

NATIONAL QUALITY FORUM

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CARDIOVASCULAR MEASURE ENDORSEMENT PROJECT
STANDING COMMITTEE MEETING

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MONDAY
APRIL 21, 2014

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The Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 11:00 a.m., Mary George and Thomas Kottke, Co-Chairs, presiding.

PRESENT:

MARY GEORGE, MD, MSPH, FACS, FAHA (Co-Chair),
Centers for Disease Control and
Prevention,

Division for Heart Disease and Stroke
Prevention

THOMAS KOTTKE, MD, MSPH (Co-Chair), Medical
Director for Population Health,
Consulting

Cardiologist, HealthPartners

SANA AL-KHATIB, MD, MHS, Duke University
Medical

Center

LINDA BRIGGS, DNP, George Washington
University,

School of Nursing

JEFFREY BURTON, RN, Clinical Performance
Improvement Specialist, United
Physicians

LESLIE CHO, MD, Cleveland Clinic

JOSEPH CLEVELAND, MD, University of Colorado
Denver

MICHAEL CROUCH, MD, MSPH, FAAFP, Texas A&M

University School of Medicine
ELIZABETH DeLONG, PhD, Duke University Medical
Center
TED GIBBONS, MD FACC FACP FASE, Harborview
Medical Center; University of Washington
School of Medicine*
ELLEN HILLEGASS, PT, EdD, CCS, FAACVPR, FAPTA,
American Physical Therapy Association
JUDD HOLLANDER, MD, FACEP, The University of
Pennsylvania
THOMAS JAMES, MD, AmeriHealth Caritas Family
of Companies
JOEL MARRS, PharmD, FNLA, BCPS (AQ
Cardiology),
CLS, Skaggs School of Pharmacy and
Pharmaceutical Sciences, University of
Colorado Anschutz Medical Campus;
American
Society of Health-System Pharmacists
KRISTI MITCHELL, MPH, Senior Vice President,
Avalere Health, LLC
GEORGE PHILIPPIDES, MD, Boston
University/Boston
Medical Center
NICHOLAS RUGGIERO, II, MD, FACP, FACC, FSCAI,
FSVM, FCPP, Thomas Jefferson University
Hospital
JASON SPANGLER, MD, MPH, FACPM, Amgen, Inc.
CHRISTINE STEARNS, JD, MS, NJ Business &
Industry
Association
HENRY TING, MD, MBA, Mayo Clinic
MARK VALENTINE, MBA, The Heart Hospital Baylor
Plano, Baylor Health Care System
MLADEN VIDOVICH, MD, Jesse Brown VA Medical
Center

NQF STAFF:

HELEN BURSTIN, MD, MPH, Senior Vice President,
Performance Measurement
WUNMI ISIJOLA, MPH, Project Manager
VY LUONG, Project Analyst
LINDSEY TIGHE, Senior Project Manager
REVA WINKLER, MD, MPH, Senior Director

ALSO PRESENT:

KYLE CAMPBELL, PharmD, FMQAI*

JENSEN CHIU, MHA, American College of
Cardiology

FRED MASOUDI, MD, MSPH, FACC, American College
of Cardiology

SOEREN MATTKE, DSc, MPH, RAND*

BRAHMAJEE NALLAMOTHU, MD, American College of
Cardiology

LARA SLATTERY, American College of Cardiology

* present by teleconference

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

11:05 a.m.

MS. ISIJOLA: Good morning,
everyone, and welcome to the cardiovascular
standing committee. It's really great to put
some faces to some of the names that we've
been working with over the past few weeks.

My name is Wunmi Isijola. I'm the
project manager here at NQF. And I just want
to kind of give you an overview of what we're
doing today just of our agenda.

So, first, we're going to start
off with some introductions. And I will turn
it over to our general counsel during that
time to talk about the disclosure of interest
followed by some of the roles and
responsibilities as you our standing committee
members.

Then we're going to follow off
with our portfolio review of the
cardiovascular measures. And then we'll get
started with consideration of the candidate

1 measures that we have within this project.

2 And I just wanted to turn it over to Helen.

3 DR. BURSTIN: Good morning,
4 everybody. Just to add my welcome. Helen
5 Burstin. I know many of you and thank you for
6 coming back for those of you who worked with
7 us the last round.

8 We're excited. This is one of our
9 first standing committee meetings. We had one
10 last week as well. And just the idea of
11 having a group who has that knowledge over
12 time and can bring measure issues back to you.

13 We did an ad hoc review, for
14 example, as part of our safety measures
15 project. It was really a huge advancement for
16 us around harmonization, alignment, keeping up
17 with the science, keeping up with the
18 evidence. So I'll be glad to join you for
19 this and thanks, all, for coming.

20 MS. ISIJOLA: Thank you, Helen.
21 And I just wanted to introduce our staff here
22 at NQF.

1 Again, my name is Wunmi Isijola.
2 I wanted to also introduce you to Vy Luong.
3 Many of you have been in contact with her over
4 the past few weeks. And we have our senior
5 project manager Lindsey Tighe who's here as
6 well. And we have Dr. Reva Winkler, our
7 senior director on the project.

8 And I also wanted to briefly
9 introduce our co-chairs. Oh, there's Vy. Say
10 hi, everyone. I also want to introduce our
11 co-chairs who will really be facilitating the
12 discussion today.

13 We have Dr. Thomas Kottke and we
14 have Dr. Mary George. We do appreciate,
15 again, everyone being here and really your
16 efforts over the last few weeks.

17 And with that being said I will
18 turn it over to Ann Hammerstein for our
19 disclosure of interest.

20 MS. HAMMERSMITH: Good morning,
21 everyone. I'm Ann Hammersmith, NQF's general
22 counsel. We're going to combine the

1 introductions with the disclosures because
2 it's a bit quicker that way and we want you to
3 be able to get to your work.

4 I see a few familiar faces so some
5 of you have heard what I'm going to say
6 before. But I will say it again.

7 Just a few reminders. You
8 received a form from us to fill out where we
9 asked you about your professional activities
10 and so on which you turned in and we reviewed.

11 What we like to do at the
12 beginning of the meeting, the first meeting,
13 is to have you go around the table and
14 disclose anything that you think is relevant
15 based upon that form and based upon your
16 activities.

17 I want to remind you you sit as an
18 individual. You do not sit as a
19 representative of your employer. You do not
20 sit as a representative of anyone who may have
21 nominated you to serve on the committee.
22 You're here because you are an expert.

1 Unlike a lot of conflict of
2 interest processes we look at things other
3 than financial issues. So, if you have served
4 on a committee, you may have served on a
5 committee as a volunteer. And if it is
6 relevant to the work that the committee will
7 do then we would look for you to disclose
8 that.

9 In addition, I want to remind you
10 that just because you disclose doesn't mean
11 you have a conflict. Part of the point of
12 this exercise is for people to understand
13 where everyone is coming from and what their
14 background is.

15 We do ask you not to summarize
16 your resume, please. Only disclose things
17 that are relevant to the committee's work. We
18 are particularly interested in any grants,
19 research or consulting work that you may have
20 done, but only if it is relevant to what the
21 committee will be looking at.

22 So with that I'll start with the

1 chairs. I always make the chairs go first.

2 DR. GEORGE: Good morning and
3 welcome. I'm Mary George from CDC in Atlanta.
4 In terms of conflict of interest I was on the
5 previous cardiovascular steering committee and
6 also on an ad hoc NQF committee that reviewed
7 some updated risk-adjusted mortality measures
8 for heart disease.

9 Other than that I don't have any
10 other conflicts of interest.

11 DR. KOTTKE: Tom Kottke from
12 HealthPartners in Minneapolis, in St. Paul.
13 I was on the prior cardiovascular committee.
14 Otherwise no conflicts of interest.

15 MS. STEARNS: Christine Stearns
16 with the New Jersey Business and Industry
17 Association. I work for a trade association
18 with 21,000 businesses in New Jersey. This is
19 the third actual NQF panel that I've worked
20 with. I was on the previous Cardiovascular
21 Steering Committee.

22 DR. HOLLANDER: Judd Hollander.

1 I'm an emergency physician at the University
2 of Pennsylvania. But by our last conference
3 call I'll be an ER doc at Jefferson.

4 I don't believe I have any direct
5 conflicts of interest related to the measures
6 that we're reviewing today.

7 DR. CLEVELAND: Good morning. I'm
8 Joe Cleveland. I'm an adult cardiac surgeon
9 at the University of Colorado here I guess
10 representing -- not representing, but
11 nominated by the Society of Thoracic Surgeons.

12 So in that realm I do have some
13 disclosures. I do and have served on the
14 Quality Measurement Task Force for the STS.
15 And also and currently a member of the Adult
16 Cardiac Surgical Database for the Society of
17 Thoracic Surgeons. Those would be the only
18 disclosures that I think I have. Thank you.

19 DR. JAMES: Good morning. Tom
20 James. And I'm not related to the Tom James
21 who did all the electrophysiologic work.

22 I'm the medical director for

1 clinical policy at AmeriHealth Caritas, a
2 managed Medicaid company. I co-chair the AQA
3 Public Reporting Workgroup and chair the NQF
4 Health Plan Council. And those are my only
5 disclosures.

6 MS. HILLEGASS: Ellen Hillegass.
7 And I'm a representative or referred by the
8 American Physical Therapy Association. I'm an
9 APTA board certified cardiovascular and
10 pulmonary specialist.

11 And I really don't have any
12 disclosures except I was recently appointed to
13 it's called Quality Insights Task Force which
14 does have a measure that was pulled for
15 tomorrow. And I did make you all aware of
16 that.

17 DR. VIDOVICH: Mladen Vidovich.
18 I'm from University of Illinois-Chicago and
19 I'm chief of cardiology at Jesse Brown VA in
20 Chicago. I don't have any direct conflict of
21 interest related to this.

22 I was also recently appointed as

1 the governor-elect for the Department of
2 Veterans Affairs at the American College of
3 Cardiology.

4 MS. DELONG: Liz DeLong. I'm at
5 Duke University. I confess that I have worked
6 on several cardiovascular databases including
7 the NCDR and the STS. I've also served on
8 some previous NQF committees not specifically
9 related to cardiovascular.

10 DR. RUGGIERO: I'm Nick Ruggiero,
11 interventional cardiologist at Thomas
12 Jefferson University in Philadelphia. And I
13 have no conflicts of interest.

14 MS. BRIGGS: Hi, I'm Linda Briggs.
15 I'm a nurse practitioner and faculty at George
16 Washington University School of Nursing. My
17 background is cardiovascular and I've worked
18 both medical and surgical cardiology. I have
19 on conflicts and no disclosures.

20 MR. VALENTINE: Hello, I'm Mark
21 Valentine. I'm the president of the Heart
22 Hospital Baylor Plano and the Heart Hospital

1 Baylor Denton. I've been an administrator for
2 the last 23 years. I have no conflicts.

3 DR. CROUCH: I'm Michael Crouch.
4 I'm a family physician at the Memorial Family
5 Medicine Residency in Sugarland, Texas. I
6 served on a previous cardiovascular NQF
7 committee. I have no other conflicts of
8 interest.

9 MR. MARRS: Hi, I'm Joel Marrs.
10 I'm a clinical pharmacist and a faculty member
11 at the University of Colorado. And no
12 conflicts of interest to disclose.

13 DR. SPANGLER: Good morning, I'm
14 Jason Spangler. I'm executive director of
15 medical policy at Amgen. And as part of that
16 role I lead our quality strategy for the
17 company. So, I am an employee of Amgen.

18 We don't have any current
19 cardiovascular products but we do have a
20 couple of products in the pipeline. None that
21 are directly related to the work that we're
22 doing for this right now in the next phase

1 possibly which I will disclose at that time.

2 Thanks.

3 MS. MITCHELL: Good morning, my
4 name is Kristi Mitchell. I am a senior vice
5 president at Avalere Health. I have no
6 conflicts to disclose. However -- rather no
7 conflicts of interest, but rather I spent 12
8 years at the American College of Cardiology.
9 So it's kind of hard to put that in a box.

10 And as a result I led the
11 development of the National Cardiovascular
12 Data Registry and several of the measures that
13 we are talking about as a staff member.

14 DR. CHO: Hi, I'm Leslie Cho. I'm
15 an interventional cardiologist from Cleveland
16 Clinic and I head the preventive and
17 rehabilitation section. I've served on
18 previous NQF committees and I currently serve
19 on the technical expert committee.

20 DR. PHILIPPIDES: Good morning, my
21 name is George Philippides. I'm a
22 cardiologist at Boston University Medical

1 Center. I was on the prior cardiovascular
2 committee for NQF and have no disclosures.
3 Thank you.

4 DR. AL-KHATIB: Good morning, I'm
5 Sana Al-Khatib. I'm a cardiac
6 electrophysiologist at Duke University. And
7 I don't have any conflicts of interest in
8 relation to the measures that we will be
9 discussing today. But I have worked on
10 performance measures. I co-chair the Measure
11 Development Task Force for the heart rhythm
12 society. I am on the steering committee for
13 the NCDR ICD registry. And I am working --
14 with a working group to inform the development
15 of performance measures for ACC.

16 DR. TING: Good morning, I'm Henry
17 Ting. I'm a cardiologist and health services
18 researcher from Mayo Clinic.

19 I do have some conflicts which
20 I've disclosed. I'm on the ABIM council. I
21 also am on the American College of Cardiology
22 and American Heart Association Task Force for

1 Performance Measures. And I've participated
2 in grant work and received grants from AHRQ
3 and NHLBI to develop some of these measures
4 which I've disclosed and recused myself from.

5 MS. HAMMERSMITH: Okay, I'm going
6 to call on two committee members who are on
7 the phone to disclose. Ted Gibbons?

8 DR. GIBBONS: Hi, I'm Ted Gibbons.
9 I'm at the University of Washington and I'm
10 chief of cardiology at Harborview Medical
11 Center, the public health hospital associated
12 with the University of Washington.

13 I have been on previous NQF
14 cardiovascular committees and I have nothing
15 else to disclose.

16 MS. HAMMERSMITH: Okay, thank you.
17 Jeff Burton? Is Jeff Burton on the line? Are
18 there any other committee members on the line?
19 Okay. Thank you for making those disclosures.

20 And my parting words to you are to
21 make sure that you understand that you are
22 important parts of a successful disclosure of

1 interest process and policy.

2 If you are sitting in a meeting
3 and you think you may have a conflict, if you
4 think a fellow committee member may have a
5 conflict, or if you think someone is behaving
6 in a biased manner please do speak up.

7 We don't want you sitting there in
8 silence if you think that there may be a
9 conflict. You are welcome to bring anything
10 up openly in a meeting. You can go to your
11 co-chairs who will consult with the NQF staff,
12 or you can go directly to NQF staff.

13 So in that spirit do you have
14 anything that you wish to discuss with each
15 other, or do you have any questions of me
16 based upon the disclosures made this morning?
17 Okay, thank you.

18 DR. SPANGLER: I didn't think
19 about this probably before because I didn't
20 think it was relevant but I want to bring it
21 up just in case there's a question.

22 We do have a product that was

1 launched in Europe that's going to be launched
2 here in the U.S. It's a heart failure
3 medicine. And one of the measures I was the
4 primary on was a heart failure one. And it
5 had to do with a follow-up appointment. So,
6 I didn't think it was directly relevant but I
7 wanted to throw that out there in case people
8 thought it was.

9 MS. HAMMERSMITH: Okay. I would
10 say it isn't. You know, if the measure
11 directly implicated that class of bugs then
12 yes, we would have something to talk about.

13 DR. SPANGLER: That's the thought
14 I had but I wanted to throw it out there.

15 MS. HAMMERSMITH: Yes.

16 DR. HOLLANDER: Just because
17 everybody else mentioned committee work, I'm
18 on the Quality and Performance Committee for
19 the American College of Emergency Physicians
20 and they're the people that nominated me. I
21 don't think it's a conflict.

22 MS. HAMMERSMITH: Okay. Thank you

1 for disclosing it. Anything else? All right,
2 thank you.

3 MS. ISIJOLA: Thank you, Ann.
4 Okay. So, I just want to go over some of the
5 roles of standing committee members. I know
6 we went over this during our orientation, but
7 just to kind of give you a recap of some of
8 the expectations that we expect from you as
9 standing committee members.

10 Given your backgrounds we do
11 expect you to act as a proxy for our NQF
12 multi-stakeholder membership and serve on at
13 least a 2- or 3-year term. We will be
14 designating your term assignment during day 2,
15 randomly selecting that. But if you do have
16 any concerns with that please do let us know
17 at that time.

18 And essentially we ask that you
19 work with our staff to really achieve the
20 goals. And in this case it's really
21 evaluating the measures that are at hand. And
22 evaluating this based on the criteria that was

1 presented to you which helps to indicate the
2 extent to which each criterion is met as well
3 as the rationale for the rating.

4 We also ask that you make
5 recommendations to the NQF membership for
6 endorsement by essentially responding to any
7 comments submitted during that review period,
8 but also responding to any direction given by
9 our CSAC committee.

10 And lastly, really just overseeing
11 the portfolio of cardiovascular measures in
12 which we have roughly about 80 measures at
13 this point. So, these are kind of some of the
14 expectations.

15 And really the reason why we opted
16 out to really hold the standing committee is
17 because we wanted to ensure that there is
18 consistency across the board. I mean, once
19 you're starting to look at these measures you
20 get a sense of what's in our portfolio, what
21 are some of the gaps. So we ask based on your
22 expertise to provide that input.

1 And knowing which measures are in
2 our portfolio and understanding what the
3 importance of these measures are.

4 And like I mentioned, just really
5 identifying what are the gaps within our
6 portfolio. Because I know we do hit on some
7 of the subtopics but there are a wide range of
8 measures that aren't necessarily in our
9 portfolio today.

10 And we ask that you are aware of
11 the measurement activities for this topic area
12 and know there are up and coming guidelines
13 within the cardiovascular arena. So we ask
14 that you are cognizant of that and really
15 bring your input as we look through this
16 portfolio.

17 And lastly, just providing your
18 feedback about the evolution of our portfolio
19 and considering additional new measures in
20 which you would like to see within the
21 cardiovascular topic area.

22 So, today we have 17 measures that

1 we will be reviewing over the next two days.
2 And these are just a snapshot of what those
3 measures are. I know we did send an email to
4 you guys about a measure that was withdrawn at
5 the last minute so we will be reviewing 17 of
6 those measures within this project.

7 And now I will turn it over to Dr.
8 Winkler and she will kind of give you an
9 overview of what our portfolio looks like and
10 what measures and how that kind of translate
11 into what we're looking at over the next two
12 days. So, Dr. Winkler?

13 DR. WINKLER: Thank you, Wunmi.
14 I'd like to turn the committee's attention to
15 your Sharepoint site because one of the
16 committee documents we have provided for you
17 is an overview of the portfolio.

18 The cardiovascular portfolio for
19 NQF is one of our largest and it does
20 encompass a wide range of topic areas and
21 measures. One of the things that makes it a
22 little bit easier to get your arms around is

1 to figure out an appropriate framework for
2 organizing and presenting the measures within
3 the framework. And so I do want to kind of go
4 through how we've organized them. But we're
5 certainly open to any input from you in terms
6 of how we might want to improve the framework
7 of the organization around cardiovascular
8 measures.

9 To start off, the cardiovascular
10 topic area is really a very important one.
11 One of the measure priorities from the
12 National Quality Strategy which NQF tries to
13 work with the National Quality Strategy in all
14 the work that we do. One of the priorities is
15 promoting the most effective prevention and
16 treatment practices for leading causes of
17 mortality. And this is where we come in,
18 starting with cardiovascular disease.

19 So, this is sort of the first
20 topic. It's by no means the only important
21 topic in NQF's portfolio but certainly it is
22 a high-profile one for the NQS. So keep that

1 in mind as we're looking at this portfolio.

2 Now, we have a lot of different
3 topic areas. We currently have more than 70
4 endorsed measures that are in this portfolio
5 that you actually oversee.

6 However, in some of our other
7 topic areas portfolio there are related
8 measures. So we want you to be aware of them
9 and not look just at your particular group in
10 a vacuum but understand that there is
11 crossover. And sometimes our assignment of
12 measures to portfolios is a bit arbitrary.

13 And so being aware that there are
14 other measures out there that may be related
15 helps you understand how any measure you're
16 evaluating fits within not just the
17 cardiovascular portfolio but NQF's portfolio
18 of measures totally.

19 So we have measures around
20 coronary artery disease and acute myocardial
21 infarction. It's one of our biggest subsets
22 of measures. So we're going to take a look at

1 those.

2 We also have a goodly number of
3 measures around heart failure, around rhythm
4 disorders, cardiac cath, actually very few
5 around hypertension considering its importance
6 overall and then some cost and resource use
7 measures.

8 So, organizing this group was a
9 bit of a challenge. But NQF has been working
10 in this area for quite awhile.

11 And so a couple of years ago, it's
12 now -- it's getting on five or six years ago
13 now there was a project in which a group of
14 folks were looking at patient-focused episodes
15 of care. And actually they created a patient-
16 focused episode of care diagram to really look
17 at it from the patient's perspective of
18 focused on the acute myocardial infarction as
19 the episode, but of course realizing there are
20 a lot of antecedent events, there are a lot of
21 related events that could occur.

22 So if you take a look at this,

1 I've heard these referred to as NQF's bubble
2 diagrams. And so you can see that there is a
3 large population at risk, either primary
4 prevention perhaps, certainly secondary
5 prevention in patients that have exhibited
6 their coronary artery disease. So as that
7 large underlying population.

8 There may be an acute phase, an
9 acute event such as an AMI but perhaps it's
10 more of a procedure such as a PCI or a CABG or
11 some other acute event for which there may be
12 an acute phase and care organized around that
13 acute event.

14 After an acute event there are
15 post-acute care, rehabilitation phases. And
16 then those folks again sort of circle back
17 into the secondary prevention.

18 The sense was that patients follow
19 several different potential trajectories.
20 Some somewhat more stable and progress on to
21 a relatively stable situation where focusing
22 in on maintaining functions, secondary

1 prevention is really important.

2 Another pathway of course are
3 those with significant cardiac damage and
4 issues around quality of life, advanced care
5 planning, palliative care, may be more
6 appropriate.

7 So as we look at this sort of
8 spectrum of care we organize the measures for
9 coronary artery disease and acute myocardial
10 infarction according to these different
11 bubbles or phases because it seems to reflect
12 the patient experience. And again, your input
13 into this would be perfectly welcome.

14 And so honestly we do have
15 measures in all the bubbles. The question I
16 think given we've got a large number of
17 measures is do we have the right measures. Do
18 we have measures -- do we have an efficient
19 number of measures. And so again, as part of
20 your oversight this is the kind of input and
21 conversation we'd like you to have.

22 So, if we look at the measures

1 around a population at risk for primary
2 prevention you'll see that we do have several
3 measures around smoking prevalence, tobacco
4 use screening, some cardiovascular screening
5 in certain populations, blood pressure
6 screening and control.

7 Some of these are not in this
8 particular cardiovascular portfolio,
9 particularly the tobacco measures because
10 those are in our what we call health and well-
11 being portfolio because they apply across the
12 board.

13 MS. DELONG: Do we have these?
14 Are we supposed to be following you here?

15 DR. WINKLER: There is a document
16 in your Sharepoint. I don't think it's
17 necessary today right now, but I think after
18 we've had a chance to talk you may find it
19 useful to refer to.

20 So the population at risk, the
21 primary prevention. Also we have several
22 measures around cardiac imaging, stress

1 imaging for relatively low-risk patients, non
2 cardiac low-risk patients, pre-operative
3 evaluation. Again, looking for the patient I
4 think that may have previously undiagnosed
5 cardiac risk factors.

6 So, again, a fairly substantial
7 number. Perhaps there are other measures that
8 are gap areas that you could consider. But
9 again, as we have our conversations going
10 forward not just today but as the committee is
11 looking at measures you may want to think
12 about measures that would be more appropriate
13 gap areas, or where do we move on from here.
14 So these are sort of the first bubble if you
15 will.

16 We talk about secondary
17 prevention. And this is another large area of
18 measures around blood pressure management,
19 antiplatelet therapy, ACE inhibitors, lipid
20 control, blood pressure control, so all the
21 usual characters.

22 I will say that we have -- are

1 postponing maintenance review of any of the
2 measures having to do with blood pressure and
3 lipid control in this immediate time frame
4 because of the recent new guidelines. We're
5 giving developers time to adjust measures to
6 those new guidelines. So it's not that we're
7 not interested, but we are spending a little
8 bit -- giving them a little bit of time to
9 adapt to the new guidelines. So these
10 measures are in the portfolio and you will be
11 seeing them in the next couple of years.

12 So, the next group is again acute
13 phase. I think these are probably measures
14 well known to everyone. They are hospital-
15 level measures as well as clinician-level
16 measures for the care of patients with AMI.
17 Again, many of them are -- the hospital-level
18 measures are reported on Hospital Compare.
19 They've been reported for a long time. We're
20 certainly seeing some high levels of
21 performance at this point in time.

22 And so you'll see that for this in

1 red I've put in the measures that are newly
2 submitted. So they are not part of the
3 portfolio yet. But this is a measure that you
4 will be evaluating tomorrow. And you can see
5 that it's a composite measure. And I'll be
6 very interested to hear your reaction to a
7 composite measure given the number of other
8 measures that already exist in this area.

9 In the acute phase around AMI we
10 have outcome measures as well as the number of
11 process measures. I think you're all aware of
12 those. Again, many of them reported on
13 Hospital Compare.

14 Certainly the readmission
15 measures. We are looking at all readmission
16 measures together in another project. So it
17 will not come to you at this point in time.
18 The readmissions measures are being evaluated
19 by a separate committee. They're meeting next
20 month. So there will be sort of concurrent
21 discussion around the AMI readmission measure
22 that you might be interested in.

1 We also have mortality measures
2 that are inpatient as well as sort of the 30-
3 day all-cause measure that I think you're
4 familiar with.

5 One of the new measures for
6 tomorrow. Again, leading edge, not unusual in
7 the cardiovascular portfolio is a 30-day
8 mortality eMeasure.

