In this case, it
22 shouldn't necessarily make a difference

1 because --

2 CO-CHAIR KNOWLTON: You can make that
3 argument, certainly. But answer the question
4 first. Is there facility-level hospital data
5 in this measure as part of the reliability?

6 MS. YODICE: I don't know the answer to
7 that question.

8 CO-CHAIR KNOWLTON: You don't know? You
9 can go on and make your point. I didn't mean
10 to interrupt you, but I wasn't getting an
11 answer to the question.

12 MS. YODICE: Okay. So, what I do know
13 is that the measures technically, they are
14 tested at a facility level based on random
15 selection from the facility.

16 CO-CHAIR KNOWLTON: What is facility
17 level? You mean like a practice?

18 MS. YODICE: Yes. Like a site, a test
19 site, a hospital.

20 CO-CHAIR KNOWLTON: It is out of a
21 hospital?

22 MS. YODICE: Yes.

1 MEMBER WADDY: But this says it was
2 based on practices. I mean, in some places a
3 practice may be at a hospital, but in other
4 places, such as Fairfax, there are like three
5 different practices within a hospital.

6 MS. YODICE: Okay. Yes. These are
7 inpatient measures only.

8 MEMBER WADDY: Right, but there may be
9 three different practices, three different
10 physician practices within a hospital. And
11 so, those may be completely different, such as
12 the INOVA Group or the Richard Seestedt group
13 at INOVA may be doing one thing; whereas, the
14 Eric Sklar Group at INOVA does something
15 completely different.

16 CO-CHAIR TIRSCHWELL: It seems like
17 there is ambiguity about the reliability as
18 presented. I don't know; do you have anything
19 further to add?

20 MS. YODICE: Well, as I was saying
21 before, I know these are inpatient measures
22 only. So, they were tested across four sites,

1 technically tested at facility level based on
2 random selection from the facility. We don't
3 test across physicians in this testing model
4 due to sample-size limitations.

5 So, essentially, I mean, that is all I
6 can say to answer the question.

7 CO-CHAIR TIRSCHWELL: So, I guess we
8 have to individually decide whether these data
9 referring to practices are reliable enough a
10 measure of facility-level reliability and vote
11 according to our conscience. I am not sure
12 there is anything else to add to that.

13 So, could we go ahead and vote on
14 reliability?

15 (Vote taken.)

16 MS. THEBERGE: There we go.

17 One high, 12 moderate, 4 low, 5
18 insufficient evidence.

19 CO-CHAIR TIRSCHWELL: So, we continue.

20 MEMBER BARSAN: Yes, onto validity, I
21 don't think there were any major issues raised
22 in the group about this specifically. We had

1 4 high, 2 medium, 1 low votes in terms of the
2 validity.

3 CO-CHAIR TIRSCHWELL: And again, you
4 know, the issue about the specifications of
5 the exclusions may be relevant in your vote at
6 this juncture.

7 Any other comments before we move to
8 vote?

9 MEMBER KAPINOS: So, I am confused. The
10 overall assessment was that, actually, a lot
11 of us did not like the fact that it was so
12 with all those exclusions or contraindications
13 and the other term that they used.

14 So, here, for 2b.1, specifications are
15 consistent with the evidence, I should still
16 say yes because that is exactly what is
17 written in the guidelines, right? But,
18 actually, we are thinking it is too specific
19 and we prefer, actually, the other. The Joint
20 Commission submitted one that just leaves it
21 up to the clinician to exclude the patients
22 just by documenting, and they did not list all

1 those contraindications to t-PA.

2 So, here I am going to score even if in
3 my heart at the end I am going to maybe vote
4 no because I prefer the other one that does
5 leave more to the clinicians' judgment? Or am
6 I a little bit confused on it.

7 CO-CHAIR TIRSCHWELL: Yes, and I think
8 there is some ambiguity in the process a
9 little bit. But let me just comment quickly
10 that we heard a lot of emotion about the
11 specifications, and we have not really seen
12 that reflected in any of the voting just yet.
13 So, I think that should be part of your voting
14 along the way. And if at the end you are
15 going to vote no, I would hope that at some
16 point along the way you voted down one of the
17 criteria. I think that would be consistent.

18 At this point, we should take each
19 measure independently, not worry about whether
20 we like The Joint Commission one better or
21 not, and just kind of take this one on its own
22 merit.

1 DR. BURSTIN: Just a thought on that,
2 David.

3 CO-CHAIR TIRSCHWELL: Go ahead, yes.

4 DR. BURSTIN: So, just to make that even
5 more clear perhaps, vote each individual
6 measure as they stand based on the criteria
7 before you. At the end of the day, when we
8 have that session outlined for competing and
9 related measures, we will actually show you
10 your votes across the competing and related
11 measures, so you can actually see how you
12 rated them on each of the criteria and overall
13 to help make that assessment. But, for now,
14 just vote on the individual measure.

15 CO-CHAIR TIRSCHWELL: Yes, sure. Go
16 ahead.

17 DR. ANTMAN: I don't mean to put our
18 Joint Commission colleagues on the spot, but
19 I am just trying to understand why there are
20 some questions about specific items that we
21 have listed as exclusions. And as Diedre
22 explained, we actually regard these as

1 discretionary exceptions from the measure.

2 I am a little unsure as to why there are
3 questions about individual items listed there,
4 given that we are fairly certain that we match
5 The Joint Commission list.

6 If I may, either to Karen or Ann at The
7 Joint Commission, is it perhaps that that full
8 list of contraindications, et cetera, other
9 possible exceptions to the measure, are those
10 bundled under what has been listed in The
11 Joint Commission measure as documented reason
12 for not initiating IV t-PA?

13 CO-CHAIR TIRSCHWELL: Just as a point of
14 process, we are probably going to need to go
15 through the Committee and not directly talk to
16 each other as side participants. But go ahead
17 and answer that question, if you will.

18 MS. KOLBUSZ: Yes, I think this came up
19 on the Work Group conference call as well. We
20 have a data element reason for not initiating
21 IV thrombolytic therapy. The guidelines for
22 instruction are included in the data element

1 definition for that particular data element.

2 And the list, the table which is called
3 "Conditions making the administration of IV
4 thrombolytic therapy inadvisable" is reference
5 material provided in our measure information
6 form. Those are not necessarily absolute
7 exclusions to the measure. We still require
8 that, for any reason for not initiating IV
9 thrombolytic therapy, that it be explicitly
10 documented in the medical record by the
11 physician, the APM, the physician assistant,
12 or pharmacist.

13 Therefore, if it is in the table, which
14 was taken directly from the FDA list of
15 contraindications, from their labeling
16 instructions, or if they had another reason
17 for not giving t-PA, that that would all roll
18 into that data-element reason for not
19 initiating IV thrombolytic therapy.

20 CO-CHAIR TIRSCHWELL: Okay. So, just to
21 clarify, it sounds to me like the lists are
22 likely identical, if we got them all out and

1 put them next to each other. And I think that
2 is your point, Mark. But the reality is these
3 guys put it on the form that we looked at in
4 more detail and are perhaps inappropriately
5 suffering as a consequence of that. And so,
6 we may want to consider whether that is
7 appropriate or not. My guess is that these
8 criteria on a list are the same, no matter
9 what.

10 MEMBER KAPLITT: Can the developer
11 explain to me the answer to 2b.3, that at the
12 time of testing the measure did not have
13 exceptions? Page 17. Because we have been
14 talking about all these exceptions, and we are
15 talking about the testing that was done in
16 these various settings of unclear relevance.
17 And it explicitly states earlier, I think, in
18 -- I forget -- 2b.1 or something, that they
19 are supposed to collect exception data which
20 I don't see presented. So, I don't understand
21 that answer.

22 DR. ANTMAN: Right. So, I recognize

1 that that is confusing.

2 So, the measure that is under review
3 currently, the T-PA-administered measure, this
4 is a new measure for us in that the pair that
5 we presented, the measure previously looked at
6 was closer, if you will, to the measure that
7 is now designated as the initiated measure.
8 Because as our Work Group discussed it, as we
9 were updating the measure set, the feeling was
10 that we should separate out the consideration
11 from the initiation.

12 So, the testing that was done on these
13 measures was on the previous version that was,
14 in fact, the considered measure, but the
15 testing was done at the data-element level
16 that we felt was still relevant to this new
17 measure, the initiation measure.

18 MEMBER KAPLITT: Well, just to clarify,
19 because I am a neurosurgeon, so I think very
20 simply. Okay? So, what you tested is not
21 what we are being asked to approve here today?

22 DR. ANTMAN: So, what we tested is not

1 an exact match to this measure, that is
2 correct. We tested at the data-element level,
3 but we felt that the data elements matched
4 this measure as revised.

5 MEMBER KAPLITT: But exceptions were not
6 part of that?

7 DR. ANTMAN: That is correct.

8 MEMBER KAPLITT: Which is the subject
9 under discussion for the last 20 minutes, as
10 I understand it, right?

11 CO-CHAIR TIRSCHWELL: And so, in fact,
12 to your question, Michael, these are
13 inaccurate answers at this point, that there
14 are no exclusions. Is that also right, Dr.
15 Antman?

16 MEMBER KAPLITT: That is the point. So,
17 the point I am trying to clarify is -- and
18 this relates to the vote we even just took, in
19 my view -- but the data we are being asked to
20 evaluate tested a measure that did not include
21 exceptions. The measure we are being asked to
22 approve does include exceptions, and that has

1 been the major subject of discussion.

2 So, what I am questioning is, how can we
3 possibly evaluate that data if it is not
4 actually including all the elements of the
5 measure we are being asked to evaluate here,
6 unless I am misunderstanding this answer? And
7 it doesn't sound like I am.

8 DR. ANTMAN: No, I don't think you are
9 misunderstanding. Again, it was tested in the
10 earlier version. We felt the testing was
11 valid for this measure because it was tested
12 at the data-element level. But it is correct
13 that in the version that it was tested it did
14 not have the exclusions or the exceptions.

15 CO-CHAIR KNOWLTON: I do have a comment.
16 The developer has a burden, I think, of
17 bringing the evidence, the assumption they
18 made that these two things are comparable,
19 there is a burden to show that, to carry the
20 question of validity, which I think is your
21 point. I agree.

22 CO-CHAIR TIRSCHWELL: Any other comments

1 related to validity issues before we go ahead
2 and vote?

3 MEMBER KAPINOS: I just wanted to make
4 the comment that I told you, to share it with
5 everybody. The concern that I have with all
6 this list clearly-stated in that measure is
7 that, then, it is going to be easy for a
8 physician in the ER to think about, "I want to
9 make my hospital have a good score.
10 Therefore, I am going to use each of these
11 things to exclude as many patients as
12 possible. Therefore, my hospital will have,
13 yes, a very good measure, but I am going to
14 give less t-PA, actually."

15 Because here it is clearly stated which
16 criteria I can use to exclude my patients from
17 receiving t-PA, as opposed to if you make it
18 more blurry, like documented evidence against
19 t-PA, like on the other measure, the one
20 proposed by The Joint Commission. Actually,
21 you are not giving a clear checklist to a
22 physician to be used to exclude the patient.

1 So, I mean, I think it is less facilitating,
2 malevolent people that would actually exclude
3 more patients with the interest to make the
4 hospital measure look better.

5 CO-CHAIR TIRSCHWELL: You know, I guess
6 that is a possibility. I have a hard time
7 believing that emergency medicine physicians
8 would really stack the deck like that.

9 I mean, vote your conscience. If you
10 really think that is a big issue, let it be
11 known. But my personal opinion is they have
12 got a checklist already. Almost every place
13 does. And it is not that hard to find a
14 reason to exclude someone. I don't think this
15 is going to really make the difference.

16 Salina?

17 MEMBER WADDY: Actually, I mean, I think
18 you are right regarding the physician and the
19 people who are the treatment teams, but this
20 is really a facility-level indicator. And so,
21 whether or not that changes things or not, I
22 think potentially it could.

1 MEMBER KAPLITT: Fundamentally, what we
2 are doing here is speculating, right? I mean,
3 we are supposed to be basing it on data. And
4 my point is we can all have our various
5 opinions of how this could be used or misused,
6 but the problem that I see here is that we
7 don't have the data. If I have a bias that
8 this could be misused, and the data says that
9 that is not happening, fine, that I would have
10 no problem with that. But we don't have the
11 data. That is my concern.

12 CO-CHAIR TIRSCHWELL: Yes, go ahead,
13 Gwen.

14 MEMBER BUHR: So, The Joint Commission
15 measure has a separate document where it
16 outlines all of the exclusions, where if you
17 are going to follow the measure, you have this
18 separate document. And it has all of the same
19 exclusions as this measure exactly. So, I
20 just wanted to make that point.

21 CO-CHAIR TIRSCHWELL: I think that is a
22 good point, but they also have data showing

1 that it is --

2 MEMBER BUHR: Yes, exactly.

3 CO-CHAIR TIRSCHWELL: -- reliable and
4 valid in its --

5 MEMBER BUHR: So, the issue is that this
6 measure doesn't have the validity data exactly
7 as presented. I don't know if it really
8 matters, the different -- I mean, they are the
9 exact same things, but they haven't presented
10 us with the data.

11 CO-CHAIR TIRSCHWELL: Any other
12 comments?

13 Gail is ready to vote.

14 I will give the developer one last
15 chance to respond. Then, I think we need to
16 vote.

17 MS. HANLEY: Yes, just one thing to add.
18 As Mark explained, we tested the prior
19 measure, the t-PA considered measure that
20 wasn't previously endorsed, at the data-
21 element level. While that measure did not
22 have exceptions, information was collected and

1 tested on the reasons why a patient may not
2 have received t-PA.

3 So, in the prior measure, the considered
4 measure, you were counted in the numerator if
5 you either received it or if you didn't
6 receive it, but, yet, there was documentation
7 for those reasons. And in our testing table,
8 we actually have some examples which look
9 quite similar to the list of the exceptions
10 that we included in this measure submission
11 form to reasons why the patient was not
12 prescribed t-PA.

13 So, I just thought I would add that.
14 Even though the data elements weren't tested
15 as exceptions in the prior measure, the data
16 elements were collected and tested.

17 CO-CHAIR TIRSCHWELL: Is that data on
18 the forms?

19 MS. HANLEY: I would have to look
20 closer. I don't think we actually included
21 that.

22 MS. YODICE: This is the actual tool

1 that the abstractors used when they were
2 abstracting the data elements from the medical
3 records. So, it is the list of inclusions.

4 MS. HANLEY: But we didn't provide that.

5 MS. YODICE: It is not in the form, no.

6 CO-CHAIR TIRSCHWELL: I think we are
7 just going to have to vote on what we have
8 seen and what we have discussed.

9 2b, validity, I think we should open for
10 voting.

11 (Vote taken.)

12 MS. THEBERGE: One high, 5 moderate, 5
13 low, and 11 insufficient evidence.

14 CO-CHAIR TIRSCHWELL: So, okay, I think
15 that reflects the discussion pretty well. So,
16 it suggests that -- I think is this a full
17 stop at this point? Okay. So, this measure
18 did not meet criteria to move forward, either.

19 So, at this point, I think we should
20 take a break, although we are way behind
21 schedule. So, if we could try to limit it to
22 a five-minute break, I think that would be

1 great, and we will retool about how much we
2 are going to try to get done before lunch.

3 (Whereupon, the foregoing matter went
4 off the record at 11:49 a.m. and resumed at
5 11:58 a.m.)

6 CO-CHAIR KNOWLTON: Okay. Welcome to
7 1952.

8 (Laughter.)

9 Dan? Where's Dan? He is over here.

10 MEMBER LABOVITZ: So, Measure 1952 is a
11 new process measure proposed by the American
12 Heart Association, again focusing on delivery
13 of t-PA, but this time not "Did you give it or
14 not or did you think about it?", but if you
15 gave it, how fast did you deliver? Basically,
16 three time points needed: time patient was
17 last-known well, time patient arrived in the
18 hospital, and time t-PA was actually started.

19 There have been several publications
20 since the original t-PA trial showing that,
21 although originally we didn't recognize it,
22 time does matter. Most recently published in

1 circulation was the review of more than 25,000
2 patients who were given t-PA with their data
3 incorporated into the Get With The Guidelines
4 database.

5 Looking there, the faster the delivery,
6 the better the chance of a good outcome and
7 the lower the risk of mortality. Other meta-
8 analyses on trials using t-PA beyond the
9 three-hour window have also shown a real time
10 effect.

11 The Work Group thought that this was an
12 important measure unanimously for impact on
13 1a. We had no concerns about that.

14 CO-CHAIR KNOWLTON: Any questions on
15 impact for Dan or the Committee or thoughts?

16 (No response.)

17 Okay. Let's go to a vote.

18 (Vote taken.)

19 MS. THEBERGE: We are at 19. Twenty-
20 one.

21 Twenty-two high.

22 CO-CHAIR KNOWLTON: Okay. Unanimous.

1 Go ahead, Dan.

2 MEMBER LABOVITZ: For 1c, the rationale,
3 again, the same data, the same concept.

4 It was broadly agreed that shorter is
5 better. However, there are concerns on this
6 point about whether -- and I am not sure it
7 fits into this area -- but concerns that a
8 rush to treat might lead to poor treatment
9 decisions. That was a subject of much
10 discussion within the Work Group.

11 Also, some concern about centers that
12 may do a more sophisticated evaluation of
13 patients that might deliver true quality,
14 might deliver better care, and cost a little
15 bit of extra time.

16 On the whole, though, the group agreed
17 that time trumps everything else. And it was
18 unanimous in favor.

19 CO-CHAIR KNOWLTON: Comments or
20 questions for Dan? Or comments to the group?

21 (No response.)

22 Okay. Let's vote.

1 (Vote taken.)

2 MS. THEBERGE: We are at 20. We still
3 need one.

4 Twenty-one yes, 1 no.

5 CO-CHAIR KNOWLTON: Okay. Dan?

6 MEMBER LABOVITZ: Okay. For 2a, the
7 scientific acceptability of the measure --

8 CO-CHAIR KNOWLTON: 1b.

9 MEMBER LABOVITZ: Oh, I'm sorry. Have
10 I skipped 1b? I do apologize.

11 Performance gap, opportunity for
12 improvement. The American Heart Association
13 has published data showing that nationally in
14 the group of hospitals that is reporting data
15 the delivery of t-PA within 60 minutes is at
16 an abysmal 25 percent. The Target Stroke
17 Initiative by the American Heart Association
18 is pushing to raise that number to at least 50
19 percent. So, there is a wide gap there in
20 terms of delivery in a timely fashion.

21 CO-CHAIR KNOWLTON: Comments?

22 Questions?

1 (No response.)

2 Vote?

3 Wait for her to get the clock up there.

4 There you go.

5 (Vote taken.)

6 MS. THEBERGE: We have 19 responses.

7 Twenty-one high, 1 moderate.

8 CO-CHAIR KNOWLTON: Okay. Evidence.

9 Oh, we did evidence. We are in reverse. I'm
10 sorry.

11 MEMBER LABOVITZ: So, I think we are at
12 scientific acceptability of measure
13 properties.

14 CO-CHAIR KNOWLTON: Right.

15 MEMBER LABOVITZ: There was again
16 discussion here about whether including the 3-
17 to-4.5-hour stretch was scientifically-valid.
18 It is not something that has been endorsed by
19 the FDA.

20 The group, though, agreed that this is
21 a measure of how quickly you deliver t-PA.
22 Whether your hospital or institution or you

1 personally think you should be delivering t-PA
2 beyond three hours is not measured by this
3 measure, and there is no ding or quality
4 assessment on that point.

5 There were no other comments on that
6 area.

7 CO-CHAIR KNOWLTON: Can I ask you a
8 question on that, then?

9 MEMBER LABOVITZ: Yes.

10 CO-CHAIR KNOWLTON: I read in the
11 scientific acceptability area the issue of
12 risk stratification and whether that was
13 pertinent to t-PA. I don't know the answer,
14 but I wonder if it was answered in the group.

15 MEMBER LABOVITZ: I am very happy to
16 bloviate on that point.

17 (Laughter.)

18 But I am not sure that -- I think that
19 is, again, a discussion that is maybe served
20 over a bottle of wine.

21 When is it that you should stratify
22 hospitals?

1 CO-CHAIR KNOWLTON: I am okay with that,
2 by the way.

3 (Laughter.)

4 MEMBER LABOVITZ: Oh, okay.

5 I can certainly say I work in a medical
6 center that has three separate institutions.
7 One of them, many more patients arrive early
8 than at another. The patients behave
9 differently. It is easier to deliver t-PA at
10 one institution, not because the doctors are
11 different or the institutional practice is
12 different, but the patients are different.

13 I still think that stratification on any
14 of these points risks losing the main focus.
15 And that is time is of value.

16 I think that delivering t-PA within one
17 hour is a goal that is reasonable and
18 achievable, no matter where you are.

19 MEMBER KAPLITT: I would note that there
20 are some reasonable exceptions that are
21 included in the measure for delay. So, you
22 know, if something happens, it won't count

1 against you if it is reasonable.

2 MEMBER LABOVITZ: Yes, there are several
3 reasons why you might exclude a patient from
4 this measure. Even though t-PA was delivered,
5 it was delivered late, but it was delivered
6 late because you had to call Mexico to find
7 out that the patient didn't have an
8 intracerebral hemorrhage. That certainly
9 happens to us in The Bronx.

10 CO-CHAIR KNOWLTON: Jocelyn?

11 MEMBER J. BAUTISTA: I just want to
12 clarify. Are we actually talking about two
13 different measures here? Because they talk
14 about the percentage of patients who receive
15 t-PA within 60 minutes, but, then, there is
16 also this second sentence of median time from
17 hospital arrive to t-PA administration. So,
18 are these two separate measures that we are
19 evaluating?

20 MEMBER LABOVITZ: That might be a better
21 question for the developers. I can comment
22 just to say I think the data acquired is

1 exactly the same. It may really just be two
2 different ways of reporting it.

3 DR. SCHWAMM: Yes, so speaking for the
4 measure developer, the measure is the
5 percentage of patients who get it within 60
6 minutes. But, in addition, the median time to
7 treatment is reported for centers to make use
8 of that information to understand where they
9 are in relation to their time-to-treatment
10 goals.

11 The other comment that I would make is
12 that, during the conversation, there was a
13 request by the Working Group that we provide
14 the other NQF-endorsed measures that have a
15 similar set of time requirements for
16 thrombolytic therapy. We have those available
17 for you, if you would like to take them in
18 writing.

19 But it is the primary PCI within 90
20 minutes of hospital arrival, which is NQF
21 0163; thrombolytic therapy within 30 minutes
22 of arrival, which is NQF 0164, and time to IV

1 thrombolytic therapy, all for acute MI. NQF
2 pending 1952 is this measure.

3 You can see that the measure exclusions
4 are all the same. They were modeled
5 specifically after the NQF endorsement
6 approach of listing reasons that relate to
7 patient factors. So, I just wanted to follow
8 up on that.

9 CO-CHAIR KNOWLTON: Jocelyn, did that
10 answer your question?

11 MEMBER J. BAUTISTA: Yes.

12 CO-CHAIR KNOWLTON: Anybody else?

13 (No response.)

14 Okay. Ready to vote on reliability.

15 (Vote taken.)

16 MS. THEBERGE: Twenty-one responses.

17 Okay.

18 We have 14 high and 8 moderate.

19 CO-CHAIR KNOWLTON: Okay. Dan?

20 MEMBER LABOVITZ: Okay. I think that
21 takes us along to No. 3, usability.

22 CO-CHAIR KNOWLTON: Validity.

1 MEMBER LABOVITZ: 2b, validity. I have
2 skipped a piece.

3 We had high ratings on this point; no
4 specific comments.

5 CO-CHAIR KNOWLTON: Questions or
6 comments from the Committee?

7 (No response.)

8 Ready to vote.

9 (Vote taken.)

10 MS. THEBERGE: We are at 20. We are at
11 21.

12 Twenty high, 2 moderate.

13 CO-CHAIR KNOWLTON: Okay. Dan?
14 Usability?

15 MEMBER LABOVITZ: Okay. Usability,
16 again, the Work Group thought that this was
17 universally high. One voted medium.

18 The only comment there was that this
19 seemed like a new measure, so maybe we don't
20 know enough about it. I do think that 25,000
21 t-PA cases is a large number. I think we do
22 know a lot about it. But that is just me.

1 Overall, the group thought that this was
2 highly-usable.

3 CO-CHAIR KNOWLTON: Comments?
4 Questions?

5 (No response.)

6 Okay. Let's vote.

7 (Vote taken.)

8 MS. THEBERGE: We are still at 21
9 responses.

10 Twenty-two high.

11 CO-CHAIR KNOWLTON: Feasibility?

12 MEMBER LABOVITZ: Feasibility. Some
13 concern about the fact that not all of these
14 data are routinely collected, but at least for
15 centers using Get With The Guidelines they are
16 routinely collected.

17 I can certainly say, as a data guy, time
18 stuff is hard. It is easy to screw it up.
19 But we are doing time all the time. So, I
20 don't think there is an escape.

21 The group thought that this had high
22 feasibility with one vote for medium.

1 CO-CHAIR KNOWLTON: Questions or
2 comments?

3 (No response.)

4 Ready to vote.

5 (Vote taken.)

6 MS. THEBERGE: We are at 21. We are
7 still at 21. Can everyone re-vote? Has
8 anyone decided not to vote? We are still at
9 21.

10 CO-CHAIR KNOWLTON: You will be
11 punished.

12 (Laughter.)

13 MS. THEBERGE: All right. We have 16
14 high, 5 moderate, and 1 low. That's 22.

15 MEMBER KAPINOS: Is there any ongoing
16 like attempts to standardize the way we report
17 time? Because, as we know, we have the time
18 in the computer, on the video when we monitor
19 patients for seizure, the time on your EKG
20 machine. All those times are different with
21 many hours sometimes at some institutions
22 between each modality that you are using for

1 the time.

2 So, actually, with that measure in
3 place, hopefully, in the future that will also
4 foster some initiatives so that hospitals
5 standardize and align their times in all the
6 different machines that we use. Because for
7 the documentation and the work of the
8 physician, I mean, it is a mess.

9 CO-CHAIR KNOWLTON: You may want to have
10 that discussion with Dan over the bottle of
11 wine he promised.

12 (Laughter.)

13 MEMBER LABOVITZ: I am buying tonight.
14 Everybody is invited, yes.

15 (Laughter.)

16 CO-CHAIR KNOWLTON: So, the overall.
17 That one passed; we go on to the last issue,
18 right? We haven't changed the screen yet. We
19 did feasibility.

20 So, we are on to overall suitability for
21 endorsement.

22 MEMBER LABOVITZ: On overall

1 suitability, the Work Group voted unanimously
2 after discussion. We had to twist one arm,
3 but it worked out.

4 CO-CHAIR KNOWLTON: Questions or
5 comments?

6 (No response.)

7 Okay. Let's vote.

8 (Vote taken.)

9 MS. THEBERGE: Twenty-two yes.

10 CO-CHAIR TIRSCHWELL: All right. The
11 next measure for review is 0438. That is a
12 Joint Commission measure, antithrombotic
13 therapy by the end of hospital day two.

14 Greg, do you want to introduce that?

15 MEMBER KAPINOS: So, actually, it is
16 only afterwards that I came up with a
17 question. I thought it was a straightforward
18 definition. So, all these patients should
19 receive antithrombotic therapy within the
20 first 48 hours, and that is the definition
21 that is used for that measure.

22 However, I couldn't find out the

1 definition of which antithrombotic regimen are
2 we talking about because I am guessing that
3 everybody is talking about like ischemic, I
4 mean secondary -- it is preventing the clot
5 from progressing and initiating early
6 secondary prevention of ischemic shock with an
7 antiplatelet agent or an anticoagulant if you
8 have some other indication for anticoagulation
9 rather than antiplatelets.

10 But the fact that it is a broad
11 terminology, I just have a question to clarify
12 that before we go on to the votes. Because it
13 would be inappropriate to count, also, as
14 antithrombotic, for instance, VT prophylaxis.
15 So, if I put my patient on hep subQ at day
16 one, I am going to match that measurement, I
17 believe, even if I did not give aspirin for
18 the stroke.

19 So, is it detailed somewhere? I missed
20 it? Okay.

21 MEMBER J. BAUTISTA: I have the data
22 dictionary, if you -- it excludes subQ

1 heparin. So, that is not considered.

2 MEMBER KAPINOS: Okay. And so, why
3 didn't we define better like aspirin, like in
4 the guidelines they tell you the use of
5 aspirin between 150 milligrams and 320
6 milligrams is exactly what we are looking for
7 for the ischemic strokes or coumadin -- well,
8 not coumadin within two days. So, actually,
9 that is the only regimen.

10 So, why didn't we replace antithrombotic
11 therapy by aspirin 150 milligrams up to 320?

12 CO-CHAIR TIRSCHWELL: I think, on a
13 process point, the additional materials that
14 are submitted with these measures are part of
15 their submission. And they do go into detail.

16 Do you have it in front of you? Can you
17 read out all of them, Jocelyn?

18 MEMBER J. BAUTISTA: Well, I have the
19 data dictionary in front of me that they refer
20 to in the submission. They simply say
21 antithrombotic therapy. They don't list
22 antithrombotic therapies, but they say

1 exclusions from antithrombotic therapies,
2 heparin subQ, heparin flush, and Hep-Lock.

3 CO-CHAIR TIRSCHWELL: It must have been
4 another measure that I saw a specific list
5 for.

6 MEMBER J. BAUTISTA: Oh, you know what?
7 There is. There is an Appendix C, Table 8.2.

8 CO-CHAIR TIRSCHWELL: You know, I think
9 they don't specify that it is just aspirin.
10 They really include all of the sort of full-
11 dose antithrombotics. And it sounds like they
12 call out that DVT prophylaxis dosing is not an
13 appropriate measure to meet the exclusion.

14 Do the developers have anything to add
15 to that?

16 DR. SCHWAMM: Yes, I would emphasize
17 just what you have said, that all FDA-approved
18 or guideline-endorsed antithrombotic agents
19 are listed in the coding instructions and the
20 data dictionary that is available to
21 abstractors.

22 But because there is confusion out there

1 around the difference between antiprothylaxis
2 for DVT, which is not appropriate
3 antithrombotic therapy -- and quite frankly,
4 the reverse, that an aspirin a day does not
5 prevent DVT. Those are called out
6 specifically, so that there is a high
7 reliability in the implementation of the
8 measure.

9 CO-CHAIR TIRSCHWELL: So, theoretically,
10 that is in place, although it was buried a
11 couple of layers down.

12 MEMBER KAPINOS: Let's look at 1a?

13 CO-CHAIR TIRSCHWELL: Impact.

14 MEMBER KAPINOS: Yes, let's vote for
15 impact. There was no specific question.

16 CO-CHAIR TIRSCHWELL: Go ahead and open
17 the voting. Okay.

18 (Vote taken.)

19 MS. THEBERGE: Twenty-two high.

20 CO-CHAIR TIRSCHWELL: Great. Go on to
21 1c.

22 MEMBER KAPINOS: Okay. For the evidence

1 supporting this, also, everybody was compelled
2 that it was high evidence. No specific
3 question.

4 CO-CHAIR TIRSCHWELL: Let's vote on 1c
5 then.

6 (Vote taken.)

7 MS. THEBERGE: We are still at 21.

8 Twenty-two high -- I'm sorry -- yes.

9 MEMBER KAPINOS: We have a question.

10 CO-CHAIR TIRSCHWELL: And then, next is
11 --

12 MEMBER KAPINOS: Hold on. We have a
13 question from Risha.

14 CO-CHAIR TIRSCHWELL: Yes, please. Go
15 ahead, Risha.

16 MEMBER GIDWANI: Thanks.

17 This is actually a comment rather than
18 a question. I notice here, and in many other
19 places in the measures, when grading the
20 quality of the evidence, folks are using
21 guidelines indicating that the highest level
22 is that from multiple randomized control

1 trials or meta-analyses.

2 And for the developers, I would suggest
3 actually disaggregating those two categories.
4 Meta-analysis is not necessarily of the same
5 level of evidence as multiple randomized
6 controlled trials. The quality of a meta-
7 analysis is usually akin to that of an
8 observational study.

9 Depending on the quality of the meta-
10 analysis, the randomized controlled trial can
11 actually trump that in terms of data validity.
12 I will refer folks to a Statistics in Medicine
13 article from Shuster in 2010.

14 I am happy to discuss this offline with
15 any developers, but just a comment and
16 suggestion to be made.

17 CO-CHAIR TIRSCHWELL: I guess I would
18 only add that meta-analyses can be of
19 randomized trials or observational studies,
20 and they should specify that.

21 MEMBER GIDWANI: I agree with that.
22 Even when the meta-analysis is, though, only

1 using randomized controlled trials, it is
2 considered to be, the meta-analysis itself of
3 the RCTs is considered to have the quality of
4 evidence of an observational study. So,
5 suggestion to disaggregate those two levels.

6 CO-CHAIR TIRSCHWELL: Okay. So, that
7 was a comment on the previous measure as to a
8 performance gap, Greg. Any comments?

9 MEMBER KAPINOS: Oh, of course. Sorry.
10 For 1b, yes. For the performance gap, yes,
11 people were considering the fact that now that
12 actually we matched -- 97 or almost 100
13 percent of the hospitals are with good
14 compliance with this measure. Actually,
15 people were saying the 1b item will be ranked
16 very low because you probably cannot improve
17 from 98 to 100 percent.