9 So this is one of the first, in
10 fact I think it is the first eMeasure that's
11 an outcome measure. We have a couple of that
12 are process measures but eMeasures are sort of
13 a new and up and coming thing. And I think
14 there is the hope that as we're able to
15 transition measures to use the unique
16 characteristics of EHRs eMeasures will become
17 an important aspect of the portfolio. So, you
18 get the first one. So we'll be talking about
19 that measure tomorrow.

20 So outcomes are, again, a big part
21 of this portfolio and evaluating those I think
22 we all agree have some methodologic challenges

1 and are significantly different than process
2 measures.

3 So the next one, again, related.
4 PCI. A lot of patients with AMIs or angina or
5 other risk factors undergo PCI. We actually
6 are going to be looking at eight measures for
7 PCI today. Two of them are new. Maybe four
8 of them are new actually. And plus the
9 existing measures. So, today that's going to
10 be our topic. We haven't looked at these
11 measures in awhile so the existing measures,
12 if you notice there are three measures for
13 mortality, one for inpatient, two for 30-day
14 all-cause. So we will have a conversation
15 about related and competing measures around
16 mortality for PCI later this afternoon.

17 Next, I don't want to overlook the
18 fact that NQS has a large portfolio of
19 measures for coronary artery bypass graft
20 surgery, but they are not for you to evaluate.
21 These belong in our surgery portfolio and that
22 committee actually will be meeting in the end

1 of May to look at measures not only of CABG
2 but other types of surgery.

3 But be aware that we do have a
4 goodly number of measures in this topic area
5 significantly related to cardiovascular
6 disease and being aware that they exist is
7 important for your understanding of NQF's
8 portfolio for cardiovascular disease.

9 So we do have some measures for
10 post-acute rehab phase. So there are some
11 measures for discharge after a PCI. And oh,
12 my mistake. If you notice underneath the red
13 PCI post-procedural optimal outcome therapy is
14 an adherence to antiplatelet therapy. That's
15 also got the large 2379 measure. That's a new
16 measure and I forgot to highlight it in red.
17 So you've got a couple of new measures.

18 Tomorrow we'll be looking at two
19 measures of referral to cardiac rehab for both
20 inpatient and outpatients. So we have a lot
21 of things happening.

22 Then -- we're not done yet. So we

1 do have a lot of secondary prevention measures
2 particularly for patients who've been
3 hospitalized at both the hospital level and at
4 the clinician level. And you can see a goodly
5 number of various types of measures for
6 various types of medications to be prescribed
7 after that acute event. So again, large
8 portfolio of measures.

9 Okay. So that was coronary artery
10 disease and AMI. But that's not the only
11 topic area where it comes to heart disease.

12 So we do have measures around
13 heart failure. And so using that same
14 patient-focused episode of care framework
15 staff has drafted sort of a heart failure-
16 specific framework using the bubbles.

17 And we really would like your
18 feedback on this because again this is one
19 we've drafted internally and we're looking to
20 your expertise to help refine it. But again,
21 it helps organize the framework into sort of
22 a patient approach and how to think about

1 measures for heart failure rather than just a
2 list of measures.

3 So next, the measures again --
4 again, we start with a population at risk.
5 And certainly the smoking, the weight
6 management, controlling high blood pressure.
7 The weight management and smoking are in our
8 health and well-being portfolio. Hypertension
9 control is for you to evaluate though not at
10 this meeting. And of course we already saw a
11 large number of measures for coronary artery
12 disease that could lead to heart failure.

13 So, evaluation and ongoing
14 management for heart failure. We do have
15 measures including one new measure that we
16 will evaluate tomorrow on symptom and activity
17 assessment. But again you can see these are
18 both facility-level measures as well as
19 clinician-level measures that are used
20 significantly in CMS's measurement programs.

21 Next, again, acute phase
22 hospitalization measures for heart failure.

1 You're probably all quite familiar with them.
2 Again, report on Hospital Compare. There's a
3 population-level admission rate that is part
4 of our population health portfolio that you
5 should be aware of.

6 There are the hospital-level
7 measures as well as clinician-level measures.
8 There is a new measure here for post-discharge
9 appointment for heart failure. We also have
10 the readmission rate that is being evaluated
11 in our readmissions project.

12 We do have the 30-day all-cause
13 mortality rate in this portfolio as well as an
14 inpatient heart failure mortality rate. So,
15 a goodly number of measures for the acute
16 phase and outcomes as well for heart failure.

17 But we haven't ignored all other
18 types of heart failure. So there are measures
19 around rhythm disorders such as EKGs for
20 patients with syncope. We have a couple of
21 measures for atrial fibrillation, several
22 measures for ICD use. Those will be coming up

1 in future meetings with you. All part of this
2 portfolio though we won't be discussing them
3 at this meeting.

4 Then we do have a couple of
5 measures for cardiac catheterization,
6 particularly one for children, an adverse
7 event outcome measure. And so we don't want
8 to forget heart disease in children when it's
9 appropriate in our measurement.

10 And then the next one is the
11 couple of measures we have for hypertension.
12 One is a controlling high blood pressure
13 measure. Another is blood pressure screening
14 for adolescents.

15 And then I do believe we've
16 finally reached the end of them. And we have
17 a cost and resource use measure which is being
18 handled by our cost and resource use committee
19 along with other measures of cost and resource
20 use. And it's a relative resource use measure
21 for people with cardiovascular conditions
22 across the spectrum usually associated with

1 hospitalization.

2 So, as you can see this is really
3 one of our largest, most diverse portfolios.
4 It's challenging to get your arms around this
5 number of measures. And so we really would
6 appreciate your input in terms of the best way
7 to organize these measures. If this works for
8 you, great. If you've got suggestions for
9 revisions and improvement, that's great too.

10 So, any comments you'd like to
11 make on the portfolio at this point I've got
12 a couple of more things to talk about before
13 we wrap up.

14 Any thoughts from anybody on the
15 portfolio? I know I kind of ran through it
16 relatively quickly. But I guess just any
17 thoughts as you're undertaking and taking on
18 this challenge? Yes, Tom.

19 DR. JAMES: This may be more of a
20 parking lot issue, but I know that -- and
21 Helen can jump in on this one. That NQF is
22 dealing with the social determinants of health

1 and how those impact these various
2 measurements.

3 As I mentioned, I come from a
4 Medicaid company and so for that reason it's
5 something which is important to our
6 population. I want to ensure that it's
7 someplace within our view.

8 DR. BURSTIN: Yes, thanks, Tom.
9 So NQF embarked about six months ago on a body
10 of work looking at whether outcome measures in
11 particular but not exclusively should be
12 adjusted for sociodemographic determinants.

13 And ultimately the report that
14 came out which is still in process, I want to
15 caution everyone of that, indicated that for
16 certain outcomes where there's a clear
17 conceptual relationship between the outcome
18 and the sociodemographic characteristics, and
19 those factors are not directly related to
20 quality of care, and thirdly, there's an
21 empiric relationship as demonstrated in the
22 analyses some of those perhaps should be

1 adjusted. It was actually quite a nuanced
2 recommendation.

3 It also said clearly that for
4 measures where you're really interested in
5 disparities and quality improvement those
6 measures should be stratified. That report is
7 still in process and actually comment closed
8 last week. We have 667 comments to review, an
9 NQF record. I don't know if that's good or
10 bad, but it clearly I think shows we've picked
11 a question where there's been a lot of
12 consternation for a lot of years. So, the
13 committee will have an opportunity to review
14 those comments. Whatever happens with that it
15 will all play out sometime in June. So we'll
16 come back to this question if we need to
17 depending on where we are with the report.

18 MS. MITCHELL: So, I know that
19 there's been some work on multiple comorbid
20 conditions. But I'm curious about how
21 cardiometabolics is being handled and what
22 sort of is the purview or not of this

1 committee.

2 DR. WINKLER: I know that the
3 conversation comes up a lot. I'm not aware
4 that we have any specific measures. Nor --
5 and this would be a good help from you all if
6 you know if there are any in development
7 around sort of metabolic syndrome and that
8 particular risk group that certainly would be
9 something that I don't think we've got any
10 measures on but it sounds, you know, it would
11 certainly be an important area.

12 If you're aware of any measures in
13 development we'd certainly want to hear about
14 it. Because again, I think you're right, you
15 bring up an important gap area.

16 DR. BURSTIN: And just to build on
17 that comment, Reva. I think the other issue
18 is there's still a fair amount of lipids for
19 diabetes, lipids for hypertension as opposed
20 to really a more holistic view of all the
21 different patient populations that should be
22 part of a measure.

1 And it's interesting, when Reva
2 made the point and there's only one
3 hypertension measure, that's actually somewhat
4 by intent. Many of the other measures have
5 fallen to the wayside as that one measure has
6 become more of the de facto standard that's
7 used by CMS and all the federal agencies now.
8 It has all the different sort of
9 characteristics and different patient
10 populations built into that measure.

11 So a lot of what you'll be talking
12 about over the next couple of days as well is
13 does this really need to be this disease-
14 specific measure to Kristi's point, or is it
15 really more of a global measure we should
16 really push the developers to ultimately move
17 towards more of a population view of who
18 should be getting what, when for the best
19 possible outcomes.

20 DR. SPANGLER: Related to that,
21 and maybe an extension of Kristi's question.
22 If there is a cardiometabolic measure, I mean

1 would that be our purview? Would it be the
2 endocrine steering committee? Are there
3 measures that -- and I guess the broader
4 question. Would there ever be measures that
5 are addressed by two different steering
6 committees at the same time?

7 DR. WINKLER: Yes, I mean we're
8 struggling with the best way to deal with
9 that. As I mentioned, sometimes the
10 assignment to projects can be arbitrary and
11 that's why we want you to be aware of the
12 crossovers. So, actually, you know, we would
13 take a look at actually how it's specified to
14 see what would be the most appropriate place
15 to put it.

16 But I think we need to really
17 think a little bit more about measures that
18 probably belong in two places. Because again,
19 our topic areas are somewhat arbitrary. We're
20 having to make some sort of cut points.

21 But perhaps there may be a way of
22 getting input from both committees so that

1 there was sort of a shared accountability for
2 the measure perhaps that we'll have to talk
3 about how that might happen.

4 But again, we would want input
5 from both certainly. And not, you know, keep
6 ourselves in our little silos. We're trying
7 to break them down actually as much as
8 possible.

9 Any other thoughts from anybody
10 else? Yes, Liz.

11 MS. DELONG: I just want to put on
12 the table that I'm a little concerned about
13 harmonization. As we grow the number of
14 measures and they cross different venues to
15 make sure that we're not coming up with
16 measures that are somewhat inconsistent. And
17 that's what I'm particularly concerned with.
18 And I just want that to be on the table.

19 DR. WINKLER: Sure. And I think
20 given the large number of measures in the
21 topic area I think that it really is a good
22 argument for the need for harmonization. If

1 we expect all of these patients to be
2 subjected to measurement and different
3 unaligned non-harmonized measures are being
4 used it just creates a bit of chaos for
5 absolutely everybody.

6 So, as we look at measures I think
7 you're aware as we discussed them in our
8 workgroups that the issues of related and
9 competing measures and harmonization is
10 something that really is our fifth major
11 criteria. And we do particularly want to
12 focus looking at that.

13 And really to the degree possible
14 get measures harmonized to facilitate their
15 implementation out there. So thank you, Liz,
16 for bringing it up because indeed it is a
17 significant priority for us.

18 DR. BURSTIN: And just one more
19 point on Reva's point. It doesn't always have
20 to just be harmonized. Sometimes it's okay to
21 say it's been measured in one setting and it's
22 kind of done there and it's time to move on.

1 It's topped out.

2 I think there's a lot of
3 measurement burden out there. Many of you on
4 the front line of health systems know this all
5 too well. We really need to be measuring the
6 right thing at the right time. And if it's
7 past due and it should be in a different
8 setting or work across settings just have it
9 done once, the right place, that's really
10 important too. I think we really want to as
11 much as possible reduce the measurement burden
12 out there.

13 DR. HOLLANDER: I'm not sure it's
14 the purview of this committee and it doesn't
15 look like it pertains to these measures, but
16 I'm gathering from what you said there's an
17 admissions/readmission group.

18 And I just want to put out there
19 for thought that what people have done with
20 all these readmission measures is simply gamed
21 the system. And now everybody's going to
22 observation. And it represents the exact same

1 failing as the health system as when they get
2 hospitalized and go upstairs.

3 And I think it's important as
4 measures deal with readmission or admission
5 that it actually consider observation as part
6 of the admission pathway rather than just an
7 excuse to not be counted in the measure. And
8 I think that's getting lost.

9 Some hospitals are now admitting
10 50 percent of their patients to observation.
11 So it's a problem that just needs to be
12 addressed, although it may not be any of the
13 measures we're talking about today and
14 tomorrow.

15 And it was a major part of the
16 discussions last round as well as this
17 upcoming round. I mean, at least the analyses
18 CMS has done would suggest the rate of decline
19 of readmissions is not due -- it's really to
20 the change to a lot of people being admitted
21 to obs. But obviously we've seen a lot of
22 that shift in the marketplace.

1 DR. WINKLER: Again, we fully
2 expect that during the course of your
3 discussions you will bring up thoughts and
4 ideas that will prompt you in terms of gaps or
5 why not measure this instead of that. Feel
6 free to please throw those out there. We'll
7 capture them and include them as part of your
8 sort of assessment of the overall portfolio.

9 Just to kind of finish things up.
10 As I said, this is a particularly important
11 area for the National Quality Strategy to
12 reduce morbidity and mortality according to
13 cardiovascular disease.

14 So the question is how well are we
15 doing. And so I think one of the best sort of
16 measurement tools to get a global population
17 view which is an important sort of bellwether
18 is the National Healthcare Quality Report.

19 And so I just picked the most
20 recent report to kind of ask the question how
21 are we doing. And so they report on three
22 different measurements that I think are

1 particularly salient for us.

2 One is around blood pressure
3 control, and as Helen mentioned blood pressure
4 control is the measure we are looking at. And
5 so I think that over time looking to see how
6 we are doing as a nation by age group over the
7 last decade we are getting a sense that things
8 are improving and that's great.

9 But if you notice the highest is
10 still only 50 percent. So we've got a long
11 way to go.

12 And I think measurement and the
13 measures we have are some of the tools to help
14 us continue to improve. By no means is it the
15 only thing that's driving improvement. It's
16 actually the work that's being done on the
17 front lines with clinicians and their
18 patients. But nonetheless, it's useful to
19 keep an eye on how are we doing globally.

20 So the next one, again, deaths
21 from heart attack. Something that's improving
22 significantly. This again per 1,000

1 admissions. Because the overall incidence of
2 MI seems to be declining as well over time.
3 Perhaps we're getting -- intervening up front
4 into the risk factors before an AMI actually
5 occurs. So there does seem to be improvement
6 in mortality around heart attack. So we hope
7 that this continues.

8 And keeping an eye on those
9 outcome measures is really an important sense
10 of how we're succeeding in improving the
11 quality of care in this particular topic area.

12 And then lastly, hospitalizations
13 for heart failure, again a chronic condition
14 that tends to be progressive at either a
15 greater or a slower rate. It's interesting
16 that when it's stratified by age groups we're
17 down low for everybody but the Medicare
18 population which of course this is a huge
19 area.

20 There does seem to be over the
21 last decade some decline in admissions for
22 heart failure. We certainly would like to see

1 ongoing improvement to decrease cost to both
2 patients and to the system. So I think that
3 in general we have a sense that improvement is
4 occurring. And so keeping an eye on how we're
5 doing over time will help provide the greater
6 context for the portfolio.

7 And perhaps as we look at the
8 measures to see -- get a better understanding
9 of what might be the greatest drivers for
10 improvement across the nation.

11 So that's the last one for me.
12 And I think we're getting ready to talk about
13 what we came to do. Sana, question.

14 DR. AL-KHATIB: Actually, I have
15 two questions. The first question is part of
16 the National Quality Strategy is to address
17 disparities. And I wanted to ask you, the
18 existing measures that you shared with us
19 today with the portfolio, are people required
20 to report on all these measures by age, gender
21 and race? Or is that measure-specific?

22 DR. WINKLER: It tends to be

1 measure-specific and more importantly program-
2 specific. Because whoever is implementing and
3 using the measures ultimately makes the
4 decision on how they're reported.

5 I do know that for many of the
6 measures in this topic area we have been given
7 data from the measure developers by various
8 strata to see how performance is among the
9 different subpopulations.

10 Whether that's actually translated
11 into the implementation programs really is up
12 to the folks that are implementing them. So,
13 that tends to be something that tends to
14 happen after sort of the NQF endorsement.

15 But the conversations around
16 appropriate use is something that we tend to
17 have here at NQF a lot. And we would
18 certainly encourage it.

19 And certainly we want to look at
20 measures that demonstrate significant
21 disparities in performance. Some measures,
22 not so much, but some measures really we do

1 find that there are significant disparities
2 and we do want to identify them and highlight
3 them as having that kind of disparity. And
4 that perhaps the measure is useful to be
5 stratified to identify them in however it's
6 being used.

7 DR. BURSTIN: I'll just add that
8 as part of our work on disparities over the
9 last several years we actually came up with a
10 protocol for identifying which measures are
11 disparities-sensitive. And we'll work through
12 that.

13 Once you have approved a set of
14 measures we'll go back through, identify
15 whether there is a quality gap, how large is
16 it, the prevalence of the condition in
17 different populations and bring that back to
18 you for your consideration.

19 We did this work, staff reviewed
20 about five or six hundred measures already,
21 identified a set of them as being disparities-
22 sensitive. And we can try to highlight as we

1 go through which ones have already been
2 identified that way.

3 And the hope is the measure has
4 been identified and disparities-sensitive.
5 There's a known quality gap, high prevalence
6 in a population, that they should routinely be
7 stratified going forward.

8 Now, whether they're stratified
9 and used that way in terms of the federal
10 programs or payment, but at least being sure
11 that they're being used that way for
12 disparities reduction and quality improvement
13 is critical. So thanks for that question.

14 DR. AL-KHATIB: My other question
15 has to do with all the measures that you
16 showed us in our portfolio right now.

17 If we as a group discuss a new
18 measure, that we consider a new measure that
19 we see a lot of overlap between the measure
20 that we're discussing and the existing
21 measure, but we really see more value in the
22 measure that we are considering, could we make

1 a recommendation to implement this measure and
2 perhaps retire the existing measure? Or how
3 does that work?

4 DR. WINKLER: I think it will go
5 along with your conversation in terms of the
6 recommendation for this one.

7 The other measures will come up
8 for your review. And so we're wanting -- we
9 will want to take note of that so when it does
10 come up for its next review. It's like guys,
11 remember last time you maybe not so much on
12 this one, you've done the other one.

13 So, again, because we get to stay
14 together for a couple of years we have this
15 opportunity that we didn't have previously.
16 And we're really seeing that as some of the
17 value of a standing committee who can actually
18 work that way.

19 We would not want to automatically
20 retire a measure until it's had a chance to go
21 through its appropriate time to review. But
22 certainly we'll want to carry forward any of

1 these conversations that you might have about
2 similar related measures to say take note,
3 next time we see this measure perhaps it won't
4 be as important in light of this new measure.

5 All right. Thank you all again.

6 All your feedback during the meeting, after
7 the meeting. If you have a thought somewhere
8 down the road feel free. We really want to
9 work with you to help guide this portfolio to
10 be as good as it can be and most useful.

11 And so particularly you folks out
12 on the front lines who really are being
13 measured and using measures can give us a lot
14 of good insight on how effective and impactful
15 these measures are going forward.

16 So that's it for me for right now.
17 Wunmi, you want to kind of get us ready and we
18 should be able to get started looking at
19 measures.

20 MS. ISIJOLA: Sure. We're going
21 to start off.

22 But just some of the ground rules

1 for today's meeting. We do expect you to have
2 reviewed all of the measures, not necessarily
3 just the measures that you are discussants
4 for. And really basing your evaluations and
5 recommendations based on the criteria at hand.
6 And that information was shared with you and
7 is also available on the SharePoint site.

8 Remaining engaged at all times.
9 Obviously at any point in time you can excuse
10 yourself to the restrooms. And making sure
11 that your comments are concise and focused.
12 We are going to turn it over to our co-chairs
13 and they're really going to facilitate that.

14 But in terms of effectively and
15 effective discussions we ask that you use your
16 name tent cards and stand them up vertically.
17 And our co-chairs will call on you
18 accordingly.

19 We do have two of our committee
20 members on the phone and they will be
21 participating in the discussion. And Lindsey
22 will make sure that that happens.

1 Cathy, our speaker, could you
2 ensure that Jeff Burton's line is open?

3 OPERATOR: He has not dialed back
4 in at the moment.

5 MS. ISIJOLA: Okay. He's not on
6 yet. Okay. Well, in that case I will turn it
7 over to Dr. Kottke and Dr. George and we will
8 begin with our first measure.

9 DR. KOTTKE: I'll turn it over to
10 Mary in a second here, but if I could draw
11 your attention to a couple of things.

12 The first measure has been given
13 an hour discussion which is twice as long as
14 all the other measures.

15 And we have a lot of measures to
16 do. As Reva said earlier this morning to me
17 we could discuss them endlessly but we're not
18 going to do that.

19 And you were very nice at keeping
20 your bios real short. And I'll let you know
21 that Mary and I have agreed that we're going
22 to run on time.

1 And there's also voting. Within
2 that 30 minutes there's four votes. And so
3 please -- if there's something very important
4 please say it. But if it's just a tangential
5 espousing on something you want us to know
6 there's beer for that. And so.

7 (Laughter)

8 DR. KOTTKE: Right, but there's no
9 beer at the meeting and so it'll have to wait
10 until after 6 o'clock. So I'll let Mary call
11 for the first measure.

12 DR. GEORGE: Thank you. So our
13 first measure is number 0964.

14 DR. WINKLER: Mary, let's bring
15 our developers up to join us at the table.

16 MS. ISIJOLA: Okay. So really how
17 it's going to run is we're going to have the
18 developer come to the table and give a brief
19 description of their measure, really brief.

20 And from there we'll ask that the
21 lead discussant kind of speak to each
22 criterion. And if there are questions we can

1 most certainly direct it to the co-chairs and
2 they can facilitate that process.

3 But we really want to make sure
4 that we're talking to each criteria as it was
5 laid out. And we have provided you guys with
6 the discussion strip so you can follow through
7 that process as you present your measure.

8 And with that being said I will
9 turn it back over.

10 DR. GEORGE: Okay, and the measure
11 developer, Dr. Massoudi. Welcome.

12 DR. MASSOUDI: Good morning.
13 Thank you, Drs. George and Kottke. And thanks
14 for having me here. I'm sorry I'm leaving
15 this evening. It sounds like the beer would
16 be fun.

17 I'm Fred Massoudi from the
18 University of Colorado. I'm a senior medical
19 officer of the National Cardiovascular Data
20 Registries or NCDR upon which this measure is
21 based.

22 Again this is therapy -- this

1 measure is 0964 therapy with aspirin P2Y12
2 inhibitor and statin at discharge following
3 PCI in eligible patients.

4 And I'm going to be very brief and
5 would be happy to answer questions. But
6 essentially this is a composite measure, a
7 guideline-based medical therapy with three
8 classes of medications following PCI. It's an
9 all-or-nothing composite.

10 It includes the aspirin P2Y12
11 inhibitor, so the clopidogrel family, and
12 statins. Each of these therapies is a 1A
13 guideline recommendation in hospitalized
14 patients through PCI.

15 It's an all-or-nothing composite.
16 That is to say each patient has to be treated
17 with all the medications for which they are
18 candidates and is reported on the hospital
19 level.

20 The feasibility and reliability
21 and validity have been tested fairly widely in
22 the CathPCI registry. It's been used as part

1 of feedback within the registry for the last
2 three years. The registry is now used in
3 1,600 U.S. hospitals and has collected data on
4 more than 14 million patients.

5 This measure again is fed back to
6 sites as part of the executive summaries and
7 will be part of the voluntary public reporting
8 program sometime this year.

9 I would add that this is a renewal
10 of a previously endorsed measure. This was
11 discussed at the last panel. Actually we had
12 submitted each of the three individual
13 components of this measure and in response to
14 NQF's requests we made an all-or-nothing
15 composite of the three individual components
16 into this all-or-nothing composite measure.

17 And so at this point, I don't know
18 if that's what you were looking for, but.

19 DR. GEORGE: Thank you. And we'll
20 go ahead with the primary discussant.

21 DR. AL-KHATIB: Okay, well, thank
22 you. First, I do want to take a minute to

1 thank whoever sent this template of how we're
2 supposed to lead the discussion because it
3 really helped me organize my thoughts in this
4 whole response.

5 So, as was stated, this measure
6 has to do with looking at patients undergoing
7 PCI looking for those patients who are
8 receiving prescriptions for all medications,
9 namely aspirin P2Y12 receptor inhibitor and
10 statin at discharge following PCI. The level
11 of the analysis is the facility or the
12 hospital.

13 And as was stated this is a
14 composite of three process measures. And this
15 was a request by NQF as we were reminded of
16 that on the phone and again today. So thank
17 you, Fred.

18 In terms of looking at the
19 evidence here this composite measure as I said
20 has three process measure components in terms
21 of providing the support and the evidence for
22 that. They based it on guideline

1 recommendations. In fact, several guideline
2 recommendations as well as a 2013 JAMA
3 systematic review that included 91
4 publications with priority given to data from
5 large randomized controlled trials, systematic
6 reviews and meta-analyses. So based on these
7 data I actually rank the level of evidence as
8 high for this particular measure. And I'll
9 open it up to others to chime in.

10 DR. GEORGE: Are there any
11 additional comments from the secondary
12 reviewer?

13 DR. CROUCH: My only comment was
14 that there was a lack of empirical validation
15 of the composite measure. It was an expert
16 consensus view as opposed to database.

17 The validity data was good. The
18 reliability was based on expert opinion.

19 MS. TIGHE: Sorry, we're just
20 talking about the evidence criteria right now.

21 DR. GEORGE: If you follow along
22 with the script that was sent we will be going

1 step by step and taking a vote after each.

2 So, at this point we'll open it up for
3 discussion on the evidence.

4 DR. WINKLER: I guess the question
5 would be we have three components and we're
6 going to have other composites so I just
7 wanted to bring this up is when you have a
8 composite measure of the components we really
9 want to look at each individual component
10 measure and the evidence for each of those.
11 So I think Sana did address that, but that is
12 an important aspect when you're looking at a
13 composite measure.

14 MS. ISIJOLA: Are we ready to
15 vote?

16 DR. JAMES: Just one question. I
17 mean, certainly as a general internist I
18 subscribe to this. You always have to keep in
19 the back of your mind as somebody who writes
20 scripts for a living on weekends that what is
21 the interaction of the various meds.

22 Clearly I saw there was evidence

1 for the use of the platelet and platelet
2 drugs, and there's clear evidence for the use
3 of statins. But what is the evidence for all
4 three together? Did I miss that in here?

5 DR. MASSOUDI: I think as with
6 many of these things there's not a lot of
7 great evidence for any of those things in any
8 field for any therapy. And so I don't think
9 -- there's not a randomized controlled trial
10 that compares to one incrementally over the
11 other two.

12 However, each of these components
13 is based on a pretty widely accepted class 1A
14 guideline recommendation.

15 DR. HOLLANDER: So, I guess since
16 this is the first time we're discussing
17 composite outcomes we know there's data on --
18 and this follows on Tom's comment I think. We
19 know there's data on layering on the
20 antiplatelet agents to aspirin. It's not
21 really clear to me there's really good data on
22 layering on statins to those two.

1 So I have no issue with this. And
2 I understand from our prior telephone
3 conversation that NQF asked for the component.
4 So I get that.

5 But my question is do we want
6 composites to be therapies that have been
7 tested together, or is it okay for composites
8 to be independent therapies all of which have
9 guideline recommendations?

10 DR. BURSTIN: I'm happy to respond
11 especially because we encouraged this the last
12 time. They are independent therapies that all
13 individually have evidence.

14 And I think the key thing for
15 structuring it and we thank ACC for doing this
16 as an all-or-none composite was the idea that
17 simply doing -- adding each one on
18 incrementally was not enough. You actually
19 want to in fact see there was evidence that in
20 fact doing all three was really important.

21 But I don't know that we need to
22 have evidence of the specific additive. I

1 think it's really just that all three of them
2 are critically important in terms of evidence.

3 DR. KOTTKE: And if I could
4 comment. One reason for the composite is that
5 you could look at each one and have a score of
6 85 percent on each one. But when you look at
7 it the perfect care score is really pretty
8 low. And that's one reason that we developed
9 the composite at HealthPartners is to drive
10 the bar upwards in terms of quality of care.

11 DR. PHILIPPIDES: Quick question.
12 Does it mention ticagrelor? Or is it just --

13 DR. AL-KHATIB: It does. The
14 initial document that was circulated mentioned
15 ticlopidine and then we clarified that that
16 was a typo. They meant to include -- yes,
17 exactly. So it has been revised.

18 DR. WINKLER: So now we get to
19 vote. Go back one, will you? Go back to the
20 beginning of the voting slides. Okay.

21 We just want to give you a sense
22 of sort of how voting goes. And for those of

1 you who have worked at this before voting has
2 changed a little bit around what is the aim to
3 each consensus.

4 And so in the past it was -- 50
5 percent plus one was enough. But we've had a
6 lot of feedback that said you know, that
7 really isn't -- that's kind of iffy.

8 So we've changed the voting
9 results, evaluating the results in the
10 following way. Anything above 60 percent of
11 the committee passes. That's what it takes to
12 pass. If it's less than 40 percent, it fails.

13 But the 40/60 corridor is an area
14 where it feels the committee really hasn't
15 reached consensus. And so there's a consensus
16 not reached.

17 And so realize that that puts us
18 in a bit of a holding pattern in terms of not
19 pass or fail. And we'll continue evaluating
20 the measure to see if we can figure out where
21 the consensus lies among the group.

22 Otherwise, if a measure fails on

1 certainly any of the importance criteria or
2 the scientific acceptability criteria we just
3 kind of stop because those are must-pass.

4 If it's in this sort of consensus
5 not reached corridor we will continue
6 evaluating the measure till we get a sense of
7 what's going on. Okay?

8 So this first measure as we go
9 through, it's the reason we gave you an hour
10 so that we could talk through all these
11 nuances around voting and what the various
12 votes mean. Okay? So that's how we're going
13 to count the votes.

14 Also, a quorum is important. We
15 need 75 percent of you. So that's why the
16 staying with us except for breaks is really
17 important, so we don't lose people. And we
18 realize tomorrow afternoon as you go to catch
19 your flights we've got time pressure. So
20 we'll be paying attention to that as well.

21 So, when we're looking at evidence
22 it is part of the importance to measure and

1 report criteria. And evidence is the first
2 but we'll talk about performance gap and
3 priority.

4 And then in a composite measure
5 we're going to look at the construct of the
6 composite. So those are the subcriteria for
7 a composite measure.

8 So we were just talking about
9 evidence. All right, let's go to the next
10 one. It's not an outcome measure, it's a
11 process measure, so we go to the next one.

12 Okay. It seems complicated. I
13 hope it's not terribly complicated. I hope
14 you've had a chance to look at the algorithms.

15 And so, based on your review of
16 those algorithms you have five voting options.
17 Sometimes too many choices is difficult.

18 You can rate the measure high on
19 evidence if indeed you have the results of the
20 quality, quantity and consistency of the body
21 of evidence. In other words, it's golden.
22 Okay?

1 Moderate is still a passing grade
2 but perhaps you don't have the details of
3 quantity, quality and consistency, or perhaps
4 if you did and the evidence isn't as stellar
5 as you might like.

6 Low means you have information but
7 the evidence really does not support the
8 relationship to outcomes.

9 And that is distinct from
10 insufficient evidence where you don't have a
11 lot of information around it. There just
12 isn't evidence to deal with.

13 So if there's insufficient
14 information you actually have two choices. If
15 it's insufficient and you're comfortable
16 saying measure goes down. There just isn't
17 enough evidence to support it and we don't
18 want to go any farther.

19 On the other hand there are rare
20 but occasional measures where there isn't
21 strong evidence or much evidence at all, but
22 yet the committee feels that despite the lack

1 of evidence it's still an important measure
2 and they feel comfortable holding people
3 accountable for something with no evidence.
4 So that's your option number 4, insufficient
5 with an exception.

6 So, if you look at the algorithm
7 you'll see that there -- you could be led to
8 any one of those options.

9 So, before we actually ask you to
10 vote you should have a copy of the algorithm
11 in front of you. I'd like you just to take a
12 look at it. And does anybody have any
13 questions on how that algorithm works?
14 Because we were asking you to use that to
15 refer when you're doing your voting.

16 MR. BURTON: This is Jeff Burton.
17 Can you hear me?

18 DR. WINKLER: Yes, hi Jeff.

19 MR. BURTON: Great, great. I do
20 have one question. When I was going through
21 the algorithm there were points for some of
22 the measures where I came to the very end and

1 based on the criteria for QQC I was kind of at
2 one point. But then if I look at another
3 statement here it says that if you feel that
4 there's moderate certainty that there's a net
5 benefit outweighs the harm.

6 Could it be either/or? So if it's
7 something that has a low consistency in the
8 systematic review and you'd actually rate it
9 as low according to the algorithm.

10 However, the overall body of
11 evidence and common sense would maybe lean
12 towards a moderate vote because there's more
13 certainty that there actually is a decent
14 benefit there. How does that work?

15 DR. WINKLER: Again, if this were
16 strictly sort of a one-two-three calculation
17 we wouldn't need you all. So, we're asking
18 you to help us find the best answer here.

19 So, if indeed your systematic
20 review, really the conclusions are there's no
21 relationship, or the -- there's too much
22 uncertainty, we really can't support that.

1 Then you're going to rate it accordingly,
2 moderate, or low as the evidence just isn't
3 there.

4 In your hypothetical, Jeff, I'd
5 have a hard time understanding a situation
6 where a good systematic review came to the
7 conclusion there was no evidence or low
8 everything to support the relationship, and
9 yet you feel there would be a moderate level.
10 Somehow that's a little inconsistent. We need
11 to talk about it further to get a better
12 understanding of what exactly those
13 discrepancies are. So that's the best I can
14 help you with right now until we have a real
15 example to talk about it.

16 MR. BURTON: Sure, sure.

17 DR. WINKLER: All right. Does
18 anybody have any questions about the criteria
19 and about the ratings for voting? Yes, Liz.

20 MS. DELONG: We're voting on the
21 entire composite for evidence?

22 DR. WINKLER: Correct. For

1 composite you're talking about the entire
2 measure. So, again, it will be the specifics
3 of the evidence for each component in
4 aggregate. Because you're talking about the
5 entire composite measure.

6 MS. LUONG: So, by now everyone
7 should have received a voting fob. Please let
8 me know if you have not.

9 And how we're going to do this is
10 I will start the timer. You'll see the timer
11 on the right corner of the screen. And if
12 everyone could just point their fob to me and
13 click the number of your choice later when I
14 start it that should be it. And we will start
15 right now for evidence 1A. The timer has
16 started.

17 Can you try pressing it again?
18 No, it doesn't double-count. Technical
19 difficulties. Excuse us real quick.

20 We have 13 for high, 7 for
21 moderate and 1 for low.

22 DR. AL-KHATIB: Moving onto

1 opportunity for improvement. The developers
2 shared information and data with us about the
3 gap in care. They shared an 88.6 percent use
4 of all three medications in patients
5 undergoing PCI.

6 And at least during our phone call
7 one of the participants didn't think that that
8 was a big gap in care. And I actually agree
9 that it's not a tremendous gap in care.

10 But I think we should try to shoot
11 for close to 100 percent in these patients.
12 Because again, when we talk about the
13 specifications we will be excluding people
14 with contraindications. But because we want
15 this draft to be as close to 100 percent as
16 possible I considered that a gap in care
17 significance.

18 MS. LUONG: So we will continue.

19 DR. KOTTKE: Secondary. Any other
20 discussion? Fred, how did you a sort of
21 frustrating portion of people just don't
22 tolerate statins.

1 DR. MASSOUDI: So, great question.
2 So if there was a documentation of a
3 contraindication for -- let's say a patient
4 comes in and they have a contraindication for
5 a statin but not to the two antiplatelet
6 therapies. They would pass the measure if
7 they receive the two antiplatelet therapies
8 and the statin wouldn't be considered because
9 they had a contraindication for that therapy.

10 DR. KOTTKE: So a patient report
11 of --

12 DR. MASSOUDI: So, a documented
13 contraindication along the lines is what's
14 done with the CMS medication measures.

15 The other thing I would just for
16 one moment just clarify in terms of the
17 distribution as well. The lowest 25th
18 percentile was an 83 percent. The lowest 10th
19 percentile in a 76 performance rate just for
20 perspective.

21 MS. DELONG: I have a question.
22 Was this generated from the NCDR? How

1 representative is this 86 percent?

2 DR. MASSOUDI: So it's generated
3 from the CathPCI registry. As we've discussed
4 before the CathPCI registry is used in about
5 1,600 hospitals which is well north of 80
6 percent of hospitals that do PCIs. And again
7 has been reported in now 14 million patients.
8 Not this specific measure but since the onset
9 of the registry more than 14 million patients.
10 At this point probably represents around 90
11 percent plus of patients undergoing PCI in the
12 United States.

13 MS. MITCHELL: To follow up on
14 your -- I think you presented a range. What's
15 the range of performance on this measure?

16 DR. MASSOUDI: The range from the
17 1st to the 90th is 55 percent to 96 percent.

18 DR. CHO: So, let's say there are
19 other measures like aspirin and P2Y12
20 inhibitors and statins, all separate measures.
21 So if we vote for this do those measures go
22 away?

1 DR. MASSOUDI: Those measures
2 actually don't exist as an endorsed NQF
3 measure. Again, we applied as individual
4 measures the last time. We're instructed to
5 include it into all-or-nothing composites. So
6 those have not been endorsed and we're not
7 asking for endorsement for the individual
8 component measures at this time.

9 DR. AL-KHATIB: I just wanted to
10 add one comment about disparities because I
11 was expected to cover that as well under
12 opportunity for improvement.

13 And one thing that the developer
14 stated in the submission is of particular
15 interest is that when compared with the
16 expected mortality rates those with private
17 insurance had significantly better survival,
18 while those with all other insurance types did
19 worse. And then they talked about some
20 geographic variations as well.

21 I wanted to ask if we ever thought
22 of using insurance status for reporting.

1 Could we require that data be reported based
2 on insurance status?

3 DR. BURSTIN: It's actually fairly
4 common. For example, if you see some NCQA
5 measures they routinely report by commercial,
6 Medicaid, Medicare. So I don't know if the
7 differences are there. It's certainly
8 something you could talk about with ACC.

9 DR. WINKLER: Fred, you mentioned
10 that this measure may become part of a
11 voluntary reporting program for ACC. What are
12 your thoughts on reporting and addressing some
13 of the disparities questions?

14 DR. MASSOUDI: At this point the
15 measures are reported. They're not
16 specifically stratified by various
17 socioeconomic status or insurance status. It
18 could certainly be performed. And the details
19 of how this will be presented and reported are
20 still in development as you can imagine, as
21 we've discussed on previous calls.

22 And just, I should have introduced

1 Lara Slattery from ACC staff before. I
2 apologize, I got so excited about presenting
3 the measure that I forgot to. So, please
4 forgive me. Thanks.

5 MR. BURTON: Was there any
6 evidence -- I don't think I saw any target
7 performance level that could be set for this
8 measure. As opposed to comparing against the
9 mean. I know that mean for all the hospitals
10 was in there. But was there any target
11 performance level that was established through
12 the evidence?

13 DR. MASSOUDI: So, as Dr. Al-
14 Khatib pointed out this is an all-or-nothing
15 composite based on three medications. For
16 each individual patient they would be excluded
17 from that particular medication if they had a
18 contraindication. So the ideal target
19 performance level on this measure as it is for
20 many process measures where you exclude
21 patients with contraindications is 100
22 percent.

1 MR. BURTON: Okay.

2 DR. GEORGE: Are we ready to vote?
3 Any other discussion?

4 DR. WINKLER: For this your voting
5 options again are really just your qualitative
6 assessment of high, moderate, or low. High or
7 moderate will be a passing grade. Low will
8 not. If you feel there isn't any evidence or
9 insufficient data for you to make a
10 determination that option is available.

11 So you will see this generic
12 high/moderate/low voting scale on several of
13 the criteria.

14 MS. LUONG: The timer has started.
15 We have -- for criteria 1B 8 for high, 13 for
16 moderate and 1 for low.

17 MR. BURTON: I just want to
18 confirm that you're getting my vote over the
19 chat, the webinar chat. This is Jeff Burton.

20 MS. LUONG: I am. I am. Thank
21 you.

22 MR. BURTON: Great, thanks.

1 MS. ISIJOLA: So we'll move onto
2 priority.

3 DR. AL-KHATIB: So in terms of
4 priority I absolutely believe that this
5 measure addresses a significant health
6 problem. CAD is a very prevalent condition.
7 PCI is a very commonly performed procedure and
8 is associated with high costs. And we really
9 need to ensure that we optimize the use of
10 evidence-based therapies that have been shown
11 to improve survival, reduce risk of
12 infarction, what have you. So multiple
13 outcomes that could be improved with the use
14 of these therapies. So, for me I think
15 priority is definitely there.

16 DR. GEORGE: Any discussion on
17 priority? We're ready to vote on priority.

18 MS. LUONG: The timer starts now.
19 For criteria 1C we have 18 for high and 4 for
20 moderate.

21 DR. WINKLER: We have one more --
22 because it's a composite we need to go to the

1 composite construct in terms of this 1D.
 2 You'll only see this on composite measures.
 3 It's the final criteria under importance and
 4 it's the quality construct of the components,
 5 the rationale for putting them together. And
 6 then any aggregation or weighting issues. So
 7 it's all about does this composite construct
 8 make sense.

9 DR. AL-KHATIB: So for the
 10 construct I ACC would argue that it's pretty
 11 good, pretty reasonable and logical. We all
 12 have concerns about component endpoints and
 13 measures because we always raise the question
 14 as to what kind of weighting system you're
 15 using.

16 And I don't know that you can ACC
 17 justify that or defend that in association
 18 with any composite measure.

19 But with that caveat in mind I
 20 actually think that the construct is pretty
 21 good.

22 DR. GEORGE: Any discussion on the

1 measure construct? All right, we'll vote on
2 the measure construct.

3 MS. LUONG: The timer starts now.
4 All right. For criteria 1C we have 18 for
5 high and 4 for moderate.

6 DR. GEORGE: So we'll move along
7 to the scientific acceptability.

8 DR. AL-KHATIB: Okay, so in terms
9 of the scientific acceptability, just a
10 summary of the specifications. The numerator
11 is all patients undergoing PCI who are
12 eligible for all these medications, aspirin,
13 clopidogrel, prasugrel, and ticagrelor and are
14 prescribed those medications.

15 Denominator is all patients
16 undergoing PCI who are eligible for all of
17 these medications, meaning they don't have any
18 contraindication to any of those medicines.

19 And I forgot to mention statins as well.

20 Exclusions are death or presence
21 of a contraindication. And the measure uses
22 the CathPCI registry. This was described

1 briefly by Fred.

2 I personally don't have any
3 concerns regarding the specifications,
4 definitions, or coding.

5 DR. GEORGE: Any discussions on
6 the scientific acceptability?

7 DR. CROUCH: There's a
8 harmonization issue with this one and the one
9 we're going to discuss next with the
10 exceptions. I don't know which way we want to
11 go, whether we want to leave that till the
12 next one or bring it up now?

13 DR. WINKLER: We'll talk about
14 that after we've talked about both of them.
15 And then we'll talk about that part.

16 DR. CROUCH: Okay.

17 DR. WINKLER: But thank you for
18 bringing it up.

19 MS. DELONG: I have a question.
20 I'm a little confused. I thought Fred said
21 that if somebody was contraindicated to one of
22 the measures, one of the components but not

1 the other two that person would still be in
2 the denominator and the numerator would ignore
3 the contraindication.

4 DR. MASSOUDI: Yes, that's
5 correct. So a patient who's eligible for any
6 one of the therapies would end up in the
7 denominator. And if they receive treatment
8 for all the medications for which they were
9 eligible they would count in the numerator.

10 MS. DELONG: Okay. So that's
11 different from excluded if they're
12 contraindicated to any of the measures.

13 DR. MASSOUDI: Yes, they're
14 excluded at the medication level if that makes
15 sense. It would be excluded entirely if they
16 had contraindications to all three
17 medications.

18 MS. DELONG: All of them, right.

19 DR. MASSOUDI: They would be
20 included entirely if they were. Yes.

21 DR. PHILIPPIDES: How were you
22 deemed to be excluded because of inability to

1 take a statin? What was the definition of
2 statin intolerant?

3 DR. MASSOUDI: Just as what's done
4 with the, say for instance, the CMS Hospital
5 Compare measures. The clinician documentation
6 of a contraindication is considered a
7 contraindication of that medication. Sort of
8 a standard contraindication exclusion.

9 DR. WINKLER: Question just on
10 that. Contraindications are captured in the
11 registry?

12 DR. MASSOUDI: Yes, that's
13 correct.

14 DR. WINKLER: Okay. Just one
15 other question that got brought up in the
16 workgroup was the issue around the age
17 indication for patients for statins. The
18 workgroup brought it up. About age 75. No?
19 Okay, not a problem.

20 DR. MASSOUDI: Just to clarify.
21 We document that a contraindication was
22 present. We don't catalogue the actual

1 contraindications, but just whether or not a
2 contraindication was present.

3 DR. JAMES: Just to reiterate the
4 discussion that Judd and I had whether there
5 is scientific evidence of the combination of
6 all three. I think it's very clear about each
7 individual component. It's what happens in
8 the individual person to handle three
9 different medications.

10 DR. MASSOUDI: You know, again, I
11 think it's an issue with any composite
12 measure. I would say that there are probably
13 numerous examples of composite measures where
14 each of the individual components are
15 evidence-based. But there's not evidence for
16 additive benefits with specific agents.

17 Having said that, however, I would
18 say that the more contemporary secondary
19 prevention statin trials are trials of statins
20 over and above antiplatelet therapy standards
21 currently.

22 Again, also the guidelines clearly

1 recommend as class 1A recommendations the use
2 of these three medications in conjunction with
3 one another in patients who might have done
4 PCI. So this is all guideline-based on a
5 class 1A recommendations for the use of all
6 these medications together.

7 DR. GEORGE: Any other discussion?
8 If not we'll go to a vote on the scientific
9 acceptability.

10 DR. WINKLER: Did we talk about
11 the reliability testing which is part of
12 reliability?

13 DR. AL-KHATIB: I don't think
14 there's a vote right now. We keep going. So,
15 reliability.

16 So in terms of the reliability
17 testing what the developer did is empiric
18 testing using the CathPCI registry with data
19 from 1,386 hospitals.

20 And testing was done at the data
21 elements level, not the measure score level.
22 And then they talked about reliability testing

1 was performed using correlation of random
2 split halves of the participating hospitals.
3 And talked about the correlation between the
4 two being pretty high at 0.92.

5 They also highlight all the
6 quality improvement and assurance within the
7 NCDR that includes onsite audits and
8 interrater reliability assessment conducted to
9 validate the audits. I actually have seen
10 those data although I don't know that the
11 results were included in the submission but
12 certainly the data are very reassuring.

13 So in terms of reliability testing
14 I believe that what they showed demonstrates
15 that the measure data elements are repeatable,
16 producing the same results. A high proportion
17 of the time when assessed in the same
18 population in the same time period. So I
19 think overall it's pretty good.

20 Based on the algorithm that was
21 shared with us if they did not do the testing
22 at the level of the measure score which I

1 actually didn't see that. I'm sorry if I
2 missed it. I only saw the one that was done
3 at the data element level. Then the highest
4 ranking that this measure would get is a
5 moderate ranking if they don't have a measure
6 score.

7 Again, Fred, please let me know if
8 I missed that. I do -- I did notice the data
9 element testing but I didn't see one at the
10 level of the measure score.

11 DR. MASSOUDI: That's not in the
12 submission.

13 DR. GEORGE: Any questions on the
14 reliability or further scientific
15 acceptability?

16 MS. DELONG: This will probably
17 pertain to a lot of these things when we look
18 at reliability. The correlation says
19 something but not everything. It would be
20 good to see the percent agreement in the -- on
21 the diagonal cells. Because then you have an
22 idea of how many patients they said yes in one

1 group but no in the other. I think that's
2 important information and I'm not sure we're
3 consistently getting that in the reliability.

4 DR. MASSOUDI: I'll bring your
5 attention to -- there are a couple of figures.
6 Again, this is on the composite, so not on the
7 individual components, again. Because we
8 haven't focused on those because we're not
9 applying for endorsement for any of those
10 measures.

11 But the figures show the first and
12 second sample validations as you can see, you
13 can see the correlation, the composite there
14 in Figure 2 between those first and second
15 samples.

16 I don't know if it helps but in my
17 document which I think would be similar to
18 yours it's Section 2A2.3.

19 DR. KOTTKE: Does anybody have any
20 overwhelming concerns about this? I'm looking
21 at Figure 2 in my document and it is blank.

22 DR. MASSOUDI: Funny, it's on page

1 56 I'm on, but it's in the mid-fifties.

2 MS. DELONG: I'm sorry if I've
3 caused a lot of confusion. All I was looking
4 for was a 2 by 2 table that had in this sample
5 yes/no and the other sample yes/no. Are those
6 dots sites then? What are the dots?

7 DR. MASSOUDI: Yes, those dots are
8 sites.

9 DR. WINKLER: Just to clarify on
10 this, are those results at sites for the
11 measure result? Or the data elements?

12 DR. MASSOUDI: The composite
13 measure.

14 DR. WINKLER: Result.

15 DR. MASSOUDI: Yes.

16 DR. WINKLER: So that's a
17 performance measure score. So you do have
18 testing, reliability assessment at the level
19 of the measure score. Well, that changes the
20 eligibility on the rating.

21 DR. GEORGE: Just to recap that.
22 Having both data element testing as well as at

1 the measure level does make this eligible for
2 a high rating.

3 Other discussions on scientific
4 acceptability or reliability?

5 MS. LUONG: The timer is starting
6 now.

7 DR. WINKLER: This is voting on
8 reliability. We'll do validity next.

9 MS. LUONG: For criteria 2A 16
10 voted for high, 6 voted for moderate.

11 DR. GEORGE: Okay, we'll move onto
12 -- you've got validity. Just wanted to make
13 sure.

14 DR. AL-KHATIB: Okay, so there was
15 no empiric testing of validity for this
16 measure that I could find. What the developer
17 mentioned was face validity was described as
18 content validity of this process was achieved
19 by the specialized expertise of various ACC
20 committee members involved in the development
21 or approval of the measure.

22 And they went onto say that we

1 believe the content validity of this measure
2 has been achieved by virtue of the noted
3 expertise as I mentioned. The individual
4 components of the composite have already been
5 shown to impact clinical outcomes. The
6 empiric analysis demonstrating the individual
7 component measures fit the overall quality
8 construct.

9 Testing will focus on construct
10 validation which will test the hypothesis on
11 the theory of the construct that following
12 these processes for patients undergoing PCI
13 would lead to better outcomes.

14 This research is expected to
15 ultimately be published in the medical
16 literature. While the analysis will likely
17 not be ready prior to the submission deadline
18 of the cardiovascular endorsement maintenance
19 project they will be available prior to the
20 close of the measure cycle.

21 And that the analysis in
22 preparation for publication can be provided

1 upon request or at publication. But that was
2 the extent of what they mentioned regarding
3 validity testing.

4 MS. TIGHE: And just to jump in,
5 this would also be the point in time to
6 discuss the validity of the specifications,
7 whether they're consistent with the evidence.
8 I believe we've touched on it but just if
9 there's anything to raise at that point too.