18 However, then, I think the Work Group
19 suggested that, even a minimal increase from
20 99.5 to 99.6 increment, since we are talking
21 about such a powerful impact from initiating
22 that therapy, will link to better outcomes.

1 Actually, it is still important to have
2 this measure ongoing and maintained. So,
3 overall, I think everybody was willing to give
4 it a high score.

5 CO-CHAIR TIRSCHWELL: Risha, do you have
6 another comment?

7 MEMBER GIDWANI: No.

8 CO-CHAIR TIRSCHWELL: Jocelyn, do you
9 have a comment?

10 MEMBER J. BAUTISTA: No.

11 CO-CHAIR TIRSCHWELL: Put your name tag
12 down, please, then.

13 Yes, Ramon?

14 MEMBER R. BAUTISTA: But the reason for
15 the gap was not given, though. In other
16 words, you could have a 2-percent performance
17 gap, but that wasn't even stated, right? So,
18 it is only known, but the reason for that was
19 not stated, either.

20 CO-CHAIR TIRSCHWELL: It shouldn't be an
21 explanation for your performance gap that
22 would exclude you from the measure, right.

1 So, I am not sure that is --

2 MEMBER R. BAUTISTA: Just to make sure,
3 what that actually taken into account, though,
4 in this study? Did they exclude people who
5 could not take --

6 CO-CHAIR TIRSCHWELL: Documented reason
7 for not administering anti-thrombotic therapy
8 by end of hospital day two. So, yes.

9 You know, the other thing that I would
10 add that was brought out in the application
11 was that the Get With The Guidelines hospitals
12 are the hospitals which have self-selected and
13 committed to high-quality stroke care. So,
14 even if the Get With The Guidelines hospitals
15 are performing at a very high level, you can
16 bet -- and again, I am making an assumption --
17 but you can bet that the hospitals that aren't
18 participating may be performing at a lower
19 level. And having this endorsed as an
20 important measure is probably even more
21 important than perhaps some of the data that
22 we are not able to observe at this point in

1 time.

2 And then, I guess I would ask the NQF
3 people, if we all agreed that it had topped-
4 out and we wanted to put it on reserve, when
5 would we say that, at the end after it is
6 approved?

7 DR. BURSTIN: Soon.

8 (Laughter.)

9 We are getting there.

10 But just a question for The Joint
11 Commission. It looks like you actually give
12 two rates, the first of which is based on
13 Joint Commission data, not Get With The
14 Guidelines, and that is still at 96-97
15 percent. Is that correct? I just want to
16 clarify it.

17 So, actually, they are both high, even
18 outside the Get With The Guidelines.

19 CO-CHAIR TIRSCHWELL: But The Joint
20 Commission data are only in primary stroke
21 centers. It might even be more selective than
22 Get With The Guidelines.

1 DR. SCHWAMM: Right. Just to clarify
2 that, there are 1600 hospitals in Get With The
3 Guidelines currently. Eight hundred of those
4 are primary stroke centers.

5 So, I think what you are seeing is a
6 sort of gradient effect there where we would
7 expect to see the highest performance among
8 primary stroke centers, but we are still only
9 capturing a third of U.S. hospitals in the
10 data presented.

11 DR. BURSTIN: So, essentially, just to
12 answer David's question, we would ask you to
13 finish all of the first criteria here, the
14 three subsets. You need to go through
15 evidence as well.

16 We would, then, ask you to then pull up
17 a slide and see, do you think -- and actually,
18 you would have to go through scientific
19 acceptability as well. So, the measure has to
20 be rated highly on scientific acceptability,
21 and, otherwise, would meet importance to
22 measure and report, with the exception of the

1 fact that the Committee thinks it has topped-
2 out.

3 And then, you could consider moving that
4 into reserve status. What that means is that
5 it is technically still endorsed, but there is
6 probably an expectation that continuing to
7 push on that -- and again, the subset of
8 hospitals issue is an important one -- may not
9 be the best strategy.

10 CO-CHAIR TIRSCHWELL: So, if the
11 performance gap was the only low score, that
12 is when we would consider that situation?

13 DR. BURSTIN: Please finish the
14 evaluation first.

15 CO-CHAIR TIRSCHWELL: Okay. So, let's
16 go ahead.

17 Yes? Oh, sorry, Gail. Go ahead.

18 MEMBER COONEY: I just want to clarify
19 with The Joint Commission. Of the data that
20 you are reporting, what proportion of those
21 hospitals are being evaluated as primary
22 stroke centers? Do you have hospitals that

1 aren't primary stroke centers that are in that
2 data or no?

3 MS. KOLBUSZ: Yes, we do give hospitals
4 that are primary stroke centers in the data
5 reported. The data came from our ORYX core
6 database. So, there is approximately 170
7 hospitals in that data collection.

8 MEMBER COONEY: And what proportion of
9 those hospitals are primary stroke centers?

10 MS. KOLBUSZ: About half.

11 DR. BURSTIN: Is there a difference in
12 performance between those that are and those
13 that aren't, I guess is the obvious next
14 question. You set it up.

15 MS. WATT: You know what? It is an
16 analysis that we haven't done, but it is a
17 good one. And thank you for suggesting it.

18 CO-CHAIR TIRSCHWELL: Daniel?

19 MEMBER LABOVITZ: This measure did give
20 me some heartburn. Because I spend, actually,
21 a lot of reviewer time gathering these data.
22 We put a lot of effort into getting this data

1 electronically. And we have given up trying
2 to fix our mistakes, which accounts for most
3 of the 2 to 3 percent of patients where we are
4 not treating with aspirin. It is a glitch in
5 the system. It is a misreading of
6 documentation. It is just a coding error.

7 I think that it is expensive to gather
8 data that you are not using. And I think any
9 center that is gathering these data is doing
10 well. I also think, to speak to Dr.

11 Trischwell's point about centers that may be
12 doing a bad job, we don't have the data on
13 them.

14 So, I think in previous discussions we
15 have said, "Hey, let's not make it up here."
16 We haven't been shown the data to suggest that
17 this measure is doing anything. And, boy, we
18 are topped-out.

19 I think somebody in our Work Group
20 discussion said, "Where is the NQF Hall of
21 Fame in endorsement, but not something that
22 CMS picks up and leaves us with for the next

1 30 years?"

2 MEMBER KAPINOS: So, let's vote?

3 CO-CHAIR TIRSCHWELL: Thank you.

4 (Vote taken.)

5 MS. THEBERGE: Three high, 8 moderate,
6 9 low, 2 insufficient evidence.

7 CO-CHAIR TIRSCHWELL: So, it is a dead
8 heat.

9 NQF, how should we proceed?

10 DR. WINKLER: Well, especially if your
11 conversation is around potentially going to
12 reserve status, it almost doesn't matter
13 because either it passed and you go on or it
14 didn't pass but you are contemplating reserve
15 status and you would go on. Regardless, you
16 are going on and finish the rest of the
17 evaluation.

18 CO-CHAIR TIRSCHWELL: Okay, then, 2a,
19 reliability.

20 MEMBER KAPINOS: No issues.

21 CO-CHAIR TIRSCHWELL: Comments or
22 questions about reliability for this measure?

1 (No response.)

2 Let's go ahead and vote then.

3 MEMBER J. BAUTISTA: But wait. Didn't
4 of the Work Group members write "Reliability
5 testing data not clearly presented."?

6 MEMBER KAPINOS: Yes, I don't remember
7 exactly where it was at. So, if you want to
8 go ahead -- who put that?

9 CO-CHAIR TIRSCHWELL: I think that was
10 me, quite honestly, and it has to do with, as
11 was already commented on, the issue
12 surrounding the way some of the data come out
13 and the denominators. I will have to pull it
14 up.

15 You know, quite honestly, I was
16 satisfied after I got further information.
17 Those comments were from sort of before the
18 Work Group meeting. so, I don't know that we
19 need to -- did anybody else have any question
20 about that?

21 (No response.)

22 MEMBER KAPINOS: See also the comment

1 about the new anticoagulants, or are they in
2 that longer list in the dictionary?

3 MEMBER J. BAUTISTA: Yes.

4 CO-CHAIR TIRSCHWELL: Yes.

5 MEMBER J. BAUTISTA: There are about
6 150.

7 MEMBER KAPINOS: Okay. That is why I
8 didn't go over it. Okay.

9 CO-CHAIR TIRSCHWELL: So, let's go ahead
10 vote then on reliability.

11 (Vote taken.)

12 MS. THEBERGE: We are at 20 responses.

13 Sixteen high, 6 moderate.

14 MEMBER KAPINOS: Moving on to validity,
15 I don't recall any specific concerns.

16 CO-CHAIR KNOWLTON: Okay. Any other
17 comments?

18 (No response.)

19 Let's go ahead and vote.

20 (Vote taken.)

21 MS. THEBERGE: Twenty responses.

22 Twenty-one. Can everyone vote one more time?

1 CO-CHAIR KNOWLTON: There we go.

2 MS. THEBERGE: There we go.

3 Sixteen high, 6 moderate.

4 CO-CHAIR KNOWLTON: So, moving along,
5 usability.

6 MEMBER KAPINOS: The same thing, I don't
7 recall any specific concerns. It is pretty
8 easy to --

9 CO-CHAIR KNOWLTON: Any comments or
10 questions about usability?

11 (No response.)

12 Let's go ahead and vote.

13 (Vote taken.)

14 MS. THEBERGE: Nineteen high, 3
15 moderate.

16 CO-CHAIR KNOWLTON: Okay, and
17 feasibility? Any comments or questions?

18 MEMBER KAPINOS: No.

19 CO-CHAIR KNOWLTON: No?

20 Yes, please, vote.

21 (Vote taken.)

22 MS. THEBERGE: Twenty-one responses.

1 Eighteen high, 3 moderate, 1 low.

2 CO-CHAIR KNOWLTON: Okay. And then, I
3 think just the overall suitability is the next
4 vote. Any other comments before we vote on
5 overall suitability?

6 (No response.)

7 I don't see any. Let's go ahead and
8 vote.

9 (Vote taken.)

10 MS. THEBERGE: Twenty-one responses.

11 Okay.

12 Nineteen yes, 3 no.

13 CO-CHAIR KNOWLTON: Okay. So, I guess
14 now we have to have the conversation about
15 reserve status. How do we start that
16 conversation? Oh, here, criteria for reserve
17 status.

18 So, evidence, is there strong, direct
19 evidence to a desired health outcome? I think
20 the answer to that is yes.

21 MEMBER KAPLITT: Can you explain reserve
22 status for a second, so that we understand it

1 better?

2 DR. BURSTIN: So, reserve status would
3 be reserved, I guess, for measures that
4 otherwise would pass all the NQF evaluation
5 criteria. They are evidence-based. They are
6 important. They are scientifically-valid.
7 But they are at such high levels of
8 performance that the question is, does
9 continuing to be measuring them on a regular
10 basis, as opposed to more periodic
11 surveillance and assessment to make sure that
12 when you kind of take the eye off of public
13 reporting that rate doesn't go down over time,
14 is really where you want to be.

15 So, does that constant, continuous
16 public reporting on this measure at that high
17 level of performance warrant it to be
18 continued? Or should it be in reserve status,
19 meaning at any point in time, if people raise
20 concerns that over time that measure is
21 creeping down as we are not keeping as close
22 an eye on it, it can potentially be moved back

1 into full status.

2 CO-CHAIR TIRSCHWELL: Mary?

3 MEMBER VAN DE KAMP: So, does the
4 reserve status then -- would they still
5 qualify for a measurement that CMS or
6 insurance or someone who is looking at payment
7 for best practice, would it still remain in
8 that check "have to have it" box, if it
9 reserve?

10 DR. BURSTIN: It would still be
11 endorsed, but clearly demonstrated to be in
12 reserve status. So, I think it would be sort
13 of used with caution, I think might be a way
14 for end-users to potentially interpret it.

15 CO-CHAIR TIRSCHWELL: And just for
16 clarification, NQF endorsement doesn't
17 mandatorily change policy of any external
18 body, CMS, ASA, anything like that.

19 MEMBER VAN DE KAMP: Right. I
20 understand that, but I just think if we are
21 looking at down the line, which we all know
22 they are looking at some sort of pay-for-

1 performance measures at some point, and this
2 group is a strong group. I am worry that we
3 take off something that is a strong process
4 that is proven in health outcomes, that you
5 don't get credit for. Back to your point, is
6 it worth measuring because you are all doing
7 it?

8 I don't know. To me, it seems like, as
9 we look at this, you have to look at the
10 broader base for ultimately what is a quality
11 organization that is going to be looked at as
12 a basis for making decisions. And if we take
13 things off because they are already a gold
14 standard, shouldn't you be rewarded? And
15 isn't there some concern that, if you take it
16 off of the gold standard and the checkbox,
17 that it won't be, then, considered later as a
18 best practice?

19 DR. BURSTIN: I think those are all
20 valid concerns, but there are real opportunity
21 costs to measurement. People tell us
22 routinely, when they have a lot of things to

1 measure, you know, they are not measuring
2 something else that might be new or
3 particularly important.

4 Again, I think this is why it is a
5 judgment call on the part of the Steering
6 Committee.

7 CO-CHAIR TIRSCHWELL: Go ahead, Mike.

8 MEMBER KAPLITT: And performance gap is
9 there for a reason, right? I mean,
10 presumably, there are a lot of things we do
11 every day that we don't measure anymore
12 because everybody does it and, as you said, it
13 is not necessarily worth continuing to do
14 that.

15 So, the question is, what can NQF tell
16 us in other areas has happened in the past to
17 things that have been placed in reserve
18 status? How have they been used? Does it
19 really matter?

20 DR. WINKLER: I think it is a little too
21 soon to tell. Reserve status was established
22 just a little over a year ago for some of the

1 measures that CMS and The Joint Commission
2 used around cardiovascular conditions. So,
3 those measures have had a long history of
4 being publicly-reported. They are at high
5 levels.

6 One thing we have seen is that some of
7 these measures CMS is not using in their
8 value-based purchasing model, because when you
9 are topped-out, the math doesn't work real
10 well.

11 So, I think we are just beginning to see
12 the implications of reserve status. So, we
13 don't have enough of a history to really tell
14 you how that is going to play out.

15 CO-CHAIR TIRSCHWELL: Go ahead.

16 DR. SCHWAMM: Yes, I just wanted to make
17 two points. I mean, I think these are all
18 really important and valid constructs. I just
19 would make two observations.

20 One is that, with 800,000 strokes a year
21 and rising, we are talking about a 4-percent
22 gap is still over 20,000 patients a year. And

1 because all the exclusion criteria are there,
2 we are still talking about 4 percent of
3 patients who could be benefitting from this
4 therapy for which we have some of the
5 strongest evidence and the largest
6 attributable benefit. So, I think that is
7 incredibly important.

8 I think the other thing is that I do
9 worry that, if it goes into this reserve
10 status, sites will not be forced to collect on
11 it. So, we will miss potentially an
12 opportunity to understand if there is a larger
13 performance gap out there than we have
14 measured from this high-performing group of
15 hospitals. If its NQF status is changed, it
16 is possible that CMS and Meaningful Use will
17 drop it as a measure, since they are not
18 currently requiring its collection.

19 So, one alternative approach would be to
20 re-endorse it for this cycle, give yourself a
21 chance to see if, in fact, it really is
22 topped-out nationwide. And then, it seems

1 like it would be very reasonable to consider
2 it for reserve status, if, in fact, you see
3 that that evidence is consistent.

4 CO-CHAIR TIRSCHWELL: Thank you.

5 Any other comments? Yes, go ahead.

6 MEMBER SULLIVAN: If I understood
7 correctly, the question to the developer
8 earlier about how the data was analyzed with
9 regard to stroke center, hospitals, and those
10 who are not, that that hadn't been looked at.
11 So, it would seem like the next cycle might be
12 an opportunity to look at that, and maybe
13 there is, indeed, a bigger performance gap
14 than we think, which an opportunity to look at
15 that seems like something we ought not dismiss
16 easily.

17 CO-CHAIR TIRSCHWELL: They do have the
18 data now, but we don't have it on which to
19 vote.

20 DR. BURSTIN: They haven't analyzed it,
21 but you have data potentially to bring to this
22 question.

1 MS. WATT: I don't know if in our Joint
2 Commission ORYX system -- I know that we don't
3 differentiate a primary stroke center hospital
4 that is reporting from another hospital that
5 is reporting. We could perhaps back into it
6 because, of course, we know who all are
7 certified.

8 But I think, though, the same argument
9 applies. Hospitals are not required to
10 collect core measure data. And so, the non-
11 primary stroke center hospitals that have
12 chosen to report as part of their
13 accreditation requirement, they obviously have
14 an interest in stroke care. And one could
15 argue that they, too, are self-selected. They
16 just haven't gone the step further to get the
17 certification, and maybe that is why they are
18 reporting it now, because that is their goal.
19 I don't know that.

20 CO-CHAIR TIRSCHWELL: Okay. So, any
21 other discussion? Fred?

22 MEMBER TOLIN: I was actually about to

1 take it down (referring to name tag).

2 But I think the comment that was made
3 about looking perhaps reserve status next
4 cycle I think seems very reasonable. No
5 measure is going to reach 100 percent. There
6 is always going to be a gap, for a variety of
7 reasons that have already been elucidated.

8 And the other perspective I like to take
9 on this is the burden that is placed on
10 facilities in gathering the data. If a
11 particular measure is doing well consistently,
12 then I am very much in favor of the idea of
13 moving that off the plate, so to speak, and
14 looking at other measures that we can go
15 forward with.

16 As Michael pointed out, we do things on
17 a daily basis we don't measure because that is
18 how we practice medicine.

19 CO-CHAIR TIRSCHWELL: Okay. Thank you.

20 So, as a process measure, do we need to
21 take another vote? It is up to me? Or the
22 group?

1 DR. BURSTIN: It is the will of the
2 Committee. Would you like to entertain this
3 measure for reserve status or do you want to
4 just let your prior decision stand?

5 CO-CHAIR TIRSCHWELL: The prior decision
6 being what?

7 DR. BURSTIN: You indicated it was
8 suitable for endorsement. It was just your
9 question as to whether -- do you want to take
10 this next vote? It is just truly the will of
11 the Committee. It, otherwise, does meet these
12 criteria. It is, otherwise, evidence-based,
13 highly-valid, reliable, et cetera.

14 Anybody can decide you want to vote.
15 You don't have to vote to vote. But it is
16 just, after this discussion, do you still want
17 to proceed with voting and reverse that?

18 CO-CHAIR TIRSCHWELL: So, I would
19 suggest we vote on whether we should proceed
20 to put this in reserve status or not.

21 Otherwise, it is endorsed.

22 Yes, Gail?

1 MEMBER COONEY: If we don't put it in
2 reserve status, it continues as a measure or
3 it disappears?

4 CO-CHAIR TIRSCHWELL: It is endorsed.

5 MEMBER COONEY: It is endorsed.

6 CO-CHAIR TIRSCHWELL: I don't know. That
7 wouldn't have been the way that I would have
8 done it, but can you type it up on the -- oh,
9 you don't have a special loader for this?

10 MS. THEBERGE: No, it is just this. So,
11 if you vote yes, you are putting it in
12 reserve. If you vote no, you are keeping it
13 as regular endorsement.

14 MS. JOHNSON: And both are endorsed.
15 Just one is with reserve status; one is not
16 with reserve status.

17 CO-CHAIR TIRSCHWELL: Okay.

18 (Vote taken.)

19 MS. THEBERGE: We are at 21 responses.

20 CO-CHAIR TIRSCHWELL: So, it is fully
21 endorsed, not in reserve status.

22 DR. BURSTIN: And just keep in mind, the

1 Steering Committee votes are fairly early in
2 the course of our process. So, this will all
3 go out for public comment, and I am sure there
4 will be some. So, we will bring that back to
5 you after the fact and continue to iterate on
6 this one some more.

7 MS. THEBERGE: For the record, that is
8 10 yes and 12 no.

9 CO-CHAIR TIRSCHWELL: I think we are
10 going to take a break at this point for lunch.

11 Okay. We need a couple of minutes for
12 public comment. First, local, the people that
13 are here, or on the phone.

14 (No response.)

15 MS. THEBERGE: Amy, can you open the
16 line for public comment?

17 OPERATOR: Fine.

18 If you would like to ask a question or
19 have a comment, please press *1 on your
20 telephone keypad. We will pause for just a
21 moment.

22 (No response.)

1 Again, that was *1.

2 (No response.)

3 There are no questions or comments on
4 the phone lines at this time.

5 CO-CHAIR TIRSCHWELL: Anyone in the room
6 have a comment?

7 (No response.)

8 Okay, then, I guess we are adjourned for
9 lunch, which is supposed to be a half an hour.
10 I guess we should at least limit it to that,
11 if not sooner. So, resume at 1:15.

12 (Whereupon, the foregoing matter went
13 off the record at 12:46 p.m. and resumed at
14 1:18 p.m.)

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

2 1:18 p.m.

3 CO-CHAIR TIRSCHWELL: The next measure
4 that we are going to do is 0435, a Joint
5 Commission Stroke Measure 2, Discharged on
6 Antithrombotic Therapy. And Gail is going to
7 guide us through that.

8 MEMBER COONEY: Yes, I sort of thought
9 that we should do this right after the other
10 one because it has got all the same questions
11 and issues.

12 This is a Joint Commission process
13 measure looking at the proportion of ischemic
14 stroke patients prescribed antithrombotic
15 therapy at hospital discharge. The data
16 collection and everything is very much the
17 same. The data for impact and importance is
18 very similar and was also rated highly.

19 CO-CHAIR TIRSCHWELL: So, let's go ahead
20 and vote, if we can, on impact, 1a, for
21 discharged on antithrombotic therapy.

22 Hang on one second until the timer comes

1 up there. Okay.

2 (Vote taken.)

3 MS. THEBERGE: It looks like 20.

4 CO-CHAIR TIRSCHWELL: Are we missing
5 somebody? Salina? Oh, there she is.

6 Thank you. All right, no debate there.
7 Sorry.

8 Evidence?

9 MEMBER COONEY: The evidence is also
10 very similar to the last measure. Again, high
11 in quantity, quality, and consistency.

12 CO-CHAIR TIRSCHWELL: Okay. So, let's
13 go ahead and vote on the evidence for
14 discharged.

15 (Vote taken.)

16 MS. THEBERGE: We are still short one
17 vote.

18 Twenty-two high.

19 CO-CHAIR TIRSCHWELL: Great. And then,
20 I guess this will be the rub, the question of
21 performance gap.

22 MEMBER COONEY: As with the last

1 measure, the issue here is in the performance
2 gap. All the different entities, The Joint
3 Commission, the Get With The Guidelines,
4 Stroke, all showed very high levels of
5 compliance, both at the time they began the
6 measurement in 2009 -- and this one is even
7 higher; it was 98.1 when they began and 99.2
8 in the last quarter reported. And The Joint
9 Commission notes a 2-percent performance gap.

10 CO-CHAIR TIRSCHWELL: Any comments?

11 Yes, Salina?

12 MEMBER WADDY: I do think it is
13 important to point out --

14 CO-CHAIR TIRSCHWELL: Could you push
15 your button (referring to the microphone)?

16 MEMBER WADDY: I do think it is
17 important to point out that, for the
18 performance gaps, it is not necessarily just
19 overall and general population, but also if
20 there is a disparity that has been identified.
21 So, that could also be an important reason to
22 measure it.

1 DR. WINKLER: Is there any data on
2 disparities from any of our data sources?

3 MEMBER WADDY: Yes, there was. There is
4 and there is a disparity.

5 MEMBER COONEY: There was data from
6 their original presentation. Oh, I'm sorry,
7 not on disparities, but on the performance gap
8 there was a difference. I don't believe there
9 was on the disparity.

10 MEMBER GIDWANI: I believe there were
11 disparities.

12 MEMBER KAPINOS: I think either they or
13 another measurer has linked to those multiple
14 publications about the fact that some groups,
15 I think of females and African-Americans,
16 there are some ethnicities that are definitely
17 not receiving antithrombotics as much as the
18 others.

19 MEMBER GIDWANI: On page 5, you will
20 notice the factual data. They say that in a
21 study using the uniform data system from
22 nursing homes in five states that Blacks or

1 African-Americans were significantly less
2 likely to receive antithrombotic therapy.
3 They adjusted for a variety of covariates and
4 found they were 80 percent as likely as Whites
5 to receive that therapy.

6 MEMBER WADDY: And also, I believe that
7 there is evidence as well in regard to that
8 there is an underuse of antithrombotics in
9 stroke in those patients, but I will have to
10 go through really quickly the data that is
11 presented here.

12 MEMBER KAPLITT: Right. It is true that
13 I think there is reasonable data presented
14 that there are disparities in use, but that is
15 not what the measure is, right? We don't know
16 what that use disparity is due to. Nursing
17 home residents may have disparities because
18 different groups go to different quality level
19 of nursing homes, and some are much better at
20 executing than others. It may have nothing to
21 do with whether there is a disparity in
22 discharge prescription, which is what is being

1 measured here.

2 So, I don't personally find the data on
3 general disparities as relevant to what is
4 being asked here.

5 MEMBER COONEY: And also, this measure
6 does not in any way tell us whether we are
7 making improvements in those areas of
8 disparity because it doesn't measure those
9 elements. It doesn't measure race. It
10 doesn't measure sex. It doesn't measure
11 location.

12 CO-CHAIR TIRSCHWELL: I have a question
13 for the developer. This is a Joint Commission
14 measure. Does the Joint Commission have any
15 specific data on disparities? I think the
16 answer is -- it is not in the report as far as
17 I know.

18 MS. KOLBUSZ: We do address it in
19 another section, that and the performance gap
20 for the disparities section, but we do not
21 collect data on disparities for any of the
22 measures at this point.

1 CO-CHAIR TIRSCHWELL: So, there is
2 evidence of more global disparities. But, as
3 far as this measure being collected by The
4 Joint Commission, there is no evidence
5 presented of disparities? Does anybody
6 disagree with that?

7 MEMBER KAPLITT: Well, no. It is just
8 that, in anticipation of Lee making the same
9 argument he made on the last one, that maybe
10 we should not -- whatever it is called --
11 reserve this because it would be nice to at
12 least know. If you are not going to collect
13 the data, then that argument would be harder
14 to buy, right?

15 DR. SCHWAMM: Yes, I mean, I think the
16 only other point I would make is that there is
17 data published two years ago in Get With The
18 Guidelines looking at disparities in the
19 prescription of antithrombotic therapy at 48
20 hours and at discharge that suggest that
21 African-American patients, even after
22 adjusting for site-level characteristics that

1 included the percentage of minority patients
2 cared for at those sites, still had systematic
3 reductions in the use of those therapies. So,
4 we do have some evidence in hospitals, which
5 includes Joint Commission hospitals, but that
6 is not Joint Commission data that was
7 submitted with this application. It is cited,
8 but it is not --

9 MEMBER KAPLITT: But if there is no
10 evidence in the disparity in the actual
11 prescribing of it, couldn't that argue --

12 DR. SCHWAMM: No, there is evidence.

13 MEMBER KAPLITT: But I thought you said
14 the evidence was that, despite all that, there
15 is evidence of a disparity in use afterwards?

16 DR. SCHWAMM: No, no, this is all about
17 hospital-based prescribing. It is all
18 relevant to these measures. My point --

19 MEMBER KAPLITT: So, there is actually
20 a gap in hospital-based prescribing upon
21 discharge, and there is data for that. We
22 just don't have it?

1 DR. SCHWAMM: Right. So, the gap is
2 that there is a differential use among
3 minority patients. So, there is a
4 differential performance there -- we do know
5 that -- even though overall performance is
6 high.

7 CO-CHAIR TIRSCHWELL: Right, and that is
8 sort of indirectly supportive of the
9 disparity, not exactly, in The Joint
10 Commission measure, but largely overlapping,
11 we would assume?

12 DR. SCHWAMM: Correct.

13 MEMBER KAPLITT: Well, okay. I mean, I
14 am not understanding because this isn't use.
15 This is prescribed, right? You are saying
16 there is data -- I just want to be clear.

17 Because I could make the argument that,
18 if the data showed that the prescribing was
19 equivalent but the use wasn't, that this is an
20 irrelevant measure.

21 DR. SCHWAMM: We don't have any data in
22 Get With The Guidelines on use after

1 discharge.

2 MEMBER KAPLITT: Okay. So, this is
3 specifically talking about prescribing, not
4 use, that there is disparity, that there is
5 data on disparities?

6 DR. SCHWAMM: Exactly.

7 MEMBER KAPLITT: Okay.

8 DR. SCHWAMM: I mean, there was also
9 data on use, but that is not the scope of
10 this.

11 MEMBER KAPLITT: Right. Okay.

12 CO-CHAIR TIRSCHWELL: Jack?

13 MEMBER SCARIANO: I think that what Mike
14 was just asking the actual same question. If
15 you just write for them or if you just tell
16 them how many people get it, there is a cost
17 factor. Also, patients worry about bruising.

18 I mean, in my clinical practice, I see
19 in the Medicaid population probably only about
20 half of them get it. Aspirin at, say, Walmart
21 costs, it is about \$10 a bottle for just one
22 month's worth of 81 milligrams. So, a whole

1 lot of them can't afford it.

2 CO-CHAIR TIRSCHWELL: I mean, that is an
3 important issue and use after discharge is, of
4 course, where the rubber hits the road, but it
5 is not what is being measured here. So, I
6 don't think we can tackle that issue today.

7 Any other comments about the performance
8 gap? Gail?

9 MEMBER COONEY: I don't know if this is
10 where it belongs, but they do make the comment
11 that there is no evidence that either higher
12 aspirin dose or any other antiplatelet regime
13 was more effective than low-dose aspirin. If
14 we are trying to increase compliance, I mean,
15 could we just measure why people didn't get
16 aspirin, aspirin unless otherwise specified,
17 and make this more useful?

18 CO-CHAIR TIRSCHWELL: I guess I am not
19 sure how that addresses the performance gap
20 question.

21 MEMBER COONEY: It doesn't. Never mind.
22 Yes.

1 MEMBER SCARIANO: Well, actually, 81-
2 milligram aspirin is a whole lot higher than
3 just regular aspirin.

4 CO-CHAIR TIRSCHWELL: Price-wise?

5 MEMBER SCARIANO: Right.

6 CO-CHAIR TIRSCHWELL: Yes. Okay.

7 Extraneous issues.

8 So, you know, I think we have to vote on
9 whether we think there is a performance gap
10 specifically about the prescription at
11 discharge, not the use after.

12 And let's go ahead and open the voting.

13 DR. BURSTIN: And just to be clear,
14 performance gap includes variation between
15 providers or populations, just to be clear.

16 MEMBER KAPINOS: But it actually goes in
17 the opposite direction. Maybe in the future
18 you should break it into two subgroups, right?
19 Because if you have a low-performance gap with
20 a lot of them compliant, but disparity, then
21 you don't know how to vote on that item.

22 (Vote taken.)

1 MS. THEBERGE: We are at 20 votes.
2 Five high, 11 moderate, 5 low, 1
3 insufficient.

4 CO-CHAIR TIRSCHWELL: Okay. So, we will
5 proceed along. We are on 2a, reliability.

6 MEMBER COONEY: Thank you. I wasn't
7 turned on (referring to the microphone).

8 Again, there is the comment about
9 confusing presentation of the reliability
10 data. That is the same issue with the
11 formatting. But, in general, the data was in
12 agreement as The Joint Commission has been
13 presenting their data. And that is with the
14 individual elements.

15 CO-CHAIR TIRSCHWELL: Any other comments
16 or questions about reliability?

17 (No response.)

18 So, we will go ahead and open up the
19 voting.

20 (Vote taken.)

21 MS. THEBERGE: Eighteen high, 4
22 moderate.

1 CO-CHAIR TIRSCHWELL: 2b, validity.

2 MEMBER COONEY: Again, the validity was
3 originally assessed by a survey, and The Joint
4 Commission also has ongoing validity testing
5 based on consumer-use feedback.

6 CO-CHAIR TIRSCHWELL: Any other comments
7 or questions about validity? Risha?

8 MEMBER GIDWANI: In this measure, and in
9 other measure specifications, it notes that
10 the face validity has been tested in previous
11 surveys. In the future, it would be very
12 useful if we could actually see the results of
13 the original surveys as opposed to having that
14 sentence only.

15 CO-CHAIR TIRSCHWELL: Noted.

16 Any other comments or questions?

17 (No response.)

18 Let's go ahead and vote on validity.

19 (Vote taken.)

20 MS. THEBERGE: Fifteen high, 7 moderate.

21 CO-CHAIR TIRSCHWELL: Okay. Moving on
22 to -- what is it, feasibility? -- no,

1 usability.

2 MEMBER COONEY: Under usability, the
3 data is available on The Joint Commission
4 website, and is also used for maintaining
5 their primary stroke center designation.

6 And then, the question came up as to how
7 usable is it if there is no performance gap.

8 CO-CHAIR TIRSCHWELL: Right.

9 Questions or comments? Risha?

10 MEMBER GIDWANI: I will ask the same
11 question I did before. And that is whether
12 the CMS Meaningful Use specifications are the
13 exact same as The Joint Commission's
14 specifications.

15 MS. WATT: The answer is the same
16 answer. They are intended to be, but they
17 have not been tested.

18 CO-CHAIR TIRSCHWELL: Any other comments
19 or questions?

20 (No response.)

21 Let's go ahead and vote, then, on
22 usability.

1 (Vote taken.)