10 DR. GEORGE: So any comments on
11 threats to validity?

12 DR. AL-KHATIB: From my
13 perspective although they did not do the
14 testing that we would like to see I don't see
15 any like major concerns about why the data or
16 the process wouldn't be valid.

17 It would have been nice to have
18 the testing to prove that, but knowing the
19 CathPCI, knowing the process, what they're
20 proposing here, I personally don't see any
21 major threats to validity.

22 DR. GEORGE: Any discussion on the

1 validity? Comments on the phone? We'll move
2 to a vote on the validity.

3 DR. PHILIPPIDES: Quick question.
4 So basically this algorithm, am I correct that
5 if they're relying on face validity and
6 there's not been empiric validity testing then
7 the highest level that can be achieved for
8 this would be moderate? Is that correct?

9 DR. GEORGE: Yes. Okay, we'll
10 move to a vote on the validity.

11 MS. LUONG: Timer starts now. For
12 criteria 2B 2 voted for high, 17 voted for
13 moderate and 3 voted for low.

14 DR. GEORGE: All right, so we'll
15 move onto feasibility.

16 DR. WINKLER: There's one other
17 criteria for the composite. And again, this
18 is looking at the empiric analyses of the
19 various composite aspects. Again, this is
20 section 2D on the submission. Whether the
21 components fit the quality construct.

22 Typically an analysis might be the

1 frequencies of performance of each of the
2 subcomponents or any issues around aggregation
3 and weighting from a testing perspective. So
4 this is kind of the scientific acceptability
5 of the composite construct if you will.

6 DR. GEORGE: Any discussion?

7 DR. AL-KHATIB: So the questions
8 that I see here under 2D on the form is do the
9 component measures fit the quality construct.
10 And I would say yes.

11 Are the objectives of parsimony
12 and simplicity achieved was supporting the
13 quality construct I would say yes as well.

14 DR. GEORGE: Any other comments?

15 DR. PHILIPPIDES: Let's say for
16 the sake of argument that everyone across the
17 country gave the antiplatelet agents 100
18 percent of the time. But all of the play, the
19 real difference in performance was in just
20 one. Would there still be a good reason to
21 pursue a composite measure?

22 Because my suspicion, and I can't

1 tell because I don't have data, is there's
2 probably more wah-wah in the statin than in
3 the aspirin and the clopidogrel.

4 And so would it be simpler and
5 allow people to spend less resource and get to
6 the same sort of benefit if we only focus on
7 statin in this case? I'm just throwing it out
8 there.

9 DR. AL-KHATIB: Well, the data
10 that they showed from their study, you know,
11 the testing that they did with CathPCI showed
12 ACC variation, significant variation in
13 relation to the use of all three medications.
14 Probably much less so for aspirin but
15 certainly they saw some evidence of variation
16 for the P2Y12 receptor antagonists and
17 statins. Less so for aspirin.

18 DR. WINKLER: George, the answer
19 to your question is specifically the purpose
20 of 2D is to answer exactly that around the
21 quality construct. Because you're right,
22 there could be a composite measure that's

1 driven solely by one component.

2 DR. GEORGE: We'll move to a vote.

3 MS. LUONG: The timer starts now.

4 MS. TIGHE: For Ted and Jeff we're
5 voting on the composite 2D criterion, what are
6 the component measures to the quality
7 construct.

8 MR. BURTON: Yes, just submitted
9 mine.

10 MS. LUONG: So for this criteria 9
11 voted high, 12 voted moderate.

12 DR. AL-KHATIB: Okay, moving onto
13 feasibility. The data source as was stated is
14 the CathPCI registry. And we raised this
15 question during the call and Fred answered the
16 question during the call.

17 And again he reminded us actually
18 participation in the CathPCI is excellent with
19 an estimate of about 90 percent of PCI that
20 are taking place in the United States are
21 being captured by the CathPCI. As such I ACC
22 have no feasibility concerns.

1 DR. KOTTKE: Fred, can I ask a
2 question? What's the demographic or the
3 epidemiology of non-participation? Do we
4 know? Is it sort of rogue, or is it
5 organizations that are really stretched
6 financially and operationally?

7 DR. MASSOUDI: So, I'll defer to
8 Lara for a little clarification. I mean, in
9 general it's hard to know what you don't know
10 in a sense.

11 We do know they tend to be smaller
12 sites. But Lara, if you have any elaboration
13 on that I'd welcome that.

14 MS. SLATTERY: Sure. So, it does
15 tend to be the smaller-volume sites or sites
16 where there may be a state reporting mandate
17 that differs from allowing to be able to
18 participate in our registry and no other
19 driver or funding within the facility to
20 support them doing both types of reporting.

21 DR. HOLLANDER: So what would be
22 the ramifications of this measure passing in

1 terms of cost to the hospitals that don't
2 participate or consequences if they continue
3 to not participate? And is there any insights
4 as to whether those are underperforming
5 hospitals or the same as every place else?

6 MS. SLATTERY: Well, we operate
7 the registries as voluntary programs. And as
8 we've mentioned part of the reason for seeking
9 NQF endorsement of this measure is that it
10 will roll out into a voluntary public
11 reporting opportunity. So, while it is not
12 our intent to disadvantage those sites the
13 structure of our reporting out of our
14 registries does mean those hospitals that
15 aren't participating in our registry are not
16 eligible for our public reporting voluntary
17 option.

18 Beyond that we do not know
19 anything about those hospitals unless they
20 happen to be participating in a state that has
21 a similar type of public reporting component
22 to it. We do not personally track that

1 though.

2 DR. GEORGE: Other comments on
3 feasibility? Tom?

4 DR. JAMES: Just a quick comment
5 and that has to do with the phenomena of code
6 creep, or measure creep. We often find when
7 things get to the MAP that those being held
8 accountable may go beyond those originally
9 intended.

10 This is clearly a facility-based
11 type of measure. It would be inappropriate
12 for this to go onto a physician health plan or
13 community as level of accountability. So I
14 want to make sure that that's clear when it
15 goes through.

16 DR. WINKLER: Tom, just to
17 clarify, the specifications of this measure
18 though are at the facility level. The next
19 one coming up actually is the same measure at
20 clinician level. I don't believe we have this
21 measure at a health plan level however.

22 DR. GEORGE: Any other comments?

1 We'll move to a vote on feasibility.

2 MS. LUONG: The timer starts now.
3 For this criteria 18 voted high, 4 voted
4 moderate.

5 DR. GEORGE: Move onto usability.

6 DR. AL-KHATIB: Several things to
7 touch on there. The measure is currently
8 being used in a program called the Blue
9 Distinction Centers for Cardiac Care. The
10 sponsor is Blue Cross Blue Shield. It's not
11 publicly reported, this is just a quality
12 improvement with benchmarking.

13 The product brought to our
14 attention that in July of last year they
15 kicked off a program to give hospitals the
16 opportunity to voluntarily publicly report
17 measures. And this was not incorporated at
18 that point but I think their plan is to
19 include this measure in that program that
20 they're working on.

21 In terms of information on
22 improving performance over time they showed

1 trends where they found that there is proof of
2 improved performance with the use of this
3 measure. And of course the improvement in
4 performance was significantly lower for the
5 top performing sites. Certainly there was
6 significant improvement in performance for the
7 sites that did not initially perform as well.

8 And in terms of unintended
9 consequences the developer mentioned
10 inaccuracies of data collection and over-
11 coding of exclusions. Certainly possible but
12 I didn't see any major unintended
13 consequences. So overall I felt that
14 usability is pretty good.

15 DR. GEORGE: Discussion on
16 usability? If not we'll move to a vote on
17 usability.

18 MS. LUONG: The timer starts now.
19 For this criteria 19 voted high and 3 voted
20 moderate.

21 DR. GEORGE: And so I think at
22 this point we move onto a discussion on

1 whether to recommend the measure for
2 endorsement. Any further discussion? If not
3 we'll go ahead and vote on overall
4 suitability.

5 MS. LUONG: The timer starts now.
6 We have 100 percent. Twenty-two voted yes.

7 MS. ISIJOLA: Well, I think we
8 will break for lunch at this time. Thank you
9 and we'll convene in about 30 minutes.

10 (Whereupon, the foregoing matter
11 went off the record at 1:01 p.m. and went back
12 on the record at 1:30 p.m.)

13 DR. KOTTKE: So despite a markedly
14 different title this is a measure that's very
15 similar to our prior measure. We'll let the
16 ACC explain it.

17 DR. NALLAMOTHU: Hi, good
18 afternoon. My name is Brahmajee Nallamothe.
19 I'm a cardiologist at the University of
20 Michigan.

21 The reason I'm here is I was the
22 co-chair on the PCI performance measures group

1 that was sponsored by the AMA's PCPI as well
2 as the ACC. And this is a measure that
3 directly relates to the work of that group.

4 With me is Jensen Chu from the
5 ACC. Any of the hard questions we will
6 definitely kick over to him.

7 The nice thing about this measure
8 is it follows on the measure that was just
9 discussed in quite some detail. The
10 difference between 2452 and 0964 can be really
11 summarized by 2452 is focused on the
12 individual level, the clinician level. And
13 that's one point that I want to make up front.

14 So initially we're talking about a
15 clinical-level measure. Again, thinking about
16 composite medication use following PCI at
17 hospital discharge.

18 The second thing that's an
19 important part of that, and then I'll kind of
20 stop and let the measure be discussed, is the
21 key concept about harmonization.

22 The issue about harmonization is

1 there was some concern about a call held a few
2 weeks ago in discussion of these two measures.
3 I just wanted to kind of emphasize to you that
4 that was a little bit of a mis-sight on our
5 part. Both those measures conceptually as
6 well as technically we see as being completely
7 harmonized. And I can go into details as the
8 discussion unfolds.

9 The last thing I'm going to just
10 say is that obviously with this being a
11 clinician-level measure I'm going to try to be
12 a little preemptive in some of the discussion.
13 I think the biggest issue is about
14 attribution.

15 Obviously the way that we see it,
16 and just to emphasize, we see that the last
17 clinician who has performed a PCI, the
18 operator is responsible for this measure.

19 There's all sorts of issues about
20 this. And I'd be kind of interested to hear
21 the discussion that happens today. But we do
22 feel that this individual is very responsible

1 for both the initial prescription of this
2 measure as well as its subsequent use of these
3 medications in this population.

4 So with that I'll stop and
5 interested to hear your guys' thoughts.

6 DR. KOTTKE: Okay, thank you.
7 Primary reviewer?

8 DR. CROUCH: Just to reiterate
9 it's the same thing as the previous measure
10 except it's on the individual provider level
11 attributed to the person who performs the PCI.

12 So as far as the evidence is
13 concerned it's the composite of three things.
14 The same issues that we've discussed before,
15 same qualifications. I don't really have
16 anything to add.

17 DR. KOTTKE: Okay, having nothing
18 to add does anybody else have anything, any
19 discussion?

20 DR. WINKLER: For consistency do
21 you want to just stipulate your vote on the
22 last one for evidence? Rather than re-vote.

1 DR. KOTTKE: Does anybody object
2 to that?

3 MR. BURTON: No objection.

4 DR. KOTTKE: Seeing no objection
5 we'll stipulate our vote on the last.

6 DR. WINKLER: We'll just carry the
7 votes from the last time forward.

8 MS. DELONG: Excuse me. A couple
9 of us are having trouble getting into the
10 site. When I clicked on the measure it took
11 me all the way out and I can't get back in.

12 MS. ISIJOLA: We are having
13 trouble getting access to the Sharepoint site
14 but we are working it internally to get it up
15 and running again. So bear with us.

16 MS. TIGHE: If there's something
17 you need us to send let us know though. If
18 there's a document you're looking to reference
19 during this discussion.

20 DR. KOTTKE: Opportunity for
21 improvement.

22 DR. CROUCH: Opportunity for

1 improvement. The 25th percentile was 84
2 percent. The mean 88.7, the median 90.3. So
3 there's modest room at best for improvement.

4 The bottom fourth have more room
5 for improvement. The top three-fourths don't
6 have very much practical room for improvement.

7 DR. KOTTKE: Any discussion. Does
8 anybody feel they need to change their vote
9 from the prior measure? Hearing none we'll
10 just record the vote -- oh.

11 MS. DELONG: Sorry, I'm not maybe
12 changing my vote but what is the variability
13 in samples? I mean, some physicians treat
14 very, very few PCIs, right? Do very, very few
15 PCIs.

16 DR. NALLAMOTHU: I can speak to
17 this briefly. It does come at some issues
18 that I'm sure are going to be raised when it
19 comes with the measure itself.

20 But in this sample we had about --
21 I think there was a little over 11,000, about
22 11,500 or so individual operators.

1 When we tried to do some
2 reliability testing we obviously tried to
3 include only those with at least 50 or more
4 PCIs and that's currently the standard by
5 which the ACC and AHA have considered volume
6 requirements.

7 And in that group that brought
8 down the group from about 11,699 to 4,064.
9 But I do want to say a couple of things about
10 that.

11 So one is obviously it suggests
12 that there are low-volume operators.

13 The second is that -- I'm sure
14 this is going to be in detail, but there are
15 some concerns about the capturing of
16 individual operator IDs within the NCDR
17 registry which was the registry we rely on for
18 some of the testing.

19 DR. AL-KHATIB: I just wanted to
20 add to that because that was a concern that I
21 had with regard to the testing that was done.
22 And I know we'll get to that.

1 You mentioned identifying the
2 actual physician. And in fact in the testing
3 phase there was a great degree of missingness
4 in relation to the MPI number. And so that's
5 something maybe we'll get to in terms of what
6 you're plans are to try to address this degree
7 of missingness. But I think you bring up an
8 excellent point.

9 DR. KOTTKE: Other discussion. So
10 anybody need to change their vote? Hearing no
11 comment, well, just should I ask for the vote?
12 Okay, go ahead, Michael.

13 DR. CROUCH: As to priority it's
14 the same issues as the other one. I don't see
15 any reason for changing my vote. Anyone else.

16 DR. KOTTKE: Any questions or any
17 further comments? Hearing none I propose that
18 we just transfer our votes. Okay. Go ahead,
19 Michael.

20 DR. CROUCH: Scientific
21 acceptability --

22 MS. TIGHE: Sorry, we've got that

1 1D composite criterion. Whether the construct
2 -- essentially whether the quality construct
3 including the components make sense which
4 mirrors the last discussion.

5 DR. CROUCH: Oh, sorry. Same
6 issues as before.

7 DR. PHILIPPIDES: Right. So I
8 guess I'll bring up the same issue. Does
9 this, as a composite does it include all of
10 the things that we feel that we should have in
11 there for adequate post-MI care. And if there
12 are things that aren't in it should we discuss
13 why they're not in it?

14 And in regards to the elements
15 that are there do we know how often they've
16 been hit in general? Is there data to show
17 how often people have done well with that
18 measure?

19 So I guess I'm questioning as to
20 how this composite was made and should we
21 consider having a different makeup of it.
22 Because this is, right, total optical medical

1 therapy for PCI, right?

2 DR. NALLAMOTHU: I can briefly
3 comment on that. Again, the structure is very
4 similar to the idea of the last measure.
5 Picking three class 1A guidelines recommended
6 therapies none of which have been studied kind
7 of in unison and that idea of a synergistic
8 effect but each individually. So I think the
9 same issues that were raised before which I
10 heard even over there and are all good points
11 still hold in this situation too.

12 DR. PHILIPPIDES: Would we as a
13 committee be better served in basically
14 creating sort of, one, metric that basically
15 takes into account all of the post-PCI care
16 that a good facility should be doing, rather
17 than have three on this metric and three on
18 that metric. Should we take this opportunity
19 to sort of bring that all together?

20 DR. KOTTKE: So for as an e.g. put
21 cardiac rehab in there.

22 DR. WINKLER: George, just to

1 clarify, are you questioning the fact that
2 there are only three components for this? And
3 then you had another sort of question was do
4 we need two measures, one at the facility and
5 one at the clinician level that are different.

6 DR. KOTTKE: Leslie and then Sana.

7 DR. CHO: I agree with George. I
8 think part of my concern is that there is a
9 fair amount of measures and you have a lot of
10 measures. And there's a lot of measure
11 overload I think.

12 And you have, you know, the first
13 initial measure, I understand that's a
14 hospital base. This is a clinician base. But
15 at some point you have too many measures that
16 hits at the same thing.

17 DR. AL-KHATIB: I think part of
18 George's question has to do with do we add
19 anything to the measure. Like you know, maybe
20 beta blockers, ACE inhibitors, what have you.
21 And my understanding is that those are very
22 well captured by other measures. And that --

1 so I assume, and please correct me if I'm
2 wrong, that you did not include the beta
3 blockers, ACE inhibitors, what have you, in
4 this measure because you felt that those were
5 very well covered in other measures.

6 DR. NALLAMOTHU: Well, I mean I
7 think that there's two points to that.

8 First of all, I'm hearing a lot
9 here. I'm not sure how much -- these are all
10 great points and probably things that this
11 committee needs to address at some point in
12 time.

13 But the two things that I could
14 say are the addition of other drugs. I do
15 think that if you start to look at beta
16 blockers after re-vascularization,
17 particularly like uncomplicated single-vessel
18 disease, it's going to run into an evidence
19 base that's much more controversial. Same is
20 true for ACE inhibitors, ARBs.

21 Again, this is not a total AMI
22 population. If a person has an AMI and a PCI

1 they probably would be grouped in both groups.
2 So to keep that separate. These are the three
3 that we think are the most critical in this
4 situation, had the most broadest appeal.

5 I don't know how to answer the
6 question about cardiac rehab and all these
7 other measures. We as a group just recently
8 came up with 11 of them. I don't know whether
9 you combine them all and create a super
10 measure or not. I think that brings its own
11 complexity to it.

12 The nice thing about sometimes
13 teasing things out, and this is a real gestalt
14 feeling, and you guys are going to be the ones
15 that decide this, but the nice thing about
16 this is it creates actionability too, right?
17 If you clump everything together and you
18 report that out it makes it a little bit more
19 difficult.

20 And I can see in my own mind, and
21 this is only a personal opinion, but cardiac
22 rehab is so separate that the idea of lumping

1 it all and then not understanding which one is
2 perhaps the gap that you're trying to deal
3 with makes it more difficult.

4 The last thing I would just say is
5 that the individual even though it totally
6 mimics it, I think the fact that you're
7 attributing at a different level is enormously
8 different. It's important. And we as a group
9 have decided that, again, it creates a
10 different market which you can kind of have an
11 actionable insight into quality improvement.

12 Most of that is editorial,
13 obviously.

14 DR. KOTTKE: Any other comments?

15 Yes, Tom.

16 DR. JAMES: My question has to do
17 with attribution. And this is set up at the
18 clinician level and it's coming from a
19 specific data set right now.

20 Expansion of this type of thing
21 though would have to recognize the matrix
22 phenomena that goes on in hospitals. I was a

1 hospitalist in the past.

2 Who do you attribute this to when
3 we're creating a measure?

4 DR. NALLAMOTHU: I mean,
5 absolutely that's a very important point.

6 So, we've decided in the creation
7 of this measure to focus on the interventional
8 cardiologists who perform the PCI. If you had
9 multiple PCIs it was the last person who
10 performed the PCI during that hospital stay.

11 I think there's probably two
12 reasons for it. The first is that we do feel
13 that the interventional cardiologist after
14 they perform the PCI in this patient
15 population, they're very critical in terms of
16 setting a lot of the mechanisms in place.

17 Even if it's not their
18 responsibility, if it ends up being a
19 cardiologist on the floor or some other care
20 provider, I think the interventional
21 cardiologist making that type of
22 recommendation and pushing forward with it

1 plays a big role.

2 And the second is at a certain
3 point to be practical about it. Exactly,
4 exactly.

5 DR. KOTTKE: Liz.

6 MS. DELONG: I'm just a little
7 confused about our role here. I mean, we
8 endorse quality measures as a reflection of
9 quality. Are we also responsible to assess
10 the attribution? I mean, I would think that
11 would be -- if it's being collected at one
12 level it can certainly be decided by whoever's
13 using it whether to break it into other
14 levels.

15 DR. WINKLER: Typically I think
16 that questions of attribution come up all the
17 time in terms of specification. So, I think
18 that question being addressed within the
19 specification can be helpful. But you're
20 right, the actual ultimate implementation
21 program may make other determinations in terms
22 of attribution.

1 Because I'm not aware that ACC is
2 saying it's the PCI operator. I didn't see
3 that ACC baked into the specification
4 specifically. So, whether it's truly baked
5 into it or not, or is it the way it's
6 currently being used by ACC in the registry.

7 DR. KOTTKE: Any other -- Henry?

8 DR. TING: I just want to comment
9 that everything we're saying about attribution
10 and whether this reflects excellent care after
11 PCI. All these comments ACC are referable to
12 the prior one which you approved 100 percent.

13 Can we attribute using these
14 medications at the hospital level yet we
15 didn't have this discussion? Can we say that
16 PCI, everything was done perfectly after PCI
17 and was at the hospital level? So all the
18 comments we've made so far are referable to
19 the prior measure which we approved 100
20 percent.

21 DR. KOTTKE: Further -- Liz, are
22 you still up? Yes.

1 DR. HOLLANDER: I don't want to
2 dwell on it too much, but the attribution to
3 the individual physician, as I think through
4 it. We just approved a measure that gives it
5 to the hospital, right? Now we're attributing
6 to a physician who may not actually be the
7 last provider which in essence is the same as
8 the hospital. It's the care pathway for that
9 individual patient.

10 And I can't speak to this as an ER
11 doc, but it makes me think what do we learn if
12 we're not 100 percent sure the meds are
13 written at discharge by the person we're
14 attributing it to over and above the measure
15 we discussed before lunch?

16 DR. KOTTKE: Further comments?
17 How about if I call the question here?
18 Anybody want to change their vote on the
19 composite construct?

20 DR. NALLAMOTHU: Can I make just
21 one point? That's a great point and I think
22 it's one that this group needs to take into

1 consideration.

2 I will mention that at least in
3 this sample that we saw, and again with all
4 the limitations I'm sure we're going to
5 discuss, about half the providers practiced at
6 one hospital. Then about 30 percent or so
7 practiced at more than one hospital. And then
8 about 20 percent practiced at more than two
9 hospitals.

10 So there is in the modern practice
11 of cardiology this idea that people do move
12 around.

13 And that potentially has some implications for
14 how you consider this attribution issue.

15 DR. KOTTKE: Henry.

16 DR. TING: Not to beat a dead
17 horse, but the perfect attribution is actually
18 at the patient level. But we don't have data
19 to make a measure like that.

20 DR. KOTTKE: And it's usually N of
21 one trials.

22 Okay, so unless somebody chooses

1 to change their vote from the prior vote we'll
2 just use the prior vote. Thank you. Michael.

3 DR. CROUCH: Okay. As for
4 reliability the only difference is the
5 denominator specification. The exclusions
6 listed differ in addition to patients that
7 died, physicians who are discharged to
8 hospice, or discharged to another acute care
9 hospital, or who left AMA, against medical
10 advice, are stipulated as inclusions in this
11 one and not in the previous one.

12 And that's a harmonization issue
13 that you may want to comment about. How do
14 you want to plan to reconcile that.

15 DR. KOTTKE: Yes, Chuck.

16 DR. HOLLANDER: I was the
17 secondary on this one. And I think that's an
18 issue.

19 The other thing that wasn't
20 addressed is the way they discussed in the
21 last measure that if you had a
22 contraindication to drug 3 you still counted

1 in the denominator for drugs 1 and 2. And so
2 I think I'd like to see these two measures
3 harmonized more precisely.

4 DR. NALLAMOTHU: You know, I'll
5 give you the easy answer. This is one of the
6 great things about the process of kind of
7 vetting and going through this you guys are
8 absolutely correct. The entire intent was to
9 make them harmonized.

10 There were two areas and both of
11 those we're working on right now. Part of the
12 issue is that this measure has, you know, the
13 ACC was responsible for the last one. PCPI
14 was responsible for this one. And that caused
15 a little bit of the issue.

16 But absolutely. I mean the last
17 thing we want to do is create confusion around
18 this. In fact, we might even think about
19 harmonizing more the titles as well which
20 would be a big issue. So we absolutely agree.

21 DR. WINKLER: Well, the title I
22 think is a perfectly good one.

1 I think the other -- the exclusion
2 exception issue I think was the other one the
3 group brought up as being areas maybe in need
4 of true harmonization as opposed to just
5 writing the same words even though the intent
6 was the same. So, to the degree we can clean
7 up the things you truly are already the same.

8 The question is going forward what
9 are the real differences between these
10 measures and are they important differences
11 that should continue. I mean, in all honesty
12 true harmonization of these measures would
13 make one measure go away. And it would be
14 just multiple levels of analysis for a single
15 measure.

16 So, the question is what are
17 really the differences between the two
18 measures and how does ACC see potentially
19 going forward with true harmonization of these
20 measures.

21 DR. KOTTKE: I think one of the
22 issues is that the cardiologists really aren't

1 asking within hospitals. It's not like Mayo,
2 you know, where you work at one site and if
3 the hospital does great then every
4 cardiologist in the practice does great. But
5 there's the rovers and folks at multiple
6 hospitals. And so they're not quite -- they
7 don't overlap. They're not nested.

8 Are we ready to consider
9 reliability? Yes, Sana.

10 DR. AL-KHATIB: I'm ACC totally in
11 favor of what you just said because they are
12 exactly the same. I mean, the only thing that
13 was mentioned is in terms of how they worded
14 the exclusion criteria. But beyond that the
15 only difference is the level of attribution,
16 the level of the measure.

17 And I would be totally in support
18 of having, combining the two into one measure
19 but having different levels of reporting.

20 DR. BURSTIN: Just one brief
21 comment on the differences. And I assume this
22 is correct but Jensen can correct me if I'm

1 wrong.

2 I assume part of the difference as
3 well is because it is a PCPI-level measure.
4 It has three fairly open-ended exceptions for
5 medical reasons, social reasons and another
6 reason I forgot.

7 But that does change the -- I mean
8 that is enough potentially to make it -- the
9 question is are those acceptable differences.
10 Because again, remember under reliability, 2A1
11 here is precise specifications. So that
12 should be a consideration for you.

13 MR. CHIU: Actually, as you know,
14 we looked at the application, to Dr.
15 Nallamothu's point. It is true. So PCPI did
16 lead the effort for this measure. But the
17 exclusions as specified actually should be
18 identical to the NCDR ones.

19 But having said that though, for
20 the other measures that isn't always the case.
21 But for this we do have like, for example, the
22 contraindicated. And how we calculate it in

1 our measure, how we noted it in the form,
2 actually I think there are some discrepancies.
3 So the calculation is exactly the same as the
4 NCDR, number 0964 if I remember correctly,
5 that measure is the same.

6 But I do think as we get to the
7 other sections there might be some differences
8 with usability and things that we'll talk
9 about in a second.

10 But just to tackle the other
11 question I think in terms of harmonization
12 with cardiac rehab and things, I'm wondering
13 -- Reva, I'll leave it to you. But if that
14 would make more sense after we look at all the
15 other individual measures before we do that.
16 Because the cardiac rehab measure I know is
17 not today but it's tomorrow.

18 Those two measures, that 0642 and
19 0643, actually there is PCI in there and
20 that's harmonized across all the registries
21 and everything. So there's heart failure, AMI
22 and all those others. So I wonder if that

1 discussion might be helpful when we're looking
2 at that measure specifically.

3 DR. WINKLER: Well, I just want to
4 caution everybody that our role here isn't to
5 make new measures. You can suggest things
6 that might be measured and you would like to
7 see measured instead but really we want to
8 evaluate what's on the table in front of us.

9 So at this particular point I
10 think the question to you is this is a new
11 measure. What's its added value to the
12 portfolio. And I think that there is the
13 consideration of whether another new measure
14 is necessary, or whether it can be
15 incorporated into the existing measure or not,
16 if they are truly identical.

17 DR. VIDOVIICH: I just have one
18 question. I think you answered it partially.
19 We are not creating a new measure or
20 harmonizing the measures. Is that correct?

21 DR. WINKLER: Ultimately the
22 developers make any changes to the measure.

1 All we can do is recommend to them and base
2 our recommendations for endorsement on our
3 evaluation.

4 DR. VIDOVICH: But if this is the
5 case I might just want to get the opinion of
6 the group. I feel that the description
7 "optimal medical therapy" might be a little
8 bit too broad.

9 I think the aspirin, P2Y12 and
10 statin is way more -- because optimal medical
11 therapy is a large term. Brahm, as you
12 mentioned, you can throw in beta blockers, ACE
13 and ARB. So perhaps maybe limiting the scope
14 of this measure. If you're harmonizing.

15 DR. KOTTKE: Any other discussion
16 on reliability? Anybody choose to change
17 their vote? Sana?

18 MS. LUONG: For the purpose of the
19 people on the phone I'm going to say all the
20 options. For reliability you can vote 1 for
21 high, 2 for moderate, 3 for low and 4 for
22 insufficient. And we can start the timer now.

1 For this criteria 3 voted for
2 high, 13 voted for moderate, 3 voted for low
3 and 2 voted for insufficient.

4 DR. KOTTKE: Validity testing.
5 Michael?

6 DR. CROUCH: The validity issues
7 are the same as for the hospital-level
8 analysis are the same issue. I don't see any
9 differences or significant issues there that
10 are different from the others.

11 DR. KOTTKE: Any concerns?
12 Anybody choose to change their vote? So,
13 let's use the prior vote.

14 Feasibility?

15 DR. AL-KHATIB: So one point I
16 brought up is the MPI issue. Because when
17 they did the testing on validity they had a
18 large degree of missingness in terms of the
19 MPI. That's how you're going to attribute it
20 to the physician. And when we brought this up
21 during the call my understanding is that that
22 was something that the developer was going to

1 look into to potentially ways by which you can
2 minimize this large degree of missingness.

3 DR. NALLAMOTHU: We're going to
4 let Lara do that.

5 MS. SLATTERY: Hi, Lara Slattery
6 from ACC. So, as you see it takes a team to
7 get a measure through your NQF endorsement
8 process.

9 I should clarify that within the
10 CathPCI registry for actually numerous
11 versions we've had the ability to capture the
12 MPI at the individual clinician level.

13 We have only recently begun using
14 that data. And so what we know is that we did
15 not spend a lot of time in earlier versions,
16 or even earlier data reporting periods
17 validating MPI that was inputted.

18 We recently, and I mean very
19 recently have undertaken some mitigation
20 steps. That started with outreach to the
21 hospitals asking them to verify that they are
22 entering in accurate MPIs for valid clinicians

1 that are performing the procedures.

2 We then have externally validated
3 the MPIs that we've received from the
4 hospitals up against the data that's available
5 from -- that you can download from the
6 government. And now have actually built the
7 pathways that allow the physicians to access
8 that data. That's a relatively recent
9 activity. And we will continue to monitor
10 that to see what additional mitigation we need
11 to put into play.

12 For instance, if you know anything
13 about the NCDR's registries and the data
14 submission, data actually goes through some
15 validation of completeness as well as validity
16 of ranges in some instances. We have not
17 taken steps to up that threshold or put in
18 valid ranges for that but we may choose to do
19 that moving forward.

20 So, it is relatively newer for us
21 to be paying as close attention to the MPI.
22 It is designed to support clinicians being

1 able to get access to that data.

2 And a lot of energy had to then be
3 expended from a resourcing perspective on
4 mapping it so the individual clinicians can
5 now look in and view that data as well. So,
6 it is an area that we are working on. It's a
7 relatively recent effort.

8 MS. BRIGGS: I personally don't
9 see that. It's a tough fix if you decide to
10 fix it.

11 DR. NALLAMOTHU: I was just going
12 to add like, you know, one of the funny
13 anecdotes is 007 was apparently one of the
14 most common MPI numbers. But in the last
15 couple of years that's gone away.

16 DR. KOTTKE: So, validity.
17 Anybody choose to change their vote? Nobody
18 chooses to change the vote. We'll use the
19 same count.

20 Again, 2d. Composite. Anybody
21 discuss? Anybody change their vote? Seeing
22 nobody changing their vote we'll take the

1 prior vote.

2 We're to feasibility, I believe.

3 DR. CROUCH: I don't think there
4 are any different issues with this.

5 DR. KOTTKE: Anybody need to
6 discuss?

7 DR. HOLLANDER: Yes, so you know,
8 I'm now thinking about it. There's 10 to 20
9 percent of hospitals that aren't in the
10 registry. And what if I'm a physician who
11 participates at hospital A which is in the
12 registry but hospital B doesn't. Is that
13 going to give an accurate portrayal of my care
14 pathways?

15 And so I don't know that
16 feasibility is the right place for it but it
17 is feasibility in measuring that individual
18 physician. And I just thought about that.
19 And I think that makes this a little different
20 than the last measure.

21 DR. NALLAMOTHU: I mean, again,
22 that's a great point. It does get to the

1 complexity of how physicians aren't
2 necessarily nested within hospitals.

3 I think the only response I could
4 really come up with, and again, understanding
5 it's a great point, is that at least the care
6 in those hospitals where that physician does
7 participate and that are visible within the
8 registry will be apparent.

9 You know, regardless of that care
10 it's going to be the same issue as before that
11 care, at least at this point in time. I mean,
12 there are just a handful of hospitals that are
13 out there but those hospitals are essentially
14 invisible to these measures.

15 DR. KOTTKE: Any other concerns or
16 comments. Anybody wish to change their vote
17 on feasibility? Seeing no one. Okay, should
18 we vote? You want to vote? Okay, let's vote.

19 MS. LUONG: For feasibility 1 is
20 for high, 2 is for moderate, 3 is for low and
21 4 is for insufficient. And the timer will
22 start now. Four voted high, fourteen voted

1 moderate, three voted low and one voted
2 insufficient.

3 DR. KOTTKE: Usability and use.
4 Anything new?

5 DR. CROUCH: I don't believe there
6 are any significant differences between this
7 and the hospital level.

8 DR. KOTTKE: Anybody care to
9 comment on usability and use? Seeing no
10 comments -- oh.

11 MS. STEARNS: Just quickly. From
12 the perspective of consumers I think that it
13 is not uncommon for report cards to reflect
14 both hospital and physician information. So,
15 consumers do often look at that information.

16
17 So, if in the end the data that is
18 collected is identical that will be
19 informative. But I think it's worth pursuing.
20 Because you find out if there will be
21 meaningful differences between whether the
22 hospital-level data and the physician-level

1 data is the same. Because if there are
2 meaningful differences among different
3 physicians consumers if you're having elective
4 PCI would want to know that.

5 DR. KOTTKE: That's true. Other
6 comments? Anybody feel the need to change
7 their vote on usability and use? Seeing no
8 indication we'll use the prior vote.

9 We are to committee voting on
10 whether to recommend measure for endorsement.
11 Any discussion?

12 DR. AL-KHATIB: A quick question.
13 If we end up endorsing this what will happen?
14 I mean, you'll have these two measures, very,
15 very similar. Not identical, I agree, but
16 very similar. Do we really need to have these
17 two measures in place?

18 DR. KOTTKE: Reva says that's the
19 key question. I agree that your vote here, I
20 mean if you vote yes to endorse this measure
21 you're saying there's need for two measures.
22 I believe there's a need for two measures.

1 Judd.

2 DR. HOLLANDER: So, I'm just a
3 little confused. Because I know we're not
4 supposed to reinvent measures. But we've sort
5 of given advice and insights which the measure
6 developers think are good ideas. Reva said
7 something about oh, they could change this,
8 they could change that. Is there like a "yes,
9 but" vote? You know? So if I vote yes now
10 does it mean the measure as is goes to the
11 next step and it's never modified again. So
12 do I need to vote no to get the modification
13 so I could vote yes next time? And that
14 sounds funny but it's a serious question.

15 DR. WINKLER: The question would
16 be what's your modification. Let's talk about
17 what it is you're actually talking about. I
18 mean, are we talking about harmonization? Or
19 are we talking about something else?

20 DR. HOLLANDER: So I'm talking
21 about harmonization and other things raised
22 here. But what if they go back and they

1 looked at some of the sort of low-hanging
2 fruit that they said we can easily look at
3 that and we don't think that's going to be a
4 problem.

5 But it turns out they can't get
6 MPI numbers on people. And does the measure
7 then go away? So you know, they have a lot of
8 good plans but they haven't proven they can do
9 the things that we've asked to have fixed yet.

10 And we just had a sidewalk
11 conversation about, well, what if physician A
12 and hospital A is 98 percent but at hospital
13 B they're 82 percent. You know, then it's
14 really a hospital difference and not a
15 physician difference. And they are looking at
16 that but we don't know the results of that.

17 And so I think maybe I need to
18 know the results of these things, maybe I
19 don't. But if they find that they're exactly
20 the same across all hospitals, well then I
21 think the measure is really valid. If they
22 find it's a crapshoot over all these different

1 hospitals for the same physician the measure
2 is not valid. And we don't know that yet. So
3 those are the kinds of things I'm talking
4 about.

5 DR. WINKLER: I think at this
6 point just because we'll use the same approach
7 to all measures is you're voting on what's
8 been submitted to you now, not the potentials
9 for going forward.

10 Once we have the on this measure
11 then we have the conversation about
12 related/competing. If there are
13 recommendations you want to make about further
14 harmonization for the developer to take under
15 advisement and hopefully maybe react to then
16 that can be part of that secondary vote. But
17 right now you're going to vote on what's
18 submitted.

19 DR. KOTTKE: So, if they harmonize
20 then it comes back for another vote here?

21 DR. WINKLER: You would see it
22 back once the harmonization has occurred.

1 Because sometimes that's not something that
2 happens within a matter of days or weeks.

3 And remember, you're a standing
4 committee. That's what's going to facilitate
5 them bringing things back. So, that's why you
6 vote today on what's in front of you.

7 DR. KOTTKE: Yes, Sana and then
8 Henry.

9 DR. AL-KHATIB: So let's assume
10 the best case scenario, that they're able to
11 convince us that the MPI data can be achieved
12 and they're accurate, that they can harmonize
13 it exactly with the other measure.

14 I guess my question that I still
15 would struggle with is what is the added value
16 from having this measure to the other one. If
17 we have the ability to collect the information
18 on the other one and report it based on
19 different levels. I'm not sure I can see the
20 added value from having this in our portfolio.

21 DR. CHO: I agree. And I think
22 one of the things is that once these things

1 are endorsed then it's difficult to change
2 them. And I think that right now there are so
3 many moving parts in this current measure, the
4 missing MPI numbers, the doctors going to two
5 different hospitals, you eliminating
6 physicians who do less than 50 PCIs a year.
7 There's so many missing and moving targets
8 that I just don't think that currently as this
9 measure stands this is ready for prime-time.

10 DR. TING: So, for discussion
11 purposes I would argue that this measure at
12 the clinician level is useful. If you think
13 about patient satisfaction you can think about
14 it at the hospital level. But thinking about
15 the individual clinician level as Christine
16 says does give you additional information.
17 Because it gives you a little more granularity
18 about the individual clinicians.

19 And if you are hospital leadership
20 or executive one of the best ways to engage
21 your staff to do quality improvement is
22 actually to report individual clinician-level

1 data as opposed to just hospital-level data.

2 Having said all that I also
3 understand the comments that are being made
4 which is if the prior measure could just be
5 stratified at hospital, clinician and other
6 levels then we wouldn't need this extra
7 measure. But that's a strategic issue that's
8 not what's in front of us and I'm not exactly
9 sure I know how to deal with that.

10 DR. VIDOVICH: Just a quick
11 comment. Physicians don't practice in a
12 vacuum, right. You know, hospitals have
13 systems of care. They have ACS order sets,
14 PCI order sets and I feel it's tough to
15 separate one from another. That's just my
16 view from the two measures. So they probably
17 would be better off to be harmonized and
18 merged into one.

19 DR. KOTTKE: On the other hand,
20 it's the physicians who do drive the order
21 sets. I mean, I agree that context makes a
22 huge impact. All of us that have practiced at

1 several different locations, we're different
2 doctors in every place we practice. But it's
3 we who drive the quality in those hospitals as
4 acceptable. We accept it or we don't accept
5 it.

6 Are we ready to vote? Yes, Liz.

7 MS. DELONG: I'm still confused.
8 If this becomes harmonized it is one measure.
9 It is one measure with two names. I'm not
10 sure that makes sense.

11 DR. KOTTKE: I don't think it's
12 one measure with two names. Because doctors
13 aren't nested within hospitals.

14 DR. NALLAMOTHU: Can I make a
15 comment? So, this is obviously a very
16 interesting discussion. And I do hear a lot
17 of the concerns. And I think it's very
18 interesting to kind of hear this.

19 I would make a couple of points.
20 I think the last point made by Christine here
21 about usability, people do use these measures
22 different at different levels.

1 The second is the one that I've
2 continued to struggle with which is what Tom
3 has mentioned multiple times is if you do just
4 create this at a different level of
5 attribution is it the hospital that's just
6 going to aggregate within their own group what
7 their operators are doing and each of the
8 different hospitals is responsible for that.
9 And you never get a cross-institutional view.

10 And then the third thing is, you
11 know, maybe we've been thinking about it
12 naively, but like Judd has mentioned which is
13 this question, and we did have this sidebar
14 conversation.

15 But you know, we see it as
16 important regardless. So if there's
17 consistency across hospitals that tells us
18 something about the operators being involved.

19 But if there is inconsistency
20 across hospitals while it does get at the
21 hospital being responsible more so there is no
22 more important lever for like actual clinical

1 action than to have an interventional
2 cardiologist not do well at a visible way.

3 And so we think it's important but
4 we're not sure if it really matters for this
5 measure in general. And that's kind of how we
6 thought about it. So.

7 DR. KOTTKE: So I think it's time
8 to call the question. So, if you vote yes on
9 this you are -- the measure would be as
10 stands. You could vote no meaning that they
11 should harmonize, change the title, et cetera,
12 and come back and -- or you could be voting no
13 because you think you don't need another
14 measure.

15 DR. BURSTIN: One clarification.
16 So harmonize means like measures are actually
17 harmonized. They have the same
18 characteristics that fits here.

19 What you're talking about going
20 beyond that is saying it's one measure with
21 different levels of attribution. I think
22 that's what people are struggling with.

1 So I think I heard Jensen say that
2 any of the discrepancies are unintentional and
3 they will in fact be fully harmonized. Is
4 that correct, Jensen? Across the two
5 measures.

6 MR. CHIU: For this measure that
7 is correct. I know another one coming up is
8 a separate issue. But for this one, the
9 exclusions, I know there are some issues in
10 the application. Those exclusions and
11 exceptions are harmonized.

12 DR. BURSTIN: So these measures
13 are actually fully harmonized or will be fully
14 harmonized by the time they come back to you.

15 And so the real question is is
16 there a reason to have two measures or one.
17 And I think you just heard the discussion of
18 how you get a different population when you
19 look at this versus hospital because you may
20 just get physician cluster within the
21 hospital. I just want to be careful with that
22 language. Because in fact they're telling us

1 they will be fully harmonized. They just may
2 be two instead of one to capture both levels
3 of analysis.

4 DR. KOTTKE: So who decides that
5 they're harmonized. Is that you, Reva? Is
6 that NQF? I mean does NQF say --

7 DR. WINKLER: I think we're
8 basically listening to what ACC is telling us
9 about the measures just as all the information
10 about the measures comes from them.

11 So indeed, what I heard is the
12 fact that even though there may seem to be
13 differences in the written materials in fact
14 that was not meant to be and that they should
15 be essentially identical.

16 DR. KOTTKE: So, do we as a
17 committee look at it again and give it final
18 approval? I mean, is this a "yes, but" vote?

19 DR. BURSTIN: It could be if that
20 is something we need to do. We can take a
21 look at Jensen sends us back. If it's
22 literally identical with the exception of

1 where it says level of analysis then we can
2 probably just share that with you in an email.
3 But we can clear that up post hoc. Right,
4 Reva?

5 DR. KOTTKE: Does everybody
6 understand what they're voting on?

7 DR. AL-KHATIB: No, I'm not sure
8 that I do. So does this mean that it will be
9 one measure but you have different levels of
10 reporting? Or it will be two different
11 measures? With the only difference being the
12 level of reporting.

13 DR. BURSTIN: The latter. Because
14 I think what they're telling you is that if it
15 was a hospital -- if they just added a level
16 of analysis it would be nested within the
17 hospital is I think what I was getting from
18 you. As opposed to the fact that physicians
19 can be across multiple hospitals.

20 DR. AL-KHATIB: But if the
21 analysis is done when using the MPI how does
22 that not capture the procedures that you do at

1 different hospitals?

2 DR. KOTTKE: It does.

3 DR. AL-KHATIB: Right.

4 DR. KOTTKE: But if it's at the
5 hospital level you only capture a portion of
6 the --

7 DR. AL-KHATIB: So I guess what
8 I'm not clear on is what is the added value of
9 having the two measures if we just go with the
10 initial measure that we all endorsed and say
11 let's report it at different levels. Report
12 it at the level of the hospital. Give the
13 option of people to report it at the level of
14 the healthcare provider. And they would use
15 the MPI and that would capture all the
16 procedures that that provider does regardless
17 of whether they're doing them.

18 MS. SLATTERY: Lara Slattery
19 again. I just want to clarify that while a
20 lot of the responses may appear to be ACC only
21 responding in fact this is a different group
22 putting forward this measure for stewardship.

1 So, in the previous measure it was only ACC
2 that is being put forth as the steward of that
3 measure for implementation which includes a
4 lot of decisions around usability for that
5 measure.

6 In this instance this was
7 developed as a PCP/ACC/AHA measure. ACC/AHA
8 will take over stewardship of it. And so that
9 does change -- that's the only mechanism by
10 which we can find to submit the measure. So
11 they are in fact two separate measures in part
12 because stewardship of those measures is
13 governed differently.

14 DR. KOTTKE: Yes, Liz.

15 MS. DELONG: We now have two
16 measures that are presumably harmonized but
17 overseen by different groups. But it's the
18 same measure nonetheless. It is described
19 exactly the same way. And are we at risk of
20 expanding this portfolio to be
21 uncomprehensible?

22 DR. KOTTKE: I think people have

1 to decide whether it is the same measure for
2 themselves. Judd?

3 DR. HOLLANDER: So I think we're
4 measuring the same thing but we're reporting
5 different things. And I kind of think it's
6 the lumper and splitter argument, whether you
7 call it one measure.

8 If there's going to be two
9 voluntary reporting websites, one by the
10 physician and one by the hospital, then I'm
11 fine either way, whether it's one measure or
12 two measures because you're filling out the
13 same data set in the same registry going to
14 the same place.

15 And so, I don't know, it doesn't
16 matter to me if it's a different title on a
17 different website, or it's a subcategory of
18 the first website. So I'm okay with it as a
19 second measure because I think it's really the
20 same thing.

21 The amount of work on the hospital
22 end is going to be the same as one measure

1 rather than two. My biggest concern is that
2 I want to make sure they get harmonized and I
3 don't know if I give the "yes, but" number 3
4 in order to do that following the rules of
5 NQF.

6 DR. KOTTKE: My understanding is
7 it would come back for a final vote to us,
8 maybe an email vote to prove the
9 harmonization. I think it's time to vote on
10 this very straightforward issue here.

11 DR. CROUCH: Can I just make one
12 last comment? As a family physician who sends
13 patients to cardiologists all the time I'd
14 like to see the cardiologist data reported by
15 individuals rather than hospital. And I'd
16 like to have that data be available sooner
17 rather than down the line.

18 DR. KOTTKE: I think Christine's
19 comment that patients would like that too.

20 Okay, it's time to vote. 1 is
21 yes, 2 is no. Vote your conscious.

22 MS. LUONG: The timer starts. So,

1 11 voted yes and 11 voted no.

2 DR. WINKLER: I think this is a
3 perfect example of consensus not reached. It
4 is.

5 I think that perhaps given the
6 conversation we've had this will be an
7 opportunity to allow ACC to verify the
8 harmonization.

9 Also, we can put it out for
10 comment with consensus not reached and see
11 what the world out there wants to tell you and
12 bring it back for another review for you all.
13 Does that seem like a plan?

14 DR. KOTTKE: Yes, there's clearly
15 considerable interest in this and it's around
16 the measure. Encourage ACC to clean it up,
17 bring it back. Henry?

18 DR. TING: Can I just make one
19 comment about process? Because if this
20 measure had been reviewed first instead of the
21 other one it could have been very different.
22 And I'm not sure this process is equitable to

1 this measure compared to the other one we just
2 reviewed and approved 100 percent to zero.

3 DR. NALLAMOTHU: And I have to say
4 one other thing too just to build on that is
5 that, you know, I found it interesting to go
6 through the entire process. And then, I
7 didn't know at the end whether you were going
8 to accumulate what you had done.

9 But this reminds me a lot of study
10 section, right? Everybody breaks down
11 different things and then you're like all
12 right, well, where did you get the impact
13 score at the end of the day.

14 So, just -- and I'm only
15 mentioning that because from the measure
16 development side, I mean we would want
17 guidance as to where we fell short in this
18 particular regard. And so I think that would
19 be an important charge for you guys.

20 DR. BURSTIN: And I would suggest
21 that before we put this out for comment we
22 allow ACC to go back with PCPI and kind of

1 work this through. I think they just need to
2 kind of work it out amongst themselves.

3 You're absolutely right. Henry,
4 there's absolutely nothing about this measure
5 versus that measure. It's just that clearly
6 half of you don't want two of them.

7 So, please go back and we'll
8 figure it out to follow. We can do it in
9 email.

10 DR. KOTTKE: Would it be
11 appropriate to get sort of a hand vote on how
12 many people think there ought to be just one
13 measure?

14 DR. BURSTIN: Is that what that
15 was?

16 DR. KOTTKE: No, I don't think so.
17 I mean, there's a whole bunch of questions in
18 there about harmonization and title. How many
19 people think that this should be rolled --

20 MS. STEARNS: Is that possible?
21 Do we have measures where we measure both
22 hospital-level data and physician-level data?

1 So that happened. Okay.

2 DR. HOLLANDER: And you combine
3 them across hospitals. Like, the advantage of
4 this measure is -- you can do that. Okay.

5 DR. KOTTKE: But if only hospitals
6 are reporting then you don't have -- you don't
7 really know how the cardiologists are doing.

8 DR. SPANGLER: I have a question
9 for Reva and Helen. I mean, this is a process
10 question. Because if you look at the voting
11 up to this point it met all the criteria to be
12 endorsed. But despite that many people voted
13 no even though they voted that it met the
14 criteria.

15 So, does that mean -- I know
16 that's happened before, but the question is
17 are we missing something then in the criteria?

18 DR. KOTTKE: It has to do with
19 composites.

20 DR. WINKLER: No, I think that you
21 combined really two votes. One was
22 suitability for endorsement as well as what we

1 would have -- you would go into the next
2 question which is the related and competing
3 issue. Because your vote on suitability for
4 endorsement wasn't final pending the
5 discussion of related and competing measures
6 which you kind of pushed together.

7 DR. AL-KHATIB: So what I wanted
8 to add is exactly that. I mean, all of us
9 actually like this measure but we still don't
10 see the added value from having it as a
11 separate measure, knowing that the first
12 measure can actually be reported at different
13 levels. That's the missing point for me
14 anyway.

15 MS. MITCHELL: I think the issue
16 really comes down to we were asked to vote on
17 what is on this piece of paper right now,
18 period.

19 And I think as a part of the
20 process we discussed what it could look like.
21 And I think there was opportunity to conflate
22 could with should and is.

1 And so I think going forward just
2 keeping in mind that we're supposed to be
3 talking about what has been submitted for
4 review for endorsement today. If that's
5 incorrect please let me know but that's how
6 I'm operating.

7 DR. KOTTKE: I hate to have ACC
8 work on this whole thing and have it rejected
9 again. How many people would like to see this
10 come back cleaned up? Just a show of hands.

11 A separate measure that they feel
12 that ACC's time is well spent to harmonize it.
13 It comes back as a second measure. Maybe the
14 title is changed so it's not quite as broad,
15 that was brought up. Combining it to one
16 measure with the other measure. So they work
17 on it, come back. So there's two measures,
18 there's a hospital-level measure, there's a
19 clinician-level measure, they're harmonized at
20 all aspects except one is hospital, one is
21 physician. I'm the only one?