2 MS. THEBERGE: Fourteen high, 8
3 moderate.

4 CO-CHAIR TIRSCHWELL: And then, finally,
5 feasibility.

6 MEMBER COONEY: Many of these elements,
7 all these elements are generated during care
8 process. Many of them are captured in
9 electronic data, but, generally, they require
10 paper as well. But they are already in use
11 successfully.

12 CO-CHAIR TIRSCHWELL: Any other comments
13 or questions about feasibility?

14 (No response.)

15 Let's go ahead and vote then.

16 (Vote taken.)

17 MS. THEBERGE: Fifteen high, 7 moderate.

18 CO-CHAIR TIRSCHWELL: And then, finally,
19 overall suitability for endorsement. Any
20 questions or comments before we vote on that?

21 MEMBER COONEY: You know, I think this
22 comes up to the same questions we dealt with

1 on the last one of an ongoing measure with
2 higher performance.

3 CO-CHAIR TIRSCHWELL: So, the only thing
4 you are suggesting might mitigate your
5 endorsement might be the high performance --

6 MEMBER COONEY: Correct.

7 CO-CHAIR TIRSCHWELL: -- that already
8 exists?

9 Anything else?

10 (No response.)

11 So, let's go ahead and vote, then, for
12 overall suitability.

13 (Vote taken.)

14 MS. THEBERGE: We are at 20. We are
15 still short two votes.

16 CO-CHAIR TIRSCHWELL: Will everybody
17 vote again?

18 MS. THEBERGE: Can everyone vote one
19 more time? You do have to point it at me for
20 the receiver to pick up. All right. There we
21 go.

22 Twenty-one yes, 1 no.

1 CO-CHAIR TIRSCHWELL: Okay.

2 DR. BURSTIN: Just one point?

3 CO-CHAIR TIRSCHWELL: Yes, please.

4 DR. BURSTIN: So, part of the work we
5 also do at NQF around disparities is trying to
6 identify which measures are disparity-
7 sensitive, primarily based on the impact, the
8 gap in care, compared to non-disparity
9 populations. And so, this just seems like,
10 particularly from the perspective of The Joint
11 Commission, a measure that would likely be
12 designated as disparity-sensitive.

13 So, there are ways, I would hope, both
14 with Get With The Guidelines as well as Joint
15 Commission, to begin collecting the data, to
16 be able to stratify it. It would certainly be
17 required by the time of maintenance.

18 MS. WATT: Good point, and thank you.

19 Up until now, and even as we speak, we
20 have not had the opportunity to look at
21 disparities particularly based on race and
22 ethnicity because these are not general data

1 elements that have been collected.

2 But we are adding them to our
3 specifications now going forward. And so,
4 because there is always a lag time, I think it
5 is probably going to be a year before we start
6 getting data on them. But, yes, we are
7 working on it. Thank you.

8 DR. SCHWAMM: And just to clarify, the
9 Get With The Guidelines has collected race and
10 ethnicity data using the Census 2000
11 recommendations. We have just moved to adopt
12 as an optional data element the more diverse
13 race classifications underneath Asian and some
14 of the other minority designations. So, we
15 are hopeful that we would be able to provide
16 a very high level of specificity around
17 undertreated populations.

18 CO-CHAIR TIRSCHWELL: Salina?

19 MEMBER WADDY: So, I was wondering how
20 does NQF plan to address that? I mean, none
21 of your elements are really specific to
22 disparities. So, for example, within this

1 question and the last one, whether or not it
2 would go in reserve, it might go on reserve
3 for the general population, but it may be of
4 value for specific populations. And so, is
5 there an opportunity to make that
6 recommendation to you?

7 DR. BURSTIN: So, just to be clear, we
8 would not put something on reserve status
9 where there are known disparities, because gap
10 refers to either a total gap or a gap for
11 different populations. So, we would actually
12 see that as something that would not move
13 something onto reserve.

14 That is why I added that point about its
15 being --

16 MEMBER WADDY: Right. No, that is
17 actually why I initially brought up --

18 DR. BURSTIN: Right.

19 MEMBER WADDY: -- the point, when I was
20 thinking about --

21 DR. BURSTIN: Absolutely.

22 MEMBER WADDY: -- to why we may consider

1 putting something on reserve status --

2 DR. BURSTIN: Right.

3 MEMBER WADDY: -- but also may consider
4 not putting it on.

5 DR. BURSTIN: So, we currently have a
6 Disparities Committee that has been going
7 through and trying to really codify exactly
8 how we will determine measures that are
9 disparity-sensitive.

10 And what we will do prospectively,
11 probably beginning in about six months, is
12 have every committee go through an exercise
13 after you say suitable for endorsement to
14 indicate whether or not it should be
15 disparity-sensitive and always recommended to
16 be stratified.

17 So, we have done a retrospective
18 analysis of about 400 measures that the
19 Committee is working through, but really doing
20 this prospectively with the data on
21 maintenance from the actual measures is really
22 how you want to do it.

1 MEMBER WADDY: And I did want to mention
2 just one more thing really quickly. I did go
3 look back through the articles that are listed
4 under the disparities section. They do list
5 some of the articles. It is not purely
6 whether or not a patient decides to take a
7 medication or not, but there are differences
8 as to whether or not physicians actually
9 prescribe the medications. Those are within
10 some of the articles, particularly in the
11 REGARDS articles that are listed.

12 CO-CHAIR TIRSCHWELL: Thank you for
13 those comments.

14 CO-CHAIR KNOWLTON: Okay. We are moving
15 on to 0325. And David is presenting.

16 CO-CHAIR TIRSCHWELL: Yes. So, this is
17 a similar measure. It is also called
18 "Discharged on Antithrombotic Therapy," but
19 there are a couple of differences compared to
20 the previous measure.

21 One of the differences is that in the
22 denominator of this measure it includes not

1 only patients with a diagnosis of ischemic
2 stroke, but also with a discharge diagnosis of
3 TIA.

4 And another big difference is that, as
5 opposed to The Joint Commission measure, which
6 was a facility-based measure, this one has the
7 level of analysis being the clinician. But,
8 otherwise, in intent and purpose, it is highly
9 similar.

10 So, then, just going to impact, I think
11 the Work Group was unanimous in endorsing a
12 high level of impact.

13 Anybody want to make any comments? Or
14 shall we just proceed to voting?

15 Sorry, Salina, go ahead.

16 MEMBER WADDY: I think this also
17 includes rehabilitation, right, performance
18 indicators within the rehabilitation center?
19 And there can be a lot of differences between
20 patients, what their discharge medications
21 versus they receive in rehab versus what they
22 receive in the outpatient setting that can be

1 really important.

2 But, I have been trying to go through
3 that really quickly right before vote. So, I
4 just think it is an important indicator if it
5 also captures that element as well.

6 CO-CHAIR TIRSCHWELL: So, you are
7 pointing out that rehab inpatients would also
8 be captured under this measure where --

9 MEMBER WADDY: Yes, at least within the
10 measure title it includes the stroke and
11 stroke rehabilitation. So, I am just trying
12 to understand what the setting exactly is. Is
13 this also within a rehab setting; whereas, the
14 other is discharged from the hospital?

15 CO-CHAIR TIRSCHWELL: I think it is
16 possible that all of the AMA measures are
17 called "stroke and stroke rehabilitation".

18 CO-CHAIR KNOWLTON: Yes, let's ask the
19 developer what they --

20 MEMBER WADDY: So, this doesn't -- sorry
21 about that. Go ahead.

22 MS. JOSEPH: So, the measure is actually

1 only in the inpatient hospital setting.

2 MEMBER WADDY: Okay.

3 MS. JOSEPH: The title "stroke and
4 stroke rehabilitation," just for your
5 knowledge, is the title of our actual whole
6 enter performance measurement set.

7 MEMBER WADDY: Okay.

8 CO-CHAIR TIRSCHWELL: Okay.

9 MEMBER WADDY: Then, never mind.

10 CO-CHAIR KNOWLTON: Then, are we ready
11 for impact?

12 (No response.)

13 Vote, please.

14 (Vote taken.)

15 Okay.

16 MS. THEBERGE: Twenty-two high.

17 CO-CHAIR KNOWLTON: Okay. Evidence,
18 Dave?

19 CO-CHAIR TIRSCHWELL: So, evidence,
20 again, was really the same evidence that has
21 been presented for all of the other measures
22 related to the effectiveness of antithrombotic

1 therapy in the prevention of subsequent
2 vascular events. And so, it met with really
3 pretty universal acceptance.

4 I should say, yes, I don't have anything
5 to add.

6 CO-CHAIR KNOWLTON: Anybody have
7 anything to add?

8 DR. BURSTIN: This measure also includes
9 TIA, in addition to stroke. So, it is not the
10 same patient population; it is broader.

11 DR. WINKLER: Right, and so, the
12 question is, is the evidence equivalent for
13 both of those groups?

14 CO-CHAIR KNOWLTON: Anything further?

15 CO-CHAIR TIRSCHWELL: Nothing further
16 from me.

17 CO-CHAIR KNOWLTON: Any questions from
18 the group?

19 (No response.)

20 Okay. Let's vote.

21 (Vote taken.)

22 MS. THEBERGE: Nineteen yes, 3 no.

1 CO-CHAIR KNOWLTON: Performance gap.

2 CO-CHAIR TIRSCHWELL: So, performance
3 gap, this was quite different than the
4 previous measure. Despite the fact that The
5 Joint Commission showed extremely high levels
6 of compliance, this performance gap as
7 presented suggested a number of very high
8 rates of non-compliance.

9 At one point, they quote 53 percent of
10 the patients did not meet the measure. In
11 other places, it says that more recent data
12 suggested 80-plus percent compliance. So,
13 there is certainly a mismatch between what
14 these guys are measuring, whether it is at the
15 clinician level. I am not sure what the
16 difference is, what explains that big gap in
17 why they are seeming like there is a big gap
18 here and not at the facility level.

19 I guess, if it is okay with the Chair,
20 I would ask the developer if they have any
21 comments on that.

22 CO-CHAIR KNOWLTON: Sure.

1 MS. JOSEPH: Sure. So, the performance
2 gap data that we have included is actually
3 from the PQRS program. And again, as you
4 stated earlier, this is at the physician level
5 of measurement.

6 So, the data that we included shows that
7 in 2008 the performance gap was 53.03 percent;
8 in 2009, 85.1 percent, which shows a great
9 improvement, and then, 2010 was 82.8 percent.
10 And that is the most recent data we have from
11 the PQRS program.

12 CO-CHAIR TIRSCHWELL: And again, I
13 don't understand -- it sounds like a huge gap
14 to me, but --

15 MEMBER WADDY: Yes. Do you have any
16 evidence as to whether or not it is because
17 you included the TIAs, and some of these TIAs
18 were more spells rather than clear-cut TIAs
19 without ABCD-squared scored or anything?

20 MS. JOSEPH: We do not have that
21 information.

22 MEMBER WADDY: And maybe they didn't

1 treat those?

2 MS. JOSEPH: We don't have the
3 information with regard to the cause and why
4 the performance rate is what it is in the PQRS
5 program.

6 CO-CHAIR TIRSCHWELL: So, I mean, in
7 contrast to The Joint Commission measure, the
8 data, as presented, suggests a large
9 performance gap.

10 DR. BURSTIN: It is probably worth
11 looking at the 2009-2010 data, which is more
12 like 85 percent, rather than the --

13 CO-CHAIR TIRSCHWELL: Still, relatively
14 speaking, that is pretty large.

15 CO-CHAIR KNOWLTON: Go ahead, Amy.

16 MEMBER BARRETT: I would make a comment
17 that this is physician-level data. So, these
18 would be people practicing, presumably,
19 physicians practicing in all kinds of
20 settings, right, stroke centers and other
21 centers as well?

22 CO-CHAIR TIRSCHWELL: Thank you.

1 CO-CHAIR KNOWLTON: Mary?

2 CO-CHAIR TIRSCHWELL: The same comment?
3 Michael?

4 MEMBER KAPLITT: Can you just clarify at
5 least for us -- I mean, I understand where the
6 data came from -- but how you generated this?
7 What exactly are you defining as a performance
8 gap within this data? This is confidential
9 data. So, the question is, what is your
10 measure?

11 MS. JOSEPH: Sorry. The 2008 data is
12 confidential. The 2009-2010 data is not
13 confidential. It is actually posted on the
14 CMS/PQRS website.

15 The way that the 2008 data is presented,
16 it is by percentile, exactly as we dropped it
17 into the form. So, the way they report it,
18 there is a gap in care shown by this data as
19 53.03 percent of patients reported on did not
20 meet the measure. All we have is the
21 performance rate to report.

22 CO-CHAIR KNOWLTON: You have got to use

1 your microphone, please.

2 MEMBER SCARIANO: Yes, is this based on
3 actually what you found in the hospital charts
4 or is it like an actual questionnaire that
5 someone fills out?

6 MS. JOSEPH: The PQRS system is
7 currently a volunteer reporting program. And
8 so, for the 2009 and 2010 Patient Experience
9 Report that is cited here to support that
10 data, it said that about 24 percent of
11 eligible professionals participated in 2010.
12 And so, the performance rates may not be
13 nationally-representative.

14 MEMBER SCARIANO: Well, that is a
15 question on this point. So, I mean, we
16 haven't gotten to that point, but, presumably,
17 their exclusions or exceptions, or whatever
18 you guys define, are those the same as what
19 PQRS defines? Do you know? Is PQRS simply
20 measuring did you do it or didn't you;
21 whereas, you guys have all kinds of
22 exceptions, in which case, then, the

1 performance gap would be very different?

2 MS. JOSEPH: So, the PQRS program, also,
3 we do have the exception rates that are
4 reported as well as the performance rates in
5 the PQRS program, and they are the same.

6 CO-CHAIR KNOWLTON: Any other thoughts,
7 questions, comments on this?

8 (No response.)

9 Anything to add, David?

10 CO-CHAIR TIRSCHWELL: No.

11 CO-CHAIR KNOWLTON: Okay. Let's vote on
12 the performance gap then.

13 (Vote taken.)

14 MS. THEBERGE: We have 13 high, 6
15 moderate, and 3 insufficient.

16 CO-CHAIR KNOWLTON: Okay. So, let's go
17 on to reliability.

18 CO-CHAIR TIRSCHWELL: So, for
19 reliability, it seems the same dataset as was
20 used for the facility-level reliability
21 earlier was used for this clinical-level
22 reliability analysis here. And they did chart

1 re-abstractation, and the kappa statistics were
2 very high. So, it seems like there is pretty
3 good evidence that this information is being
4 reliably-obtained as far as the evidence
5 presented.

6 CO-CHAIR KNOWLTON: Questions or
7 comments? Greg?

8 MEMBER KAPINOS: But that is where we
9 had the issues about the TIA definition,
10 right? That would be impacting the
11 reliability, correct? Or should we keep that
12 coming for a little bit later?

13 CO-CHAIR TIRSCHWELL: I think the
14 reliability refers to whether what they are
15 getting first-pass from the charts is then
16 recreated by an independent abstractor getting
17 a second-pass. So, they are sort of
18 identifying the patients already. It doesn't
19 really address the reliability of the
20 diagnosis of the TIA or ischemic stroke.

21 CO-CHAIR KNOWLTON: Therese?

22 MEMBER RICHMOND: Can I just go back?

1 So, it is the same dataset that is being used,
2 but here it is called the clinician level, and
3 previously it was called the facility level.
4 So, I am confused in terms of what I am
5 looking at. Could somebody clarify that for
6 me?

7 CO-CHAIR KNOWLTON: Developer? Did you
8 have a question?

9 MS. HANLEY: Hello?

10 So, yes, this is the same dataset. This
11 was tested at the physician level. There are
12 four sites. Again, we don't report out
13 performance rates by site. However, this is
14 reported at the physician level. It is an
15 inpatient measure, though.

16 CO-CHAIR KNOWLTON: Go on with your
17 question, Therese.

18 MEMBER RICHMOND: I am not sure how else
19 to ask it. When I look at the data sample, it
20 looks identical to me. So, I just want to
21 verify that, from the same sample, sometimes
22 it is reported at the provider level and

1 sometimes it is reported at the facility
2 level? It just does not seem logical, I guess
3 is where I am.

4 CO-CHAIR TIRSCHWELL: I think I might be
5 able to partially address that. I think it
6 says in a couple of different places that this
7 reliability testing was done at the element
8 level. So, they were looking at the
9 reliability of the data elements. And then,
10 sort of the logic of how it falls out, whether
11 it is facility level or clinician level, is
12 sort of subsequent to the reliability of the
13 assessment of the individual data elements.

14 And so, I think that is how they were
15 able to use the same dataset, because they
16 were really just looking at individual item
17 reliability. And you know, there are 20 items
18 that go into the logic for each one of these
19 things. It was just the reliability of the
20 individual items that they were assessing. Is
21 that correct?

22 MS. HANLEY: It really comes down to how

1 the measure results are aggregate.

2 CO-CHAIR KNOWLTON: Any other questions
3 on reliability?

4 (No response.)

5 Okay. Let's vote.

6 (Vote taken.)

7 MS. THEBERGE: We need one more vote.

8 Tied at 11 high and 11 moderate.

9 CO-CHAIR KNOWLTON: Validity?

10 CO-CHAIR TIRSCHWELL: So, validity --
11 and this is, in the form it has the same face-
12 validity evaluation that the others do where
13 the experts voted on whether they thought it
14 was a valid measure. You know, they strongly
15 agreed in most cases and a few just agreed
16 without strength. But that was the data
17 presented.

18 CO-CHAIR KNOWLTON: Jolynn, you had a
19 comment on this issue?

20 MEMBER SUKO: Yes, I am really struck by
21 the difference between this and The Joint
22 Commission measure, considering that even with

1 the TIAs, we are measuring, essentially,
2 similar concepts.

3 And I know the PQRS program has two
4 different methods for measure submission, one
5 which is a database method, which is, I think,
6 based largely on chart abstraction, and one
7 which is a super-bill method. At least that
8 is the way it was two years ago; it may have
9 changed.

10 And I am wondering, has there been any
11 testing done to compare these data? I mean,
12 is it a function of how we are submitting
13 these data that we are getting such what
14 appear to be differences in our impact on
15 this?

16 I mean based upon this face validity, I
17 am having a really hard time understanding the
18 differences.

19 CO-CHAIR KNOWLTON: Do you want to
20 comment or will I go to the developer?
21 Developer, do you want to comment on that?

22 MS. HANLEY: Sure. So, CMS it the

1 primary implementer of this measure. And you
2 are correct, you can either report through a
3 claims-reporting mechanism, where the
4 individual physician reports whether or not it
5 was prescribed or whether or not there is a
6 valid exception for that patient, or they can
7 work with a registry that actually works with
8 the practice, for the individual physician to
9 aggregate the results and report the aggregate
10 results on behalf of CMS.

11 MEMBER SUKO: So, to me, that begs a
12 question of, in your testing, are you testing
13 that claims-based method against the actual
14 chart?

15 MS. HANLEY: The answer to that question
16 is, yes, when we could. There are four of the
17 measures that we were able to do parallel
18 forms of reliability and do that comparison.

19 For this one -- give me one moment to
20 find my place here -- this site was actually
21 not submitting on this measure. So, we
22 weren't able to perform that test.

1 CO-CHAIR TIRSCHWELL: So, I would just
2 add that somebody on the Work Group call
3 brought up whether the low performance could
4 just be related to non-documentation in claims
5 data or something along those lines,
6 artifactual of the data collection, as opposed
7 to a true performance gap. And it sounds like
8 it is not specifically answered for this
9 performance measure.

10 And I mean, we are talking about
11 validity now, and 2b.1 there says,
12 "specifications consistent with evidence".
13 So, I think it is appropriate to bring up the
14 TIA question again and see. It seems like
15 there were some feelings about whether that
16 should be included or not, and at least there
17 was some comment about trying to harmonize it
18 a little bit, which I think I am not supposed
19 to say until later in the day, but with the
20 other measures that don't include TIA.

21 Does anybody want to comment about the
22 applicability of TIA?

1 CO-CHAIR KNOWLTON: Anybody have a
2 comment on that? Oh, I didn't see it. I'm
3 sorry. Salina?

4 MEMBER WADDY: So, I think what would be
5 potentially helpful is if you had two separate
6 measures, one that was simply stroke and then
7 one that was simply TIA, instead of just this
8 stroke and then stroke plus TIA, if you really
9 wanted to know how people with TIAs are
10 actually being treated.

11 CO-CHAIR KNOWLTON: Anybody else? Dan?

12 MEMBER LABOVITZ: I am one of the Work
13 Group members with feelings.

14 (Laughter.)

15 I have actually done some work on
16 diagnosis of TIA. The validity of the
17 diagnosis is widely known to be problematic.
18 What I have been seeing is wide ranges of
19 ratio of TIA to TIA-plus-infarct across
20 institutions, between states, between
21 hospitals that have neurology house staff and
22 those that don't.

1 You also have a problem with billers who
2 will look for any mention of TIA and then that
3 becomes the diagnosis. If somebody writes,
4 "Rule out TIA," that generates a lot more
5 money than carpal tunnel. So, it is a
6 problem, but it is a problem that I think
7 needs to be fixed.

8 But I think if we don't measure TIA, if
9 we don't include it, and if we don't hold
10 hospitals' feet to the fire, we will never fix
11 it. I think TIA, if we abandon it, will
12 remain a garbage pail forever.

13 CO-CHAIR TIRSCHWELL: And I would just
14 reiterate that point. I think that is a great
15 point.

16 If, in fact, the billers are somewhat
17 inappropriately moving the TIA to the primary
18 diagnosis, when in fact the clinicians really
19 didn't think so -- and God knows that
20 clinicians have nothing to do with the
21 discharge coding, as far as I can tell -- then
22 this would theoretically identify those

1 hospitals, and they would suddenly be
2 performing lower on this measure. And then,
3 it would all come around the horn and,
4 hopefully, improve that issue.

5 CO-CHAIR KNOWLTON: Salina?

6 MEMBER WADDY: I definitely agree with
7 that point, but I do think it is important to
8 be able to tease apart those two things. That
9 is why I think having a separate measure for
10 TIA that is just as rigorous and emphasizes it
11 just as much would be important.

12 MEMBER COONEY: This is not, as I
13 understand it, a facility-based measure. So,
14 I don't think it is going to tell us anything
15 about how a hospital's data abstractors
16 recognize or don't recognize TIA, because this
17 is coming off physician claim forms.

18 CO-CHAIR TIRSCHWELL: I guess it depends
19 upon how your physicians generate their bills
20 and all sorts of variations, although, yes,
21 well, that is a good point.

22 MEMBER KAPINOS: Actually, about that,

1 like teach me something like -- I was told,
2 and I am a junior attending, and for my first
3 year of billing, actually, subarachnoid
4 hemorrhage, when you have vasospasm, I bill
5 actually exactly the code of a TIA, I was
6 told, for vasospasm-induced. So, it is
7 transient or sometimes permanent, but not
8 necessarily resulting in an infarct. It is
9 ischemia due to vasospasm after a subarach.

10 So, I may be participating greatly in
11 that big mess.

12 (Laughter.)

13 So, is there another code?

14 CO-CHAIR TIRSCHWELL: So, for your
15 inpatient strokes, I am sure that your primary
16 diagnosis is a subarachnoid hemorrhage which
17 has got to reimburse at a DRG rate much higher
18 than a TIA.

19 You know, that is all speculation, and
20 it is probably not the main point here.

21 CO-CHAIR KNOWLTON: Do you have a point?

22 DR. BURSTIN: Yes, I would just make a

1 point. So, it does appear, though, that the
2 denominator is still based on a hospital
3 discharge ICD-9 code. So, that is still the
4 denominator; is that correct? It appears to
5 be.

6 And if so, one potential option would be
7 that you could recommend that the measure have
8 two rates as part of it, one for stroke, one
9 for TIA.

10 DR. DROZDA: This is Joe Drozda. Could
11 I say something? I am one of the measure
12 developers?

13 CO-CHAIR TIRSCHWELL: Yes, please go
14 ahead.

15 DR. DROZDA: Yes, I am Co-Chair of the
16 PCPI Work Group. We developed this measure.

17 As far as the two measures go, I am
18 finding myself taking the opposite side of an
19 argument that we had during discussion of the
20 chronic coronary artery disease measures where
21 there were two measures up for consideration.
22 I believe this was an aspirin measure, and I

1 think our chronic coronary disease measure set
2 called for the denominator to be patients with
3 chronic coronary disease. And there was a
4 competing measure that had the denominator as
5 patients with ischemic vascular disease of all
6 types.

7 And ultimately, the broader measure was
8 chosen because of NQF's desire or principle to
9 go for broader populations rather than
10 narrower populations. We find ourselves going
11 the other direction here where we have
12 actually put in this measure a broader
13 population.

14 So, I think what I am asking for is some
15 sort of consideration of consistency across
16 measure sets, because I rather eloquently made
17 the argument that was just made for dicing out
18 patients with coronary disease previously and
19 lost that argument. So, I am a little bit
20 personally conflicted, but I think we are
21 trying to be consistent here and choose the
22 broader population.

1 DR. BURSTIN: And, Joe, this is Helen.

2 Just to respond, I completely understand
3 your point. And our preference, obviously, is
4 that measures should be as broad as the
5 evidence is appropriate. And so, in this
6 case, it has already passed through the
7 evidence category with a clear sweep that it
8 is fine to include both stroke and TIA. The
9 only questions, I think, were up to validity.
10 If there are concerns about the validity of
11 the coding of TIA, then you want to be able
12 to, in fact, see those differences.

13 I think the broad population is great.
14 The question is, is it possible to just report
15 two rates?

16 DR. DROZDA: And if we find ourselves
17 arguing over validity of coding, I mean I
18 don't if we will ever be able to get any
19 measures through because we run into that
20 everywhere. We have to rely on the validity
21 of the coding. How else can we do this?

22 CO-CHAIR KNOWLTON: Dan?

1 MEMBER LABOVITZ: I am feeling
2 everybody's pain.

3 (Laughter.)

4 I think validity of coding is a problem,
5 congestive heart failure perhaps the worst
6 area. We suffer in a lot of places. But it
7 is possible to make it better.

8 I work with our billers. We go back and
9 forth. Every diagnosis gets reviewed.

10 And I think hospitals will be pressured
11 because we are using hospital data, even if it
12 is individual private providers doing it, we
13 are using hospital ICD-9 codes, I think
14 hospitals are going to be pushed to perform
15 better in deciding, yes, that really wasn't a
16 TIA. They have a financial incentive right
17 now to diagnose it every time possible. Now
18 they are going to have another incentive to
19 perhaps dial back a bit.

20 DR. DROZDA: And I really like that
21 argument. I resonate with that strongly. And
22 I think that is even true at the physician

1 coding level, if there are concerns about
2 that. I think this puts discipline in coding.

3 CO-CHAIR TIRSCHWELL: Bill, go ahead.

4 MEMBER BARSAN: Yes, that idea of
5 splitting these out, making them be reported
6 separately, is great. When does that happen?
7 I mean, do you go all the way through the
8 process and then it comes out later as a
9 recommendation? Or where does that, how do
10 you do that?

11 DR. BURSTIN: Some of that could just be
12 a recommendation that you would potentially
13 make to the developer. Again, we are probably
14 getting a little bit ahead of ourselves. You
15 guys raised the issues of harmonization to The
16 Joint Commission measure. This might be
17 something best saved for later when we talk
18 about comparability to the other measure.

19 CO-CHAIR KNOWLTON: Yes, are we ready to
20 vote on validity?

21 (No response.)

22 Okay.

1 (Vote taken.)

2 MS. THEBERGE: We have 9 high, 7
3 moderate, and 6 low.

4 CO-CHAIR KNOWLTON: Okay. So, now we
5 move on to usability.

6 CO-CHAIR TIRSCHWELL: Usability in the
7 Work Group, there was a little bit of mixed
8 feeling about it, but no strong objections at
9 all. And I don't have any particular reason
10 to argue against it.

11 CO-CHAIR KNOWLTON: Anybody else have a
12 comment in this arena?

13 (No response.)

14 Okay. Let's vote on usability.

15 Oh, yes, Salina? Sorry.

16 MEMBER WADDY: I think that the
17 usability question gets back to the same topic
18 that we were discussing regarding the
19 inclusion of TIA, how do you define the TIA,
20 how important or how really clean that
21 definition is within the hospital system
22 setting and ICD-9 coding.

1 CO-CHAIR KNOWLTON: Dan, is that a
2 residual card up on your desk or --

3 MEMBER LABOVITZ: Yes.

4 CO-CHAIR KNOWLTON: Okay.

5 MEMBER LABOVITZ: I was enjoying all the
6 attention.

7 (Laughter.)

8 CO-CHAIR KNOWLTON: Anything else?

9 (No response.)

10 Let's vote on usability.

11 (Vote taken.)

12 MS. THEBERGE: Twelve high, 8 moderate,
13 2 low.

14 CO-CHAIR KNOWLTON: Okay. Feasibility.

15 CO-CHAIR TIRSCHWELL: Again, not much to
16 report here. I mean, it has been used. It
17 has been collected. It seems feasible.

18 We had some discussion in our Work Group
19 -- I don't know if it was this one or one of
20 the other PCPI ones -- about claims, that it
21 is all in the electronic health record, and
22 there was some ambiguity around that. But I

1 think at the end it could be implemented
2 electronically.

3 CO-CHAIR KNOWLTON: Yes, Risha?

4 MEMBER GIDWANI: I see in the measure
5 specifications that there is both ICD-9 or
6 ICD-10 codes as well as CPT codes for the
7 denominator. I am just not really familiar
8 with, do physicians have access to both or is
9 it generally that they have the CPT codes and
10 the hospital has the ICD-9 codes?

11 CO-CHAIR KNOWLTON: Helen, can you
12 answer her question, so she can hear you?

13 DR. BURSTIN: Well, I mean, the
14 clinician has access to both, but the hospital
15 would have ICD-9. CPT is uniquely, my
16 understanding, outpatient.

17 CO-CHAIR KNOWLTON: Any other questions
18 on feasibility?

19 (No response.)

20 Okay. Let's vote.

21 (Vote taken.)

22 MS. THEBERGE: Fifteen high, 7 moderate.

1 CO-CHAIR KNOWLTON: Okay. And we move
2 on to overall suitability for endorsement.
3 David?

4 CO-CHAIR TIRSCHWELL: I don't have
5 anything further to add. It was unanimously
6 approved in the Work Group.

7 CO-CHAIR KNOWLTON: Other thoughts?

8 (No response.)

9 Okay. Let's vote.

10 (Vote taken.)

11 MS. THEBERGE: Twenty yes, 2 no.

12 CO-CHAIR KNOWLTON: Okay.

13 CO-CHAIR TIRSCHWELL: All right. We
14 have to jump out of order a little bit because
15 one of the developers needs to leave. So, I
16 think it is 2017 that we have to do next. So,
17 we are going to temporarily skip over 0439.

18 And so, 2017, Ramon, can you --

19 MEMBER R. BAUTISTA: Yes. Thank you,
20 Mr. Chairman.

21 Yes, we are going to be discussing the
22 use of CT scans and MRI reports. So, the

1 study numerator is the final report of initial
2 CT scan or MRI that includes documentation of
3 the presence or absence of each of the
4 following, hemorrhage, mass lesion, and/or
5 acute infarction, while the denominator are
6 all the final reports of CT scans and MRIs of
7 the brain performed either in the hospital 24
8 hours of arrival or in the outpatient imaging
9 center to confirm diagnosis of stroke, TIA, or
10 intracranial hemorrhage for patients more than
11 18 years or older with a diagnosis of ischemic
12 stroke or TIA or intracerebral hemorrhage.

13 There was a healthy discussion during
14 the Work Group. So, I may need the help down
15 the line of my colleagues from radiology,
16 stroke, and maybe even the non-neurologists in
17 the group.

18 There were three Committee members who
19 actually evaluated this during our Work Group
20 meeting. We were looking at the impact of 1a.
21 There was one high, one medium, and one low
22 score.

1 And I think part of the reason was there
2 was maybe at that point a little bit of an
3 uncertainty if we were actually looking at
4 importance of the measure or scientific
5 acceptability.

6 Some of the comments given, though, were
7 that while stroke affects large amounts of
8 people, the link between neuroimaging and
9 being able to improve outcomes was not well-
10 established. Some people in the group felt
11 that we are not sure if the issue was the lack
12 of documentation or the lack of actual imaging
13 that took place. That wasn't really clear in
14 the initial measure. So, that was how that
15 turned out.

16 CO-CHAIR TIRSCHWELL: Anybody want to
17 comment on the impact? Salina?

18 MEMBER WADDY: I just have a question to
19 the people who developed the measure, why mass
20 lesion was included.

21 CO-CHAIR TIRSCHWELL: Is the developer
22 here?

1 DR. SEIDENWURM: Yes, sure.

2 CO-CHAIR TIRSCHWELL: Go ahead.

3 DR. SEIDENWURM: The reason we included
4 that is for two reasons. Mass lesion was one
5 of the exclusions in the NINDS trial and,
6 also, the secondary analysis of the ECASS and
7 the follow-on ECASS showed that the presence
8 of mass effect was a predictor of adverse
9 outcome from t-PA administration. So, that is
10 why we included that.