22 MS. TIGHE: And I do think we need

1 to clarify. It's not necessarily that these
2 are ideas in opposition to each other. We
3 don't know that ACC can expand the level of
4 analysis for the first measure. So it may be
5 that we have two measures that measure the
6 same thing at different levels of analysis
7 because they have some stewardship issues. So
8 I don't know if you guys want to speak to
9 that.

10 MS. SLATTERY: Yes, I mean --
11 again, Lara Slattery. I do want to emphasize
12 that this is -- this measure being put forth
13 is a collaborative measure that is jointly
14 developed with our partners the American Heart
15 Association.

16 So, you know, I appreciate and our
17 desire is to have a harmonized measure that is
18 efficiently leveraging the same data source
19 that is accurately reflecting to the best
20 degree that we can the performance of the
21 clinicians, understanding that they may not
22 have control over the data being submitted

1 because they don't directly make the decision
2 of whether to participate in the registry or
3 not.

4 However, if the recommendation is
5 to create one measure it is from our
6 perspective somewhat disingenuous to the
7 contributions that our partner societies, in
8 this instance PCPI and American Heart
9 Association have made in developing this
10 measure.

11 So I just don't know how within
12 NQF's structure we can reflect those stewards
13 the way they would like to be acknowledged in
14 contributing to this measure which is why you
15 have two measures that have been put forward.

16 DR. BURSTIN: And we can certainly
17 work with you on that. I mean, actually, Mary
18 probably knows this best from the stroke world
19 how many co-stewards there are, for example,
20 on the stroke measures. That's not a problem.
21 There's a way to in fact make it ACC/AHA/PCPI
22 for the combined measure. We can work with

1 you on that.

2 MS. SLATTERY: But the reverse may
3 not be the case where they want to accept
4 stewardship at the hospital level.

5 DR. BURSTIN: Well, they can be a
6 co-developer but not the steward. There's
7 plenty of -- I mean, don't let those technical
8 legal issues affect what you think is the best
9 way to get the measure information from docs,
10 hospitals and get the best information out
11 there.

12 MS. SLATTERY: So then in essence
13 these are the same measure, it's just --

14 DR. BURSTIN: Yes.

15 DR. KOTTKE: Tom?

16 DR. JAMES: I don't know whether
17 you want to invite more comments and I can
18 shut up if that's the case. But it seems that
19 I've grabbed the floor.

20 Rob Huckman at Harvard has made
21 the point that if there's not a significant
22 variation among physicians in an area, that

1 perhaps that's not a good measure to look at.
2 It's better to look at whether it's the
3 variation in the therapies offered.

4 In this case when I look at this
5 data, the difference between the 75th
6 percentile and the 25th percentile is not that
7 great. So to me I think this is a better
8 hospital measure than a physician
9 differentiator.

10 MS. TIGHE: On that just to
11 clarify process. So, when we draft the report
12 we'll post it for NQF member and public
13 comment. And that will give ACC some time to
14 consider these issues that you've raised and
15 potential responses to them.

16 We have a call after the comment
17 period where you'll consider all of the
18 comments, any additional information from ACC,
19 and you'll have the opportunity to re-vote on
20 the measure at that point in time. So, this
21 is a first vote but not necessarily a final
22 vote.

1 DR. KOTTKE: I think it's time to
2 move on. Thank you.

3 DR. GEORGE: So, just to let you
4 all know we're a little bit behind schedule.
5 We'll be going to the next measure, adherence
6 to antiplatelet therapy. Are the developers
7 available?

8 MR. CAMPBELL: Hey, Reva. This is
9 Kyle Campbell at FMQAI. Can you hear me okay?

10 DR. GEORGE: Yes.

11 MR. CAMPBELL: Okay. Did you want
12 me to kick off the measure?

13 DR. WINKLER: Yes, Kyle. Go
14 ahead.

15 MR. CAMPBELL: Thank you. All
16 right, well, good afternoon. My name is Kyle
17 Campbell and I'm the pharmacist and executive
18 director at FMQAI for the CMS Medication
19 Measures Special Innovation Project. Our
20 project is tasked with both maintaining and
21 developing new medication-related measures for
22 CMS.

1 The measure submitted for your
2 consideration today really picks up from the
3 prior measures and focuses on adherence to
4 antiplatelet or P2Y12 inhibitor therapy for
5 patients in the 12-month period following
6 stent placement.

7 As directed by NQF we worked
8 closely with the Pharmacy Quality Alliance to
9 establish a standard methodology for NQF
10 adherence measures. And the PDC methodology
11 or proportion of days covered methodology
12 selected was based on extensive testing to
13 establish its validity.

14 The measure was developed under
15 the guidance of a multidisciplinary technical
16 expert panel and has undergone rigorous
17 development and testing processes as specified
18 by the CMS measure management system
19 blueprint.

20 The measure is based on
21 administrative claims data and has been tested
22 with 100 percent 10-state sample and also a

1 convenient sample of 31 accountable care
2 organizations.

3 From an importance perspective
4 this measure addresses two of the National
5 Quality Strategy goals, namely promoting
6 effective treatment practices for the leading
7 causes of mortality and also engaging patients
8 in their care.

9 Stent placement procedures are
10 frequently performed. They account for high
11 resource use and lack of antiplatelet
12 adherence is associated with severe patient
13 and societal consequences.

14 As this is a shared accountability
15 measure we are proposing the measure for
16 multiple levels starting with the physician
17 group, moving up to health plan and
18 accountable care organization as well as the
19 state level.

20 Finally, we did receive questions
21 in our workgroup review of the measure from
22 the steering committee. And we have submitted

1 a memo under separate cover answering those
2 questions as requested.

3 We appreciate your consideration
4 of this measure today and look forward to
5 answering any questions you may have. Thanks.

6 DR. GEORGE: Thank you. And we'll
7 move onto the primary discussant.

8 MR. BURTON: Yes, hi, this is Jeff
9 Burton. Can you guys hear me okay?

10 DR. GEORGE: Yes.

11 MR. BURTON: So, since Kyle gave
12 that very detailed introduction I'll hop right
13 into the evidence.

14 Obviously this is a process
15 measure that demonstrates medication adherence
16 and how it potentially leads to decreased
17 adverse cardiac events and lower mortality
18 rates.

19 The overall body of evidence is
20 good when it comes to supporting the use of
21 antiplatelet medication following a PCI. I
22 don't think many would argue that.

1 Some of the intricacies I think of
2 how we actually measure adherence to a
3 medication is where we may run into a couple
4 of challenges that were noted during our
5 workgroup call and that Kyle provided some
6 clarification or some answers to.

7 So, to give a brief overview there
8 were three practice guidelines that were
9 presented. They did not have QQC ratings but
10 they were important to establish the
11 guidelines for the use of antiplatelet therapy
12 following a bare-metal stent or drug-eluting
13 stent, all of which were class 1 level A or B
14 recommendations.

15 The one thing here to note though
16 is that the guidelines, one of the guidelines
17 for bare-metal stents in non-acute coronary
18 syndrome did indicate that clopidogrel be
19 given for a minimum of one month and ideally
20 up to 12 months.

21 I think that in the response to
22 this that it only represents about 67 percent

1 of the members in the denominator. And that
2 the technical expert panel made a
3 recommendation to include these patients in
4 the denominator even though the evidence
5 wasn't definitive on a time period and stated
6 that it was superior to have the therapy for
7 12 months as indicated in the measure even
8 though that the body of evidence said that 1
9 month as a minimum would be sufficient.

10 There was a systematic review
11 providing evidence that related directly to
12 actually adherence of medication by a
13 discontinuation of clopidogrel at different
14 points following the stent.

15 The QQC for this was high in
16 quantity, moderate in quality and one could
17 argue low to moderate in consistency as some
18 of the studies did have different directions
19 that supported the data.

20 So, two additional studies were
21 conducted where a critical threshold of 80
22 percent medication adherence was established

1 given the difference in mortality rates for
2 cohorts that had below or above 80 percent.
3 So taking all that into account and using the
4 NQF algorithm to rate the body of evidence I
5 believe it could fall into a moderate
6 category. And I'll leave it up for the
7 committee for discussion.

8 DR. GEORGE: Do we have discussion
9 on the evidence for this?

10 DR. HOLLANDER: I sort of have a
11 problem with this one because they're using
12 the term "adherence" and none of this is about
13 adherence. It's about did the medication get
14 filled.

15 And so if you're in a prescription
16 plan where every month or three months they
17 send you a 90-day supply and you never take
18 the medication it appears to be adherence.
19 And so I think it's sort of a fallacy here
20 that it just depends on your prescription plan
21 as to whether or not you're going to appear to
22 be adherent. So I don't think they're

1 actually measuring what they claim to be
2 measuring, at least the way I read it.

3 MR. BURTON: That's something that
4 I was going to bring up in the usability of
5 this. I know that medication adherence is
6 very hard to measure because with the
7 administrative claims data you're measuring
8 prescriptions that were actually filled. And
9 not so much the actual adherence of a patient
10 taking those medications which can apply to
11 any medication adherence measure.

12 I do know that the NQF has
13 endorsed other measures relating to medication
14 adherence based on administrative claims. Is
15 that correct?

16 DR. WINKLER: Yes, it is. In
17 fact, a couple of years ago we did have a
18 project around medication and this was a huge
19 issue, it was measuring adherence.

20 I would just ask the question, say
21 the measure we just looked at where it was was
22 it prescribed on discharge. Do we know the

1 patients ever took them there either.

2 I think it's probably the question
3 that comes up most commonly with any measure
4 around medication is it's a little hard to
5 measure whether they put it in their mouth or
6 not.

7 DR. HOLLANDER: All right, so I
8 could see doing it at the ACO level or at the
9 payer level. Because if we're encouraging
10 payers to find ways to get medications into
11 patients' hands it makes sense.

12 But it's hard for me to envision
13 doing this at the clinician or institution
14 level since they don't necessarily control all
15 the difficult prescription plans the patients
16 are on. And I think a lot of it will be
17 driven by that.

18 MR. CAMPBELL: So, this is Kyle
19 Campbell for the measure developer. Just a
20 couple of points.

21 I think we aren't recommending
22 this measure for the individual clinician

1 level. We are recommending it, however, at
2 the physician group level. So if there's a
3 group practice they can by using the data
4 available from the measure be able to
5 determine what the overall adherence pattern
6 looks like in terms of fills for their
7 patient.

8 MR. BURTON: Kyle, this is Jeff,
9 primary discussant.

10 I know a couple of other committee
11 members had some questions as to the amount of
12 physician groups that were actually included
13 due to the fact that there wasn't enough data.
14 It wasn't reliable enough and there was only
15 13 percent of those physician groups.

16 So, we're jumping ahead here I
17 know a little bit to the I believe
18 feasibility. If you're going to be measuring
19 at a physician group and you're only looking
20 at about 13 percent of all physician groups
21 that are able to have enough data to do the
22 measure. And that's I think a little bit of

1 a concern.

2 DR. WINKLER: Guys, it would be
3 helpful if we could right now just focus on
4 evidence. It would kind of keep the
5 conversation a little bit crisper for
6 everybody.

7 MS. BRIGGS: So, we did talk a
8 little bit about the fact that there is not
9 sufficient data for bare-metal stent use of
10 the P2Y12 inhibitor for 12 months. The
11 recommendation within the guideline is 1 month
12 to 12 months. And there's only evidence for
13 that level of recommendation within the
14 guideline.

15 So, the evidence really doesn't
16 follow basically what's being asked for by
17 this measure. The measure is basically
18 blanketly saying anybody that got a stent
19 should have 12 months of P2Y12 therapy. While
20 that might be optimal that's not what the
21 guideline says. And we were using the
22 guideline as our evidence, then we're really

1 not following that evidence.

2 DR. GEORGE: Any other comments?

3 Yes?

4 DR. VIDOVIICH: My feeling is the
5 measure may not completely accurately
6 discriminate the acute coronary syndrome from
7 elective PCI. Because then the guidelines
8 change for 1 month to 12 months. As written
9 it might cause some confusion because of this
10 similar topic that you mentioned about the 12
11 months.

12 MS. BRIGGS: This guideline is
13 only for electives.

14 DR. VIDOVIICH: It's elective only?

15 MS. BRIGGS: Yes. This measure is
16 only for electives.

17 DR. VIDOVIICH: Okay.

18 DR. GEORGE: This is a really
19 important point to consider when we look at
20 these things right off the top. Any other
21 comments?

22 MR. BURTON: I did have another

1 comment that I briefly mentioned. There were
2 a few studies in the systematic review that
3 they didn't show the same effect of
4 clopidogrel cessation on stent thrombosis as
5 they saw in other studies. So, the lack of
6 consistency of those studies was a concern to
7 me.

8 MR. CAMPBELL: This is Kyle
9 Campbell again for the measure developer. I
10 would just suggest that the additional studies
11 did show consistency.

12 We do recognize that the -- for
13 the recommendation related to the bare-metal
14 stent for those non-acute coronary syndrome
15 indication as has been discussed it was
16 suggested that it would be optimal for 12
17 months of therapy. And when the measure was
18 specified that was felt to be the way to go in
19 terms of aligning everything with the ACC
20 guidelines.

21 That said, since that time and
22 since the workgroup we have looked at the

1 feasibility of stratifying by ACS and non-ACS.

2 And we are able to do that.

3 And with the ACO sample there's
4 about 2,000 patients overall in that
5 denominator. And if you exclude patients with
6 bare-metal stents for non-ACS indications
7 that's about 10 percent.

8 The reliability of the measure
9 does not change. The rate of the measure
10 increase slightly from an overall mean of 0.78
11 to 0.80. And the range of the measure -- it
12 still has a wide array of variation with a min
13 of 0.69 to a high of 0.85.

14 DR. GEORGE: Do we feel we're
15 ready to vote on this in terms of the
16 evidence? Okay, we'll go ahead and vote.

17 MS. LUONG: So, for those on the
18 phone 1 is high, 2 is moderate, 3 is low, 4 is
19 insufficient evidence with exception and 5 is
20 insufficient evidence. The timer starts now.

21 For evidence 2 voted high, 11
22 voted moderate, 5 voted low and 4 voted

1 insufficient evidence.

2 MS. TIGHE: So this just falls
3 within our consensus not reached criteria. So
4 we'll move forward with discussion of the
5 measure.

6 MR. BURTON: So the gap in care,
7 the opportunity I stated before, the critical
8 value of performance was 80 percent for
9 medication adherence. The developer evaluated
10 performance based on the Medicare claims for
11 eight states over a two-year period looking at
12 the prescription drug plan level, looking at
13 the state level, the physician group level and
14 the ACO level.

15 The states, the plans and the
16 physician groups all had -- or each had an
17 average performance level of 75 percent, but
18 the ACOs had a 78 percent. So there's a small
19 gap from the 80 percent critical value of
20 performance.

21 However, as a process measure
22 ideally you get to 100 percent performance.

1 So I do think that there is a gap in care here
2 and an opportunity for improvement.

3 DR. GEORGE: Discussion on
4 opportunities for improvement? Yes?

5 MS. DELONG: I didn't follow where
6 they got the data. If they can't measure
7 adherence in a lot of situations where did
8 these data come from?

9 MR. CAMPBELL: This is Kyle
10 Campbell again for the measure developers.
11 So, these data are derived from Medicare
12 administrative claims data that include Part
13 A which is generally the hospital, Part B
14 which is the outpatient benefit and Part D
15 which is the prescription drug benefit.

16 The numerator compliance is
17 measured with the days covered from those
18 prescription drug claims. So those data are
19 readily available to calculate for the measure
20 for this population.

21 MS. DELONG: So you can tell of
22 the numbers prescribed which prescriptions

1 were filled and for how long?

2 MR. CAMPBELL: That's correct. We
3 can tell which medication was filled and the
4 days supply for that medication. And then
5 that gets put into the measure algorithm to
6 develop a days covered which would actually
7 adjust slightly to the overlap of any fills in
8 prescriptions.

9 DR. AL-KHATIB: Just a quick
10 question. As we all know, a lot of the
11 beneficiaries have other ways to get their
12 medications other than CMS.

13 So, do you have a handle on what
14 percentage of patients at least in your sample
15 that you looked at had other ways, other
16 coverage if you will for their medications?

17 MR. CAMPBELL: So, we did just
18 briefly look at that with a sensitivity
19 analysis where we looked at the potential
20 frequency by imputing patients didn't have
21 Part D-covered drugs, what would be the effect
22 if we imputed 100 percent adherence rate on

1 those patients. And we didn't really find any
2 effect.

3 And I will say that there's
4 probably more concern -- even though this is
5 also limited, there's more concern for drugs
6 that would be on a generic formulary where
7 patients would be likely to pay cash. In this
8 case, you know, I don't think that that would
9 be the case with any of the P2Y12.

10 So, it is conceivable that
11 patients within our population could have a VA
12 benefit let's say. But that would be true of
13 all other NQF-endorsed adherence measures that
14 are based on claims of which we're a steward
15 of and any other organization is a steward of.

16 So, we haven't looked at it as a
17 limitation particularly when there's a gap in
18 care. And we know that as was said that these
19 measure rates should be much closer to 100
20 percent. And we don't really think that that
21 would have -- it would have a meaningful
22 impact on the measure.

1 MR. MATTKE: And one more comment.
2 Soeren Mattke for the developers.

3 Remember that in order to get
4 identified for the measure we must see
5 prescription fills under your Part D benefit.
6 So it would only be of concern if people use
7 sometimes Part D, sometimes other sources of
8 coverage.

9 DR. GEORGE: Linda?

10 MS. BRIGGS: When we discussed
11 this within the workgroup we did have
12 questions to go back to the developer related
13 to the fact that there is some gap in coverage
14 in the Part D Medicare benefit. When patients
15 get to a certain dollar amount they fall into
16 the "doughnut hole."

17 Now, based on that information
18 there could be potentially a gap which
19 patients are supposed to submit the charges
20 for those drugs so that they get credit for it
21 so they get out of the doughnut hole.

22 However, depending on the

1 patient's other medications the timing of when
2 that occurs is variable. So that if somebody
3 was close to the end of the year, let's say
4 November, and they just hit the doughnut hole,
5 they may not be inclined to submit that data.
6 So that the data set that they're working from
7 is not perfect.

8 But just to point out that there
9 are some reasons why patients might have
10 adherence discrepancies that are not truly
11 reflective of the patient taking or not taking
12 the drug.

13 MR. CAMPBELL: So this is Kyle
14 Campbell for the developer again. And we did
15 submit a response to that question in a memo
16 under separate cover on April 17.

17 Just a couple of points about
18 that. CMS does require Part D plans to
19 process claims and track the true out-of-
20 pocket costs paid by the beneficiary in
21 realtime.

22 Secondly, and I think maybe more

1 importantly is with the passage of the
2 Affordable Care Act the Medicare drug coverage
3 gap affectionately known as the doughnut hole
4 will be phased out completely by 2020. And
5 based on the current provisions within the act
6 the amount beneficiaries pay for those out-of-
7 pocket prescription drugs has already begun to
8 decrease.

9 Originally it was 100 percent for
10 both brand name and generic drugs in 2010.
11 It's now for 2014 47.5 percent for brand name
12 drugs and 72 percent for generic drugs. So
13 there is an incentive for beneficiaries to
14 have these claims under their plan.

15 And by 2020 the percentage will be
16 25 percent for all drugs which is essentially
17 the same as the percentage paid by
18 beneficiaries for up to the point of the
19 coverage gap.

20 So therefore we anticipate minimal
21 to no impact on the measure rates. This
22 measure is new. It hasn't been proposed -- I

1 mean, implemented into a program so presumably
2 it would be at least another year before it
3 could be implemented in which case the
4 Affordable Care Act would decrease even
5 further the amount the beneficiaries pay in
6 the coverage gap.

7 DR. JAMES: And it's just for
8 those particular comments that have just been
9 raised that I think this is a good measure for
10 health plans and for large populations.

11 It becomes problematic at the
12 smaller individual group level. But for a
13 health plan it means I'm holding myself
14 accountable. I think this is a fair measure.

15 DR. GEORGE: Are we ready to move
16 to a vote?

17 MR. BURTON: I think so.

18 DR. GEORGE: On opportunity for
19 improvement.

20 MS. LUONG: So, 1 is for high, 2
21 is for moderate, 3 is for low and 4 is
22 insufficient. The timer starts now.

1 Eight voted for high, 12 voted for
2 moderate, 1 voted for low and 1 voted for
3 insufficient.

4 DR. GEORGE: Onto priority.

5 MR. BURTON: So the priority.
6 Same thing as before when we were talking
7 about the nature of the PCI and either
8 medication following a PCI or in this case
9 adherence to a high-priority given the sheer
10 number of PCIs, given the cost per PCI.

11 But maybe even more importantly
12 the importance of making sure that the medical
13 community is focused on strong adherence in
14 any way possible for their patients when
15 things may be out of their hands just because
16 something may be an imperfection in the
17 measure and we should de-prioritize it as an
18 important part of the software.

19 DR. GEORGE: Any comments on
20 priority? Should we move to a vote on
21 priority?

22 MS. LUONG: For priority 1 is for

1 high, 2 is for moderate, 3 is for low and 4 is
2 for insufficient. The timer starts now.

3 If you could just keep pressing
4 your vote here. Sorry. Eleven voted high,
5 ten voted moderate, and one voted
6 insufficient.

7 MR. BURTON: Maybe you could move
8 onto scientific acceptability.

9 DR. GEORGE: Just one question.
10 We're almost at 3 o'clock. Do you want us to
11 start the discussion?

12 DR. WINKLER: Yes, let's go ahead
13 and do that. But we will want to take a break
14 shortly for public comment. Go ahead, Jeff.

15 MR. BURTON: Oh, okay. So, as far
16 as the scientific acceptability again we're
17 using administrative claims. The numerator is
18 equal to the sum of the days covered by the
19 days supply of all antiplatelet prescriptions
20 during the days measured in the denominator.

21 The denominator is equal to the
22 sum of the days measured for all individuals

1 who undergo coronary artery drug-eluting stent
2 or bare-metal stent at any time during the
3 first 12 months of the 24-month measurement
4 period and have at least two prescriptions for
5 antiplatelet therapy during the 12 months
6 following the stent.

7 I think the key thing here is the
8 two prescriptions at a minimum to capture
9 those who may have intolerance or allergic
10 reaction to medications which would throw them
11 out of the denominator.

12 As far as any other coding issues
13 the developer did submit a list of all the NDC
14 codes as well as the contraindications which
15 focus on intracranial hemorrhage, GI bleed and
16 peptic ulcer disease.

17 DR. GEORGE: Any discussion?
18 Ellen?

19 MS. HILLEGASS: I think I may not
20 be able to find the information that was said
21 to us before, but I was looking for an
22 exclusion of acute MI. And I don't see it

1 anywhere in there.

2 From what I'm understanding the
3 developer believes that this is for just new
4 PCI, no AMI before. But I can't find this in
5 the writing anywhere. Can anybody address?
6 I have not been able to find it in exclusions.
7 I haven't been able to find it in numerator or
8 denominator.

9 MR. CAMPBELL: That's correct. We
10 do not exclude those patients with the prior
11 MI. And Soeren, I don't know, from RAND if
12 you want to comment on that?

13 MR. MATTKE: Someone else might
14 actually be a better person to comment on
15 that. Can you clarify why we would exclude
16 patients with prior MI?

17 DR. KOTTKE: Ellen was saying that
18 she didn't find exclusion for patients with an
19 acute MI, not prior MI.

20 MR. MATTKE: Oh. But we have
21 patients with implantation for acute coronary
22 syndromes which does include AMI and patients

1 with elective implantation.

2 DR. VIDOVICH: Did we mention that
3 this measure excluded ACS? I was just told
4 that a few minutes ago. Because I just
5 searched like "eligible" through the document.
6 I can't find that word anywhere in the
7 document.

8 MR. CAMPBELL: The measure does
9 not exclude those patients with ACS. It is
10 inclusive of patients with ACS.

11 MR. MATTKE: Because the patients
12 with acute coronary syndromes like unstable
13 angina or acute infarction actually have a
14 much higher risk for stent complications. So
15 we definitely want to keep those.

16 DR. VIDOVICH: But the indication
17 is for duration of dual antiplatelet therapy
18 are different for elective PCI and ACS.
19 Right? Hypothetically, pre-operative. I'd
20 say pre-op BMS could get away with one month
21 of dual antiplatelet therapy.

22 MR. MATTKE: No, I think the

1 recommendation is --

2 DR. VIDOVIK: ACS is 12 months
3 regardless of the stent type. But non-ACS,
4 they do differ.

5 DR. PHILIPPIDES: Right, but I
6 don't think the inclusion of ACS would change
7 that. You'd still have to give them dual
8 antiplatelet therapy out for a year.

9 DR. VIDOVIK: But I believe that
10 they should score non-ACS. Then the measure
11 might incorrectly measure that they should
12 have received 12 months whereas only 1 month
13 might have been sufficient.

14 DR. PHILIPPIDES: Correct, but the
15 problem here is not including the MI patients.
16 The problem is requiring that BMS stable
17 patients get 12 months. That's where their
18 issue is.

19 DR. VIDOVIK: Correct. That's
20 right.

21 DR. PHILIPPIDES: The MI is not
22 the one that's --

1 DR. VIDOVICH: Yes, the MI is not
2 a problem.

3 DR. PHILIPPIDES: It's the other
4 guys.

5 DR. KOTTKE: But this would be a
6 case where you could include both in a single
7 measure because you have a different code. I
8 assume that interventionalists code ACS
9 differently than stable coronary. Yes. So
10 here you could -- you put them both in the
11 same measure.

12 MR. MATTKE: So, to go back. The
13 measure does include both stable and acute
14 coronary syndromes. The indicate, the
15 recommendation is to treat all patients
16 regardless of the indication and regardless of
17 stent type for 12 months.

18 However, since the risk-benefit
19 rate for stable patients on bare-metal stents
20 is a little bit less favorable the guideline
21 suggests that you could get away with at a
22 minimum one month treatment.