11 MEMBER WADDY: So, is it mass effect and
12 not necessarily mass lesion? Is that what you
13 were asked?

14 DR. SEIDENWURM: Well, both.

15 MEMBER WADDY: So, it could be a brain
16 tumor?

17 DR. SEIDENWURM: Yes, that is a
18 contraindication to the administration of
19 t-PA.

20 CO-CHAIR TIRSCHWELL: It seems to me a
21 lot of what drove some of the contents -- and
22 correct me if I am wrong -- is sort of

1 contraindications to IV t-PA and imaging
2 reports. And so, I think those were some of
3 the other things that could imitate an acute
4 stroke, although I would hope a slow-growing
5 brain tumor wouldn't mimic an acute stroke,
6 but there are times when they bleed, or
7 whatever.

8 Bill?

9 MEMBER BARSAN: Yes, I am just curious,
10 I mean, if this is supposed to get back to
11 something to do with t-PA treatment, my
12 experience is usually the radiology readings
13 come up hours or days after you have treated
14 somebody with thrombolytic therapy, and it is
15 really of no value to the person actually
16 doing the treatment. I mean, you rarely, if
17 ever, get a read by that. I mean, what is the
18 point? I'm not sure.

19 Does the developer want to respond to
20 that? Or, actually, why don't we let Dr.
21 Hackney respond first?

22 MEMBER HACKNEY: Well, I agree that I am

1 not enthusiastic about this as a measure, but
2 if you are a stroke center, you are not
3 supposed to be generating your reports hours
4 and days after the study is done.

5 But the concern I have is what
6 difference it makes. It matters whether you
7 have a mass lesion, for example, and that is
8 correctly diagnosed. But I don't think it
9 matters whether you say that there isn't one
10 when it is true that there isn't one if you
11 said the study is normal. Without saying
12 anything specifically about mass lesion, you
13 would have conveyed the same information. So,
14 I am not sure that it makes sense as a
15 performance measure. We have our residents do
16 it to remind them of what they are looking
17 for, but not because we think it has any
18 influence on patient care.

19 CO-CHAIR TIRSCHWELL: And I think that
20 is a great point. I would have one other
21 comment about the specifications, but it is
22 sort of an overall question.

1 They also say that they are including
2 patients with one documented symptom
3 consistent with ischemic stroke or TIA or
4 intracerebral hemorrhage. And I guess I have
5 no idea how you even identify who the people
6 are that had one of the symptoms for that.
7 Can the developer comment on that?

8 DR. SEIDENWURM: Well, there are two
9 questions that have been asked. I will
10 address the first one, and then staff will
11 take the second.

12 With respect to the need for the correct
13 documentation, I think the point that we are
14 getting at here is a clear and unambiguous
15 interpretation of a CT or MRI scan that can be
16 relied upon rapidly in the emergency room.
17 And it is particularly in settings where there
18 aren't residents, where there aren't stroke
19 teams, where there might be an emergency room
20 doctor with telephone neurology backup or no
21 neurology backup.

22 So, the point is to remove the

1 uncertainties from the reporting of the CT
2 scans and to encourage timely reporting of
3 these necessary data elements. So, I think
4 that is what we are getting at here. That is
5 the nexus between this type of a performance
6 measure and the improvement in stroke care.

7 MS. HANLEY: And to the point about the
8 symptoms, as Dr. Seidenwurm mentioned, the
9 focus is to address these areas on the report,
10 which is just as important to do if the
11 patient actually has a stroke or a hemorrhage
12 as if they don't. And so, it includes those
13 CTs or MRIs for patients who come in with
14 symptoms that might be suggestive of stroke,
15 but aren't actually, then, diagnosed within
16 the time --

17 CO-CHAIR TIRSCHWELL: And I apologize.
18 I don't have the details. So, you are saying
19 that the denominator is defined by the
20 symptoms that are written on the top of the
21 radiology report?

22 MS. HANLEY: The denominator is defined

1 with the procedure, CT or MRI, and then those
2 studies that either have a final diagnosis of
3 stroke or hemorrhage or TIA, but, also, for
4 those, essentially, they are the negative
5 finding reports. So, where perhaps the
6 findings are inconclusive and --

7 CO-CHAIR TIRSCHWELL: Well, it says you
8 are including people that had a symptom
9 suggestive of a stroke. How do you identify
10 those patients?

11 DR. SEIDENWURM: Perhaps I think I
12 understand the spirit of your question. What
13 you are concerned about is that this casts too
14 wide a net perhaps in the scans that are
15 included in the measure. I think that that
16 perhaps is a valid criticism, but I think one
17 prefers to cast too wide of a net than a net
18 that is not wide enough in this setting.

19 CO-CHAIR TIRSCHWELL: Bill?

20 MEMBER BARSAN: Yes, you spoke to
21 something about the timeliness of the study,
22 so it would be useful to clinicians in places

1 where they don't have house staff or stroke
2 teams, or whatever. There is nothing in this
3 measure that says anything about timeliness.
4 I mean, it counts just as much if it was
5 reported within 30 minutes as within 30 days.

6 CO-CHAIR TIRSCHWELL: Risha?

7 MEMBER GIDWANI: Well, I have sort of
8 the same concern as Bill. The timeframe that
9 is noted here is that the CT or MRI report is
10 within 24 hours of hospital arrival. So,
11 could the developers speak to how this is
12 reconciled with their desire to have timely
13 treatment for stroke?

14 DR. SEIDENWURM: Yes. I think the
15 intent here was to capture the first one. We
16 don't have always a very good ability to
17 capture the timing of some of these things.
18 There was also a problem of crossing from day
19 to day and some things like that that we were
20 addressing.

21 CO-CHAIR TIRSCHWELL: Gail?

22 MEMBER COONEY: I am just confused as to

1 whether you are measuring whether that report
2 is there at the time of discharge or whether
3 you have got a way of knowing when that report
4 hit the clinician.

5 DR. SEIDENWURM: This performance
6 measure does not address the issue of timing
7 except for the 24 hours to try to get at the
8 first scan.

9 You know, we are taking this one step at
10 a time. We would like to address that issue
11 at some point, but at this exact moment we are
12 addressing the content of the report, and
13 timing is a separate topic for another day
14 perhaps.

15 CO-CHAIR TIRSCHWELL: Dan? And then,
16 Ramon.

17 MEMBER LABOVITZ: I think the radiology
18 report is a very poor place to try to look for
19 a diagnosis. As it is constructed now, this
20 measure is asking my radiologists to make the
21 diagnosis of TIA or not. They are not good at
22 that.

1 It also has a problem in that it is
2 looking for intracranial hemorrhage. So, that
3 includes subdural hematomas, traumatic
4 hemorrhages, subarachnoid. What are we really
5 going for here?

6 CO-CHAIR TIRSCHWELL: Do you want to
7 respond?

8 DR. SEIDENWURM: Well, each of the
9 hemorrhagic conditions that you named are
10 equally contraindications for the
11 administration of t-PA, I think. So, I think
12 that would be the reason to be inclusive.

13 CO-CHAIR TIRSCHWELL: Wait. Ramon?

14 MEMBER RICHMOND: They are also
15 accounting for non-stroke presentations like
16 MS exacerbations, for example, or Todd's
17 paralysis. I mean, this blows your
18 denominator beyond recognition in a way it
19 makes no sense.

20 CO-CHAIR TIRSCHWELL: Okay. Greg? And
21 then, Michael.

22 MEMBER KAPINOS: Yes. So, it sounds

1 like you tried to implicate more the
2 radiologist into the hyper-acute treatment.
3 But 24 hours, as we said, that is not
4 adequate. So, if the real goal is to get
5 radiologists to do a report for t-PA, then it
6 should be within three hours. You should be
7 at the console doing the report, the same
8 stroke neurologists are reading on time, and
9 the majority of radiologists are not doing
10 that at all, even at the very good centers.
11 So, I think it is useless to incorporate this
12 measure.

13 CO-CHAIR KNOWLTON: David was first,
14 actually. Sorry.

15 CO-CHAIR TIRSCHWELL: Okay. I think the
16 problem we are struggling with is that this
17 measure is really defined on the wording that
18 is used in the report essentially, what
19 findings are declared to be present or absent.
20 It is taking any report, the report of the
21 first study done on such a patient, if it was
22 done with 24 hours, and people have pointed

1 out that you don't really -- I mean, that is
2 a heterogenous group that includes people who
3 are in a treatment window which you care about
4 and people who are far outside one that for
5 this it doesn't seem to make much difference.

6 But my basic concern is it assumes that
7 even the interpretation of their symptoms is
8 static. It assumed by going through and
9 looking at their charts, you get an idea of,
10 you decide which patients presented with the
11 symptoms that would include them. That is not
12 necessarily what their symptoms were perceived
13 to be at the time the study was ordered, which
14 was the basis for their radiological
15 interpretation, so you could get down-scored,
16 because at the time you read the study you
17 didn't know that was what people thought was
18 going on. And the same problems that were
19 already mentioned about figuring out who is in
20 and who is out.

21 I guess I am just having trouble. It
22 looks like it is an awkward attempt. I think

1 the idea of trying to make sure you are
2 getting an appropriate interpretation in a
3 timely manner is a good idea, but it looks
4 like some of these problems have led it off
5 the track, and to get back on, I think you
6 would have to narrow the focus to the people
7 who are in a treatment window and come up with
8 practical answers to these other problems
9 about who that is and what you are really
10 measuring, which isn't so much the wording of
11 the report, but the accuracy and timeliness of
12 the information.

13 CO-CHAIR KNOWLTON: Michael?

14 MEMBER KAPLITT: So, let me just ask the
15 developer very directly: the numerator
16 statement says "Final reports of the initial
17 CT or MRI that include documentation of the
18 presence or absence" of these things. So,
19 just clarify for me. The CT scan is done
20 within 24 hours. The report comes back a week
21 later and says that there was a documented
22 infarct. That counts in the numerator, is

1 that correct?

2 Yes? You are nodding? Yes? Okay.

3 DR. SEIDENWURM: Yes.

4 MEMBER KAPLITT: Okay. Tell me how that
5 changes practice or improves stroke care.

6 DR. SEIDENWURM: Sure. It is rather
7 similar to the argument that was made about
8 coding. There is enormous pressure in the
9 system to have your preliminary report and
10 your final report match with respect to
11 content. So, the data element that we chose
12 was the final report. Because the preliminary
13 report and all these other things appear in a
14 lot of different places, in different charting
15 mechanisms, in different communication
16 schemes, in different institutions. So, in
17 order to have reproducible data elements, we
18 chose that.

19 Now there are other imperatives in
20 medical care to have the preliminary report
21 and the final report match. So, it is rather
22 analogous to the argument that was made

1 earlier with respect to coding.

2 MEMBER KAPLITT: With all due respect,
3 I mean, you are telling me about matching
4 reports, but maybe I am the only one here who
5 is not understanding, but, again, I don't
6 understand how that affects stroke treatment
7 or practice. How a report that is a week
8 later which may be more accurate data, how it
9 is actually affecting practice?

10 CO-CHAIR TIRSCHWELL: Doesn't it suggest
11 that the report has to be finalized within 24
12 hours, not a week later?

13 PARTICIPANT: If I could just clear
14 something up --

15 CO-CHAIR TIRSCHWELL: Sure.

16 PARTICIPANT: -- the operand of
17 documenting hemorrhage and mass lesion and
18 acute infarction is the critical part. So,
19 presence or absence, and they have to document
20 all of those three. So, in the final report,
21 sometimes it might say "no hemorrhage," but it
22 doesn't mention mass lesion or acute

1 infarction. So, language, the presence or
2 absence has to be documented on each of those
3 three elements.

4 And the final reports are of the initial
5 CT. So, if you have a drip-and-ship, somebody
6 gets CT'ed in a rural area and then they get
7 shipped, there may be another CT done, et
8 cetera. So, the wording is carefully crafted
9 to collect all that information.

10 MEMBER KAPLITT: Again, I don't
11 understand, though. Okay, so let's take it to
12 the extreme. So, let's say the final report
13 is six months later. Isn't that included in
14 this numerator statement, unless I am
15 misreading something?

16 DR. SEIDENWURM: Well, of course it
17 would be, but that is a situation that, even
18 in our imperfect system, doesn't happen
19 frequently.

20 CO-CHAIR TIRSCHWELL: Can I just add one
21 more thing? And I really think we should put
22 it to a vote because then we will see what

1 happens.

2 But affecting impact, I think the
3 implication is that I think anybody who has a
4 TIA or a stroke symptom, if they don't get a
5 CT scan, that counts against the facility, is
6 that right, or the physician? It is not just
7 the ones that get the scan? Or is it just the
8 ones that get --

9 DR. SEIDENWURM: This is just the ones
10 that get the scan.

11 CO-CHAIR TIRSCHWELL: Okay.

12 DR. SEIDENWURM: We are requesting that
13 one --

14 CO-CHAIR TIRSCHWELL: All right

15 DR. SEIDENWURM: -- narrow issue.

16 CO-CHAIR TIRSCHWELL: Any last comments?
17 Dave?

18 MEMBER HACKNEY: I agree with Michael's
19 point. It seems to me that the way the
20 numerator is written, it could be a report
21 generated a year from now. But the
22 limitations on the denominator, to take it a

1 step further, mean that you are not
2 necessarily looking at the same populations
3 because the denominator has a restriction that
4 has to be either within 24 hours inpatient or
5 in an outpatient setting. But the numerator
6 does not have any such restriction.

7 MEMBER KAPLITT: No, but the
8 denominator, again, it is only the restriction
9 on when the CT was performed, but the measure
10 is the final report. The denominator places
11 not time restriction on the final report. The
12 restriction is on what the final report is
13 reporting on.

14 MEMBER HACKNEY: Right. But I am saying
15 that --

16 MEMBER KAPLITT: The final report can
17 occur anytime.

18 MEMBER HACKNEY: Right, but it is still
19 not necessarily they don't match. They are
20 not necessarily the same population.

21 CO-CHAIR TIRSCHWELL: Yes, and I think,
22 you know, if the spirit of the measure was to

1 urge comprehensively-worded, timely reports,
2 it doesn't seem like this is what -- this
3 isn't what this measure is forcing people to
4 do.

5 So, I would suggest that we call for a
6 vote on whether there is high impact. Could
7 we do the voting, please?

8 (Vote taken.)

9 MS. THEBERGE: One high, 1 moderate, 15
10 low, 5 insufficient evidence.

11 CO-CHAIR TIRSCHWELL: So, I think that
12 concludes our work on this measure for now.

13 DR. BURSTIN: I just want to let the
14 group know that there was a measure endorsed
15 about a year ago that was head CT or MRI scan
16 results for acute ischemic stroke or
17 hemorrhagic stroke with an interpretation
18 within 45 minutes of arrival. So, that has
19 already been endorsed.

20 MEMBER KAPLITT: That is useful.

21 CO-CHAIR TIRSCHWELL: Can we go back to
22 0439?

1 CO-CHAIR KNOWLTON: 0439 is "Discharged
2 on Statin Medication". Jolynn, I believe you
3 are doing this.

4 CO-CHAIR TIRSCHWELL: Salina wants to
5 make a comment.

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

7 MEMBER WADDY: So, if that was endorsed,
8 if that measure was endorsed a year ago, I
9 mean, will that measure continue going
10 forward? Okay.

11 DR. BURSTIN: It was a measure preferred
12 by CMS. I don't know if they have put it
13 forward for any uses yet. I think there may
14 still be testing.

15 CO-CHAIR KNOWLTON: Jolynn?

16 MEMBER SUKO: Yes, this is discharged on
17 statin medication. This is a measure that was
18 originally endorsed on July 31st, 2008. It
19 includes ischemic stroke patients with LDL
20 greater than or equal to 100 who are on a
21 lipid-lowering medication prior to arrival,
22 who are prescribed statin medication at

1 hospital discharge. And the denominator is
2 ischemic patients with an LDL greater to or
3 equal to 100 or LDL not measured or who were
4 on lipid-lowering medication prior to hospital
5 arrival.

6 The Work Group, on impact, there was
7 general agreement important to measure.
8 Again, this is a similar theme to some of our
9 others discharged on antithrombotics in the
10 sense that we have a very high performance
11 rate around this. But, again, the Work Group,
12 six rated it high, one medium.

13 CO-CHAIR KNOWLTON: Questions or
14 comments?

15 (No response.)

16 Seeing none, let's vote.

17 (Vote taken.)

18 MS. THEBERGE: We need one more vote.
19 Or somebody stepped away.

20 Nineteen high, 1 moderate, 1 low.

21 CO-CHAIR KNOWLTON: Okay. Jolynn,
22 evidence?

1 MEMBER SUKO: Evidence, yes, this was
2 unanimously seen as having high evidence
3 behind it by the Work Group, not much further
4 discussion.

5 CO-CHAIR KNOWLTON: Any discussion here?

6 MEMBER J. BAUTISTA: Well, don't the
7 Work Group scores reflect medium for quality
8 or moderate for quality?

9 MEMBER SUKO: Oh, sorry.

10 CO-CHAIR KNOWLTON: I don't know who is
11 talking. I can't hear --

12 MEMBER KAPINOS: So, can somebody
13 explain again the criteria for how many RCTs
14 do we need to vote for?

15 DR. BURSTIN: It is also in your Quick
16 Guide at your table, if you would like. So,
17 it specifically says for quantity, for high,
18 it is five-plus; moderate, two to four; low,
19 one. But you also have this sheet in front of
20 you.

21 CO-CHAIR KNOWLTON: Any comments on
22 evidence?

1 CO-CHAIR TIRSCHWELL: You know, I guess
2 I would comment that, although the SPARCL
3 study is the dominant theme here, there are
4 other large statin trials that had a subset
5 that had already had a stroke who also seemed
6 to benefit from it. So, I think, in my
7 opinion, there is more than one study that
8 shows the benefit here.

9 CO-CHAIR KNOWLTON: Anybody else?

10 (No response.)

11 Okay. Let's vote.

12 (Vote taken.)

13 MS. THEBERGE: We are still short one
14 response.

15 All right, can everyone vote one more
16 time?

17 Somebody stepped away?

18 Nineteen yes, 2 no.

19 CO-CHAIR KNOWLTON: Okay. Performance
20 gap.

21 MEMBER SUKO: Like in our discussion
22 around discharge on antithrombotics, this

1 performance is very, very high for this
2 measure. There is some evidence that there
3 are disparities in minority populations.

4 The Committee rated this four high and
5 three medium.

6 CO-CHAIR KNOWLTON: Comments?

7 (No response.)

8 Okay. Let's vote.

9 (Vote taken.)

10 MS. THEBERGE: Ten high, 10 moderate, 2
11 low.

12 CO-CHAIR KNOWLTON: Okay. Scientific
13 acceptability, starting with reliability.

14 MEMBER SUKO: Reliability, six rates
15 this as high, one medium. And I think the
16 medium rating was based largely on
17 presentation of the data.

18 CO-CHAIR KNOWLTON: Comments?

19 Questions?

20 (No response.)

21 Let's vote.

22 (Vote taken.)

1 MS. THEBERGE: Nineteen high, 3
2 moderate.

3 CO-CHAIR KNOWLTON: Validity?

4 MEMBER SUKO: A similar theme for
5 reliability (sic), six voted high, one voted
6 moderate.

7 CO-CHAIR KNOWLTON: This is validity,
8 right?

9 MEMBER SUKO: Yes.

10 CO-CHAIR KNOWLTON: Okay. Questions or
11 comments?

12 (No response.)

13 Okay. Let's vote.

14 Oh, I'm sorry. Salina?

15 MEMBER WADDY: I do agree with the
16 comment that was made by the group regarding
17 which patients really we should be talking
18 about. I mean, there is some evidence that
19 globally stroke patients may benefit, but they
20 did make the comment regarding atrial
21 fibrillation, cardioembolic stroke, and the
22 subarachnoid hemorrhage patients.

1 Is that going to be teased out in some
2 way or is it just globally all stroke patients
3 who should receive the statin?

4 CO-CHAIR TIRSCHWELL: Well, in the
5 numerator it says ischemic stroke. So, I
6 think that removes the subarachnoid hemorrhage
7 patients from the group pretty rapidly.

8 And then, you know, my own personal
9 opinion about the atrial fibrillation is that,
10 if you meet the other criteria for the
11 measure, she should probably be on a statin
12 anyway, although --

13 MEMBER WADDY: No, I agree with that as
14 well. But, in terms of the evidence that is
15 really out there, I mean, that is a bit of a
16 more controversial topic.

17 MEMBER BARSAN: There are also
18 dissections that fit into there, too, and
19 stop. So, if you had a dissection and you
20 don't measure cholesterol, you get dinged if
21 you don't start them on a statin.

22 DR. SCHWAMM: David, can I just clarify?

1 CO-CHAIR TIRSCHWELL: Sure.

2 DR. SCHWAMM: So, in the measure logic,
3 patients who have a documented reason for not
4 having an indication for statins are
5 eliminated from the denominator. So, if you
6 wrote in the record, "quad-dissection, no
7 atherosclerosis, no indication for statin,"
8 you would be excluded from the measure.

9 So, the only way you would get,
10 quote/unquote, "dinged" is if you didn't
11 document any reason why statin wasn't
12 considered and simply discharged the patient.

13 CO-CHAIR TIRSCHWELL: Anything else?

14 MEMBER KAPINOS: We will have to really
15 like create some templates. Once those
16 measures are implemented, yes, there will be
17 a great need for templates for clinicians to
18 be matching all those like sets of -- it
19 becomes so convoluted not to just follow your
20 pathway as a clinician, but just to match all
21 those like --

22 CO-CHAIR TIRSCHWELL: So, Greg, I am not

1 sure where you are practicing, but these are
2 already implemented, and the templates already
3 exist in most cases. So, you are absolutely
4 right, and it gets to, are we doing what is
5 right for the patient? We then also have to
6 document that we are doing what is right for
7 the patient. That is just an inherent burden
8 in this whole quality measure phenomena.

9 MEMBER KAPINOS: Oh, patient did not
10 have an MI. That is why I didn't give him --
11 I mean, did not have MS and did not have --

12 CO-CHAIR TIRSCHWELL: Don't give them
13 any ideas.

14 CO-CHAIR KNOWLTON: Other comments?
15 Salina?

16 MEMBER WADDY: I mean, to me, it seems
17 simpler to at least list the ones that have
18 the strongest evidence. If they have
19 intracranial stenosis, extracranial stenosis,
20 rather than parsing out which people may think
21 lacunar strokes should or should not -- it
22 just gets to be very --

1 CO-CHAIR TIRSCHWELL: So, I guess if you
2 are getting to ischemic stroke subtypes, other
3 than the a-fib, which is pretty clean, whether
4 somebody else has an atherothrombotic ischemic
5 stroke or not, and then relying -- in many
6 cases, it is some sort of person in the QI
7 department who is trying to figure this out.
8 I think it is a real setup for problems.

9 CO-CHAIR KNOWLTON: Okay. Anything
10 else?

11 (No response.)

12 On some of these things, the issues are
13 interesting, but they don't speak to the
14 measure that is before us. You know, they are
15 suggestions that we might make for later.

16 Other thoughts on this?

17 (No response.)

18 Then, let's vote. This is on validity.

19 (Vote taken.)

20 MS. THEBERGE: We need one more vote.

21 Twelve high, 9 moderate, 1 low.

22 CO-CHAIR KNOWLTON: Okay. Usability.

1 MEMBER SUKO: So the subgroup
2 unanimously ranked this as high. And I would
3 note that this has been in practice and
4 undergone cycles of improvement for at least
5 three years.

6 CO-CHAIR KNOWLTON: Burning issues?

7 (No response.)

8 Okay. Let's vote.

9 (Vote taken.)

10 MS. THEBERGE: Twenty-one high, 1
11 moderate.

12 CO-CHAIR KNOWLTON: Feasibility.

13 MEMBER SUKO: Again, similar to
14 usability, this has been in place for quite
15 some time. It was ranked very high by the
16 subgroup.

17 CO-CHAIR KNOWLTON: Comments?

18 (No response.)

19 Okay. Let's vote.

20 (Vote taken.)

21 MS. THEBERGE: One more vote.

22 Twenty high, 1 moderate, 1 low.

1 CO-CHAIR KNOWLTON: And overall
2 suitability for endorsement.

3 MEMBER SUKO: So, the subgroup
4 unanimously recommended this for endorsement.

5 CO-CHAIR KNOWLTON: Comments?

6 (No response.)

7 Okay. Let's go.

8 (Vote taken.)

9 MS. THEBERGE: All right. Twenty.
10 Still at 21. Okay.

11 Twenty-one yes, 1 no.

12 CO-CHAIR KNOWLTON: Okay. According to
13 my agenda, we should now have lunch.

14 (Laughter.)

15 Just saying. Just saying.

16 CO-CHAIR TIRSCHWELL: All right. We are
17 going to plug right along, and I guess now we
18 are on Stroke Measure No. 1 from The Joint
19 Commission, Venous Thromboembolism.

20 And, Jocelyn, are you going to start us
21 off?

22 MEMBER J. BAUTISTA: Okay. So, this

1 measure is titled, "Venous Thromboembolism
2 Prophylaxis". And it is meant to capture
3 those patients with ischemic or hemorrhagic
4 stroke who either receive VTE prophylaxis or
5 have documentation of why prophylaxis was not
6 given by the second hospital day.

7 So, the numerator is as mentioned, and
8 the denominator is all ischemic or hemorrhagic
9 stroke patients 18 years of age and older,
10 between a length of stay of 2 and 120 days,
11 and they have exclusions as listed.

12 And they define receive VTE prophylaxis
13 as either pharmacological or mechanical. And
14 under mechanical, they include IPCs,
15 intermittent pneumatic compression devices, as
16 well as venous foot pumps. But they did not
17 include the TED hose compression hose.

18 And in order to meet the measure, you
19 simply have to document that it was given for
20 the first time by the second hospital day.

21 And also to meet the measure, if there
22 is documentation of why not VTE prophylaxis

1 was given by a licensed provider, that is also
2 considered a pass.

3 Patient refusal is acceptable as a
4 reason for not giving.

5 CO-CHAIR TIRSCHWELL: Do you want to
6 comment on impact?

7 MEMBER J. BAUTISTA: Okay. So, impact.
8 I think the Work Group, five rated it as high,
9 one moderate. Stroke, I believe per the
10 measure submission document, PE is seen in
11 about 1 percent of stroke patients, DVT in a
12 higher percentage, and VTE prophylaxis reduces
13 PE by 50 percent, 50 to 70 percent.

14 CO-CHAIR TIRSCHWELL: Anybody want to
15 comment on impact?

16 (No response.)

17 Okay. Let's go ahead and vote.

18 Wait. Wait for the timer. Okay, now
19 vote.

20 (Vote taken.)

21 MS. THEBERGE: Seventeen high, 5
22 moderate.

1 CO-CHAIR TIRSCHWELL: Okay. Moving on
2 to evidence -- Greg, go ahead.

3 MEMBER KAPINOS: Why did we lump
4 together the pharmacological and the
5 mechanical devices? Because, actually, for
6 the timeliness issue, we could actually
7 separate those two and say that there
8 shouldn't be any reason not to apply at least
9 the mechanical devices on day one, and then,
10 actually, the pharmacological one on day two.

11 So, by lumping it together, when we know
12 that there is definitely more risk of
13 hemorrhagic complication with the
14 pharmacological one, I am scared that, then,
15 you could become compliant by just, oh, now it
16 is day two after a stroke; we need to think
17 about applying those compression devices and
18 starting the hep subQ. To me, that is not the
19 best practice. It is to start with the
20 compression devices and, then, think about the
21 pharmacological one.

22 CO-CHAIR TIRSCHWELL: Risha?

1 MEMBER GIDWANI: In reviewing the
2 evidence, it looks as though, based off of the
3 data the developers presented, that the actual
4 mechanical prophylaxis was not found to reduce
5 VTE, but the low-molecular-weight heparin was.
6 So, why are those not be differentiated?

7 CO-CHAIR TIRSCHWELL: Does the developer
8 want to comment on that?

9 DR. SCHWAMM: Sure. I will take the
10 first comment.

11 I just want to call your attention to
12 the fact that this measure is actually for all
13 stroke patients, not just ischemic stroke
14 patients, in line with the previous comments
15 about having the largest applicable
16 population.

17 And for many patients with hemorrhagic
18 stroke, low-molecular-weight heparin or other
19 anticoagulants are contraindicated, at least
20 in the first several days after the event.

21 And so, the effort here is to ensure
22 that appropriate therapy is being initiated in

1 all patients by the second hospital day. So,
2 I think that is the emphasis here. Rather
3 than just segregating out a smaller
4 denominator who would be eligible for chemical
5 prophylaxis, the decision was made to
6 incorporate a larger denominator.

7 CO-CHAIR TIRSCHWELL: And I would just
8 comment that the way the days are coded, it is
9 possible that you could be admitted at 11:59
10 p.m., and you would be on your second hospital
11 day two minutes later. And so, we thought we
12 should give them at least two minutes to get
13 the DVT prophylaxis going.

14 (Laughter.)

15 So, I think that is why it is not a one-
16 day thing. If there was a way to accurately
17 account for within 24 hours, maybe that would
18 be preferable, but it doesn't seem like that
19 is easily implemented.

20 Risha, go ahead.

21 MEMBER GIDWANI: I am sorry. I am not
22 a clinician. So, maybe that is where my lack

1 of understanding stems from. But when I see
2 a sentence that says that "Graduated
3 compression stockings were not found to reduce
4 VTE risk or death within the first seven days
5 post-stroke," I am wondering, and then, in
6 light of the comment that you just made, I am
7 wondering, is it potentially, then, more
8 reasonable to talk about doing
9 chemoprophylaxis in a smaller group of
10 patients?

11 DR. SCHWAMM: So, maybe just to clarify,
12 graduated compression stockings, also called
13 TED hose, are not sufficient for DVT
14 prophylaxis. Pneumatic compression devices or
15 sequential compression devices -- pneumoboots
16 is what they are often called -- are
17 considered appropriate. So, actually, the
18 stockings alone do not give you credit for
19 this measure, even though in the broader
20 hospital-based VTE prophylaxis measure, which
21 includes all sorts of patients at very low
22 risk for VTE, for those patients, stockings

1 alone would be sufficient. So, I think that
2 is the piece that distinguishes this.

3 CO-CHAIR TIRSCHWELL: Any other comments
4 about evidence? Questions?

5 MEMBER J. BAUTISTA: Yes.

6 CO-CHAIR TIRSCHWELL: Jocelyn?

7 MEMBER J. BAUTISTA: The measure
8 includes venous foot pumps as a valid
9 prophylaxis. And yet, I didn't see that in
10 the evidence, that venous foot pumps had been
11 demonstrated --

12 CO-CHAIR TIRSCHWELL: I have been
13 practicing for 20 years. I don't even know
14 what a venous foot pump is.

15 (Laughter.)

16 What is a venous foot pump?

17 DR. SCHWAMM: So, I think you see them
18 largely in places like the burn unit. They
19 are essentially intermittent compression
20 devices that don't require application to the
21 entire limb. I think their use is quite rare.
22 But I think they are FDA-approved for use in

1 prevention of VTE prophylaxis, which is
2 probably why they are still listed as
3 acceptable devices.

4 CO-CHAIR TIRSCHWELL: Okay. Thank you
5 for that clarification.

6 Any other comments? Yes, Gwen?

7 MEMBER BUHR: So, the evidence presented
8 here does say that, going back to what Risha
9 was saying, that intermittent compression
10 devices, which is not the TED hose, where it
11 says here "with a non-significant trend toward
12 decreased risk of VTE," but that is non-
13 significant, with no impact on deaths. So, I
14 am still questioning the quality of the
15 evidence here.

16 CO-CHAIR TIRSCHWELL: I mean, my
17 impression is that the evidence is not as
18 strong for SCDs. I don't have much more to
19 add to that.

20 Dr. Schwamm, do you?

21 DR. SCHWAMM: The real question, I
22 think, is in patients who are not eligible for

1 chemoprophylaxis, these appear to be better
2 than no form of treatment.

3 So, I think you are right. I think the
4 evidence for those is somewhat weaker, but I
5 think that it is still important for patients
6 to go with some form of treatment to reduce
7 the risk of DVT/VTE if they can't be treated
8 with chemoprophylaxis.

9 CO-CHAIR TIRSCHWELL: Okay. Let's go
10 ahead and vote, then, please.

11 (Vote taken.)

12 MS. THEBERGE: Fifteen yes, 7 no.

13 CO-CHAIR TIRSCHWELL: Okay. Going back
14 to 1b, evidence of a performance gap.

15 MEMBER J. BAUTISTA: So, the developers
16 note performance of 93 percent for third
17 quarter 2011. They also report another rate
18 of 88 percent for the same time period. And
19 from 2003, the rate increased from 74 to 90
20 percent. So, the Work Group did feel there
21 was a gap.

22 CO-CHAIR TIRSCHWELL: Comments?

1 Questions?

2 (No response.)

3 No? Let's go ahead and -- oh, go ahead,
4 Greg.

5 MEMBER KAPINOS: The gap, if we broke it
6 into a subgroup within pharmacological versus
7 mechanical, it would have been interesting,
8 also, to see.

9 CO-CHAIR TIRSCHWELL: So, there is a
10 suggestion that pharmacological versus
11 chemical (sic) be broken down. For that
12 matter, it would be interesting to look at
13 ischemic versus hemorrhagic as well.

14 Let's go ahead and vote on whether there
15 is a performance gap.

16 (Vote taken.)

17 MS. THEBERGE: Eleven high, 9 moderate,
18 2 low.

19 CO-CHAIR TIRSCHWELL: Okay. Very good.
20 So, I think that means we are moving on to
21 Question 2, scientific acceptability, and
22 starting with reliability.

1 MEMBER J. BAUTISTA: So, reliability was
2 tested at the data-element level only.
3 Otherwise, I don't think there were any
4 specific concerns.