1 To keep in mind, however, the way
2 that you get into the denominator for the
3 measure is that you have to have two fills
4 which indicates to us that somebody is
5 actually trying to treat the patient for
6 longer than a month because the fill is
7 actually 30 days.

8 So our assumption is once you get
9 into the denominator it's the stated intent of
10 the clinician to actually treat for a year
11 because the risk-benefit rate has been
12 determined to warrant ongoing treatment.

13 DR. TING: That's not completely
14 accurate. Just to quote the guidelines it
15 actually says two weeks for bare-metal stents
16 in non-ACS patients. If there's a tradeoff
17 for bleeding and risk of bleeding.

18 MR. MATTKE: Yes, but you can
19 still see once you are in the denominator you
20 must have been on 60 days of treatment
21 already. So those were really -- it's
22 unlikely that we are talking about patients at

1 that point in whom bleeding complications are
2 a major concern because they would never be on
3 60 days to begin with.

4 DR. TING: There's probably a
5 group of patients that you discontinue the
6 DAPT because of upcoming cardiac surgery at
7 two weeks.

8 DR. VIDOVICH: ACS in particular
9 is an example right there where you have to
10 discontinue because of delivery. Or upcoming
11 surgery.

12 DR. HOLLANDER: I think the
13 measure developer's point is that you have to
14 get two prescription refills. So you wouldn't
15 have gotten two refills if you're going to get
16 stopped at two weeks, or if you're going to
17 get CABG within the next month. So I'm still
18 not sure I agree with that as the criteria but
19 I think that's --

20 DR. GEORGE: Linda?

21 MS. BRIGGS: Again we come back to
22 bare-metal stent recommendation, either two

1 weeks if there's a bleeding concern but one
2 month is the recommendation, at least one
3 month and up to a year.

4 A clinician might decide that the
5 risks outweigh the benefits beyond a certain
6 point in time for that particular patient and
7 they would be totally justified according to
8 the guidelines of stopping it even after two
9 prescriptions. So it might be two months, it
10 might be six months in that maybe it's an
11 elderly person who has a fall and has some
12 kind of complication related to that. There
13 are a million reasons why a clinician might
14 feel justified for that. And they would be
15 well within the guideline parameters.

16 DR. GEORGE: So I'm hearing a lot
17 of concern about the fact that both bare-metal
18 and drug-eluting stents are included in this.
19 Is that?

20 DR. PHILIPPIDES: The same
21 recommendation for length of dual antiplatelet
22 therapy. I think if they had tweaked it and

1 said for bare-metal stents we're going to
2 really come out to about a month I think most
3 of us would be okay with that.

4 But oftentimes there's nothing
5 wrong with putting a patient on a bare metal
6 stent and putting them on dual therapy for two
7 or three months until they see you again.

8 Then you say you know, I've
9 tweaked the drugs long enough. There was a
10 reason I put a bare-metal stent in the first
11 place. I was worried about bleeding. I'm
12 going to stop it now. And that would be
13 considered by the guidelines -- Henry, I think
14 you'd agree -- perfectly adequate therapy.

15 The way this metric would have it
16 was not adequate or wasn't as good as the
17 other clinician. So I think that's what's
18 giving us pause.

19 DR. AL-KHATIB: I completely agree
20 with that comment.

21 The other question that I would
22 raise is since we're using administrative

1 claims data I'm not aware of any way by which
2 just based on the coding we can capture
3 whether a bare-metal stent was used versus a
4 drug-eluting stent. And without being able to
5 make that distinction you either have to limit
6 this to one type which you won't be able to
7 capture. That raises certainly concerns about
8 how we're going to be able to implement this
9 measure.

10 MR. MATTKE: Soeren Mattke for the
11 developers again. These are actually two
12 different CPT codes. Partly because the drug-
13 eluting stents are considerably more
14 expensive. And so you can distinguish them in
15 administrative data.

16 DR. VIDOVICH: I have a
17 nomenclature semantic question. We are asking
18 adherence. How do we know which duration was
19 prescribed to the patient? Do we know that
20 the patient should have received the month or
21 12 months?

22 If you're calling this adherence,

1 right? Because adherence would imply that we
2 did know what the duration of therapy was
3 prescribed. So how would you know this from
4 this measure?

5 MR. CAMPBELL: This is Kyle
6 Campbell for the developer. It's measured
7 just the same way that all the other adherence
8 measures are. We don't have specifically the
9 ability to know the intent of the physician
10 from the administrative data that they
11 intended for 6 months or 12 months.

12 But we can see all the
13 prescriptions filled and the days covered.
14 And so those are basically added up to
15 determine the proportion of days covered.

16 And in this case there's a fixed
17 follow-up time such that it's one year post
18 the stent placement after the successful fill
19 of two prescriptions.

20 Just one more note. We have been
21 able to operational because we did look at
22 this after the workgroup concerns. We are

1 able to separate bare-metal stents and drug-
2 eluting stents as well as determine from the
3 claims data who has it for acute coronary
4 syndrome and who has elective. So we can do
5 that as well.

6 DR. AL-KHATIB: Actually, a
7 question pertinent to this last comment. Have
8 you done any studies to validate the accuracy
9 of these codes in terms of using them for
10 bare-metal stent versus drug-eluting stent or
11 I think the other would be easier.

12 But especially in relation to this
13 particular issue do we have any data that show
14 that you have validated those codes and
15 they're actually accurate?

16 MR. CAMPBELL: So, this is Kyle
17 Campbell for the developer again. We have not
18 done any sort of validation with the chart
19 review to take a look at those codes. And I
20 don't know, Soeren, if you have anything to
21 add with regard to that.

22 MR. MATTKE: No, but it's unusual

1 to validate the coding accuracy because these
2 are administrative data that get routinely
3 audited for accuracy because they are being
4 used for pain. And since we're talking about
5 a high-value procedure it's very unlikely that
6 any major inconsistencies or errors would go
7 unnoticed.

8 MS. TIGHE: This is Lindsey. I'm
9 going to jump in and just circle us back to
10 the reliability discussion because I think
11 we've jumped well into validity at this point.
12 Do we have anything else to say about the
13 precision of the specifications or the
14 reliability testing that was supplied? I
15 don't think we've touched on the reliability
16 testing at this point.

17 MR. BURTON: So, I'll cover that
18 briefly here. The signal-to-noise analysis
19 that yielded 0.99 for the ACO group and the
20 drug plan group. There was like we had
21 mentioned before an issue with the physician
22 group that only 13 percent of those had sample

1 sizes large enough to generate reliability.

2 Just going with the 0.99 that is
3 high reliability but only for those, the
4 larger groups.

5 DR. GEORGE: Any discussion on
6 that? Liz?

7 MS. DELONG: Yes. Could you -- I
8 have no idea. I've seen that before and maybe
9 it's my own ignorance, but what did you do for
10 a signal-to-noise reliability test?

11 MR. CAMPBELL: Sure. So, the
12 signal-to-noise ratio is calculated as a
13 variance of the between measured entities
14 which is considered the signal and the
15 variance within a measured entity which is
16 considered the noise. And then the
17 reliability is estimated using data --

18 MS. DELONG: So when you say
19 within and between, can you be more specific?

20 MR. CAMPBELL: Yes. So, it would
21 be like if we were talking about an ACO or a
22 physician group you would look at the within

1 variance. So within that group statistically
2 is there more noise that sort of drowns out
3 the signal of being able to make comparisons
4 between physician groups.

5 So, if you can't discern -- I
6 guess the best way to say it, if there's more
7 variability internally within a physician
8 group than there is externally compared to the
9 peers then generally your reliability will be
10 poor.

11 And so as the reliability
12 approaches 0.7 we can begin to distinguish
13 statistically significant differences between
14 providers from the mean as it approaches 1.

15 MS. DELONG: Okay, so you're
16 basically looking at the inter-class
17 correlation and -- but you're assuming that
18 you don't have misclassification, right? That
19 you have valid data to work with.

20 MR. CAMPBELL: That's correct.

21 DR. GEORGE: Linda?

22 MS. BRIGGS: So, I just wanted to

1 echo what we said earlier in that if we're
2 looking at this at reporting the physician
3 group level data the report from the authors
4 of this measure says that only 13.3 percent of
5 the physician groups have an adequate number
6 of patients for reliable measurement. So
7 that's not a very large number of physician
8 groups.

9 MR. CAMPBELL: This is Kyle again.
10 Go ahead.

11 DR. GEORGE: Go ahead on the
12 phone.

13 MR. CAMPBELL: Sure. So,
14 basically the way we do that across the
15 measures is we look to see if there's some
16 minimum denominator or threshold size.
17 Because this signal-to-noise ratio is
18 sensitive to sample size.

19 So, with that minimum denominator
20 of about 3,650 days or 10 patients within the
21 denominator we do get reliable scores for
22 physician groups. And so that threshold would

1 have to be considered if the measure were to
2 be used at the physician group level.

3 DR. GEORGE: Are we ready to vote
4 on reliability? Okay, we'll go ahead.

5 MS. LUONG: The timer starts now.
6 One for high, two for moderate, three for low
7 and four for insufficient.

8 Ten voted moderate, ten voted for
9 low and two for insufficient.

10 DR. GEORGE: We are going to move
11 forward and finish this measure before we go
12 onto public comment. Validity.

13 MR. BURTON: So with validity we
14 spoke a little bit before we got into this
15 section.

16 Just as far as the validity
17 testing there was a face validity that was
18 assessed by a technical expert panel in which
19 80 percent strongly agreed or agreed that the
20 measure was valid.

21 And given that number and the fact
22 that only face validity was used I think our

1 highest rating could be moderate. And that
2 the results did demonstrate that this measure
3 is a reflection of quality of care.

4 I didn't really have too much else
5 on validity. We talked a lot about the data
6 as far as the codes and exclusions. This
7 measure is not risk-adjusted as a process
8 measure. But I'll leave it to the rest of the
9 group for discussion in the purpose of time.

10 DR. WINKLER: Just sort of
11 pertinent to your previous discussion, this is
12 the point where you want to determine whether
13 the specifications are consistent with the
14 evidence.

15 DR. HOLLANDER: I sort of said my
16 piece before. I'm not sure this is really
17 adherence. And that speaks to validity.

18 And although the expert panel that
19 they employed thought it did and I guess NQF
20 has used measures like this before I still
21 don't feel it actually speaks to whether the
22 patient is taking the medications.

1 And the issues raised by George
2 and Henry, having them out twice means they
3 should be taking it for a year and how it
4 works. So I have major issues with the
5 validity that I don't think I could get at.

6 DR. GEORGE: And thank you for
7 reminding us of that prior discussion. Any
8 other discussion on it?

9 DR. TING: This is actually for
10 Kyle. Many people have been critical and made
11 comments, but this is an incredibly important
12 area which is adherence. So if this measure
13 was statins at one year would we know
14 adherence is somewhere around 60 or 70
15 percent? None of us would have any
16 reliability or validity issues if we could
17 measure adherence to statins at one year.

18 And this issue of using dual
19 antiplatelet therapy at one year after the
20 stenting is an issue. We know that upwards of
21 15 to 20 percent stop at six months. And it's
22 correlated with mortality. But the comments

1 that have been brought up still stand, that
2 there may be some issues with this measure but
3 it's an incredibly important issue in terms of
4 quality of care.

5 DR. GEORGE: Liz, did you have a
6 comment? Yes.

7 MR. MARRS: I guess I have just an
8 add-on. The validity issue with the PDC and
9 measuring adherence this way. It is a very
10 validated surrogate marker for adherence.
11 It's used across lots of different
12 disciplines.

13 And so even though it's not a
14 perfect measure of adherence and it doesn't
15 necessarily make sure that the patient took it
16 it has been validated in lots of other disease
17 states and pharmaceutical studies looking at
18 whether people are adherent or not.

19 DR. HOLLANDER: So with that in
20 mind I could see there's certain people that
21 the adherence or whether they got their
22 medication should be attributed to. So if

1 it's at the ACO or the health system level and
2 they're the person who decides the manner in
3 which the patients can get the medication.
4 And I'll go back to is it via mail or do they
5 have to go get it. Then I can see some
6 responsibility. I still wouldn't call it
7 adherence. I'd call it getting the
8 medications or something else.

9 But if it's a physician group and
10 they're taking care of someone and they have
11 no say over what insurance or how those
12 medications come to that patient I have a real
13 issue with that physician group being
14 responsible for this measure or even be
15 reported with them because they really have no
16 control.

17 If they're prescribing the best
18 medication that has a class 1A recommendation
19 and it costs too much for a patient making
20 \$10,000 a year that patient may take it for
21 two months and stop taking it. And you can't
22 blame the physician group for that. They

1 don't have a lot of alternatives. And so I
2 have a problem with it at that level.

3 I don't really have a problem with
4 it at the ACO or the health system level.

5 DR. KOTTKE: Tom here. I think
6 just jumping ahead for a moment that this
7 would be extremely burdensome for physician
8 groups because they just don't have -- they
9 don't have in their database who fills and who
10 doesn't.

11 I think for health plans it's
12 quite easy and it's very appropriate. And
13 health plans could do something like hey,
14 you're five months out, you may be thinking
15 about quitting your dual platelets, don't.
16 You know, that kind of stuff.

17 But my major issue with validity
18 is what Henry and George brought up is that if
19 I'm going along and at four months I think I
20 got by with this old guy and he hasn't bled
21 yet, I'm going to stop his, you know, I'm
22 going to go back to just an 81 of aspirin

1 there's no way to detect that.

2 And that well made clinicians very
3 upset. Even if you say well, there's a
4 certain proportion where you misclassify. But
5 clinicians don't like to be misclassified with
6 crude measures.

7 DR. GEORGE: Are we ready for a
8 vote? I'm sorry.

9 MS. BRIGGS: So, I would agree
10 that the method might be appropriate and might
11 be used for other measures that NQF does.

12 However, I think that we have a
13 little bit of a special case here in that
14 we're trying to measure the DES and the bare
15 metal by the same standard. And this is
16 different than saying did you take your statin
17 and other medications like diabetic
18 medications and so forth that may not have a
19 criteria that would be 1 month versus 12
20 months.

21 Whereas you want those people to
22 take it chronically. So I think that we have

1 to take that into consideration.

2 And again, because those are all
3 lumped together we need to decide whether we
4 need to ask for stratification as a criteria
5 or just not take the measure at this point.

6 DR. GEORGE: Any other final
7 comments before we vote on the validity? If
8 not we'll vote.

9 MS. LUONG: The timer starts now.
10 One is for high, two is for moderate, three is
11 for low and four is for insufficient.

12 Six voted moderate, eleven voted
13 low and five voted insufficient.

14 MR. BURTON: Feasibility?

15 MS. TIGHE: Sorry, I'll jump in.
16 The measure was not recommended because it
17 failed to meet the validity criteria. So
18 we'll stop discussion of that measure.

19 And actually, given the time on
20 the agenda we're running a bit behind. So if
21 we could take this opportunity to see if there
22 are any public comments from those on the

1 phone. Operator, if you would check and
2 anyone in the room.

3 OPERATOR: To make a comment
4 please press * then the number 1. No, no
5 public comments at this time.

6 MS. TIGHE: Okay. It appears
7 there are none in the room so we are -- yes.

8 DR. PHILIPPIDES: Despite the fact
9 that I brought up several of the issues here
10 that I felt might have torpedoed this I did
11 want to actually -- and I wish that I had said
12 what Peter said.

13 Which is I do think this issue of
14 taking medications is a huge issue. And I
15 actually don't think that none of it should be
16 laid at the level of the office. Because
17 almost every cardiologist sees a patient after
18 they've had an MI, a stent, within a few -- we
19 try to do it within 8 to 10 days and then
20 again in a few months.

21 And at that time if you do nothing
22 else you want to make sure that they know what

1 medicines they should be taking and you get
2 them the medicines. And that means working in
3 conjunction with the ACO and the healthcare
4 system.

5 So I actually think as do you this
6 is an incredibly important area, not just for
7 aspirin -- you know, this is the beginning of
8 it.

9 And if they made the tweaks in
10 regards to the bare-metal stents I personally
11 would be much more enthusiastic were it come
12 by our desk again. I don't think we should
13 lose the general concept because of that one
14 detail. I think that would be a loss for us,
15 a disservice to our patients. So I just
16 wanted to echo what you said, Peter.

17 MR. BURTON: This is Jeff. I'll
18 second that.

19 MS. BRIGGS: I would agree it's a
20 very important topic.

21 MS. TIGHE: Certainly the
22 developer has heard that and our staff will

1 work with him on making these refinements and
2 potentially bringing it back to the committee
3 for review at a later date.

4 That said we are overdue for a
5 break. I'm looking to the chairs. Do we want
6 to take the full 15 or can we shorten it to
7 10?

8 DR. KOTTKE: We can try 10 but it
9 will probably mean 15.

10 (Whereupon, the foregoing matter
11 went off the record at 3:24 p.m. and went back
12 on the record at 3:41 p.m.)

13 DR. NALLAMOTHU: So, we're ready
14 to start. So, I'm going to be brief. I'm
15 sure this is going to start up a lot of
16 discussion. So, I'll save my comments for
17 later after listening to your guys' reaction.

18 But essentially this is a measure
19 related to comprehensive documentation of the
20 indication for PCI among all adults undergoing
21 this procedure. It's a process measure and
22 it's performed at the facility level.

1 And you can see the text around it
2 is essentially focused on five aspects of a
3 procedure and how well those aspects are
4 documented within the procedural record.

5 DR. KOTTKE: Linda?

6 MS. BRIGGS: Okay. So, as they
7 have said there are five different criteria.
8 So it's a component process measure.

9 In terms of the evidence to go
10 with that they used guidelines as the
11 evidence. The one guideline is the
12 appropriate use criteria guideline from the
13 American College of Cardiology. And that
14 appropriate use criteria guideline was
15 generated by looking at about 180 scenarios
16 that were developed originally to say what
17 would be circumstances under which people
18 would have PCIs. And then an expert panel was
19 convened to judge the appropriateness of use
20 for those particular scenarios.

21 In order to meet those scenarios
22 they have to use these criteria basically.

1 So, for patients that had acute coronary
2 syndrome they don't have to meet quite as many
3 of the criteria because they meet it under the
4 acute coronary syndrome and that's reflected
5 actually later on when they looked at the data
6 for this.

7 But the other patients have to
8 have things, the other items such as the
9 stress tests and the presence and severity of
10 anginal symptoms. And the big one being the
11 stress test.

12 The other guideline has much more
13 evidence to back that in terms of randomized
14 controlled trials and that is the PCI
15 guidelines from 2011.

16 So, based on the information that
17 was given about the evidence for this measure
18 the measure does not actually reflect
19 something going on with the patient per se.
20 It's only documentation that we're looking at.

21 And the assumption is that
22 documentation then mirrors what actually is

1 done for the patient, and that this would then
2 facilitate quality of care.

3 There was no quality statement at
4 all for the information that was given in the
5 guidelines. However, at least one of the
6 recommendations that's used is a class 1
7 recommendation with grade A evidence which
8 would make it multiple randomized controlled
9 trials.

10 Based on the majority of the
11 information I would say the evidence is
12 moderate for this particular measure.

13 DR. KOTTKE: Jeff, do you have any
14 comments you'd like to add?

15 MR. BURTON: Sorry, I was on mute
16 there. No, I don't.

17 I guess my concern -- I'm not too
18 versed in this area -- is I guess is a lack of
19 making the connection to the outcomes. And if
20 there was -- if there is other evidence that
21 points to how that happens is that -- is that
22 just not available through the guidelines? Or

1 is there something else out there?

2 DR. NALLAMOTHU: So, I think
3 that's what's been stated up to this point has
4 been fairly accurate. This is a measure
5 that's focused on documentation.

6 I think the natural question is
7 how does that relate to outcomes. It's a
8 difficult question because the real focus of
9 this measure is to even get to the point where
10 subsequent measurement can be done. So, it's
11 challenging.

12 I can tell you that, you know, we
13 did look at individuals where within the
14 criteria -- I'm going to pause here because I
15 want to make sure I explain this in the
16 correct way.

17 But if you do measure
18 appropriateness which is part of the goal of
19 this measure is to comprehensively document so
20 that can be done, there's really no
21 correlation between appropriateness and
22 outcomes in general. There's very little

1 evidence.

2 And that's because appropriateness
3 has very little to do with what we would
4 consider traditional outcomes measurements if
5 you're looking at the basic ones of mortality
6 and procedural complications.

7 Whether or not that procedure was
8 right for that patient at that time is much
9 more challenging to assess. And so I think
10 that that's been a great challenge for
11 thinking about the link between this and what
12 I would consider traditional outcomes. I hope
13 I didn't confuse everybody.

14
15 MS. MITCHELL: Was there a
16 translation of the AUC criteria in two
17 measures? Is this an attempt to do that, or
18 is this completely separate?

19 DR. NALLAMOTHU: So, to step back.
20 That's exactly -- I mean, that's a great way
21 of putting it.

22 So, this is essentially a measure

1 that has developed mainly because of the
2 limitations of measuring AUC. So, it turns
3 out that about one in five, maybe a little
4 less than one in five, all PCIs can even be
5 mapped to AUC.

6 And then when you look at the
7 elective ones it's much more. It's like about
8 one-third can even be mapped to AUC because
9 the data are just not recorded.

10 And fundamentally, I mean I think
11 this measure is so important mainly because it
12 moves the field forward with being able to
13 actually even start to assess this really
14 important aspect of care.

15 Right now these procedures are
16 essentially invisible and we don't have the
17 ability to kind of assess quality in any way.

18 DR. KOTTKE: Other comments?

19 DR. AL-KHATIB: I completely agree
20 with that. I actually see a lot of value in
21 this performance measure.

22 And in fact, if you look at the

1 Affordable Care Act among many of the quality
2 improvement initiatives that were mentioned is
3 ensuring appropriateness of cardiovascular
4 care is what was mentioned in the Affordable
5 Care Act. I truly see this as a very helpful
6 measure. Hopefully we'll be able to make sure
7 that all the other aspects of it are fine.
8 But I certainly can see a lot of value in this
9 measure.

10 DR. VIDOVIK: I would just like
11 to echo this. I think it's a very valuable
12 measure.

13 My question to the developer is
14 how granular will be the measure, the
15 requirement for granularity? What -- will you
16 require that some specific categories are
17 filled in, or anything goes? You mentioned
18 FFR or IVUS for indication criteria. So these
19 synchronize with the AUC at some degree.

20 DR. NALLAMOTHU: So that's a great
21 question. So, again, there is granularity.
22 The measure itself does get into the specifics

1 of how that's described.

2 But to give you a sense it not
3 only requires, for example, the presence of a
4 non-invasive stress test or an FFR, an IVUS,
5 but also in some kind of quantitative terms
6 the results as well.

7 I think one of the biggest
8 problems has been in some cases, for example,
9 with stress tests there might be documentation
10 that a stress test was performed. But then
11 it's remarkable how that never -- the result
12 of that never actually makes its way into I
13 believe the most important document related to
14 a procedure.

15 DR. KOTTKE: Any other discussion
16 on evidence? Are we ready to vote?

17 MS. LUONG: So the timer starts
18 now. One is for high, two is for moderate,
19 three is for low, four is for insufficient
20 evidence with exception and five is for
21 insufficient evidence.

22 So for evidence 4 voted high, 17

1 voted moderate and 1 voted low.

2 DR. KOTTKE: So, we move on.

3 Opportunity for improvement. Jeff?

4 MS. BRIGGS: Actually, it's me.

5 So just to back up a second. The database for
6 this just to be clear is the CathPCI registry
7 again. So, this is a really large, very rich
8 database that we're dealing with. And we've
9 already discussed how reliable and how it's
10 being used.

11 Opportunity for improvement. In
12 2011 they reported that the mean unmappable
13 which means they couldn't find any of those
14 180 scenarios that based on the amount of
15 documentation that they had for the patient
16 that they were able to map it to one of those
17 scenarios. The mean was 42 percent with the
18 median being 39.5 percent. So, there's a lot
19 of opportunity for improvement.

20 In 2012 it was slightly better.
21 The lower number actually, the better in terms
22 of the unmappables here. So we're still at

1 over one-third of patients being unmappable at
2 37 percent as the mean in 2012 and the median
3 being 35 percent unmappable based on missing
4 data at that point in time.

5 So there is substantial variation
6 among the various practices that were
7 reporting and the hospitals reporting. They
8 ranged from zero basically to 100 percent. So
9 there was a great deal of opportunity for
10 improvement.

11 DR. KOTTKE: Jeffrey, any
12 comments?

13 MR. BURTON: Yes, I just wanted to
14 maybe get a better understanding. I know
15 there was an issue on a prior call about
16 missing data versus other data that was never
17 collected because either a test wasn't done or
18 whatnot. It was a process of care that was
19 broken down.

20 So, is there any detail that the
21 developer can provide that shows the breakdown
22 of what is actually data that is out there but

1 the hospital was unable to get due to the fact
2 that maybe there was a stress test that was
3 done somewhere else versus a process of care
4 not being in place to generate the data.

5 DR. NALLAMOTHU: That's an
6 important gap and that was something that was
7 mentioned in the call as was mentioned.

8 I think what we've philosophically
9 kind of felt about that is even if the stress
10 test was done let's say by the referring
11 cardiologist at their own office and then the
12 patient ended up going for a PCI that
13 somewhere within that PCI record that stress
14 test needed to be documented. So that's kind
15 of how we would approach that question
16 philosophically.

17 But we just don't have the ability
18 to kind of tease out how much of this is a
19 lack of results being communicated or the test
20 was never done.

21 MR. BURTON: Yes, and I'm just
22 trying to get an understanding. I think that

1 it's valuable regardless of whether or not the
2 data wasn't there for one reason versus
3 another that -- the fact that the data is
4 there during the time of the PCI is the most
5 important part. So, I didn't want to devalue
6 that.

7 MR. CHIU: And if I can add just
8 one thing to Dr. Nallamothe's point.

9 I think this measure is a little
10 different than other ones in that there are no
11 exclusions. So in terms of gaming it's kind
12 of a slightly different answer but just to
13 add. There's no gaming.