5 CO-CHAIR TIRSCHWELL: Okay. Any
6 questions or comments on reliability?

7 (No response.)

8 Let's go ahead and vote.

9 (Vote taken.)

10 MS. THEBERGE: Fourteen high and 8
11 moderate.

12 CO-CHAIR TIRSCHWELL: Validity, 2b.

13 MEMBER J. BAUTISTA: The Work Group
14 thought, well, half of us thought it was high,
15 the other half moderate validity. Some
16 questioned the exclusions in the measure,
17 which we have already discussed.

18 CO-CHAIR TIRSCHWELL: Okay. So, the
19 question of the exclusions might reflect this
20 vote.

21 Any comments or questions?

22 (No response.)

1 Let's go ahead and vote.

2 (Vote taken.)

3 MS. THEBERGE: Five high, 16 moderate,
4 1 low.

5 CO-CHAIR TIRSCHWELL: All right. Moving
6 on to usability.

7 MEMBER J. BAUTISTA: Yes. So, this
8 measure has been in use. I don't think we had
9 any issues with usability.

10 CO-CHAIR TIRSCHWELL: Comments?
11 Questions?

12 (No response.)

13 Vote.

14 (Vote taken.)

15 MS. THEBERGE: Fifteen high, 7 moderate.

16 CO-CHAIR TIRSCHWELL: Okay, and the
17 second-to-last, feasibility.

18 MEMBER J. BAUTISTA: Yes, similar to
19 most of the other measures, there is a fair
20 amount of abstraction that is required from
21 this measure, but it has been in use for
22 several years now.

1 CO-CHAIR TIRSCHWELL: Let's go ahead and
2 vote if there are no comments.

3 (Vote taken.)

4 MS. THEBERGE: We have 21 votes.

5 CO-CHAIR TIRSCHWELL: Whoever voted
6 early, vote again.

7 Everybody vote one more time, please.
8 Sorry.

9 MS. THEBERGE: Nine high, 12 moderate.

10 CO-CHAIR TIRSCHWELL: And then, finally,
11 overall suitability for endorsement.

12 Any further comments, Jocelyn?

13 MEMBER J. BAUTISTA: No, and we will get
14 to the fact that it overlaps with another
15 measure later, but the group did think it was
16 suitable as stands.

17 CO-CHAIR TIRSCHWELL: Okay. Wait until
18 you see the timer before you vote. Okay, go
19 ahead and vote now.

20 (Vote taken.)

21 There we go.

22 MS. THEBERGE: Twenty-one yes, 1 no.

1 MEMBER KAPINOS: I just realized that,
2 for the first time in those measures, somebody
3 mentioned we have an exclusion about patient
4 refusal. How come patient refusal didn't make
5 it through all the other measures, like
6 patient can refuse t-PA and he can refuse
7 everything?

8 CO-CHAIR TIRSCHWELL: My guess is that
9 many of the other measures that say physician-
10 documented reason for exclusion, you would be
11 able to probably apply that.

12 MEMBER KAPINOS: But why does it stand
13 out in this measure?

14 MEMBER J. BAUTISTA: Because I think it
15 is a real issue with the devices. Patients do
16 refuse the devices because they are
17 uncomfortable.

18 MEMBER KAPINOS: Oh, yes. Okay.

19 CO-CHAIR TIRSCHWELL: Or the shots in
20 the stomach, for that matter.

21 Dr. Schwamm, did you have a final
22 comment?

1 DR. SCHWAMM: No.

2 CO-CHAIR TIRSCHWELL: No? Okay.

3 CO-CHAIR KNOWLTON: Let's move on to
4 0240, Deep Venous Thrombosis Prophylaxis for
5 Ischemic Stroke or Intracranial Hemorrhage.

6 This is maintenance on an original
7 endorsement, and let's see where we are.

8 Jack? You are presenting it?

9 MEMBER SCARIANO: No.

10 CO-CHAIR KNOWLTON: Oh, didn't you
11 present it in the Work Group?

12 Who else is in that Work Group that
13 remembers it?

14 CO-CHAIR TIRSCHWELL: Does anybody
15 remember presenting Measure 0240?

16 CO-CHAIR KNOWLTON: Salina, do you
17 remember that?

18 MEMBER J. BAUTISTA: I remember that
19 Jack was assigned, but he didn't realize he
20 was assigned.

21 CO-CHAIR KNOWLTON: Okay. Well, does
22 anybody want to pick it up or shall we just go

1 through it?

2 (No response.)

3 Okay. This is a measure that was
4 originally endorsed in May of 2007. It is the
5 percentage of patients aged 18 and older with
6 a diagnosis of ischemic stroke or intracranial
7 hemorrhage who are administered DVT
8 prophylaxis by the end of hospital day two.

9 The numerator and denominator statements
10 appear to be straightforward. And the Working
11 Group -- I was not on this Working Group --
12 but the Working Group felt that it had impact:
13 four high, one medium.

14 Anybody want to comment on this? Yes?

15 MEMBER J. BAUTISTA: So, I am in the
16 Work Group. It is very similar to the measure
17 I just presented. So, I could kind of walk
18 through it.

19 This is something I didn't realize when
20 we were discussing it in the Work Group, but
21 patients who have expired during the inpatient
22 stay are excluded from the measure. So, you

1 know, potentially, you have a patient who
2 comes in with an ischemic stroke, develops a
3 DVT/PE, dies a week later, and they are
4 excluded from the measure.

5 CO-CHAIR KNOWLTON: Does this come under
6 bury your mistakes?

7 (Laughter.)

8 Does the developer want to comment on
9 this wrinkle?

10 MEMBER KAPINOS: The other thing is the
11 VTE prophylaxis is a better terminology than
12 DVT because what you are proven to do is not
13 only to prevent DVTs, but PEs. So, actually,
14 the other measure is using a better --

15 CO-CHAIR KNOWLTON: Yes, but let's not
16 harmonize them yet. Let's just go through.
17 It will take you a longer time to do that. We
18 will harmonize.

19 Did the developer demure on the --

20 MS. HANLEY: I mean, I think the
21 exclusion criteria to not include patients who
22 expired is simply more of a methodological one

1 to make sure that we have a more clear-cut
2 denominator.

3 MEMBER J. BAUTISTA: It would make more
4 sense to me to exclude patients who have
5 expired by day two, obviously, but why exclude
6 the others?

7 CO-CHAIR TIRSCHWELL: I am guessing to
8 some degree, but my thought is that a lot of
9 the patients that expire after a stroke, it is
10 often because it was very serious. And I
11 think that is probably what you are referring
12 by saying that they expired by day two. I
13 guess I don't know that there is a guarantee
14 that a severe stroke patient would die by day
15 two.

16 MEMBER J. BAUTISTA: No, I mentioned day
17 two because this is a measure that is measured
18 at day two.

19 CO-CHAIR KNOWLTON: Well, we can vote on
20 whether that impacts the impact statement or
21 whether we want to make it a recommendation to
22 clean up the measure to the measure developer.

1 MEMBER KAPLITT: But it is a good point
2 relative to the impact, because the developer
3 says that part of the impact of this is that
4 10 percent, they say, of stroke deaths are due
5 to PEs, right, which is a significant
6 percentage.

7 CO-CHAIR KNOWLTON: Yes.

8 MEMBER KAPLITT: If you are going to be
9 excluding those patients, it relates to
10 impact. I am just reading from what it says
11 here.

12 CO-CHAIR KNOWLTON: This is also, as I
13 read it -- this is currently being measured,
14 is that correct? Yes? Okay.

15 Other comments on impact for a concern
16 about the expiration of the patient?

17 (No response.)

18 We can't edit the measures.

19 So, anything else?

20 (No response.)

21 Okay. Let's vote on impact.

22 (Vote taken.)

1 MS. THEBERGE: We are still at 21
2 responses.

3 I think the problem may be with the
4 right side of the table. There might be too
5 much stuff in between you and the receiver.

6 Okay. Seven high, 11 moderate, 3 low,
7 1 insufficient evidence.

8 CO-CHAIR KNOWLTON: And we move on.

9 Jocelyn, will you continue to go through
10 this?

11 MEMBER J. BAUTISTA: Sure, sure.

12 CO-CHAIR KNOWLTON: Thank you.

13 MEMBER J. BAUTISTA: So, for the
14 evidence, I think similar issues,
15 pharmacologic prophylaxis is strong evidence,
16 less so for the mechanical devices. But the
17 group overall thought there was sufficient
18 evidence.

19 CO-CHAIR KNOWLTON: Any questions or
20 comments?

21 (No response.)

22 I am going to move through this quickly

1 because it is the same type of issues, unless
2 something emerges that is different.

3 Anything else?

4 (No response.)

5 All right, let's vote.

6 (Vote taken.)

7 Okay, got that.

8 MS. THEBERGE: Seventeen yes, 5 no.

9 CO-CHAIR KNOWLTON: Okay. Performance
10 gap.

11 MEMBER J. BAUTISTA: Right. So, the
12 estimated performance -- current performance
13 is 79 to 84 percent, based on 2009-2010 data.

14 CO-CHAIR KNOWLTON: Questions?

15 (No response.)

16 Vote.

17 (Vote taken.)

18 You right-wingers want to aim carefully
19 over there.

20 MS. THEBERGE: We are still at 21.

21 There we go.

22 Fourteen high, 8 moderate.

1 CO-CHAIR KNOWLTON: Scientific
2 acceptability, reliability.

3 MEMBER J. BAUTISTA: All right. So, two
4 of us voted high, two moderate. No specific
5 comments.

6 CO-CHAIR KNOWLTON: Any comments?

7 (No response.)

8 Okay. Let's vote.

9 (Vote taken.)

10 MS. THEBERGE: Nine high, 13 moderate.

11 CO-CHAIR KNOWLTON: Okay. Validity, I
12 believe. Yes, validity.

13 MEMBER J. BAUTISTA: There was some
14 discussion about exclusions and reasons, but
15 similar to the past discussion.

16 CO-CHAIR KNOWLTON: Comments?

17 (No response.)

18 Vote.

19 (Vote taken.)

20 MS. THEBERGE: Five high, 16 moderate,
21 1 low.

22 CO-CHAIR KNOWLTON: Okay. Usability.

1 MEMBER J. BAUTISTA: So, the measure is
2 in use currently.

3 CO-CHAIR KNOWLTON: Questions?

4 MEMBER J. BAUTISTA: No real issues.

5 CO-CHAIR KNOWLTON: Comments?

6 (No response.)

7 Okay.

8 (Vote taken.)

9 MS. THEBERGE: Fifteen high, 7 moderate.

10 CO-CHAIR KNOWLTON: Okay. Feasibility.

11 MEMBER J. BAUTISTA: Again, there are
12 data-abstraction issues, but no significant
13 concerns.

14 CO-CHAIR KNOWLTON: Okay. Let's vote.

15 (Vote taken.)

16 MS. THEBERGE: Twelve high, 10 moderate.

17 CO-CHAIR KNOWLTON: And suitability for
18 endorsement. There is nothing really to say
19 about it. Let's just vote.

20 (Vote taken.)

21 MS. THEBERGE: Twenty-one high -- I'm
22 sorry -- 21 yes, 1 no.

1 CO-CHAIR TIRSCHWELL: Moving along, the
2 next measure on the docket is Stroke Measure
3 No. 3 from The Joint Commission,
4 Anticoagulation Therapy for A-Fib/Flutter.

5 Fred, do you want to start us off?

6 MEMBER TOLIN: Well, thank you.

7 This is a measure that is already in
8 place. It has been for several years. And as
9 pointed out, it is one of the eight measures
10 used by The Joint Commission.

11 The need for anticoagulation in patients
12 who have non-valvular atrial fibrillation and
13 flutter, the medical evidence is really not
14 very controversial, and the exclusions are
15 relatively straightforward.

16 The only real thing that came up in this
17 was a question of timing in terms of how soon
18 after stroke should the antithrombotic therapy
19 or anticoagulant therapy be initiated. As
20 pointed out on one of the other measures, this
21 is also silent as to the agent used.
22 Traditionally, warfarin, as I think everybody

1 is aware, was the only agent available, but
2 now there are newer agents available. So, it
3 doesn't define which agent is used, just the
4 fact that an anticoagulant is ordered.

5 CO-CHAIR TIRSCHWELL: Right. So, to
6 clarify, aspirin wouldn't count.

7 MEMBER TOLIN: Aspirin would not count.
8 Warfarin or --

9 CO-CHAIR TIRSCHWELL: But the newer
10 agents and warfarin --

11 MEMBER TOLIN: One of the newer drugs
12 would.

13 CO-CHAIR TIRSCHWELL: Yes. And to me,
14 that seems okay.

15 So, any other questions or comments
16 about impact before we vote on impact?

17 (No response.)

18 Let's go ahead and activate the system
19 and now vote.

20 (Vote taken.)

21 MS. THEBERGE: Twenty-one high, 1
22 moderate.

1 CO-CHAIR TIRSCHWELL: Thank you.

2 Moving on to 1c, evidence.

3 MEMBER TOLIN: In the Committee meeting,
4 the vote was three for yes, one for no.

5 The evidence is certainly available and,
6 as I pointed out previously, is not
7 controversial. The only question, again, came
8 up in terms of timing and, also, the agent,
9 the lack of specificity of the agent.

10 CO-CHAIR TIRSCHWELL: Okay. Ramon, you
11 had a comment?

12 MEMBER R. BAUTISTA: Yes. Just for the
13 stroke neurologists here, is this true, 52
14 percent of patients do not meet the measure?
15 Is that correct? So, half the patients with
16 atrial fib do not receive anticoagulation? I
17 mean, I don't know the answer.

18 CO-CHAIR TIRSCHWELL: I think those are
19 some more community-based --

20 MEMBER R. BAUTISTA: That is true,
21 though, huh?

22 CO-CHAIR TIRSCHWELL: -- things, but

1 there's lots of literature suggesting a large
2 gap, not necessarily in hospitalized patients
3 at the time of discharge, but in a broader
4 view, I think, of the effective treatment with
5 atrial fibrillation.

6 And I guess some of those data are
7 older. I am hoping it is not as big a gap
8 these days, but I am not 100 percent sure.

9 As far as the timing issue goes, I guess
10 that speaks to the evidence a little bit or
11 the validity. I agree with raising the
12 question about timing. I don't know that
13 there is -- certainly, long-term, secondary
14 prevention, there is no doubt about the
15 anticoagulation.

16 There was one particular study that
17 showed that in the first two weeks full-dose
18 low-molecular-weight heparin, so
19 anticoagulation, versus just a regular aspirin
20 a day, there was no difference in outcomes at
21 the two-week mark. And in fact, the low-
22 molecular-weight heparin group had more

1 complications. And then, of course, everybody
2 was anticoagulated long-term.

3 So, I often suggest, especially with
4 larger strokes, that we don't start until two
5 weeks after they are discharged. And we are
6 not getting dinged. So, somehow, maybe that
7 is written down as a reason why they are
8 excluded, but I do think it is an issue.

9 Salina?

10 MEMBER WADDY: Actually, there are a
11 couple of other reasons why people don't
12 prescribe or may not prescribe. One is in
13 minority populations there has been a
14 disparity identified, both in the prescription
15 as well as in patients who, for whatever
16 reason, have been told that they had atrial
17 fibrillation and they don't take the
18 medication.

19 But the other major issue is people who
20 have significant deficits who either (a) don't
21 have a family member that can appropriately,
22 a family member or a caretaker to administer

1 coumadin, as well as people who are going on
2 to rehabilitation. There is the concern in
3 some of the physicians that these people may
4 be at fall risks. And so, they will just put
5 them on aspirin instead in the acute period.

6 CO-CHAIR TIRSCHWELL: In the acute
7 period, and those are probably deemed to be
8 valid reasons, as long as you, of course,
9 document that you have done so.

10 So, any other comments on evidence?

11 (No response.)

12 I suggest we activate the voting and go
13 ahead and vote on evidence.

14 (Vote taken.)

15 MS. THEBERGE: Twenty-one yes, 1 no.

16 CO-CHAIR TIRSCHWELL: Okay. Great.

17 And then, back to 1b, performance gap.

18 MEMBER TOLIN: So, in the time period
19 since 2008, when this measure was first
20 initiated or enacted, the actual performance
21 has increased. And so, the performance gap is
22 less than it was previously, and the number we

1 are looking at now is probably somewhere
2 around 95 percent. So, there is not a
3 significant performance gap, which is similar
4 to some of the other measures we have talked
5 about earlier today.

6 CO-CHAIR TIRSCHWELL: Any comments?
7 Questions about that?

8 MEMBER TOLIN: The only other comment,
9 I think it has also been pointed out there is
10 a gap, a bigger gap, in some minority
11 populations. I should point that out also.

12 CO-CHAIR TIRSCHWELL: And there is
13 evidence for that in the literature, although
14 not necessarily as the data presented from the
15 measure itself, from The Joint Commission.
16 They don't have those data. I don't know; Get
17 With The Guidelines probably does, but they
18 are not 100 percent overlap there.

19 MEMBER WADDY: Right. Some of them
20 don't tease out the minority.

21 CO-CHAIR TIRSCHWELL: Yes. Anyway,
22 performance gap, let's go ahead and vote.

1 (Vote taken.)

2 MS. THEBERGE: Eight high, 12 moderate,
3 2 low.

4 CO-CHAIR TIRSCHWELL: So, we proceed
5 along to 2a, which is reliability.

6 MEMBER TOLIN: In Committee, this was
7 all unanimously high in terms of -- I'm sorry
8 -- moderate in terms of reliability, not high.

9 Thank you, Karen. She is giving me that
10 evil eye.

11 (Laughter.)

12 One of the concerns was that some of the
13 exceptions are not exactly well-spelled-out,
14 and there is some inconsistent evidence in the
15 exceptions in the denominator.

16 CO-CHAIR TIRSCHWELL: Does anybody want
17 to comment on the lack of consistency with the
18 evidence?

19 (No response.)

20 No?

21 The comment from the Work Group call,
22 that certain elements only had an 82 or 85

1 percent agreement.

2 MEMBER J. BAUTISTA: The developer
3 commented on that issue. If I remember
4 correctly, the issue was that some of the
5 newer anticoagulants weren't yet on the list,
6 and that caused some confusion among the
7 abstractors.

8 CO-CHAIR TIRSCHWELL: I see. Okay.
9 Fair enough.

10 Any other concerns? Comments?

11 (No response.)

12 Let's go ahead and vote on reliability.

13 (Vote taken.)

14 MS. THEBERGE: Four high, 16 moderate,
15 2 low.

16 CO-CHAIR TIRSCHWELL: Okay. Next is
17 validity.

18 MEMBER TOLIN: And similar statements
19 made about validity.

20 CO-CHAIR TIRSCHWELL: Comments or
21 questions?

22 (No response.)

1 Okay. Let's activate the system and now
2 vote.

3 (Vote taken.)

4 MS. THEBERGE: Eight high, 13 moderate,
5 1 low.

6 CO-CHAIR TIRSCHWELL: Okay. Continue to
7 proceed along. We are up to usability.

8 MEMBER TOLIN: Also, sort of a split
9 feeling in the Work Group meeting about the
10 usability. As I pointed out earlier, this has
11 been in place for several years. It started
12 out not much lower, and there has been some
13 improvement in the percentage of patients who
14 are receiving anticoagulation therapy. But,
15 again, it is already being used.

16 CO-CHAIR TIRSCHWELL: Okay. Salina?

17 MEMBER WADDY: So, I think one of the
18 challenges is not only the treatment of atrial
19 fibrillation. So, this is more of a note to
20 the NQF. It is the actual detection of atrial
21 fibrillation. There is a lot of variability
22 across the country in terms of whether or not

1 people place patients on telemetry, whether or
2 not they just do a quick screening, EKG.

3 And so, you are going to have a huge
4 discrepancy in terms of the number of patients
5 that are actually detected. As well, there
6 was up until about a year ago the assumption
7 that, for example, African-Americans didn't
8 have atrial fibrillation until the ERIC data
9 came out. And so, patients weren't even being
10 screened. There were whole hospital systems
11 that didn't have telemetry access,
12 particularly in underserved communities, as
13 well as in some rural and remote places.

14 So, both of the measures, that I am
15 saying I don't think there is a third measure,
16 is really just on the treatment with
17 anticoagulation, but it really doesn't address
18 the underdiagnosis.

19 CO-CHAIR TIRSCHWELL: I think that is a
20 great point.

21 DR. WINKLER: Just as a comment, these
22 are the kinds of suggestions that we collect

1 from you, because it sounds like there's
2 perhaps another performance measure around
3 screening and diagnosis and identifying
4 appropriate patients.

5 And we do create a recommendation for
6 measure development kind of section that goes
7 along with all your other recommendations.
8 So, I think we can put it in there.

9 CO-CHAIR TIRSCHWELL: Fantastic.

10 Any other comments on usability?

11 (No response.)

12 Let's go ahead and -- oh, yes? Go
13 ahead.

14 MEMBER BARRETT: In the same vein, with
15 regard to public reporting, the issue that was
16 brought up before about rehabilitation and
17 falls and identification of medication
18 adherence is an area for future development,
19 particularly because future medications will
20 not be able to be monitored objectively as
21 well.

22 CO-CHAIR TIRSCHWELL: Okay. Thank you.

1 Any more comments?

2 (No response.)

3 Let's go ahead and vote on usability.

4 (Vote taken.)

5 MS. THEBERGE: We are at 20.

6 Thirteen high, 8 moderate, 1 low.

7 CO-CHAIR TIRSCHWELL: Then, feasibility.

8 MEMBER TOLIN: Again, this is something
9 that is already being used. As Salina pointed
10 out, probably there is some underdiagnosis of
11 some of these things, particularly underlying
12 atrial fibrillation.

13 CO-CHAIR TIRSCHWELL: Any comments on
14 feasibility?

15 (No response.)

16 Let's go ahead and vote.

17 (Vote taken.)

18 MS. THEBERGE: Thirteen high, 9
19 moderate.

20 CO-CHAIR TIRSCHWELL: And then, finally,
21 overall suitability for endorsement. Anybody
22 want to make some comments?

1 MEMBER TOLIN: The only thing, again,
2 this is a measure that is already in place,
3 and it is very similar to one of the other
4 measures which I know we will be discussing
5 later, David.

6 CO-CHAIR TIRSCHWELL: Yes. Let's go
7 ahead and activate the voting. Go ahead and
8 vote.

9 (Vote taken.)

10 MS. THEBERGE: Twenty-two yes.

11 CO-CHAIR TIRSCHWELL: Fabulous.

12 CO-CHAIR KNOWLTON: Moving on to 0241,
13 Stroke and Stroke Rehab, Anticoagulation
14 Therapy Prescribed by Atrial Fib at Discharge.

15 This is clinician level, Reva tells me.

16 It is an original endorsement from May
17 of 2007. So, this is a maintenance action.

18 And Salina?

19 MEMBER WADDY: Sure. Yes. Hi.

20 So, yes, this is already in place and
21 was originally endorsed in 2007. This is
22 different in that the previous atrial

1 fibrillation treatment question was based on
2 the level of the facility; whereas, this one
3 is for the clinician or group practice.

4 And it really is just is to detect the
5 number of patients that are actually treated
6 with anticoagulation who either have TIA or
7 ischemic stroke; whereas, the other measure
8 was purely, I believe, ischemic stroke.

9 Let's see. So, really, there wasn't a
10 whole lot of additional comments beyond that.

11 This adds the TIA as well as the level
12 of the clinician and the group practice.

13 In terms of impact --

14 CO-CHAIR KNOWLTON: Yes.

15 MEMBER WADDY: -- everyone agreed that
16 this was either high- or moderate-level
17 impact.

18 CO-CHAIR KNOWLTON: Questions?

19 Comments?

20 (No response.)

21 Vote.

22 Wait for the little prompt. There you

1 go.

2 (Vote taken.)

3 MS. THEBERGE: We are at 18 responses.

4 All right. We are short one.

5 CO-CHAIR KNOWLTON: David is not here.

6 MS. THEBERGE: There we go.

7 Twenty high, 1 moderate.

8 CO-CHAIR KNOWLTON: Okay. Salina?

9 MEMBER WADDY: So, in terms of the
10 evidence, the group, there was actually some
11 disagreement for a lot of these questions, but
12 they agreed that there was a significant
13 quantity of information, however, some thought
14 that there was insufficient data. And there
15 was largely agreement that the quality was
16 high or moderate.

17 We did think -- and this was kind of a
18 recurring theme -- that there were some
19 patients, it wasn't really clear in patients
20 who may have intermediate risk from the atrial
21 fibrillation really what to do with those
22 patients who, for example, only had a stroke,

1 but didn't have the other elements that would
2 push them over into anticoagulation,
3 particularly if they had a TIA.

4 CO-CHAIR KNOWLTON: Comments?

5 (No response.)

6 Vote.

7 (Vote taken.)

8 MS. JOHNSON: We are going to do a redo
9 on that one.

10 MS. THEBERGE: Sorry about that.

11 We are at 21.

12 Twenty yes, 2 no.

13 MEMBER WADDY: So, in terms of the
14 performance gap, as you can see, this measure
15 was at treatment in only 79 percent of
16 patients, and that is different from the other
17 measure, but this measure, as I mentioned,
18 also includes TIAs as well as it has a
19 different level of analysis. So, it is
20 different, for whatever reason.

21 CO-CHAIR KNOWLTON: Questions?

22 (No response.)

1 Vote.

2 MEMBER WADDY: And there has been a
3 disparity in care as well in the population.

4 (Vote taken.)

5 MS. THEBERGE: Seventeen high, 5
6 moderate.

7 CO-CHAIR KNOWLTON: Okay. Scientific
8 acceptability, starting with reliability.

9 MEMBER WADDY: So, in terms of
10 reliability, everyone thought that this was at
11 least above the low level, but there was a
12 mixed opinion. There were some questions
13 regarding -- or I actually brought up the
14 question in terms of how atrial fibrillation
15 was defined. And in part, that is because
16 there is some disagreement, particularly with
17 cardiologists when they are brought onto the
18 case, in terms of the length of time. You
19 have these very, very brief runs. What does
20 that really mean if you only have three beats?
21 Do you commit someone to anticoagulation? And
22 I wasn't sure whether or not that should

1 really be more defined in the definition or
2 not.

3 But there wasn't a whole lot of
4 generation of questions beyond that.

5 MEMBER R. BAUTISTA: Is the reliability
6 data here the same as the prior study? It
7 seems like it would be the same study as the
8 last one we saw.

9 MEMBER WADDY: I'm sorry?

10 MEMBER R. BAUTISTA: The data we are
11 using for reliability appears to be the same
12 as the last study we actually analyzed. If
13 you go to the old study, it is the same
14 information they are giving here.

15 MEMBER WADDY: Yes, it is the same
16 study.

17 MEMBER R. BAUTISTA: But one study
18 actually looks at --

19 MS. YODICE: It is the same study, but
20 it is still a different population that you
21 are including.

22 MEMBER R. BAUTISTA: Right, but one

1 study actually looks at anticoagulation on
2 discharge.

3 MEMBER WADDY: Right.

4 MEMBER R. BAUTISTA: But the other one
5 is supposed to be on a few days after. So, it
6 is supposed to be two different studies, then,
7 right?

8 MS. YODICE: It is the same project, but
9 not necessarily the same patients.

10 MEMBER R. BAUTISTA: Could you just make
11 sure? Because the numbers seem pretty close
12 to the last study. 0436 and 0241 are
13 presenting with the same reliability data, I
14 think.

15 They use four sites. They have 52
16 patient charts were eligible, which is the
17 same as the last study. It seems pretty
18 similar to the last study we looked at.

19 CO-CHAIR TIRSCHWELL: But these are
20 different developers, are they not?

21 MEMBER WADDY: Yes, they are different
22 developers.

1 CO-CHAIR TIRSCHWELL: So, it would be a
2 different --

3 MEMBER R. BAUTISTA: But the question,
4 though, being, what are we actually looking at
5 now? I mean, one study here looks at
6 anticoagulation on discharge, and the other
7 one is anticoagulation --

8 MEMBER WADDY: It just says
9 anticoagulation, but if you read within it, it
10 says at hospital discharge.

11 MEMBER R. BAUTISTA: Well, the other one
12 is on hospital day two.

13 MEMBER WADDY: That is the DVT, I think.

14 MEMBER R. BAUTISTA: No, no.

15 CO-CHAIR TIRSCHWELL: Let's make sure.

16 MEMBER KAPLITT: Both of the atrial
17 fibrillation ones are at hospital discharge.

18 MEMBER WADDY: Just one includes the
19 TIAs, and the other doesn't.

20 MEMBER R. BAUTISTA: It does not include
21 TIAs.

22 MEMBER SUKO: I guess this is similar to

1 our other harmonizing measures between the AMA
2 and the PCPI and The Joint Commission.

3 And just to clarify, this is based upon,
4 it looks like, more physician Part B claims
5 data than the facility data that The Joint
6 Commission. Is that accurate? Okay.

7 MEMBER R. BAUTISTA: Go ahead. I am
8 actually just looking at both studies right
9 now.

10 CO-CHAIR KNOWLTON: Anything further?

11 (No response.)

12 We are ready to vote on reliability.

13 (Vote taken.)

14 MS. THEBERGE: We have 21.

15 Seven high, 15 moderate.

16 CO-CHAIR KNOWLTON: Validity.

17 MEMBER WADDY: And in terms of validity,
18 there was agreement that at least it wasn't
19 low, but it was split once again between high
20 and moderate.

21 MEMBER BARRETT: I would just comment
22 again that the exceptions are high on this

1 measure, 46 percent, and the definition of
2 exceptions is an area I think for measure
3 development to ensure that disparities in
4 severe stroke that may be amenable to
5 rehabilitation are not excluded
6 inappropriately.

7 CO-CHAIR KNOWLTON: Okay. You raise
8 that these are issues you want included as
9 they consider these measures? You are not
10 arguing for a particular position on this
11 vote?

12 MEMBER BARRETT: Well, I am arguing that
13 it may reduce the validity of the measure to
14 some extent, but also stating for measure
15 development for the future.

16 CO-CHAIR KNOWLTON: Okay. Thank you.

17 Yes, Michael?

18 MEMBER KAPLITT: Can I just clarify what
19 that exception number is? Because you are
20 talking about the reliability number? When
21 you say it is the exception rate, that is what
22 I am not understanding. Is this the --

1 CO-CHAIR KNOWLTON: Just a minute.

2 Ann, do you want to respond to Michael?

3 Put your microphone on.

4 MEMBER BARRETT: Sure. As I understand,
5 Salina may be able to give us some further
6 guidance, but there are quite a few exceptions
7 for either medical- or patient-based reasons.

8 But, you know, I could just see a
9 patient who lives on his own and say, "Well,
10 this patient is an exception because he
11 doesn't have anyone else with him." But we
12 don't know if that patient was actually
13 incapable of taking the medication. They were
14 confirmed to be reliable based on the
15 documentation, I assume.

16 MEMBER WADDY: And actually, our group
17 brought up that point, that there needs to be
18 further clarity regarding what the physician
19 reason may be for not including the patient.
20 And that is one of the challenges. That is
21 what I brought up in the other one, that
22 patients who have a severe stroke, physicians

1 may not put them on anticoagulation -- or a
2 large stroke, I should say -- may not put them
3 on anticoagulation, and whether or not that
4 really should be counted as a true exclusion
5 or an exception.

6 There is a lot of argument regarding
7 that, patients who go to rehabilitation and
8 may fall, but have not had any falls. Is that
9 really an acceptable patient -- you know,
10 there is a question in terms of whether or not
11 they can be given anticoagulation and how well
12 that can be tested.

13 I mean, some physicians have
14 conversations with their patients that are in-
15 depth and some really don't.

16 CO-CHAIR KNOWLTON: Michael, does that
17 answer your concern?

18 MEMBER KAPLITT: Well, I guess what I am
19 wondering -- sort of, but if the reliability
20 of the exceptions is high, which it is,
21 doesn't that suggest that there's reasonable
22 validity to the exceptions, even if the rate

1 is high?

2 I mean, we could all take exception; you
3 know, we can all argue why certain exceptions
4 could create problems. But let's say a
5 theoretical group of practitioners, if 100
6 percent all agree that the exception is valid,
7 then that is the best we can do, right? I
8 mean, unless I am misunderstanding
9 reliability.

10 CO-CHAIR TIRSCHWELL: The reliability
11 just says that it was documented once and they
12 can find it again when somebody else looks for
13 the documentation.

14 MEMBER KAPLITT: Okay.

15 CO-CHAIR TIRSCHWELL: It doesn't say
16 anything about the appropriateness.

17 MEMBER WADDY: I think it is more the
18 validity question.

19 MEMBER KAPLITT: Okay. All right.

20 CO-CHAIR KNOWLTON: Hold it. We are not
21 talking -- oh, I'm sorry, Michael. We are not
22 talking reliability here; we are talking about

1 validity. And validity is whether the test or
2 the measure is measuring what it purports to
3 measure. Reliability would be whether it does
4 it consistently.

5 So, we are talking about -- I assume you
6 are saying that some of these exclusions would
7 go to the validity question. Is that --

8 MEMBER KAPLITT: Correct.

9 CO-CHAIR KNOWLTON: Okay.

10 MEMBER WADDY: That is what I was hung
11 up --

12 CO-CHAIR KNOWLTON: Yes, I think we are
13 ping-ponging between two issues.

14 Anything else?

15 (No response.)

16 Okay. Let's vote on validity.

17 (Vote taken.)

18 MS. THEBERGE: Five high, 14 moderate,
19 3 low.

20 CO-CHAIR KNOWLTON: Okay. We will move
21 on to usability. Salina?

22 MEMBER WADDY: So, in terms of

1 usability, it was, once again, split, but no
2 one thought it was low. So, it was pretty
3 much the same discussion: should there be
4 more identification of absolute
5 contraindications to anticoagulation versus an
6 open-ended statement?

7 CO-CHAIR KNOWLTON: Any other thoughts?

8 (No response.)

9 Okay. Let's vote.

10 Oh, wait a minute. Jolynn, your hand is
11 up.

12 Anything else?

13 (No response.)

14 Okay. Let's vote.

15 (Vote taken.)

16 MS. THEBERGE: Fourteen high, 8
17 moderate.

18 CO-CHAIR KNOWLTON: Okay.

19 MEMBER WADDY: And for feasibility,
20 everyone agreed, for various reasons, that
21 there were some challenges to the feasibility,
22 but everyone rated it above low.

1 There was a question, once again,
2 brought up of how patients were detected. And
3 in the various types of settings are we
4 missing a lot of patients, and then they are
5 going home untreated?

6 CO-CHAIR KNOWLTON: Thoughts on
7 feasibility? Risha?

8 MEMBER GIDWANI: Just so that I
9 understand this properly, if a patient is
10 discharged from a hospital and isn't
11 prescribed the therapy, then goes to rehab and
12 is prescribed the therapy in rehab, the
13 physician who treated the patient on an
14 inpatient basis would be dinged, but the rehab
15 physician would not be dinged? Is that
16 correct?

17 MEMBER WADDY: That is the way I
18 understand it. There is no rehab because this
19 is purely on discharge. Oh, I'm sorry. Yes,
20 actually, it could be discharge from a
21 rehabilitation facility.

22 MEMBER GIDWANI: No, no, according to

1 this, it is. The numerator says whether it is
2 as an inpatient or a rehab facility.

3 MEMBER WADDY: Or a rehab facility.

4 MS. HANLEY: The measure is for
5 discharge from the hospital. So, what you
6 described is correct. The patient who is
7 discharged from the hospital and not
8 prescribed could fail the measure.

9 MEMBER WADDY: I'm sorry, who is
10 talking? Oh, okay. Hi.

11 Except for in the numerator statement,
12 it says discharged from a care setting,
13 whether patient receives care in the ER or as
14 an inpatient or rehabilitation facility.

15 So, I thought it included
16 rehabilitation, in which case, yes, the first
17 physician -- well, actually, if you went back,
18 if the atrial fibrillation was not detected --
19 so, for example, it was in an ER setting; they
20 only did a 12-lead EKG; they didn't detect it,
21 sent the patient to rehab for whatever reason.
22 And then, the rehab physician, say the patient

1 developed palpitations or whatnot, and then
2 they detected it. Then, I am not sure how you
3 would resolve --

4 MS. HANLEY: Yes, this measure, you are
5 right, it is not as clear as it could be. And
6 that is something that the group can work on.
7 But I think the intent of this measure was for
8 hospital, in acute-care hospital inpatient
9 setting as opposed to rehab.

10 MS. JOHNSON: And just so you know where
11 this is on the form, it is in Section
12 2a1.3435, Care Setting. It would tell you
13 where they have specified this measure.

14 MEMBER KAPLITT: I mean, it does say
15 specifically "acute-care setting". So, even
16 in the rehab term, it would have to be acute
17 rehab as part of the acute recovery. I mean,
18 this wouldn't include somebody goes to rehab
19 for two months or subacute, or anything like
20 that, because that is not an acute care.

21 MS. HANLEY: Right.

22 MEMBER KAPLITT: I assume the intent

1 here is that a lot of places the patient
2 recovers and then goes to the hospital's rehab
3 center for another week or so as they are
4 trying to be discharged, because there is a
5 specific definition of acute rehab.

6 MEMBER BARRETT: And that is post-acute
7 care, right?

8 MEMBER KAPLITT: Right.

9 MEMBER BARRETT: And so, the measure
10 developers can confirm it is not used in the
11 post-acute rehab setting, correct, in the
12 post-acute care?

13 CO-CHAIR KNOWLTON: Okay. Dan?

14 MEMBER LABOVITZ: This is probably a
15 non-issue, just a question. In terms of whose
16 ICD-9 code identifies the a-fib, are we
17 relying on the private practitioner? This is
18 practitioner data. Or are we relying on the
19 hospital which may not have spoken to the
20 practitioner at all? Who is making the code?

21 MS. HANLEY: This is the physician-level
22 billing.

1 MEMBER LABOVITZ: So, I worry that a lot
2 of physicians say "stroke," and that is the
3 only ICD-9 code they submit. And they are
4 going to skate away scot-free.

5 Physicians, when they are submitting
6 their private billing, aren't highly-motivated
7 to put in a lot of ICD-9 codes. In fact, the
8 disincentive is strong because most of it is
9 paper billing, and they are just scrawling a
10 number on a card.

11 I worry that, whereas a hospital wants
12 a high level of acuity and will code
13 everything, including warts -- so, I think
14 that is a real validity problem.

15 MEMBER WADDY: We actually brought up
16 that question within our Work Group, and what
17 I was told was that this was still at the time
18 of discharge and not in terms of when you go
19 back and follow up with your primary
20 physician.

21 MEMBER LABOVITZ: It is still the
22 physician's ICD-9 code at the time of

1 discharge. You know, Dr. X, taking care of
2 Patient Y, bills for stroke, discharges with
3 a CPT code and an ICD-9 code. And maybe it is
4 just one ICD-9 code.

5 MEMBER COONEY: It is a CPT II code,
6 which are the specific codes for the
7 performance improvement. So, I don't
8 understand them well enough, but it is a whole
9 different thing.

10 MEMBER LABOVITZ: I guess I am still
11 confused.

12 MEMBER WADDY: The person who developed
13 it, can they clarify?

14 DR. KATZAN: You know, I am speaking on
15 behalf of the group, and they might actually
16 have more input than I do. But I think this
17 is based upon physician billing. So, it is
18 correct. So, if somebody comes in and they
19 just bill stroke, 434.01 or 436.01, and they
20 don't bill for a-fib, then this patient would
21 be in the denominator for this measure. I
22 believe that that is an accurate statement.

1 MEMBER SUKO: Yes, I would echo Daniel's
2 concerns.

3 And just a consideration for future
4 testing: this is going to become an issue
5 more and more on the physician and the
6 hospital side, and there has got to be a way
7 to test on the patient level what did the
8 physician submit and what did the hospital
9 submit in terms of testing and validity. And
10 I would just throw that out to the developers.
11 I recognize that that is not an easy thing to
12 do, but we need to get to a point where we can
13 figure that out.

14 Also, administratively, we are having
15 the physician submit the exact same measures
16 that the hospitals are submitting. So, we are
17 creating a lot of work.

18 And so, as we develop this more and
19 more, I mean, to the extent that we can
20 streamline this, I think that is really
21 important.

22 CO-CHAIR KNOWLTON: Other comments on

1 feasibility?

2 (No response.)

3 Okay. Let's vote.

4 Oh, I'm sorry, Mary.

5 MEMBER VAN DE KAMP: I was just going to
6 say I think that it is difficult because so
7 much of the outcome data currently is being
8 driven off of ICD-9 codes. I mean, that is
9 sort of the data-mining. I think that, unless
10 there are other ways that we should recommend
11 they look at this, unfortunately, the
12 importance of ICD-9 coding and the hospital
13 quality improvement has got to start around
14 ICD-9 codes.

15 So, I think while it would be nice, I
16 think we also have to recognize that much of
17 the claims data is going to be driven off what
18 is a code. And so, it may not be the
19 developers' issue; it may be a practice issue.

20 CO-CHAIR KNOWLTON: Other comments?

21 (No response.)

22 Okay. Now let's vote.

1 (Vote taken.)

2 MS. THEBERGE: One high, 18 moderate, 2
3 low, 1 insufficient.

4 CO-CHAIR KNOWLTON: And the preliminary
5 assessment, overall suitability for
6 endorsement. Salina?

7 MEMBER WADDY: Everyone agreed to
8 endorse it in our group, despite the
9 challenges.

10 CO-CHAIR KNOWLTON: Any questions or
11 comments?

12 (No response.)

13 Okay. Open it up.

14 (Vote taken.)

15 MS. THEBERGE: Twenty-one yes, 1 no.

16 CO-CHAIR KNOWLTON: I am going to
17 suggest that we take a break, for all kinds of
18 reasons. We will make it a 10-minute break.
19 Does that work? Okay.

20 (Whereupon, the foregoing matter went
21 off the record at 3:50 p.m. and resumed at
22 4:01 p.m.)

1 CO-CHAIR TIRSCHWELL: We are going to
2 get started.

3 So, the next measure is screening for
4 dysphagia. It is an AMA/PCPI measure, and
5 Michael is going to get us started.

6 MEMBER KAPLITT: So that we all don't
7 become numerators in the DVT prophylaxis
8 outcome measure, I will try to move this
9 along.

10 (Laughter.)

11 CO-CHAIR KNOWLTON: We are all using
12 mechanical measures.

13 (Laughter.)

14 DR. SCHWAMM: You are assuming that you
15 are getting treatment.

16 (Laughter.)

17 MEMBER KAPLITT: All right. So, this is
18 re-endorsement of a measure that was
19 originally endorsed in 2007 to do dysphagia
20 screening in patients within, well, prior to
21 PO intake following a stroke. And elsewhere,
22 I think the ideal is within 24 hours of the

1 stroke, but the numerator statement is just
2 patients for whom dysphagia screening was
3 performed prior to PO intake, period.

4 In terms of the impact, I think that
5 there was general agreement in the group that
6 this was high impact. Clearly, they gave
7 plenty of evidence to support the idea that
8 aspiration from dysphagia is a major problem
9 in stroke and represents a significant
10 morbidity and even mortality, and probably the
11 lion's share of pneumonias, for example,
12 following stroke. And there were good papers
13 to support it.

14 My only personal editorialization is
15 that I found this to be an incredibly-
16 convincing argument for a new measure. It
17 would be nice -- and this was a common theme
18 throughout a lot of these -- that if it is a
19 measure that has been out for five years, you
20 know, it would be nice in terms of impact to
21 see like what data they have collected over
22 the last five years among those that have used

1 this thing to see, is it making an impact?

2 You know, I think the potential impact
3 is great, but it is still presented a little
4 more theoretically than might be nice. But
5 that is not really unique to this.

6 So, I think the impact, we all agreed,
7 was high. I mean, it is important to do this.

8 CO-CHAIR TIRSCHWELL: Okay. Any
9 comments about impact?

10 (No response.)

11 Let's go ahead and vote.

12 Wait. Wait. Now we can vote.

13 (Vote taken.)

14 One short. There we go.

15 MS. THEBERGE: Twenty high, 1 moderate.

16 MEMBER KAPLITT: Okay. Next, evidence?

17 CO-CHAIR TIRSCHWELL: Yes, go ahead to
18 evidence.

19 MEMBER KAPLITT: So, there was complete
20 agreement on this that the evidence was
21 justifiable in terms of the subscores. There
22 was variable agreement on high versus

1 moderate, but, overall, there was complete
2 agreement.

3 And the basic issue, as with a lot of
4 these things, is that it was felt that there
5 were a lot of studies that were presented that
6 justified this. It is just there weren't that
7 many randomized controlled trials, but there
8 were a lot of studies, and they were
9 supportive. So, the evidence was felt to be
10 high or acceptable, or whatever.

11 CO-CHAIR TIRSCHWELL: Great.

12 Any comments? Bill, was that a hand or
13 that was just a yawn?

14 (Laughter.)

15 Okay. Let's go ahead and activate the
16 voting then. Go ahead and vote.

17 (Vote taken.)

18 MS. THEBERGE: Twenty yes, 2 no.

19 CO-CHAIR TIRSCHWELL: Now to performance
20 gap.

21 MEMBER KAPLITT: Right. So, in terms of
22 performance gap, there was pretty good

1 evidence presented, one, from published
2 literature, that dysphagia screening prior to
3 feeding is all over the place, anywhere from
4 19 percent to 81 percent.

5 Again, this developer uses the CMS/PQRS
6 reporting measures. They have for a lot of
7 other things. And so, whatever we think of
8 that, the performance gap based on that was
9 68.3 percent of patients did not meet the
10 measure, but it seemed like the numbers were
11 getting better in 2009, 2010. But, again, we
12 all feel -- and I certainly feel -- that I
13 think the PQRS overestimates, because these
14 are people who are reporting because they get
15 paid to report. So, I think that the
16 performance gap, what they have documented is
17 probably worse than that, and we all, I think,
18 generally agreed on that in the group.

19 CO-CHAIR TIRSCHWELL: So, any other
20 comments on performance gap?

21 (No response.)

22 Let's go ahead and activate the voting.

1 And now, go ahead and vote.

2 (Vote taken.)

3 MS. THEBERGE: Nineteen high, 3
4 moderate.

5 CO-CHAIR TIRSCHWELL: Okay. Moving on
6 to scientific acceptability, first comes
7 reliability.

8 MEMBER KAPLITT: Right. So, with
9 reliability, just to make clear that the type
10 of screening that they are referring to in all
11 of this, which maybe I should have made clear
12 earlier, can be a variety of things, including
13 a video fluoroscopic swallow eval, fiber optic
14 evaluation, a modified barium swallow, or a
15 structured bedside evaluation. So, anywhere
16 from extremely high-tech to more easily
17 implemented.

18 And I think that the data that they
19 presented was felt to show pretty high
20 reliability or extremely high reliability with
21 a good kappa score as well.

22 Again, this used, I think, the data

1 based on -- they used the four practice sites
2 that I think we saw in some of the earlier
3 things, where one was like a small group in
4 the Midwest; one was a hospital in a city in
5 the Southeast. I think it is that same group
6 that we had sort of fleshed-out earlier. So,
7 I think we already went through whatever
8 issues there were with that.

9 And the only other thing is that the
10 only exception, the only exclusion was death.
11 Again, we could all argue about, well, if
12 somebody died from aspiration, that is maybe
13 not so great. But I don't think that that
14 probably represents a significant enough
15 number to be an issue.

16 And then, the exceptions were the usual
17 exceptions, you know, documenting medical
18 reason why you couldn't do the test for
19 whatever reason. And they found, again, that
20 there was 100 percent reliability in terms of
21 the exceptions.

22 So, that is the reliability.

1 CO-CHAIR TIRSCHWELL: Yes, Salina?

2 MEMBER WADDY: So, I was just
3 wondering -- I wasn't going to bring this up,
4 but since you pointed out the various testing,
5 why is this considered a screening for
6 dysphagia rather than just dysphagia
7 detection? Because once you go into
8 fluoroscopic detection, then you are kind of
9 beyond just a plain, old screening test.

10 MEMBER J. BAUTISTA: It is probably
11 because it does include bedside screening as
12 a valid measure or a valid action.

13 CO-CHAIR TIRSCHWELL: So, Jocelyn,
14 activate your tent.

15 MEMBER J. BAUTISTA: So, even though
16 they have various measures, they don't require
17 the high level. So, just doing a bedside
18 screening eval is enough to meet the measure,
19 right.

20 MEMBER WADDY: And I am fine with the
21 inclusion of the bedside screening test, but
22 the actual title is that this is just a

1 screen. Is it just a screen? Or is it just
2 any testing for dysphagia, is really my
3 question, just really the overall title of it.

4 CO-CHAIR TIRSCHWELL: Does the developer
5 want to comment?

6 DR. KATZAN: Yes. So, the minimum
7 standard is a screen. And if they fail that
8 screen, then they will go on to further
9 testing to see if they are appropriate to take
10 PO. But the minimum requirement is a screen.

11 But if people actually have -- and some
12 hospitals do; some hospitals actually have the
13 speech therapy department that can come to the
14 bedside immediately. And in those cases, I
15 mean, that would count as well.

16 CO-CHAIR TIRSCHWELL: So, it is anything
17 at the screening-level-plus meets the
18 criteria.

19 Any other? Yes, Mary?

20 MEMBER VAN DE KAMP: I think you bring
21 a great point. I think it is just being in
22 the field, I think that there is a big

1 difference between a screen and an evaluation.
2 One is a physician engagement.

3 And so, I think that if it is just going
4 to be a screen, they should leave it at that
5 and not identify it as an evaluative process,
6 because there is a very big difference in the
7 field between a screen and an evaluation.

8 So, it is misleading, I think, to say
9 that it is a screen. I think detection would
10 be better, and you can describe it, the full
11 range. Or you leave it at a screen and you
12 allow for it to be a non-evaluative, because
13 I do think this is a very confusing thing in
14 the field already with the screening process
15 and who can do a screen. Does it have to be
16 a skilled clinician or can it be who does it
17 all the time?

18 So, while it may seem small in light of
19 this, when in actual practice, it is a really
20 big discussion and gets into a lot of payment
21 issues as well down the line for when a screen
22 is to be done and when you need to have a

1 physician order.

2 CO-CHAIR TIRSCHWELL: I guess I don't
3 understand how having a higher level really
4 confuses it. It would be one thing if --

5 MEMBER VAN DE KAMP: Because I don't
6 think the validity of a screen is the same
7 level of the validity of a test. So, you
8 could say I have a high validity with modified
9 barium swallow or with a FEES. You might not
10 have the same high validity with just a
11 screen.

12 CO-CHAIR TIRSCHWELL: So, why don't we
13 save that for the next point on validity?

14 MEMBER VAN DE KAMP: Okay. I will just
15 make that point now, and I won't go back and
16 say it again.

17 CO-CHAIR TIRSCHWELL: Yes.

18 Daniel?

19 MEMBER LABOVITZ: Just to add a comment,
20 the business of keeping somebody NPO until you
21 can get a FEES means sometimes you are not
22 feeding a patient for three or four days. I

1 think that comes at a very, very high price.
2 This may be one of the unintended consequences
3 of having this sort of measure.

4 I think dysphagia screening, it has been
5 a while, but, as I recall, it has been shown
6 that centers that at least pay attention to
7 this do better than centers that don't. But
8 paying attention is much, much different than
9 specifying sort of tests count and what don't,
10 and that sort of thing.

11 CO-CHAIR TIRSCHWELL: Well, I think they
12 go to great lengths to leave it pretty wide-
13 open, probably reflecting the lack of evidence
14 about what the best way to screen is.

15 I mean, at my center, to get this done,
16 half the time you have to do it in the
17 emergency department somehow because they are
18 wanting to give them pills by mouth. So, it
19 is a big deal; there is no question about it.

20 And I think, as a result, we have
21 progressively lowered our definition for what
22 becomes an adequate screen. And we might even

1 let the residents do it, which, you know, is
2 a really questionable practice, I think.

3 (Laughter.)

4 But I think it is important. But I
5 think it speaks more to the validity of this
6 as a measure than reliability necessarily. I
7 mean, the reliability, if you --

8 MEMBER WADDY: No, no, completely agree.

9 CO-CHAIR TIRSCHWELL: Okay. So, let's
10 vote on reliability. Activate it. Go ahead
11 and vote now.

12 (Vote taken.)

13 MS. THEBERGE: Fifteen high, 7 moderate.

14 CO-CHAIR TIRSCHWELL: Okay. It seems
15 like we partially discussed the validity point
16 already. Anything?

17 MEMBER KAPLITT: So, the validity was
18 based, in part, on surveying of their expert
19 panel, as well as, again, the CMS sort of PQRI
20 reporting data.

21 All I would say to the point that was
22 just discussed is, while I understand sort of

1 the point, so the consequence of it is let's
2 say their measure only did bedside screening.
3 Essentially, what you would be saying is that,
4 if you had a medical reason why you felt that
5 the patient needed a higher-end test, you
6 would then be requiring that that bedside
7 screen be done before that test is done, even
8 though you know that that test needs to be
9 done. Or else that patient would wind up
10 getting excluded.

11 So, I mean, I don't personally see sort
12 of the downside, unless they were to require
13 that. I agree that the data -- so, in the
14 validity testing, I don't see -- maybe the
15 developer could add to this -- I don't see any
16 -- it is not that granular where they break it
17 down by type. But I don't see the downside.

18 MEMBER WADDY: Actually, I was more in
19 favor. I mean, I think exactly what you said
20 was what you related much more eloquently than
21 I did, but I am more in favor of just changing
22 the name of this item from "screening for

1 dysphagia" to something that actually reflects
2 what is being done, right.

3 MEMBER KAPLITT: So, your point is that
4 screening has a certain connotation to some
5 people.

6 MEMBER WADDY: Yes.

7 MEMBER KAPLITT: But, technically, I
8 mean, I guess the developer can deal with
9 that, but, technically, as far as the document
10 is concerned, they do define what they mean by
11 screening in the numerator definition because
12 the numerator says it is a screen, whatever,
13 and then their definition of the numerator
14 lists all these things. So, they have defined
15 screening their way.

16 You're right, that might not be what the
17 general public views it as, but --

18 CO-CHAIR TIRSCHWELL: And I mean, as far
19 as validity goes, of the expert group, this
20 one had more disagreement, more less-strong
21 agreement than many of the other ones that the
22 expert group did.

1 Ramon?

2 MEMBER R. BAUTISTA: I mean, I share the
3 same sentiment. If they are going to get
4 dinged for something like this, then he or she
5 must take responsibility for screening the
6 patient.

7 But, even among the group in this room,
8 I am sure we are going to be screening these
9 patients differently because we haven't been
10 formally trained on how to screen dysphagia.

11 So, how do you resolve that? I mean, we
12 all know it is important. But if you don't
13 know how to do it, though, I am not sure what
14 this measure really tells you then.

15 DR. KATZAN: Can I respond?

16 CO-CHAIR TIRSCHWELL: Yes, please, go
17 ahead.

18 DR. KATZAN: So, your points are well-
19 taken. And actually, the semantics that are
20 used to define what is actually dysphagia
21 screening versus formal bedside swallow, all
22 that stuff is really a critical issue that is

1 confusing to many people. And so, changing
2 the name is something that we really need to
3 take into consideration, and I think we are
4 all for.

5 Regarding the tools that are used, I
6 mean, it is spelled out what tools there are.
7 There is the 3-ounce water swallow test, the
8 dysphagia screening test, and then you can do
9 something that is more specific.

10 And one of the points that is made here
11 is that a screening tool is approved by the
12 hospital's speech pathology/language services.
13 And so, there is some regimented system that
14 the speech pathology/language group approves
15 of that is used in a systematic fashion.

16 So, most hospitals, for instance, that
17 are primary stroke centers, they have a tool
18 that has been approved by that hospital that
19 is done in a systematic, similar fashion, and
20 actually documented as such prior to PO
21 intake. And so, that is the thing; that is
22 the point that we want to get across, that

1 tools could vary. And actually, a lot of
2 people actually pass tools around in
3 hospitals, share similar tools, but that the
4 tool has to be or should be approved by that
5 hospital.

6 CO-CHAIR TIRSCHWELL: There was a Get
7 With The Guidelines measure. Is that NQF-
8 approved currently?

9 Dr. Schwamm, do you know off the top of
10 your head?

11 DR. SCHWAMM: So, there was a Joint
12 Commission measure --

13 CO-CHAIR TIRSCHWELL: Sorry. Excuse me.

14 DR. SCHWAMM: -- that was not approved
15 at the previous cycle, which is a hospital-
16 based measure that complements this measure,
17 I think largely because there was some
18 confusion and concern about this issue around
19 screening versus thorough evaluation.

20 What I would just say is that I think
21 there is a bare minimum that all patients have
22 some assessment prior to something being put

1 in their mouth. If you notice that the
2 patient is so obviously at risk for swallowing
3 impairment that you didn't perform the formal
4 screen, but simply went ahead and ordered the
5 speech consult, that we ought to give credit
6 for that as opposed to excluding those
7 patients from the denominator, which would be
8 the alternative construct.

9 So, I actually support the current
10 construct in terms of the idea that everyone
11 deserves a screen. If you do a more thorough
12 version of a screen, followed immediately,
13 essentially, by a full evaluation, terrific.
14 Not every hospital has the resources to do
15 that, and not every patient needs that level
16 of evaluation.

17 MEMBER WADDY: I am actually in favor of
18 just calling it a dysphagia assessment and
19 just leaving it at that.

20 CO-CHAIR TIRSCHWELL: Okay. Well, that
21 will be a recommendation.

22 Any other comments on validity?

1 (No response.)

2 We are not allowed to, I think, just
3 change it unilaterally.

4 (Laughter.)

5 She is in charge.

6 Any other comments on validity?

7 (No response.)

8 Let's go ahead and vote then.

9 (Vote taken.)

10 MS. THEBERGE: Six high, 14 moderate, 2
11 low.

12 CO-CHAIR TIRSCHWELL: Okay. So, moving
13 on to usability.

14 MEMBER KAPLITT: I mean, there wasn't a
15 whole lot to say about usability there. You
16 know, the majority of the group felt that
17 there was high usability of the measure
18 itself, you know, that it is fairly easy to
19 use and report on.

20 CO-CHAIR TIRSCHWELL: Any other
21 comments?

22 MEMBER KAPLITT: It has been used for

1 five years.

2 CO-CHAIR TIRSCHWELL: Let's go ahead and
3 activate, and now go ahead and vote.

4 (Vote taken.)

5 MS. THEBERGE: Seventeen high, 5
6 moderate.

7 CO-CHAIR TIRSCHWELL: Feasibility,
8 Michael?

9 MEMBER KAPLITT: Right. Similarly, I
10 mean, we can debate the feasibility of
11 actually doing these various tests at various
12 times. The feasibility of implementing the
13 outcome measure, I think everybody felt
14 largely was high and, you know, feasible.

15 CO-CHAIR TIRSCHWELL: Any other
16 comments?

17 (No response.)

18 Let's go ahead and activate the voting,
19 and go ahead and vote now.

20 (Vote taken.)

21 MS. THEBERGE: Fourteen high, 7
22 moderate, 1 low.

1 CO-CHAIR TIRSCHWELL: Okay. And then,
2 overall suitability for endorsement. Any
3 comments?

4 MEMBER J. BAUTISTA: Question?

5 CO-CHAIR TIRSCHWELL: Yes, Jocelyn.

6 MEMBER J. BAUTISTA: This doesn't sit
7 well with me. So, if there is a similar
8 measure that failed to get NQF endorsement,
9 shouldn't that be a part of our discussion,
10 why it failed?

11 MEMBER KAPLITT: Aren't we evaluating
12 the thing before us? I mean, there could be
13 a lot of reasons why it failed, right? If
14 there is concern specifically about what we
15 are seeing, then that is a different story.

16 MEMBER WADDY: They may have thought of
17 something --

18 CO-CHAIR KNOWLTON: I was actually on
19 the Committee on this issue. This was
20 probably the most debated issue on that
21 Committee because it rested upon who was going
22 to do the screening and whether the screening

1 would be timely. Because, as it was
2 originally configured, it had to be a
3 specially speech and hearing person or
4 physician.

5 And it went back and forth and back and
6 forth with the developer. The language was
7 finally compromised to allow the use of a
8 screening tool.

9 And it was tied into the direct
10 experience of a stroke survivor who got
11 screened on Thanksgiving weekend, and there
12 was nobody to undo the NPO hold until four
13 days later. Okay? So, that became the
14 poignant issue at the time of the debate.

15 But there was a hasty compromise that
16 was crafted after a good hour debate on this
17 issue. So, that is what happened, you know.

18 It is unusual for NQF to compromise like
19 that, but it was because of the specific thing
20 that occurred at that time.

21 CO-CHAIR TIRSCHWELL: I would also note
22 that in the interval years -- I mean, that was

1 a number of years ago?

2 CO-CHAIR KNOWLTON: Yes.

3 CO-CHAIR TIRSCHWELL: There have been a
4 number of reports that have done a little bit
5 better job linking the dysphagia screening to
6 pneumonia rates and things like that. So, the
7 evidence base has probably improved a little
8 bit and maybe adding to some more momentum at
9 this meeting as opposed to a previous meeting.

10 CO-CHAIR KNOWLTON: There was no
11 consideration that this wasn't valuable. It
12 was, the way the measure was defined, it could
13 only be done by two classes of people, and
14 that got to be impractical on weekends and
15 evenings, and so forth. That was the problem.

16 CO-CHAIR TIRSCHWELL: Dr. Schwamm?

17 DR. SCHWAMM: We would certainly welcome
18 a recommendation from NQF that a hospital-
19 based measure of this be resubmitted, because
20 we do think it is important. So, we would be
21 delighted to resubmit a companion, a
22 similarly-formatted measure related to

1 hospital-level compliance.

2 CO-CHAIR TIRSCHWELL: Well, it seems
3 like there is a lot of enthusiasm from the
4 group. Although I don't know that we have the
5 ability to officially endorse it, I think you
6 have heard comments to support that for sure,
7 and I would certainly support it.

8 MEMBER LABOVITZ: Just make sure you
9 name it right.

10 DR. SCHWAMM: We will call it "The Do
11 The Right Thing Measure".

12 (Laughter.)

13 CO-CHAIR TIRSCHWELL: Okay. So, overall
14 suitability, can we vote on that now? Let's
15 just go ahead and trigger that.

16 (Vote taken.)

17 MS. THEBERGE: Twenty-one yes, 1 no.

18 CO-CHAIR TIRSCHWELL: Okay. Excellent.

19 CO-CHAIR KNOWLTON: Okay. The next one
20 is stroke education. Gwen?

21 MEMBER BUHR: Okay. So, this measure is
22 measuring the people who have had ischemic or

1 hemorrhagic strokes and who themselves or
2 their caregivers have been educated on five
3 specific things: the activation of the
4 emergency medical system, the need for
5 followup after discharge, medications
6 prescribed at discharge, risk factors for
7 stroke, and warning signs and symptoms of
8 stroke.

9 It is part of the bundle of measures
10 that are used in The Joint Commission's
11 hospital accreditation and disease-specific
12 care certification programs.

13 So, on the impact, the data submitted do
14 not specifically address education or stroke
15 education particularly. It talks about how
16 stroke is very common and disability from
17 stroke. And it talks about that patient
18 education programs in general are impactful.
19 But it doesn't say anything about stroke
20 education and, in particular, about stroke
21 education on patient outcomes. So, that was
22 our sort of issue with this measure.

1 CO-CHAIR KNOWLTON: I was actually going
2 to comment on this. I was thinking if I am
3 thinking in the right place.

4 Does anybody else have any comment on
5 this? Risha?

6 MEMBER GIDWANI: Well, I was just
7 reading. It says here -- I don't know if
8 this, Gwen, speaks to your question about the
9 lack of information -- but this is saying here
10 that less than 10 percent of acute stroke
11 admissions arrive at the ED within one hour of
12 stroke symptom onset, and less than 25 percent
13 arrive within three hours.

14 And the developers then linked that to
15 the need for mass public education to increase
16 awareness about the importance of seeking care
17 as soon as possible.

18 CO-CHAIR KNOWLTON: But that is not the
19 measure, is it?

20 MEMBER BUHR: Yes.

21 CO-CHAIR KNOWLTON: That is not the
22 measure.

1 MEMBER BUHR: Right. So, I think that
2 this is like one step away from even a process
3 measure. They are saying that people aren't
4 arriving in time for stroke. And so, then,
5 they are assuming that they don't know, and
6 that if they educate them, well, then they
7 will arrive on time. So, it is like, you
8 know, really many steps to get to where they
9 want to go.

10 CO-CHAIR KNOWLTON: Do you have a
11 comeback, Risha?

12 MEMBER GIDWANI: I agree, Gwen, with
13 what you are saying. I just wonder if that
14 might be a very difficult research study to
15 operationalize and even to be able to measure
16 that link. So, I wonder if we may need to
17 make that leap of faith ourselves. I would
18 consider it to be a reasonable leap of faith,
19 but, of course, we all have to make that
20 decision ourselves.

21 MEMBER WADDY: Actually, we have ongoing
22 research at NIH regarding that. There is a

1 SWIFT study in order to try to get patients
2 into the hospital in time.

3 Largely, there is a challenge with the
4 stroke education programs in that they just
5 measure whether or not you present someone
6 with information, and whether or not they take
7 in that information, not whether there is
8 actually a behavior change that occurs because
9 of it.

10 The second point I wanted to make is
11 that this is really information at the level
12 of information being provided to the patient.
13 Unfortunately, a lot of patients who come in,
14 they may either have aphasia or they may have
15 some other cognitive --

16 CO-CHAIR KNOWLTON: It says caregiver.

17 MEMBER WADDY: It includes caregivers?

18 CO-CHAIR KNOWLTON: Yes, it does.

19 MEMBER WADDY: Oh, I'm sorry. Then,
20 never mind. I will, then, stop there on that
21 one. Thanks.

22 CO-CHAIR KNOWLTON: I am chairing this

1 one, but I do have a comment on it. And that
2 is, in my experience, not only as a stroke
3 patient, but also in what I have observed
4 since, this ends up being a little plastic bag
5 filled with a bunch of leaflets and
6 documentation in the file, which is absolutely
7 useless.

8 I was functional post-stroke, stroke
9 patient. But this doesn't, in my view,
10 capture whether they -- it just says they were
11 discharged home with documentation that they
12 were given this or their caregivers were given
13 it, not that there was any teach-back or there
14 was any "Do you understand?", any of those
15 variables.

16 Bill, did you have a point?

17 MEMBER BARSAN: Yes, I would agree. And
18 I agree with the others, too. I think there
19 is a big gap between, gee, people don't know
20 a lot about stroke and the fact that, if we
21 educate people, we are going to change
22 behavior, because I don't think the evidence

1 is there to do that. I am not sure I buy it.

2 CO-CHAIR KNOWLTON: Anybody else on the
3 Committee? Yes, go ahead, Ann. And then, I
4 will get to you, I promise.

5 MEMBER BARRETT: I would just comment
6 that it is absolutely correct; the exclusions
7 don't even include what language the patient
8 speaks, whether or not they are illiterate.
9 So, the materials can be given and the
10 checkbox can be checked.

11 CO-CHAIR KNOWLTON: I don't know what
12 language you could have used when I had my
13 stroke. I was speaking in tongues.

14 (Laughter.)

15 But go ahead.

16 MEMBER BUHR: The other issue that we
17 talked about is that it is for people who have
18 had a stroke, and that the evidence that they
19 give is for people who haven't had a stroke.
20 The general population is not aware of this
21 major symptoms of stroke. They don't present
22 any evidence for what stroke survivors are

1 aware of or not. And the only people that
2 this measure is requiring you to educate are
3 people who have had a stroke.

4 CO-CHAIR TIRSCHWELL: And they are going
5 home, right?

6 MEMBER BUHR: Yes.

7 CO-CHAIR KNOWLTON: Other members of the
8 Committee? Bill? Dan? I'm sorry.

9 MEMBER LABOVITZ: The problem with
10 education is you can do it badly or well. But
11 even if you do it well, what we have learned
12 with attempts at stroke education in patients
13 who haven't had stroke, where you are
14 educating the community, is that the learning
15 fades extremely rapidly. So, it is gone in
16 three to six months. Even if you can find a
17 signal at three months, it is gone by six.

18 There has been a fair amount of effort
19 done on this. That experience shapes my view
20 on this measure because this measure doesn't
21 present us with any data at all. So, I am
22 just looking for other experiences.

1 I have no reason to think that the
2 little packet, the little stroke packet that
3 we give to our patients, or the little line
4 that says, "Smoke cessation is a good idea if
5 you smoke," which gets us 100 percent rating
6 on our smoking score, does any good at all.

7 CO-CHAIR KNOWLTON: Salina?

8 MEMBER WADDY: Actually, I'm sorry. So,
9 the comment that I should have been making
10 previously was that, even if a patient has an
11 aphasia or some other problem with retaining
12 information or understanding information, they
13 will still get a checkoff, according to this,
14 even if they don't understand, for whatever
15 reason, whether or not it is because it is not
16 culturally-appropriate. It is just a
17 checkoff.

18 CO-CHAIR KNOWLTON: That was Ann's
19 point, yes.

20 Lee?

21 DR. SCHWAMM: Yes. So, I would say that
22 I certainly recognize that the measure is not

1 the strongest measure in the set by any means.
2 There is, as Dr. Waddy was implying, the SWIFT
3 trial which was conducted by Bernadette Boden-
4 Albala in Columbia, based on a cohort of
5 multi-racial/ethnic populations.

6 The data is in press, but has not been
7 published. So, I can only tell you what I
8 know from speaking to the principal
9 investigator.

10 All patients were randomized to receive
11 either an educational intervention or usual
12 care. And those who received the educational
13 intervention were followed for the subsequent
14 years. If they had a recurrent event in this
15 captive community, they were, then, assessed
16 as to whether or not they had increased their
17 frequency of activating EMS coming in early
18 and being eligible to receive t-PA. And the
19 treatment group did show a statistically-
20 significant improvement and a behavior change.

21 It is not published. It is not
22 available to you. So, you can't include that

1 in your packet.

2 But I think all I would say is that,
3 when this measure changed from simply provide
4 education to actually specifying the five
5 domains that needed to be addressed with the
6 patient, there was huge pushback from
7 hospitals because they found that actually
8 onerous. So, not just a checkbox, but
9 actually onerous, meaning they were doing
10 something.

11 And my only concern would be that
12 removing the measure sends a message that it
13 is really maybe not important; whereas,
14 strengthening the measure would be something
15 that could actually lead to further change.

16 But I don't think the measure is causing
17 any harm besides maybe doing education better
18 than others, but I do think that it is
19 critically-important. And when we don't
20 require it, sites don't do it at all, nor do
21 they document it, but they don't do it all.

22 So, I would just encourage you to think

1 about the fact that education in this domain
2 is quite important, maybe not the best
3 education being provided, documented, and
4 established with teach-back, but it is still
5 critically-important.

6 CO-CHAIR KNOWLTON: David?

7 CO-CHAIR TIRSCHWELL: I mean, I agree.
8 Even if there is a little bit of a leap of
9 faith here, I think that doing your best to
10 providing education to stroke patients is a
11 standard, just a tremendously-important
12 standard of care.

13 My recollection of the SWIFT trial,
14 though -- and I have only seen some peripheral
15 things -- is that it was more than just a
16 little packet at discharge, that their
17 educational intervention was a bit more
18 intensive.

19 DR. SCHWAMM: Yes.

20 CO-CHAIR TIRSCHWELL: And I am sure we
21 are not doing that widely. If that supports
22 a more intensive educational intervention, I

1 am all for it.

2 But I think I agree that this is a
3 common-sense thing, and I agree that the leap
4 to better outcomes for patients is really hard
5 to demonstrate. But I also think that
6 supporting the concept to providers that this
7 is an important thing we want you to
8 participate in, and hoping that hospitals, in
9 good faith, try to do a great job of it, is
10 something that is important.

11 CO-CHAIR KNOWLTON: Michael?

12 MEMBER KAPLITT: So, my concern about
13 the harmful aspect of this is, when you say,
14 "Well, it probably won't do any harm," is that
15 if certain types of more intensive education
16 can be helpful, and we have a measure that
17 basically can be satisfied by, as you say,
18 throwing a piece of paper in a plastic bag and
19 saying on the way out the door, "Here, you're
20 educated," the concern is that you will
21 falsely conclude that education doesn't work
22 because the vast majority are going to do

1 that. And the evidence of that is you are
2 saying that, when there were attempts to
3 mandate more intensive education, that there
4 was pushback. There is pushback because it is
5 hard.

6 DR. SCHWAMM: Just to clarify --

7 CO-CHAIR KNOWLTON: Well, don't reply
8 yet.

9 DR. SCHWAMM: Oh, I'm sorry. Excuse me.

10 CO-CHAIR KNOWLTON: We will get back to
11 you.

12 MEMBER KAPLITT: So, my concern is that,
13 you know, unless there is data -- and I agree
14 that there is a lot of common-sense aspect to
15 all of this stuff, but unless there is data to
16 support the measure as presented, which is
17 that any type of education, you take a broad
18 population of people, you know, hospitals, let
19 them do whatever type of education they want,
20 and show that that actually has some impact.
21 And in the absence of a published paper that
22 says specifically what was done to actually

1 achieve this difference, my concern is that it
2 is not just, well, maybe it will help and
3 maybe it will do nothing; it could be very
4 harmful because of the false interpretation.

5 CO-CHAIR KNOWLTON: Okay, Lee, go ahead.

6 DR. SCHWAMM: So, I think I just want to
7 make two points.

8 The first one is that the measure
9 specifications as documented would not permit
10 stuffing an envelope in the bag as meeting the
11 measure specifications. So, the measure
12 specifications actually address five specific
13 domains and need to be individualized to the
14 patient's specific conditions.

15 So, I think hospitals may not be
16 following the guideline and may not be
17 abstracting properly, and could be being
18 deceitful as to what they provided, but, as
19 specified, it is more rigorous than that.

20 CO-CHAIR KNOWLTON: Not what is before
21 us, though. What is before us is that they or
22 their caregivers, we are giving educational

1 material. It doesn't say spoken to. It
2 doesn't say that material is culturally-
3 specific or language-specific. It just says
4 they were given educational material.

5 And I do believe, unless I misunderstand
6 the measure -- and I would be happy to have
7 you clarify that -- shoving the pamphlets in
8 the plastic bag does that, would meet the
9 measure. Am I wrong?

10 DR. SCHWAMM: Well, I think it depends
11 on how you interpret those specifications.
12 The specification says that it has to be
13 relevant to the patient's specific condition.
14 So, if you have atrial fibrillation, that
15 needs to be discussed with you, and the
16 medications that you are prescribed to treat
17 that condition need to be linked to that as
18 part of the education.

19 So, yes, I suppose you could have a
20 pamphlet that addressed all five domains and
21 said to the patient on the way out the door,
22 "Your risks are covered in here. Read them."

1 So, I don't think, from my reading of it, that
2 that would actually address the measure
3 specifications, but we don't know how
4 hospitals are abstracting that.

5 So, the answer is I can't reassure you
6 that that is not happening. On the other
7 hand, that is not how the measure is written.
8 Just like I can't reassure you that hospitals
9 are making up reasons for non-treatment with
10 antithrombotic therapy or anticoagulation
11 therapy, but we hope that hospitals are doing
12 their best in good faith to comply with the
13 measure.

14 I just want to say, I mean, I agree with
15 you; it would be ideal to have an even
16 stronger measure. I think part of the problem
17 is we don't have data that tells us
18 specifically which types of educational
19 interventions have been proven to have an
20 outcome link. So, a little bit, we lack the
21 evidence to further refine the measure to make
22 sure that it meets all of those elements.

1 But I just did want to address the
2 original comment that this would be harmful.

3 CO-CHAIR KNOWLTON: Fred, you are all
4 set?

5 Ramon?

6 MEMBER R. BAUTISTA: I mean, I agree
7 with Michael's comment a while back. I mean,
8 when we approve a measure, especially in the
9 first get-go, the so-called leap-of-faith-type
10 approval, I mean, after "X" amount of years,
11 you need to actually come back to us and say,
12 "Is it working or not?" I mean, to say that
13 we don't have any new development at that
14 point; that we have just got to keep going
15 with what we have so far because we have
16 nothing better, is I think, frankly, a bit of
17 a copout.

18 In other words, it doesn't excuse not to
19 get better. I mean, for all we know, we
20 could do a couple of things better here with
21 this measure, right, and just accept what we
22 have from three years ago.

1 So, I mean, we think we probably should
2 be doing more than just accepting something
3 because there is no better data out there.

4 CO-CHAIR KNOWLTON: Therese?

5 MEMBER RICHMOND: You know, I am in
6 Section 2a1.3, which is the measure
7 specifications. I don't see where it says it
8 is individualized, et cetera. I just see --
9 and maybe I am just not reading this correctly
10 -- that there is documentation that they were
11 given written instructions about this, about
12 this, about this, about this. So, what I am
13 reading is not what I think I am hearing you
14 say.

15 MEMBER KAPLITT: We don't want to be
16 unfair. You have got to tell us what pages
17 what you said are on.

18 DR. SCHWAMM: Yes. So, we are looking
19 to find that. Each of the five domains are
20 specified in the Hospital Specification
21 Manual, but give us a minute to try to
22 identify that for you.

1 CO-CHAIR KNOWLTON: While you are
2 looking, Risha?

3 MEMBER GIDWANI: I agree with actually
4 all the points that have been made here. I
5 think that these measures are far from
6 perfect. I think it is right that they need
7 to be addressed for cultural-sensitivity,
8 literacy, and that data do need to be
9 presented, that these measures have been in
10 effect for a long time.

11 For me, though, the overarching concern
12 is that, if we do not endorse this measure,
13 the message that sends, in the absence of
14 having any other education measures, is that
15 education is not considered important from an
16 NQF perspective. That, to me, is more
17 dangerous.

18 I would rather see an endorsement with
19 a requirement that The Joint Commission
20 present data next time and make a more
21 comprehensive and cogent measure than to see
22 no measure at all.

1 MEMBER LABOVITZ: Just let me explain
2 something, and Reva can kick me under the
3 table or above the table.

4 We don't have the option of endorsement
5 with a recommendation to do it in a particular
6 way that forces it. Your only clout, if you
7 want to change something, is by not approving
8 the measure, which will bring about a change
9 in the measure. Now we can debate whether
10 that is good or that is bad, which may be to
11 your point, but we don't have the option you
12 suggested.

13 The problem, the dilemma you get into
14 here is whether you let a measure that has
15 been around for a long time -- everything you
16 say here is being transcribed and it goes to
17 everything is here. So, it doesn't go back,
18 "Oh, they just rolled over and decided this
19 was a bad idea. Education is a bad idea." It
20 won't go that way. This entire debate will be
21 heard or will be read. So, it doesn't go
22 quite that way.

1 But there is still an element -- I am
2 not denigrating your argument; I am just
3 fleshing it out a little bit to say we don't
4 act in vacuum. Everything you do here, when
5 we said, "God Bless you" to Gwen when she
6 sneezed, it is on the transcripts. So, it is
7 a real-time thing.

8 Did you have something to add to that,
9 Reva?

10 DR. WINKLER: The only thing, just in
11 response, is really what we are asking you is
12 to please use the criteria, apply the
13 information that has been presented, and
14 answer the question to your best ability of,
15 does the measure information provided meet the
16 criteria as we have described them? And you
17 have had plenty of experience today knowing
18 what those are. So, that is really the
19 fundamental question we are asking of you.

20 CO-CHAIR KNOWLTON: Bill?

21 MEMBER BARSAN: So, let me take a little
22 different tact. You know, I agree that

1 education is important. I don't disagree with
2 that. I think that should be something that
3 we think is important.

4 What I am thinking of is, okay, if I go
5 back to my institution or another institution
6 and talk to people who are responsible for
7 carrying this out, and they say, "What's the
8 evidence that this helps?", I mean, I would
9 like to be able to say, "Yes, we have good
10 evidence," not "Gee, we're just trying to get
11 you to do the right thing, even though we
12 don't have any evidence that this is
13 effective." I would have a really hard time
14 taking that stance.

15 I think it is really important that we
16 stress things that are important, but that
17 there is evidence to back them up and we don't
18 just do them because we think it is a good
19 thing.

20 CO-CHAIR KNOWLTON: Dan?

21 MEMBER LABOVITZ: I think we have been
22 very focused on data where it exists and have

1 really grilled our developers and each other
2 on what these data mean and how valid it is.

3 And now, here we are in a data-free
4 zone. I think there is real harm in spending
5 money, and it costs money to do proper
6 education, it really does. It is real nursing
7 time. It is real doctor time. It is time I
8 spend in my office.

9 But mandating that money be spent where
10 we have no known benefit, none, I think is
11 really a failure to do proper triage, which is
12 the situation we are in. We are all strapped
13 for cash. I want to spend my cash where it
14 really makes a difference. I have a lot of
15 places to spend it.

16 And these measures become mandates.
17 They are unfunded, but I have to do it and I
18 have to spend a nurse to do it. I don't want
19 to spend that money unless I know it is really
20 paying off.

21 CO-CHAIR KNOWLTON: Salina?

22 MEMBER WADDY: I do think it is

1 important that physicians educate their
2 patients as well as family members and
3 caregivers. But how you do it is completely
4 a new question. And considering this is a
5 stroke education component, I think it has to
6 live up to the same stringency and criteria
7 that the other measures have.

8 I do think that -- and you can correct
9 me if I am wrong from the NQF -- I mean, we
10 can make a recommendation, right, regarding
11 strengthening this -- what is this called? --
12 strengthening this measure.

13 DR. WINKLER: Are you trying to say you
14 would like to see better measures of stroke
15 education in the future?

16 MEMBER WADDY: Yes, in the near future.

17 DR. WINKLER: Fine. The near future.

18 MEMBER WADDY: But the way that it is
19 written as-is, it is very limiting.

20 CO-CHAIR KNOWLTON: Greg?

21 MEMBER KAPINOS: Dr. Labovitz said we
22 didn't have any data. The same way we --

1 CO-CHAIR KNOWLTON: Move closer to your
2 microphone a little bit, Greg.

3 MEMBER KAPINOS: The same way earlier on
4 we used some of the evidence that was not
5 purely targeting stroke patients, for
6 instance, for statins when there is only one
7 trial, but the other trials were in a more
8 broadened group of cardiovascular disease,
9 couldn't we do the same with education. Like
10 next time somebody submits a measure that is
11 addressing education, if we broaden it to
12 cardiovascular disease, I think the cardiology
13 literature has some evidence that education
14 has been very helpful in ameliorating outcome.

15 Or maybe there will be a little bit more
16 data than the zero data that we have now. So,
17 I am just saying, what is our threshold to
18 extrapolate data from other slightly different
19 diseases into fields when we don't have enough
20 data targeting exactly the population that we
21 are talking about?

22 MEMBER WADDY: May I answer?

1 CO-CHAIR KNOWLTON: Yes.

2 MEMBER WADDY: Actually, there are some
3 ongoing stroke education behavior change
4 interventions, one that was actually
5 mentioned, that was mentioned in the writeup,
6 "the Protect D.C.," that enrollment has now
7 completed or -- yes, that enrollment now has
8 been completed. And in the next year, that
9 data will be out. The SWIFT study is out as
10 well.

11 I am actually in charge of the
12 initiative for the stroke prevention
13 intervention research project in which there
14 are multiple --

15 CO-CHAIR KNOWLTON: So, you are not
16 going to let us drop it?

17 MEMBER WADDY: Huh?

18 CO-CHAIR KNOWLTON: You are not going to
19 let us drop it?

20 MEMBER WADDY: Oh, no, absolutely not.

21 (Laughter.)

22 DR. WINKLER: Just to respond to Greg,

1 you have opened that door rather interestingly
2 about looking to other areas. And NQF, not
3 too long ago, removed the endorsement on the
4 heart failure education measure, for exactly
5 the same issues that have been raised here.

6 CO-CHAIR KNOWLTON: Michael?

7 MEMBER KAPLITT: I would also just add,
8 for those concerned about message, two things.
9 First, if we know that there is paper coming
10 out that may have a more rigorous standard and
11 that shows a positive result, and we wind up
12 endorsing a less-rigorous standard with lesser
13 data, I am worried about that message, No. 1.

14 And No. 2, I think that since the
15 developer clearly has an ongoing interest in
16 this, I don't think that this developer is
17 going away and going to become disinterested
18 in this subject.

19 If there were pushback from the
20 hospitals, et cetera, for a more rigorous
21 measure, I would argue that, if there is
22 justifiable reason to withdraw endorsement,

1 that would arm the developer to do a better
2 measure later on, rather than send the wrong
3 message.

4 CO-CHAIR KNOWLTON: Everybody all in?
5 Are we done?

6 (No response.)

7 Okay. We are voting on the impact of
8 this particular measure as written. Open the
9 voting.

10 (Vote taken.)

11 MS. THEBERGE: Two high, 4 moderate, 4
12 low, and 12 insufficient evidence.

13 CO-CHAIR KNOWLTON: We're done with that
14 measure.

15 Okay. Next is me.

16 CO-CHAIR TIRSCHWELL: Okay. The next
17 measure, Dave, NIH Stroke Scale Reported.

18 CO-CHAIR KNOWLTON: This is Measure
19 1955. It is the NIH Stroke Scale recorded
20 measure, which measures the percentage of
21 patients 18 or older with ischemic or non-
22 specific stroke with an initial NIH Stroke

1 Scale recorded. It is a process measure
2 endorsed by the American Heart Association and
3 the American Stroke Association.

4 It is a graded neurological exam that
5 assesses speech, language, recognition, and
6 attention, visual field abnormalities, motor
7 and sensory impairments, and ataxia. And it
8 lists some exclusions that you can read.

9 The group voted to say that it was
10 important to measure.

11 Do we have any comments or questions?

12 MEMBER KAPINOS: I am curious to know if
13 anybody -- I mean, why didn't we bring up,
14 also, the fact that there is at least higher
15 reliability, I believe, with -- yes, I think
16 it was higher reliability -- with the Modified
17 NIH Stroke Scale?

18 So, one of the developer NIH folks here,
19 maybe one of your friends, since the stroke
20 communities are really small, can relook again
21 at each of those items. And I think there are
22 two or three items that were removed and one

1 that was modified for the sensory. Instead of
2 0-1-2, it is like 0 and 1.

3 So, Modified NIH Stroke Scale, according
4 to the recent literature, is actually more
5 reliable than the NIH Stroke Scale. So, maybe
6 we should think about that before we endorse
7 again --

8 CO-CHAIR TIRSCHWELL: Does the developer
9 want to address that?

10 DR. SCHWAMM: Yes. So, Patrick Lyden
11 did develop a modified version of the NIH
12 Stroke Scale, largely in an effort to try to
13 increase adoption and improve reliability. It
14 has never really taken hold. And in fact,
15 subsequent studies of the NIH Stroke Scale
16 have shown very high rates of weighted kappa
17 agreement.

18 And so, I think that there is good
19 justification for continuing with the full NIH
20 Stroke Scale, and all of the data we have
21 about the use of the NIH Stroke Scale to
22 predict mortality, functional outcomes, that

1 is all based on the full scale, not the
2 modified scale.

3 CO-CHAIR TIRSCHWELL: Bill?

4 MEMBER BARSAN: I actually was part of
5 the group that helped develop the original NIH
6 Stroke Scale. I believe in that, and I think
7 it is a great measure. And I do think it is
8 very valuable in predicting outcome and doing
9 all the other things.

10 I am just not sure -- I don't see the
11 link with improved outcomes. It is good for
12 predicting outcomes. It is certainly good for
13 evaluating stroke patients. But where is the
14 link there? And I am not sure where the
15 evidence is on that.

16 CO-CHAIR KNOWLTON: Bill, we discussed
17 that during our Working Group meeting, a phone
18 call. And it was the use of this -- and I am
19 not the clinician here -- but it was the use
20 of this in making the determination regarding
21 initiation of t-PA. So, the outcome -- am I
22 saying all this right? -- so, the outcome was

1 tied to making that decision. It might not
2 necessarily be the outcome in terms of the
3 specific patient.

4 That was the argument. I am just
5 reiterating the argument we made during our
6 session.

7 MEMBER KAPINOS: But, actually, there is
8 also data that -- I mean, there are a lot of
9 neurologists that practice saying that you
10 should not use the NIH Stroke Scale because,
11 actually, you can have an NIH Stroke Scale of
12 zero and still receive t-PA if you are a
13 pianist and it is involving your right hand.
14 And you can have an NIH Stroke Scale of 23-25
15 and many stroke neurologists will still give
16 you t-PA, even if it listed as a warning, or
17 whatever, in that long list. So, the NIH
18 Stroke Scale by itself is not necessary to
19 decide about t-PA.

20 CO-CHAIR TIRSCHWELL: I guess I would
21 ask the developer if they want to respond to
22 the impact that this measure would have.

1 DR. SCHWAMM: Yes. So, I think these
2 are all very reasonable concerns. I think
3 measuring the NIH Stroke Scale itself, in and
4 of itself, doesn't change outcome, just like
5 doing a CT scan, in and of itself, doesn't
6 change outcome. But it enables decisionmaking
7 that can have a profound impact on patient
8 outcomes.

9 So, No. 1, whether you pick this or some
10 other arbitrary scale -- and this is by far
11 the one that is most commonly used -- it is
12 necessary to assess stroke severity or stroke
13 disability to determine eligibility for t-PA.
14 Whether you have a strict cutoff or not, you
15 need some assessment of the degree of
16 disability.

17 I think the second thing is that we have
18 good data to suggest that NIH Stroke Scales
19 above a certain threshold, say 10, have a high
20 predictive relationship to proximal arterial
21 occlusion, and those patients benefit from
22 transfer to centers that have stroke units and

1 more comprehensive stroke care.

2 And I think the last, and most
3 important, issue, I think, is as it relates to
4 risk adjustment for stroke outcomes. Without
5 stroke severity measured on all patients, it
6 is impossible to risk-adjust outcomes to
7 understand if care is different at different
8 centers. And no degree of propensity-matching
9 or other approximate variables captures the
10 power that the NIH Stroke Scale does in models
11 both in Medicare patients, in the fee-for-
12 service Medicare dataset, which is 65 and
13 older, as well as models with patients ages 18
14 and above.

15 The NIH Stroke Scale by itself, with no
16 other additional variables, has a C statistic
17 of .83 for predicting mortality and outcome.
18 So, it is a tremendously-powerful variable.
19 I think we all know that intuitively.

20 All of the models that you will hear
21 about, I think it is probably tomorrow, that
22 look at risk adjustment for claims-based risk

1 adjustment, have no severity marker, and
2 therefore, cannot adequately risk-adjust the
3 way that we would all like them to.

4 So, having an NQF-endorsed measure
5 related to stroke severity would permit CMS to
6 collect NIH Stroke Scale scores and allow that
7 to become part of an appropriate risk-
8 adjustment report that could be used on all
9 hospitals, not just those selective hospitals
10 who take the effort to record an NIH Stroke
11 Scale score.

12 CO-CHAIR TIRSCHWELL: I guess I will
13 make one comment, and then Salina and Risha.

14 It seems like, if that is the purpose,
15 then it should be included as a component of
16 a mortality measure, and not necessarily
17 standing on its own.

18 Salina, I think you were next.

19 MEMBER WADDY: Yes. So, my comments are
20 largely along this same line.

21 First, if it is really for t-PA
22 decisionmaking, we are already measuring t-PA.

1 And so, you can use whichever scale you feel
2 is necessary in order to make that decision,
3 and that is really the metric.

4 But I really did like your second point
5 regarding being able to equalize across
6 centers and determine whether or not there is
7 increased severity. Whether or not CMS needs
8 that information, and they should make that
9 decision, but you certainly threw a wrinkle in
10 there for me because of it. You rescued it.

11 (Laughter.)

12 DR. SCHWAMM: Am I not supposed to
13 respond? Sorry.

14 MEMBER GIDWANI: I may drown that. I
15 think the NIHSS is important. I can't speak
16 to the clinical aspect of things, but I can
17 speak to the risk-adjustment component.

18 While it is and can be an important
19 factor for risk adjustment, I severely
20 question the actual use of it for risk
21 adjustment. If there is no billing code
22 associated with the NIHSS score, then that

1 can't be used for the CMS models or for the
2 vast majority of models that actually rely on
3 ICD-9 billing codes.

4 Even if there was an ICD-9 billing code,
5 the likelihood is that that billing code would
6 just assess whether the NIHSS was administered
7 or not, rather than provide the actual score
8 associated with the NIHSS. And that latter
9 component is what would be necessary for the
10 risk adjustment.

11 So, if the purpose of this is really to
12 use NIHSS for risk adjustment, I don't know
13 that this measure actually sets the parameters
14 up so that it can be utilized thusly.

15 CO-CHAIR TIRSCHWELL: Do you want to
16 respond, Dr. Schwamm?

17 DR. SCHWAMM: Yes. So, I think this is
18 the Catch-22. Everyone who builds risk models
19 says, "Well, we can't do any better because we
20 don't have a stroke severity marker. So,
21 these models are good enough."

22 This is the first step to getting stroke

1 severity markers into the administrative
2 claims database. I suppose this is
3 appropriate to share with the Committee. CMS
4 has approached us about the possibility of
5 creating a code that would actually codify the
6 NIH Stroke Scale value itself as the measure
7 of adherence. So that the information related
8 to severity would be coded in the
9 administrative datasets, which would then
10 allow appropriate risk adjustment.

11 So, we see this both as having immediate
12 clinical benefit, which is assessing stroke
13 severity is an important component just like
14 assessing the need for rehabilitation
15 services, just like assessing presence or
16 absence of hemorrhage. It is a component that
17 helps determine the level of care that is
18 provided and raises concerns about risks or
19 benefits of other therapies which we know are
20 efficacious, like t-PA.

21 But it also sets the stage for the
22 opportunity to really dramatically leverage

1 this incredibly-important variable which has,
2 until now, been unavailable for large-scale
3 assessments of performance in the United
4 States.

5 CO-CHAIR TIRSCHWELL: Ramon?

6 MEMBER R. BAUTISTA: I may be
7 paraphrasing you here. I really like the idea
8 of standardizing the way strokes are maybe
9 quantified. And I think of the mini mental
10 status exam, for example, or the Klasco-
11 Coleman Scale as having reached that level of
12 wide use.

13 But aside from the fact that this is
14 mainly for t-PA at this point, it is mainly a
15 research, outside of the t-PA protocol, it is
16 mainly a research endeavor. And my only fear
17 is that it may be misused for things other
18 than what it was really intended for.

19 CO-CHAIR TIRSCHWELL: Ann?

20 MEMBER BARRETT: I will just comment
21 that, although I, too, am moved by the idea of
22 a severity measure, it is very important, if

1 this is going to be used in some way across
2 populations, and particularly for individuals,
3 in predicting risk of disability or cost of
4 care or determining these variables, that it
5 be valid across different types of stroke.
6 And, of course, it is known that the NIH
7 Stroke Scale underrepresents right brain
8 stroke, the severity of right brain stroke.
9 And thus, those survivors who may have as much
10 as twice as long clinical stay or other higher
11 risk of falls may be systematically
12 underrepresented, as well as those who have
13 thrombotic stroke, and that may introduce
14 health disparities in different populations.

15 CO-CHAIR TIRSCHWELL: Ramon again.

16 MEMBER R. BAUTISTA: And also, requiring
17 non-neurologists, ER doctors, hospitalists,
18 family practice docs, to perform an NIH Stroke
19 Scale may be a problem in implementation down
20 the road.

21 MEMBER BARSAN: Let me address that.

22 CO-CHAIR TIRSCHWELL: Bill, go ahead.

1 MEMBER BARSAN: Actually, when it was
2 validated to begin with, it was tested on
3 residents, attending physicians, emergency
4 medicine docs, nurses, and it has good
5 validity across all groups. So, there is
6 really not an issue with one group being able
7 to do it better than another.

8 MEMBER R. BAUTISTA: But this would be
9 to require pretty much everybody who sees a
10 stroke patient to do that.

11 CO-CHAIR TIRSCHWELL: Any other
12 comments?

13 (No response.)

14 I think we should go ahead and open the
15 voting on impact.

16 (Vote taken.)

17 MS. THEBERGE: Five high, 10 moderate,
18 3 low, 4 insufficient evidence.

19 CO-CHAIR TIRSCHWELL: Okay. Moving on
20 to evidence.

21 CO-CHAIR KNOWLTON: Okay. As we look at
22 evidence, the Committee -- only three of us

1 voted on this -- but all three found that
2 there was evidence, although there was one
3 rating of low.

4 We kind of discussed many of the issues
5 that were raised in that, in the discussion by
6 the Committee. So, I will only go further if
7 you need it or if someone has a comment.

8 CO-CHAIR TIRSCHWELL: Any other comments
9 about the amount of evidence supporting this?

10 (No response.)

11 Okay. Let's go ahead and open up,
12 activate the voting. Don't vote. Now you can
13 vote. If you voted early, you probably want
14 to vote again.

15 (Vote taken.)

16 Still too short.

17 MS. THEBERGE: We are short two votes.

18 MEMBER KAPINOS: In hemorrhagic stroke,
19 it would have dropped significantly the
20 quality of the evidence for the measure if we
21 included an NIH Stroke Scale for hemorrhagic
22 stroke, too?

1 CO-CHAIR TIRSCHWELL: We are kind of
2 post-vote here. It was pretty close and one
3 missing. So, I think we probably need to do
4 that again.

5 So, why don't you go ahead and make your
6 comment? And Dr. Schwamm, we will let you
7 respond.

8 MEMBER KAPINOS: I wanted to know if
9 right now this measure is focusing only on the
10 ischemic stroke patients to receive an NIH
11 Stroke Scale. Why didn't we broaden that to
12 also hemorrhagic stroke? Is the only reason
13 the lack of evidence in hemorrhagic stroke?

14 DR. SCHWAMM: So, traditionally, it has
15 not been a scale that has been applied in
16 hemorrhagic stroke patients. But in Get With
17 The Guidelines, we do collect it, and many
18 sites report it for their hemorrhagic strokes.

19 And actually, we presented an abstract
20 at last year's International Stroke Conference
21 showing that it retains the same degree of
22 predictive outcome capacity when you look at

1 a global model of stroke, so all stroke types
2 together.

3 So, I think it is more a question of
4 custom, and there is not a lot of data out
5 there on its use within hemorrhagic
6 populations, but it probably remains valid.

7 MEMBER KAPINOS: That's fine.

8 CO-CHAIR TIRSCHWELL: Any other
9 comments?

10 (No response.)

11 I think we have to re-vote on the
12 evidence. So, let's all try to wait for the
13 -- okay. Now everybody raise your hands high.

14 (Re-vote taken.)

15 MS. THEBERGE: We are still at 20.

16 CO-CHAIR TIRSCHWELL: One more time,
17 everybody.

18 MS. THEBERGE: You have to vote either
19 1 or 2.

20 There we go.

21 (Laughter.)

22 CO-CHAIR TIRSCHWELL: All right.

1 MS. THEBERGE: It is 10 yes and 12 no.

2 CO-CHAIR TIRSCHWELL: That was very
3 close.

4 Okay. So, I guess we are done, then,
5 discussing this measure at this point, and we
6 are moving on to 0244. Sorry. We are going
7 to change again. We are going to change to
8 0441 first, Stroke No. 10, "Assess for
9 rehabilitation" from The Joint Commission.

10 And David?

11 MEMBER HACKNEY: All right. Let me
12 first give a little disclaimer. I don't do
13 stroke rehabilitation, and I was originally
14 mistakenly assigned and then re-assigned to a
15 more appropriate topic. So, I am still
16 supposed to do this introduction, but I wasn't
17 on the conference call. So, some of my
18 comments may have been dealt with on the
19 conference call, but I didn't get that from
20 reading the summary. And the rest may come
21 from the fact that, as I said, I don't do
22 stroke rehabilitation.

1 So, anyway, the goal of this is to, I
2 suppose the goal is to ensure that patients
3 who are admitted for stroke are appropriately
4 assessed for rehabilitation and to document
5 that that has happened. So, this looks at
6 patients who are admitted for stroke and the
7 proportion of them who are either assessed for
8 or receive rehabilitative services before they
9 are discharged.

10 There are exclusion criteria to remove
11 from consideration: patients are transferred
12 to another hospital rather than discharged,
13 left against medical advice, died, or were
14 sent to hospice care. So, it attempts to get
15 at that group of patients who, presumably,
16 should be evaluated for rehabilitation.

17 So, going on to 1a, impact, stroke rehab
18 is believed to be an important component of
19 stroke care. It is not entirely clear to me
20 that this measure really addresses that, for
21 reasons we will get into as we move through.

22 But the vote for impact was strong

1 support for impact among the Work Group when
2 they discussed it. So, maybe we should stop
3 at that point.

4 CO-CHAIR TIRSCHWELL: Okay. Any
5 comments on impact for assessment for stroke
6 rehabilitation?

7 (No response.)

8 Okay. Let's go ahead and open the
9 voting. And now you can go ahead and vote.

10 (Vote taken.)

11 MS. THEBERGE: Fifteen high, 7 moderate.

12 CO-CHAIR TIRSCHWELL: Okay. Moving on
13 to evidence.

14 MEMBER HACKNEY: Okay. Next, I have
15 performance gap.

16 CO-CHAIR TIRSCHWELL: Well, we do
17 evidence first. We are doing them out of
18 order. Sorry.

19 MEMBER HACKNEY: Oh, okay. All right.

20 CO-CHAIR TIRSCHWELL: We have been doing
21 that all day.

22 (Laughter.)

1 MEMBER HACKNEY: Yes, I know, but my
2 notes are in the order that they were when I
3 started.

4 Evidence. So, evidence was rated high
5 by everyone. My not being a stroke person,
6 not being a rehab person, the evidence talked
7 about the value of rehabilitation, but not
8 about the impact of making the rehabilitation
9 decision before discharge. And I didn't see
10 that there was really any data on that
11 specifically. You can understand the logic.
12 Presumably, that is when the people are
13 accessible and you can collect the data. But
14 whether making that decision and evaluation in
15 followup is acceptable or not, I have no
16 opinion.

17 CO-CHAIR TIRSCHWELL: Any comments on
18 the evidence?

19 (No response.)

20 Let's go ahead and vote on the evidence.

21 (Vote taken.)

22 MS. THEBERGE: Eighteen high -- 18 yes,

1 4 no.

2 CO-CHAIR TIRSCHWELL: Okay. And now,
3 back to the performance-gap issue.

4 MEMBER HACKNEY: Okay. Performance gap,
5 estimates of compliance are very high, in the
6 high nineties, and they have been going up
7 very slightly. They can't go up much; they
8 were 97 percent in 2009 and up to 97.4 in
9 2011. So, there is not much room for
10 performance improvement, but if this is
11 important, then it may be important to make
12 sure that people keep doing it.

13 I had some question about whether a
14 compliance rate that high might be different
15 than 100 percent only because of discordances
16 in the coding of the charts rather than actual
17 failure to do it. But there isn't room for
18 much improvement by performance gap.

19 There is a discussion of disparities
20 that says there are disparities by ethnic
21 group in stroke outcome and to some extent in
22 stroke treatment, but not about whether there

1 were disparities in assess for rehabilitation
2 or getting rehabilitation services.

3 MEMBER WADDY: There are.

4 MEMBER HACKNEY: There are? Okay. That
5 wasn't documented.

6 CO-CHAIR TIRSCHWELL: So, there are big
7 disparities in rehab --

8 MEMBER WADDY: For African-Americans as
9 well as Alaskan Natives, there are different
10 reasons for that. Unfortunately, rehab as
11 well is tied into insurance and how long your
12 insurance for pay for it and whether or not
13 they will pay for it at all, which it is a bit
14 separate, but it is what it is.

15 CO-CHAIR TIRSCHWELL: Yes.

16 Any other comments on the presence of a
17 performance gap and whether these very high
18 ratings that The Joint Commission reports may
19 not capture the whole picture, which is what
20 I think what is being suggested?

21 (No response.)

22 Okay. Let's go ahead and activate the

1 voting, and go ahead and vote now.

2 (Vote taken.)

3 MS. THEBERGE: We are at 20. There we
4 go.

5 Eleven high, 8 moderate, 3 low.

6 CO-CHAIR TIRSCHWELL: Okay. Great. So,
7 then, we are on to 2a, which is reliability.

8 MEMBER HACKNEY: Okay. There was a
9 feeling that the reliability of the measure
10 was high. So, there wasn't a lot of debate
11 about that.

12 CO-CHAIR TIRSCHWELL: Okay. Any
13 comments on reliability?

14 (No response.)

15 Let's go ahead and activate the voting.
16 Go ahead and vote now on reliability.

17 (Vote taken.)

18 MS. THEBERGE: Nineteen high, 3
19 moderate.

20 CO-CHAIR TIRSCHWELL: And validity, 2b.

21 MEMBER HACKNEY: There was also
22 generally strong support with most people

1 voting high for validity. There was some
2 concern, as is stressed throughout the
3 document, that since these are voluntary
4 reports, they might have a biased set of
5 institutions that are reporting. So, the
6 actual results might not be as good as
7 suggested. But, basically, people supported
8 the validity.

9 CO-CHAIR TIRSCHWELL: Comments on
10 validity?

11 (No response.)

12 Let's go ahead and activate the voting.
13 Go ahead and vote now.

14 (Vote taken.)

15 MS. THEBERGE: Seventeen high, 5
16 moderate.

17 CO-CHAIR TIRSCHWELL: Usability.

18 MEMBER HACKNEY: There was strong
19 support about usability. It has been widely
20 used, and it is believed to be easy to
21 interpret. So, I don't think there were any
22 concerns raised about usability.

1 CO-CHAIR TIRSCHWELL: Any comments?

2 (No response.)

3 Let's go ahead and activate. Now go
4 ahead and vote on usability.

5 (Vote taken.)

6 MS. THEBERGE: Twenty-one high, 1
7 moderate.

8 CO-CHAIR TIRSCHWELL: Feasibility.

9 MEMBER HACKNEY: There were some
10 concerns about feasibility because this
11 requires abstracting data from the medical
12 record, and not all that information is
13 necessarily in the electronic health record.
14 And there were some concerns about how
15 reliably you would get it all out.

16 On the other hand, the report indicates
17 that they have data from an enormous number of
18 hospitals. So, it would certainly suggest
19 that it is practical for -- they didn't
20 address what proportion of stroke patients are
21 represented, but it is such a large number of
22 places reporting it, that I would suggest that

1 that alone is proof that it is feasible.

2 CO-CHAIR TIRSCHWELL: Any further
3 comments on feasibility?

4 (No response.)

5 Activate the voting, and vote on
6 feasibility.

7 (Vote taken.)

8 MS. THEBERGE: Twelve high, 9 moderate,
9 1 low.

10 CO-CHAIR TIRSCHWELL: And then, finally,
11 overall suitability for endorsement. Any
12 further comments, David?

13 MEMBER HACKNEY: Everyone endorsed it.

14 CO-CHAIR TIRSCHWELL: Let's go ahead and
15 open the voting.

16 (Vote taken.)

17 MS. THEBERGE: Twenty-one yes, 1 no.

18 CO-CHAIR TIRSCHWELL: All right. I
19 guess we should go back now to 0244.

20 Do you want to do this one, Dave?

21 Also consideration of rehab services.

22 Also, Dr. David Hackney.

1 MEMBER HACKNEY: So, this is the same
2 preface as the last one. I won't repeat it.

3 Here, unfortunately, there were only two
4 people on the Work Group call. So, we only
5 have two sets of votes, but I will proceed.

6 This is a very similar measure to the
7 last one, slightly different definitions of
8 who included. And this is looking at patients
9 in whom it is ordered, rehabilitation is
10 either ordered or documented that such
11 services are not indicated, as opposed to the
12 prior one which was assessed or received.
13 There are no exclusions.

14 There was a general feeling that this
15 was important, at least that stroke
16 rehabilitation was important. The same
17 questions about whether documenting that this
18 was ordered as an inpatient is critical, they
19 didn't have evidence, but they believed that
20 rehabilitation itself was important.

21 CO-CHAIR KNOWLTON: Any discussion on
22 impact?

1 (No response.)

2 Okay. Let's vote.

3 MEMBER KAPLITT: Can I just ask a quick
4 question?

5 CO-CHAIR KNOWLTON: Okay. I'm sorry.

6 MEMBER KAPLITT: I am sorry, I know it
7 is late.

8 But, as written, I mean, is it possible
9 that someone could order, let's say, speech
10 therapy for someone who has no speech problem,
11 but has, let's say, a paralyzed arm, and that
12 would count? Am I misreading this?

13 MEMBER HACKNEY: I believe so if they
14 wanted to do that.

15 MEMBER KAPLITT: Because my numerator,
16 I mean, the numerator that I am reading --

17 MEMBER HACKNEY: Do you mean does it say
18 "appropriate"?

19 MEMBER KAPLITT: Because as opposed to
20 the last one, where it was that they were
21 assessed and rehab was sort of based on the
22 assessment, presumably, here it is based on

1 the order, as you said, right?

2 MEMBER HACKNEY: Yes. You mean if
3 somebody could just default order that on
4 every single patient, no matter what the
5 nature of their problem was.

6 MEMBER KAPLITT: Something like that.
7 Or they make a mistake and it still counts.
8 Or they whatever. I mean, I am just -- am I
9 missing this?

10 CO-CHAIR KNOWLTON: Well, at some point,
11 you have some clinical judgment. And, yes,
12 could clinical judgment be abused --

13 MEMBER KAPLITT: Well, no, but I
14 disagree because the last one was more
15 relevant to what is going on with the patient.
16 They are assessed for whatever their problem
17 is. Here it is just based on an order. There
18 is no indication of relevance of that order to
19 the patient.

20 MEMBER HACKNEY: The presumption was
21 that the assessment preceded the order, but,
22 I mean, you know, technically, I guess you

1 could order it without assessing.

2 MEMBER KAPLITT: I mean, I am just
3 looking at this for the first time.

4 MEMBER HACKNEY: Yes.

5 MEMBER KAPLITT: I am just asking. If
6 I am wrong about this, you know, then tell me
7 I am wrong.

8 MEMBER KAPINOS: I agree there are
9 institutions that have order sets for every
10 stroke patient regardless of ischemic,
11 hemorrhagic, or whatever. And so, at my
12 institution every stroke patient gets the
13 whole PT/speech therapy order. It is a
14 blanket order for everybody. So, yes,
15 patients with no speech deficits, I mean the
16 speech therapist will receive the order in the
17 computer. And when they come at the bedside,
18 then they will ask, "Do you really want me to
19 see that patient?" And then, we realize, "Oh,
20 no, actually, cancel that order."

21 CO-CHAIR KNOWLTON: Anybody else?

22 MEMBER COONEY: I was just going to

1 comment that I think the reason that it is
2 based on the order is because it is a
3 clinician-specific measure, and that is what
4 the physician does, is they order it. They
5 don't actually perform it. So, that would be
6 my presumption.

7 MS. HANLEY: Yes, I was just going to
8 say that the intent is that the physician
9 determine what is appropriate for that
10 patient, and then take that next step to order
11 it, if indicated, or document that it is not
12 indicated.

13 MEMBER KAPLITT: I have no problem going
14 on faith. I am just saying that that is not
15 what it says. You could do an order where it
16 says that it is disability-appropriate or
17 based on the physician evaluation; it gets
18 ordered. I mean, there are ways to do it that
19 are physician-specific that still makes it
20 clear that they have had to actually make the
21 order relevant to the patient, because you are
22 giving a broad array of things they could

1 order that are not all equivalent.

2 But that's fine. I am happy to take it
3 on faith. If that is what everybody else
4 thinks, that's fine.

5 CO-CHAIR KNOWLTON: Oh, yes, I'm sorry.
6 Jolynn?

7 MEMBER SUKO: Well, I just wanted to
8 respond because at one point in my
9 organization I wore the compliance hat. And
10 so, typically, a pre-checked order for speech,
11 OT, and PT, at least the way we interpreted
12 that was that that was a potential compliance
13 risk.

14 So, CMS would -- I mean, it gets to
15 protecting, to creating that actual
16 assessment, and that there is actually some
17 physician judgment in the services that are
18 being ordered. Now I am not going to say that
19 every organization is going to interpret it as
20 conservatively as we did, but that is from the
21 compliance world what they would probably say
22 about it.

1 CO-CHAIR KNOWLTON: So, change your
2 order sets, Greg.

3 Anything further?

4 (No response.)

5 Let's vote on the impact.

6 (Vote taken.)

7 MS. THEBERGE: Thirteen high, 9
8 moderate.

9 CO-CHAIR KNOWLTON: Moving on to
10 evidence, David.

11 MEMBER HACKNEY: So, there was support
12 for the idea that there is evidence, an
13 evidence base to this.

14 Do you want to do the subgroups of
15 evidence or just that statement first?

16 CO-CHAIR KNOWLTON: Just the evidence,
17 yes or no.

18 MEMBER HACKNEY: Yes or no, the feeling
19 was, yes, there is evidence on the subject.

20 CO-CHAIR KNOWLTON: Comments? Thoughts?

21 (No response.)

22 Let's vote on evidence, up or down.

1 (Vote taken.)

2 MS. THEBERGE: That is 20 yes, 2 no.

3 CO-CHAIR KNOWLTON: Okay. Now we move
4 on to performance gap.

5 MEMBER HACKNEY: Okay. There was mixed
6 feeling about performance gap, and I think the
7 reason for that is they weren't happy with the
8 relationship between the performance-gap
9 evidence about how many stroke survivors get
10 stroke rehabilitation and this particular
11 measure, because there was good evidence that
12 a lot of stroke survivors don't get stroke
13 rehabilitation.

14 But the feeling, I gather, not having
15 been on the call, was that it wasn't clear how
16 important the stroke rehab was to the people
17 who weren't getting it, and it wasn't clear
18 whether the problem was that they didn't get
19 assessed or ordered while they were inpatient.
20 So, it wasn't exactly on point to this
21 measure, but there is certainly evidence that
22 a lot of people have strokes and don't get

1 rehab.

2 CO-CHAIR KNOWLTON: Comments on the gap?

3 (No response.)

4 Okay. Let's vote.

5 (Vote taken.)

6 MS. THEBERGE: Eleven high, 9 moderate,
7 1 low, 1 insufficient.

8 CO-CHAIR KNOWLTON: Okay. Reliability.

9 MEMBER HACKNEY: The two people thought
10 that the reliability was high. When they did
11 repeat abstraction from the medical charts,
12 they got very good reproducibility.

13 CO-CHAIR KNOWLTON: Comments on
14 reliability?

15 (No response.)

16 Let's vote.

17 (Vote taken.)

18 MS. THEBERGE: Sixteen high, 6 moderate.

19 CO-CHAIR KNOWLTON: Validity.

20 MEMBER HACKNEY: That was assessed by
21 expert consensus evaluating face validity, and
22 there was very high agreement in that it was

1 a valid measure.

2 CO-CHAIR KNOWLTON: Comments?

3 (No response.)

4 Okay. Let's vote.

5 (Vote taken.)

6 MS. THEBERGE: Thirteen high, 9

7 moderate.

8 CO-CHAIR KNOWLTON: Usability.

9 MEMBER HACKNEY: This is already in use
10 in several large QI programs that we have been
11 discussing here. So, there is a feeling that
12 it has demonstrated usability.

13 CO-CHAIR KNOWLTON: Salina?

14 MEMBER WADDY: Was there any discussion
15 regarding -- and I guess this actually gets
16 more to both usability as well as feasibility
17 -- but some of these small hospitals, I mean,
18 they take care of a lot of patients around the
19 country. And for them to have PT, OT, speech,
20 or even rehab services, I mean, a lot of them
21 just don't have it.

22 And I am not saying to get rid of this

1 measure because of it, but there is a real
2 reality when this measure is for whether or
3 not the service was ordered at or prior to
4 discharge. So, they may only have outpatient
5 rehabilitation that may or may not happen.

6 MEMBER HACKNEY: This measure, somebody
7 would be in compliance if they ordered, while
8 the patient was an inpatient they ordered
9 outpatient rehab.

10 MEMBER WADDY: Okay.

11 MEMBER HACKNEY: You would be in
12 compliance with that, whether it actually
13 happened or not.

14 MEMBER WADDY: Right.

15 MEMBER HACKNEY: If that addresses your
16 question --

17 MEMBER WADDY: Yes, I mean, I can
18 certainly think of -- I mean, I grew up in
19 Alabama. When you are in the middle of
20 western Alabama, you can order outpatient
21 rehab all you want, but -- (laughter) --
22 Alabama, Mississippi, it is a huge gap.

1 MEMBER HACKNEY: Yes.

2 MEMBER WADDY: I mean, unless you have
3 somebody that can actually take you 300 miles
4 away, it is not going to happen.

5 MEMBER HACKNEY: Yes, I think that is
6 true. I don't know if there is anything in
7 terms of this is a performance measure --

8 MEMBER WADDY: The middle of Alaska --

9 MEMBER HACKNEY: Yes.

10 MEMBER KAPLITT: Correct me if I am
11 wrong, but just usability I thought relates to
12 the usability of the measuring instrument,
13 right, not to the intervention? Right? It is
14 supposed to relate to --

15 MEMBER HACKNEY: Right.

16 MEMBER KAPLITT: -- how usability the
17 measuring instrument is here. If people can't
18 do the actual intervention because of -- you
19 know, that is part of the deal, is that it
20 will, hopefully, help get more resources, or
21 whatever.

22 CO-CHAIR TIRSCHWELL: Perhaps, Salina,

1 your point is more to validity and whether
2 there should be some exclusion for I work in
3 the boonies and it is not possible.

4 (Laughter.)

5 MEMBER WADDY: I think that it is so
6 important that it is not okay to just exclude
7 it, but whether or not things that are now
8 coming down the line are using more technology
9 such as home telerehab or things like that,
10 that really aren't built into the system, I
11 mean, I have been in the middle of Native land
12 or the frontier of Alaska, and you have got to
13 travel by dogsled in the middle of the winter
14 or get on one of those little, bitty planes
15 that are death traps.

16 Oh, I should probably strike that.

17 (Laughter.)

18 But, no, those little, bitty planes, I
19 won't get on them.

20 But, I mean, there is a reality to it,
21 that they are not going to put their family
22 member who has an NIH Stroke Scale score of 16

1 and send them that far away, where no one can
2 visit and no one can see them, and they don't
3 know what is going on at all.

4 MEMBER HACKNEY: If I understand it,
5 this is more a measure of the behavior of the
6 physicians who are managing the patient while
7 they are an inpatient. And that, the
8 situation you described, would be out of their
9 hands. I can see the concern that a hospital
10 could show extremely high compliance even
11 though very few of their patients are actually
12 getting any rehab.

13 MEMBER WADDY: Exactly. Right. It
14 won't mean anything.

15 MEMBER HACKNEY: But that would require
16 a totally different measure that is looking at
17 rehab achieved as opposed to -- which would be
18 done by people other than those who are
19 managing them during their inpatient
20 admission.

21 So, I agree it is a consideration.

22 CO-CHAIR KNOWLTON: We can just add

1 Alabama and Mississippi to the exclusion.

2 Right?

3 (Laughter.)

4 MEMBER KAPINOS: Doesn't it go along
5 with what we have been discussing like for all
6 those measures? It sounds like we have been
7 bashing on like the fact that, if a measure is
8 just to document something or to put an order,
9 it won't have any impact on the outcome
10 directly. Therefore, we should not vote for
11 those measures.

12 And now, like we are going along with --
13 yes. So, I think this measure is the same as
14 the other ones. If you are only documenting
15 that you ordered something or just checking a
16 checkbox, I don't think that is a good
17 measure. Right? Or am I wrong?

18 CO-CHAIR KNOWLTON: Well, I don't know
19 if you are right or wrong. But, in terms of
20 how it is used, very often, this becomes
21 documentation of the need in an area that,
22 without this measure, you wouldn't have.

1 So, while I agree with what Salina said,
2 it is a problem in certain areas, and there
3 are certainly disparity issues that surround
4 it, you never get at those disparity issues if
5 you don't have some measure. And you don't
6 have the forcing function of the doc saying,
7 "This is what should happen."

8 See, the other problem you get into is,
9 then, you don't write them in Alabama because
10 you know it is 300 miles away, and that is a
11 problem, too.

12 Go ahead. Go ahead.

13 MEMBER WADDY: I completely agree with
14 that, but that is why I --

15 CO-CHAIR KNOWLTON: That is why I said,
16 "Go ahead." I knew you were going to agree.

17 MEMBER WADDY: Huh?

18 CO-CHAIR KNOWLTON: That is why I said
19 you could go ahead. I knew you were going to
20 agree.

21 (Laughter.)

22 MEMBER WADDY: I am actually proposing

1 or suggesting or thinking about not getting
2 rid of this measure, but actually having an
3 additional measure that captures whether or
4 not patients actually receive those services.

5 The same, it is not good enough just to
6 order a medication if it never makes it into
7 the patient's body because t-PA was not at
8 that hospital. But, yes, we went ahead and
9 ordered it; that is awesome.

10 CO-CHAIR KNOWLTON: Well, you have just
11 made that recommendation because it was on the
12 record.

13 Mary?

14 MEMBER VAN DE KAMP: I was just going to
15 say that I think that in this case, while
16 there are exceptions to where you can access
17 therapy -- and we certainly see that -- it is
18 more for the overall impact of ordering the
19 rehabilitation services.

20 But, to your point, I think when you get
21 out of the hospital, it is difficult. And I
22 think everyone is having that with the post-

1 acute arena: how do you really follow the
2 patient once they have left?

3 But I think, while those are the
4 exception, the majority still are impacted by
5 the ordering appropriateness.

6 CO-CHAIR KNOWLTON: Greg, do you have a
7 point?

8 MEMBER KAPINOS: Didn't we just endorse
9 actually a measure that was actually slightly
10 better, and like getting rid of all this
11 discussion that we just --

12 CO-CHAIR KNOWLTON: Yes, but that is for
13 later. We are going to reconcile. We are
14 going to harmonize.

15 You look at the measure standing alone.
16 Then, you look at it compared. We did a
17 number of measures that measure the same
18 thing.

19 Anything else on this? This is on
20 usability.

21 (No response.)

22 Okay. Let's vote.

1 (Vote taken.)

2 MS. THEBERGE: Sixteen high, 6 moderate.

3 CO-CHAIR KNOWLTON: Feasibility.

4 MEMBER HACKNEY: The two Work Group
5 members on the call thought it was feasible,
6 and the primary evidence is that it is very
7 widely-used. There was some concern raised
8 that not all the information is necessarily
9 easily extractable from the electronic health
10 record, but because places have been using it
11 successfully, it looks like the measure itself
12 is feasible.

13 CO-CHAIR KNOWLTON: Comments?

14 (No response.)

15 Okay. Let's vote.

16 (Vote taken.)

17 MS. THEBERGE: Seventeen high, 4
18 moderate, 1 low.

19 CO-CHAIR KNOWLTON: And finally, the
20 overall suitability. David?

21 MEMBER HACKNEY: I'm sorry. The Work
22 Group people found it suitable for

1 endorsement.

2 CO-CHAIR KNOWLTON: Comments?

3 (No response.)

4 Okay. Let's vote.

5 You were quick on the flip there,
6 Suzanne.

7 (Vote taken.)

8 MS. THEBERGE: We are at 20.

9 Twenty-one yes, 1 no.

10 CO-CHAIR TIRSCHWELL: Okay. That is the
11 end of the measures, although there is still
12 the consideration of candidate measures.

13 Would people like to take a five-minute
14 bio break or just power through and get out of
15 town here? Bio break? One person, two
16 people. That is a minority. Why don't you
17 all just excuse yourselves for a minute and we
18 will power through? Oh, more than two.

19 (Laughter.)

20 All right, five minutes. Come back in
21 five minutes.

22 (Whereupon, the foregoing matter went

1 off the record at 5:36 p.m. and resumed at
2 5:42 p.m.)

3 MS. JOHNSON: I know everybody is going
4 to be very disappointed to find out that we
5 are not going to have two hours to talk about
6 related and competing this evening.

7 (Laughter.)

8 So, what I am going to do is give you a
9 one-minute spiel, I think, on what related and
10 competing is. And I think you guys already
11 know because it has come up many, many times
12 as you have talked about different measures
13 and such.

14 And while I am doing that, Jessica is
15 going to be walking around giving you a
16 handout. And you can use it as homework
17 tonight, if you choose to do so, or we will
18 look at it tomorrow, so however you want to do
19 that.

20 So, I don't remember if this is on your
21 Quick Guide or not, not exactly. But,
22 basically -- yes, more stuff -- basically, we

1 want to think about different measures,
2 measures that are in the project that you are
3 in, so in the neurology project. And we also
4 bring in potentially other measures that you
5 have not looked at but may be in our portfolio
6 that have been endorsed previously.
7 Basically, we think about them at a conceptual
8 level.

9 So, what we do is we pretty much think
10 about the patient population, so the
11 denominator, and we think about the measure
12 focus. What is being measured? That is
13 usually the numerator.

14 So, what you want to think about is,
15 conceptually, do two or more measures look at
16 the same measure focus? So, are they
17 measuring the same thing? And/or are they
18 measuring the same population? Okay?

19 So, let's do, hypothetically, if we have
20 two measures and one of them is looking at --
21 I will make this up -- mortality amongst
22 patients with stroke 18 and older. And

1 another looks at mortality among stroke
2 patients 65 and older.

3 So, in that example, both of them are
4 looking at stroke mortality. So, that would
5 be the measure focus, and that would be the
6 same, right? Both of them would be looking at
7 mortality.

8 But the populations are a little
9 different. But, really, the population,
10 conceptually, are stroke patients. The fact
11 that one set is 18 and older and the other set
12 is 65 and older is a detail, but,
13 conceptually, you are still looking at stroke
14 patients.

15 So, you have to kind of get yourself a
16 little bit out of being very concrete about
17 the specs and work backwards and think about
18 conceptual. Are they the same or are they
19 different?

20 Well, we do that work for you. So, we
21 present to you the ones that we think are
22 related or competing. Sometimes they are

1 almost both. And sometimes, conceptually, you
2 can argue that one is one or the other.

3 But, at the end of the day, what we ask
4 you to do is, if measures are competing, we
5 want you to try, if you can, to select the
6 best measure. Because if they are competing,
7 basically, what you are saying is I am
8 measuring the same basic thing in the same
9 basic population. And why are there two
10 measures when there could be one? So, if
11 possible, we would ask you to pick the
12 superior measure. If you can't do that, then
13 we would ask you to justify the reasons why
14 you think there is a need for two measures.

15 Now in orientation we went very quickly
16 through that. I will go through that a little
17 bit more in detail tomorrow. But if you
18 happen to want to look over the orientation
19 slides, there is a little flowchart that gives
20 you the steps to think about what you do. In
21 other words, how do you pick a superior
22 measure?

1 For related measures, either your target
2 population is different or your measure focus
3 is different, but they are related. So, when
4 you have related measures, what you would like
5 to have are measures that are as similar in
6 their specifications as they can be.

7 So, that is where we start talking about
8 harmonization. So, to go back to my example,
9 if you had stroke mortality measure, two of
10 them, it is not a great example, but you would
11 ask yourself, is there any way that we could
12 do something so you didn't have two measures
13 and the only difference is age? Okay?

14 So, to give you a flavor of tomorrow, we
15 have already heard that some of the measures
16 have TIA in the denominator and some don't.
17 That would be a place where you would start
18 thinking about, is there a way to harmonize
19 those measures, so that they are very similar
20 in their specs? And again, if yes -- or you
21 can justify the differences.

22 It is probably one of the harder things

1 that we ask you to do, thinking about
2 related/competing. So, that is why (a) we are
3 not going to do it, because we don't have
4 time, and (b) I think if you are like me, you
5 might not have the brain space to be able to
6 do that this afternoon.

7 But go ahead and ask questions.

8 MEMBER KAPLITT: That's fine. If you
9 can clarify one thing? We talked today, we
10 had several measures today that were similar,
11 but one was measuring the physician -- it's on
12 (referring to the microphone).

13 MS. JOHNSON: Oh, sorry. That's fine.

14 MEMBER KAPLITT: We had several measures
15 today where they were measuring basically the
16 same thing, but one was measuring the
17 physician, let's say the order, and one was
18 measuring the hospital doing it. So, what
19 category would that fall under? If they are
20 measuring the same thing in the end, or they
21 are theoretically measuring the same thing,
22 but they are measuring whether the physician

1 is doing it versus whether the hospital is
2 accomplishing it, how is that dealt with?

3 MS. JOHNSON: We would call that,
4 according to NQF definitions, we would call
5 those competing measures. And if possible, we
6 would ask you to state if you think one is
7 superior over the other.

8 Now, often, in those particular cases,
9 having a different level of analysis is often
10 a reason that Steering Committees would say
11 that is a justifiable reason to have two
12 measures, because one looks at clinician and
13 one looks at facility. So, you would have to
14 decide for yourself whether you think that is
15 enough of a difference to justify having two.

16 CO-CHAIR TIRSCHWELL: Can we still
17 suggest harmonization if they are still --
18 like we need the clinician versus the
19 hospital, but the criteria are a little
20 different, and we would really like the
21 criteria to be the same?

22 MS. JOHNSON: Yes, you can make

1 recommendations. They are like every other
2 recommendation that you have made today.

3 CO-CHAIR TIRSCHWELL: Non-binding.

4 (Laughter.)

5 MS. JOHNSON: We will put that in the
6 report. There is no mechanism to assure that
7 your recommendation will be taken. That said,
8 developers, of course, do try to accommodate,
9 when they can, but a lot of changes may make
10 a lot of difference in terms of whether their
11 testing would still apply. So, it can be a
12 very big question and a big deal, even
13 something that seems small.

14 So, really, your only stick, if you
15 will, is to say, okay, if there is no
16 opportunity at all for harmonization, then we
17 could actually reverse our recommendation for
18 endorsement. So, what you have done today is
19 you have recommended a lot of measures as
20 suitable for endorsement, but that is kind of
21 the pre-related/competing. So, things that
22 you have recommended today could still go down

1 tomorrow if you think that, for example, one
2 is less superior than another.

3 CO-CHAIR TIRSCHWELL: Gail?

4 MEMBER COONEY: Most of the ones that
5 are similar to what Michael was describing are
6 in the physician/the hospital setting. And if
7 you just look at the ones on the front of the
8 page, it is prescribing antithrombotic therapy
9 at discharge, which is something only a
10 physician can do. But the way the measure was
11 constructed and The Joint Commission
12 materials, it was more consistent and
13 supportive, and yet, it is really a physician
14 -- I mean, can the hospital affect whether or
15 not a physician writes the prescription? I
16 mean, does that come into play at all when you
17 are trying to sort these out?

18 MS. JOHNSON: I think it would come into
19 play, yes, although, hopefully, you thought
20 about some of these issues when you went
21 through the measure the first time. So, you
22 know, what you just asked is, I believe, a

1 validity question. Is this measure really
2 accurate and can that really distinguish
3 quality between facilities? So far, if you
4 had that, then you have, by your vote, said
5 that you believe that it is a valid measure
6 for facilities.

7 MEMBER LABOVITZ: Speaking as a
8 physician, I can say hospitals make us do all
9 kinds of stuff.

10 (Laughter.)

11 MEMBER WADDY: I was going to say the
12 same thing, too, but it really is, overall,
13 what is going on in that hospital. I said
14 previously there are three different practices
15 in the Fairfax INOVA Hospital. And so, if you
16 really wanted to know is everyone being
17 treated that comes into that hospital with
18 antithrombotics, that is one question. But if
19 you went to individual practitioners and
20 individual practices, they may have or may not
21 have different practices.

22 MS. JOHNSON: So, if you take a peek at

1 the homework sheets that we sent around, there
2 are two overarching questions just to kind of
3 keep in the back of your mind as you think
4 about related/competing tomorrow. One is, do
5 we need all of these measures? And then, the
6 second, if so, have they been harmonized as
7 much as possible? So, that is what we are
8 trying to get to with the related and
9 competing conversation.

10 I think if we have no more questions and
11 we are almost out of time, we still have to
12 open this up to public comment.

13 You're on the ball. Does anybody have
14 any more questions before we end and hand it
15 over?

16 CO-CHAIR KNOWLTON: We have to open for
17 NQF comment.

18 I also want to highlight we have an
19 early start tomorrow, which will be especially
20 important to us getting out tomorrow
21 afternoon. Having sat through a number of
22 these, I can warn you that really is a risk.

1 So, please be timely tomorrow.

2 Can we have them open the phone line for
3 comment, if there is any public comment?

4 MS. JOHNSON: Amy, can you open the
5 lines for public comment?

6 OPERATOR: Okay. If you would like to
7 leave a comment or have a question, please
8 press *1.

9 (No response.)

10 There are no comments at this time.

11 CO-CHAIR KNOWLTON: Anybody in the
12 public seated here have any comments?

13 (No response.)

14 Seeing none, we are adjourned.

15 (Whereupon, at 5:54 p.m., the meeting
16 was adjourned for the day, to reconvene the
17 following day, Thursday, June 21, 2011.)

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