14 And it's really simple in terms of
15 what you do with missing data. If there's
16 missing data you basically have failed, you've
17 failed. Because the thought to Dr.
18 Nallamothe's point, you really should be
19 documenting these indications in the long
20 description. Those five points there.

21 I just wanted to add the missing
22 values should actually be included in the

1 denominator but you'd actually fail the
2 measure in the numerator.

3
4 DR. KOTTKE: So sort of as perhaps
5 an amicus comment that you don't really need
6 the stress test in the record. You need a
7 report or something that indicates this
8 patient had a positive stress test at two
9 minutes with angina. So I'm doing an
10 angiogram.

11 DR. NALLAMOTHU: Absolutely. It's
12 not the original record but the fact that
13 there was some -- and a lot of times, you
14 know, we, again as a proceduralist myself we
15 make the assumption that, yes, I know it, it's
16 in my brain and I know what I'm doing. But
17 that documentation it turns out is just -- I
18 mean, it's -- as people have mentioned, the
19 opportunities here are pretty tremendous.

20 DR. KOTTKE: So, any further
21 discussion? Yes, sir.

22 DR. CLEVELAND: I just wanted to

1 ask, and maybe Jensen can weigh in too. I
2 know we've struggled with this too in looking
3 at appropriateness and trying to actually data
4 map elements. Are there any plans within the
5 NCDR to data map? Because that would
6 certainly add more robustness to the
7 appropriate use criteria. I mean almost a
8 module type of thing. Do you know? Except
9 that might then take the missing argument
10 pretty well.

11 MR. CHIU: I think the challenge
12 obviously is -- this doesn't just pertain to
13 just this measure but other kind of measures
14 in NCDR.

15 So, this one, you know, going
16 through the test and everything once this is
17 endorsed we put it in the registry, in the
18 Cath.

19 But the challenge always is there
20 are going to be missing data regardless. That
21 is, how much missing data. Unfortunately at
22 this juncture it's a little hard to tell how

1 much the missing data there is. It's a little
2 challenging to really know all the -- how much
3 truly is missing, how much you can really
4 quantify, because you really don't know what
5 you don't know.

6 This is a challenge I know STS
7 also has struggled with as well. So it's kind
8 of a challenge.

9 But the one thing I would add
10 though too just to recall. I don't know if
11 it's in the application, but all the measures
12 that become in Cath and other NCDR registries,
13 the suite, there's a data quality report so
14 that you can have too much missing data. So
15 I don't know the core elements off the top of
16 my head but I'm sure some of these elements
17 are core.

18 And really that just means that if
19 you have more than a certain percentage that
20 are not being captured you actually are
21 failing. You actually don't get a report.
22 Your site doesn't get a score back to them.

1 So that's -- we can kind of go back and take
2 a look at what the elements are and then
3 report back on that.

4 But all registries, Cath probably
5 being -- you know, I don't want to jump the
6 gun but I think probably being more robust
7 than some of the other registries we have.
8 But there is a data quality report that every
9 year is audited. Certain variables.

10 But the missing again, if a site -
11 - some site or something has too much missing
12 data they don't get a report out.

13 DR. KOTTKE: Liz?

14 MS. DELONG: So you have if
15 performed you need the information. But
16 suppose it is performed at an external lab.
17 It was performed but if it's missing you ding
18 the hospital who performs the PCI? You don't
19 know if it was missing unless you link, right?

20 DR. NALLAMOTHU: So I think the
21 way to think about it is more simpler. Look,
22 whether it was performed or not there has to

1 be documentation. So if you didn't do it
2 that's not missing.

3 But what happens is if you didn't
4 do it and you get a PCI and you're
5 asymptomatic and it was just because there was
6 a lesion there then at least you can say that
7 that was inappropriate.

8 Right now if you don't even have
9 that there that patient falls out. So, again,
10 two scenarios. Somebody who's asymptomatic.
11 Let's say they're not on any medical therapy
12 and they have a limited coronary lesion. That
13 person gets a stent. If they actually record
14 it, if they went to the step of saying, you
15 know what? We didn't even do a stress test
16 that patient gets identified as inappropriate.
17 That patient is at least visible.

18 What this measure is trying to do
19 is deal with the other side of it which is the
20 invisible. We're in Washington, D.C. so it
21 would be Donald Rumsfeld's unknown unknowns.
22 It's the idea that, you know, if you just

1 don't even say well, I didn't even record
2 whether it was done or not that person is
3 invisible to the measure as it currently
4 stands. Does that make sense?

5 MS. DELONG: So, it's actually two
6 items for each thing then. Was it done and
7 what are the results.

8 DR. NALLAMOTHU: You need to have
9 the results as well too because in some cases
10 like, you know, again a stress test and then
11 not knowing the results of the stress test
12 makes it unmappable as well.

13 DR. KOTTKE: Any further
14 discussion? We're ready to vote. We're
15 voting on opportunity for improvement.

16 MS. LUONG: So the timer starts
17 now. One is for high, two is for moderate,
18 three is for low and four is for insufficient.
19 Eighteen voted high, two voted for moderate.
20 Four, sorry.

21 DR. KOTTKE: Priority.

22 MS. BRIGGS: Okay. So, as has

1 been pointed out there are a fairly high
2 number of patients who received in particular
3 elective procedures that are deemed actually
4 inappropriate from one of the studies quoted
5 by the authors that the measure one in eight
6 elective procedures is actually an
7 inappropriate procedure.

8 And there's a 1.2 percent
9 mortality rate associated with any PCI. So we
10 are exposing patients needlessly in some cases
11 to the procedure if it's inappropriate.

12 And it's also a fairly costly
13 procedure. In the estimates provided in other
14 documentation by ACC a cath or PCI can cost
15 somewhere about \$72,000 by the time you add in
16 the hospitalization component of it. So we
17 are talking about high cost and a possible for
18 harm for patients. So it is a high priority
19 indicator.

20 DR. KOTTKE: Jeffrey, anything to
21 add?

22 MR. BURTON: No, completely agree.

1 DR. KOTTKE: Any discussion? Liz?

2 MS. DELONG: According to the data
3 that you collected did you see a difference
4 between the inappropriate mortality rate and
5 the appropriate mortality rate?

6 DR. NALLAMOTHU: So, that's a
7 little bit different. Again, those are people
8 who could even be mapped.

9 But I do want to emphasize that
10 point about why this is so critical. And
11 using the traditional measures of mortality is
12 probably inadequate.

13 So, when we've in the past looked
14 within NCDR and we've just mapped based on
15 appropriate indeterminate or appropriate. So
16 all these people could be mapped. And then we
17 just correlated it with simple kind of in-
18 hospital outcomes, typical ones. There's
19 actually very little correlation.

20 And the way that we interpret that
21 is, and the clinicians here, I mean it would
22 be almost intuitive is that it actually turns

1 out that it's pretty safe to put in a stent in
2 someone who doesn't need one.

3 And there's two aspects of care
4 that are being assessed here. And that's why,
5 you know, again, I'm kind of curious to see
6 how this discussion flows. But I really do
7 think that this is such an important first
8 step. Because otherwise it's impossible to
9 assess this other side of it.

10 DR. KOTTKE: Maybe I can call the
11 question. I think we all believe that putting
12 a patient at any risk whatsoever for no
13 justifiable reason is wrong. So let's vote.

14 (Laughter)

15 MS. LUONG: Voting starts now.
16 One is for high, two is for moderate, three is
17 for low and four is for insufficient.

18 If we all can just point your fob
19 back to me and vote for your number. Yes,
20 thank you. Nineteen voted high and three
21 voted for moderate.

22 DR. KOTTKE: Scientific

1 acceptability specifications.

2 MS. BRIGGS: Okay, so as I
3 mentioned this is a component or a composite
4 measure. So the numerator statement has to do
5 with having all of these criteria in order to
6 be mappable. So there has to be a priority
7 rating, there has to be presence of the
8 documentation of the severity of angina, use
9 of anti-anginal agents, the presence and
10 results of non-invasive stress testing or the
11 fractional flow reserve or IVUS therapy, or
12 estimation. And the significance of the
13 angiographic findings as well. So that's the
14 numerator statement. And if there's a no on
15 any of those then they're not met in terms of
16 having adequate documentation.

17 The denominator is all patients
18 age 18 and older for whom PCI was performed.
19 There are no exclusions. And in terms of the
20 acceptability for that I think it's
21 reasonable.

22 DR. KOTTKE: Jeffrey, any

1 comments?

2 MR. BURTON: No comments.

3 DR. KOTTKE: Any discussion?

4 Seeing no discussion let's vote. Oh, I'm
5 sorry. Reliability testing.

6 MS. BRIGGS: So, in terms of
7 reliability the testing done was signal-to-
8 noise. And with greater than or equal to 80
9 percent or 0.80 being very good the authors
10 indicated that it was moderate across all
11 centers and it was very good in centers that
12 were more high-volume centers. So there's at
13 least moderate reliability across all centers
14 reporting. And there were over 1,100 centers
15 involved in the data set.

16 DR. KOTTKE: Jeffrey, any
17 additional comment?

18 MR. BURTON: I just had one
19 question about the minimum number of cases in
20 a hospital. Was it 10 cases that was used as
21 a minimum to include a hospital in the
22 testing? Or is that -- that seems low to me.

1 DR. NALLAMOTHU: I think your
2 point's well taken. It is low when we set the
3 standard. Most hospitals were much higher
4 than that.

5 The issue with CathPCI is that
6 there is at times these hospitals that report
7 kind of in and out. And I have to double-
8 check on this. I apologize, but I'm not sure
9 if it was greater than 10 per quarter as well.
10 Because this reliability testing was done
11 across that. So I think that was the
12 criteria.

13 But we should know and we should
14 double-check. I'm not sure if Lara or anyone
15 else can check.

16 DR. KOTTKE: Any further comment?
17 Seeing no action, let's vote.

18 MS. LUONG: The voting starts now.
19 One is for high, two is for moderate, three is
20 for low and four is for insufficient.

21 For reliability 7 voted high and
22 15 voted moderate.

1 DR. KOTTKE: Validity.

2 MS. BRIGGS: Okay, in terms of
3 validity there -- the indicators themselves
4 align very well with the data set. So you can
5 actually map across the different indicators
6 that have been used as part of the composite.
7 So that part was very high.

8 As I mentioned there were a large
9 number of sites involved in the testing for
10 validity. There were in 2011 1,146 sites and
11 in 2012 the data they presented was from 1,178
12 sites. So, there's a great deal of patients
13 involved.

14 In terms of potential threats to
15 the validity there is a degree of threat in
16 the sense that there was the all-or-nothing
17 failure to meet the measure has to do a lot
18 with missing data related to the stress
19 testing. And in some cases it was almost 40
20 percent of stress test data missing.

21 And part of the criteria there if
22 you go back to the actual PCI registry itself

1 and look at the data entry points, it can be
2 a stress test or IVUS report from up to six
3 months before.

4 So, there's maybe some mechanistic
5 kinds of problems with entering that data.
6 Again, the cath-ing interventionalist may well
7 have that data in his head, but if it's not
8 entered into the PCI registry, if the data
9 never gets there from whatever center did the
10 particular stress test then it's recorded as
11 not met and not documented. So it's then not
12 meeting the criteria. And so something
13 probably needs to be looked at to address that
14 particular issue.

15 DR. KOTTKE: Jeffrey?

16 MR. BURTON: No comment here.

17 DR. KOTTKE: Anybody else?

18 Comments? Seeing no -- oh.

19 DR. WINKLER: I have a question.

20 And maybe it's just I'm missing something.

21 This to me seems more than just
22 documentation. So, I want to be sure I

1 understand what the measure result is.

2 Linda, you said that in 2011 the
3 mean result of unmappable patients was 42
4 percent. So, you know, the performance on the
5 measure was 58 percent.

6 But we've got 40 percent of people
7 that are unmappable. And are they unmappable
8 just because they didn't document? Or it's
9 possible that they're unmappable because they
10 don't meet the criteria, the appropriateness
11 criteria. I mean, is it purely documentation,
12 or are you capturing both together? Those
13 that are inappropriate as well as those that
14 are sloppy in their documentation. Is this
15 picking up both of those?

16 DR. NALLAMOTHU: The best way I
17 can kind of point this out is so the --
18 probably the most well known paper associated
19 with this is a paper by a good friend of mine,
20 Paul Chan and his colleagues in JAMA. And I
21 think it was around 2010 or so.

22 But I'm just going to read from

1 here the figure. So when PCIs are excluded it
2 turns out that that's -- out of this there
3 were 600,000 PCIs that were done. One hundred
4 thousand of them had to be excluded because
5 they couldn't be mapped to the AUC.

6 About 50,000 of those were non-
7 acutes with no prior stress test. And of
8 those because of that about half of those were
9 unable to be matched to the appropriate use
10 criteria specifically because they didn't have
11 a prior stress test.

12 About 40,000 of them had a prior
13 stress test documented but there was no
14 ischemia risk specified, making it difficult
15 to assess what the actual value of the
16 procedure was.

17 So, you know, a lot of this is
18 tied to the stress test, no question about it.
19 That's the documentation that's probably the
20 most challenging and difficult to overcome
21 here.

22 But I think it is interesting

1 because the -- it gets at kind of what you're
2 mentioning, whether again, without that
3 information it's just very difficult to use
4 the AUC.

5 So, there would be about 10,000
6 left where it was because of other reasons,
7 either other missing data elements or the fact
8 that it was one of these -- you know, I mean
9 they looked at about 200 scenarios and I guess
10 there are other scenarios besides those 200.
11 But for the most part they're of small
12 proportion.

13 DR. WINKLER: And the reason I
14 raise it is because the word "documentation"
15 is going to raise a red flag for certain
16 stakeholders who feel that documentation
17 measures are pretty minimal if you will. You
18 know, did you document symptoms. Did you
19 document this or document that. And I wonder
20 if that in the title is maybe misleading, that
21 there's more to this measure than simply
22 documentation, that actually we've got a lot

1 more appropriateness built into this measure
2 than whether they check the box or not? And
3 that's -- I'm just wondering if this is going
4 to get perceived with that in the title as is
5 it just another documentation measure as
6 opposed to something quite a bit more robust.

7 DR. RUGGIERO: The question I had
8 is if you don't have an objective study maybe
9 percent lesion as written in a chart would be
10 a documented -- not necessarily a documented
11 failure given the story. So, I think your
12 point is well taken.

13 DR. KOTTKE: Leslie?

14 DR. CHO: I think it's a very,
15 very important measure for many reasons. I
16 think, number one, it's the amount of PCIs
17 done in this country without really
18 appropriateness.

19 And I think that NQF, one of the
20 roles of NQF is really to guide clinicians
21 into appropriate criteria. More than just did
22 you get an aspirin, did you not get an

1 aspirin, did you get a statin or not.

2 But I think the missing data
3 component is appropriateness criteria came out
4 in 2009. And it's been a moving target. And
5 many of the hospitals are just figuring out
6 how to put these things into a database. And
7 that's why there's some missing variables.

8 For example, FFR is not included
9 in the 2009 appropriateness criteria. And so
10 I don't think this measure is diminished
11 because of the missing variables.

12 DR. KOTTKE: Judd?

13 DR. HOLLANDER: Trying to be
14 forward-looking on this there's another set of
15 appropriateness criteria that's coming out now
16 for low-risk chest pain, and coronary CTA is
17 prominent in that. It doesn't show up as even
18 something that's being collected here.

19 And although one could argue if
20 you have an 80 or 90 percent lesion should you
21 go to cath next it's certainly happening. And
22 so I would urge you to at least collect that

1 data and record that as well because it's
2 getting more commonly used these days.

3 DR. NALLAMOTHU: The only thing I
4 would say to that is that I think that these
5 are all people who ultimately are going to
6 have a PCI and they have an angiographic, you
7 know, it's an invasive angiographic as opposed
8 to a coronary CTA.

9 And I think the question is really
10 you should probably still get a functional
11 assessment in somebody who. You know, because
12 you're absolutely right.

13 I think, you know, if you're
14 thinking about a documentation measure of
15 whether they should even get a diagnostic cath
16 coronary CTA should be right up there with a
17 stress test. Does that make sense?

18 DR. HOLLANDER: Well taken. Once
19 you have the diagnostic cath you go by that.

20 DR. GEORGE: I would just add that
21 I think oftentimes the documentation of
22 appropriate use is so important. Without it

1 you're not able to develop appropriate outcome
2 measures.

3 DR. KOTTKE: Further discussion or
4 are we ready to vote? Looks like we're ready
5 to vote on validity.

6 MS. LUONG: Voting starts now.
7 One is for high, two is for moderate, three is
8 for low and four is for insufficient.

9 Six voted for high, 14 voted for
10 moderate, 1 voted for low and 1 voted for
11 insufficient.

12 DR. KOTTKE: Feasibility.

13 MS. BRIGGS: So, this is a new
14 measure so it has not been used by itself at
15 this point in time. There is another NCDR
16 indicator, the 30-day mortality that's being
17 tested apparently presently. And so it was
18 felt that that would be a good surrogate for
19 the testing, for this related to the PCI data
20 registry.

21 I think given that it is the PCI
22 registry and that we're using that for a

1 number of other indicators that it is a
2 feasible study.

3 DR. KOTTKE: Jeffrey?

4 MR. BURTON: Nothing much other
5 than the fact that it's the CathPCI registry
6 again. You know, we have a large majority of
7 hospitals participating but some that do not
8 which would give them access to the data. But
9 that's been mentioned before.

10 DR. KOTTKE: Henry?

11 DR. TING: Yes, so I've reserved
12 my comments for the feasibility section, not
13 the reliability and validity section.

14 But just for me to understand
15 this, Brahmajee and Jensen. This is about
16 improving documentation of these criteria so
17 you can map more procedures to appropriate,
18 inappropriate, or indeterminate. It's not
19 really actually a measure of how many
20 procedures that we're doing are actually
21 appropriate, it's just mapping the ones that
22 we can't map right now to appropriateness.

1 And the reason I ask that is it's
2 almost -- I don't know if this is the first
3 time NQF is evaluating a measure like this for
4 quality and performance. Because appropriate
5 use criteria are based almost on opinions of
6 16 to 20 experts in a room, 180 clinical
7 scenarios using a RAND modified Delphi
8 technique where you vote and you don't even
9 discuss the case. So it's very much expert
10 consensus.

11 And you wonder why any payer would
12 actually pay for a procedure where there's no
13 indication of why it was done, you know, be it
14 a CT scan or a PCI. And whether this is an
15 NQF performance or quality measure as opposed
16 to why are we paying for this if there's no
17 documentation that the person needed a
18 procedure.

19 Which gets back to Tom's
20 statement. You know, if you don't need a
21 procedure you shouldn't be exposed to any
22 risk. So, I'm just asking that question under

1 feasibility how does that fit within the NQF
2 measures.

3 DR. HOLLANDER: I was following up
4 on comments from before, say, that maybe this
5 isn't about documentation. Maybe this is
6 about the ability to determine
7 appropriateness. Right? Because that's what
8 it's all about.

9 And then I would say that that
10 probably does fall within NQF if the title is
11 changed to reflect that.

12 DR. WINKLER: In terms of NQF we
13 would be totally delighted to have measures of
14 appropriateness.

15 I agree that we may have to flex a
16 little bit of the criteria because it isn't
17 the traditional structure-process-outcome sort
18 of thing. And you're right on expert
19 consensus.

20 Under the current thing if you
21 were talking about evidence this would be one
22 of the very best reasons for an exception.

1 But we probably -- if indeed hopefully this is
2 the beginning of a new type of measure. We'll
3 have to adjust the criteria to account for it.

4 But by no means -- our
5 stakeholders would be delighted to have an
6 appropriate use criteria measure. No doubt
7 about it.

8 DR. TING: Again, I'm not trying
9 to develop a new measure, but why wasn't
10 something just like percent of procedures that
11 are deemed appropriate the measure? As
12 opposed to trying to get the ones that are
13 unmappable, Brahmajee.

14 DR. NALLAMOTHU: Well, I would say
15 that ultimately I think that that's an
16 important kind of goal to shoot for.

17 But when you have one-third of the
18 PCIs and sometimes at some centers 100 percent
19 of the PCIs unmappable I think it really -- it
20 sets a disincentive for being able to -- I
21 mean the easiest way to meet criteria is just
22 don't say it.

1 And I think what's more
2 interesting, and maybe I'm misunderstanding,
3 but I do think what I hear about what you're
4 saying is is this even a quality measure or is
5 this just like a standard for getting paid.
6 And that's a broader question.

7 I do think it is within the purvey
8 of the NQF, but that's a personal opinion.

9 DR. TING: So for -- and just,
10 again, I don't want to sort of say anymore.
11 It's my last comment.

12 New York State, for example, if a
13 procedure is not deemed -- if it's
14 inappropriate and SNAP as such it's actually
15 not reimbursed if you're Medicaid in New York
16 State. I mean that's already been a payer
17 decision state level.

18 MS. SLATTERY: So we're talking to
19 New York State about that and the appropriate
20 application of our appropriate use criteria or
21 potential inappropriate.

22 I do think that that's an

1 important distinction though. The appropriate
2 use criteria do not function like traditional
3 performance measures. And one of the
4 discussions that happened earlier with our
5 first measure was what's the target. And when
6 it's a performance measure we know and think
7 it's fairly reasonable usually that they can
8 get to 100 percent. That is not the case with
9 the appropriate use criteria.

10 More to the point, if we were to
11 even attempt to put forward any type of
12 performance measures with a target around
13 appropriateness we would need to understand
14 and have more complete reporting going on with
15 patients to say well, what really is the
16 target that we think we could reasonably move
17 the hospitals towards.

18 Which means better documentation,
19 ergo why we're putting this measure forward.
20 Because we need better documentation from the
21 hospitals. Just reporting out appropriate use
22 criteria is not sufficient to get them moving.

1 DR. NALLAMOTHU: And just to build
2 on what Lara said is imagine if we came to you
3 -- we do have a measure that's like that. But
4 imagine if we came to this group with that
5 measure and we said oh yes, by the way, about
6 one-third of them we can't even tell. I mean,
7 that would definitely be an uncomfortable
8 discussion. So I think that this is that
9 first step.

10 DR. KOTTKE: Ready to vote on
11 feasibility?

12 DR. AL-KHATIB: I just wanted to
13 add one quick comment, that I completely agree
14 and I completely see this as part of the
15 quality improvement initiative here.

16 Because even if it's just
17 documentation you're getting the healthcare
18 providers to think about these things. And to
19 question do I have an indication here. So I
20 certainly see it fitting into the quality
21 improvement initiative.

22 DR. KOTTKE: You could define

1 documentation as part of the process. I mean,
2 it's like washing your hands before you cut
3 somebody open. It's a process.

4 Okay, ready to vote on
5 feasibility.

6 MS. LUONG: The timer starts now.
7 One is for high, two is for moderate, three is
8 for low and four is for insufficient.
9 Thirteen voted high and nine voted moderate.

10 DR. KOTTKE: Usability and use.

11 MS. BRIGGS: I think I actually
12 already reported on this under the
13 feasibility, but this is not currently being
14 used. They're piloting a surrogate of 30-day
15 risk for readmission. And there's no public
16 reporting of this currently.

17 The documentation piece I think is
18 again useful information. Again, it's
19 probably a good first step to getting to the
20 actual appropriate use.

21 DR. KOTTKE: Jeffrey, any comment?

22 MR. BURTON: No comments here.

1 DR. KOTTKE: Discussion? Any
2 discussion? Seeing no motion, let's vote.

3 MS. LUONG: Voting starts now.
4 One is for high, two is for moderate, three is
5 for low and four is for insufficient
6 information.

7 The usability criteria has 13 for
8 high, 8 for moderate and 1 for insufficient
9 information.

10 DR. KOTTKE: Final vote, overall
11 suitability.

12 MS. LUONG: The timer is now. One
13 is yes, two is no.

14 Twenty-one voted yes, one voted
15 no.

16 DR. KOTTKE: So you're batting
17 500. You could play for the Angels.

18 (Laughter)

19 DR. NALLAMOTHU: Thank you.

20 DR. GEORGE: Next we are moving
21 onto measure 2459 in-hospital risk-adjusted
22 rate of bleeding events.

1 MS. TIGHE: Do we have anyone from
2 ACC joining us for this measure?

3 DR. MASSOUDI: Okay, I know we're
4 behind schedule so I'll give you like three
5 sentences.

6 But this is a measure that uses
7 again the CathPCI data registry to report
8 risk-adjusted rates of periprocedural bleeding
9 after PCI using a validated model that's been
10 published in JACC Interventions by Rao and
11 colleagues.

12 This is unlike the previous
13 measures we've been discussing which are
14 process measures and in the last case sort of
15 an appropriateness measure, this is an
16 outcomes measure. Again, using a validated
17 risk-standardized model.

18 And that's all I'll say unless
19 there's -- okay.

20 DR. AL-KHATIB: I guess I'll delve
21 into it. So, as was stated unlike all the
22 other measures that we've discussed today this

1 is an outcome measure. I'll get to the
2 evidence here.

3 The developer provided evidence,
4 or at least results from several large studies
5 to make the case that there are processes of
6 care that can influence the outcome. So, they
7 mentioned a study that was published by the
8 group at the Mayo Clinic that determined that
9 there were certain factors related to the
10 sheath size, intensity, duration of
11 anticoagulation with heparin and procedure
12 time that are independent predictors of
13 complications. Talking about several other
14 studies as well highlighting really several
15 factors that are linked with increased risk of
16 bleeding. And certain things that we
17 certainly could do to try to minimize the risk
18 of bleeding. Based on that I think the level
19 of evidence is high.

20 DR. WINKLER: Just to remind
21 everybody that what we're expecting for
22 evidence for outcome measures is not the same

1 as for process measures. And simply are there
2 things can we do to influence the outcome.
3 It's a straight yes or no on the evidence.

4 DR. GEORGE: Any discussion on the
5 evidence? We'll move to a vote then.

6 MS. LUONG: The timer starts now.
7 One is yes, two is no.

8 We have 100 percent 21.

9 DR. AL-KHATIB: So moving onto the
10 opportunity for improvement. They did a study
11 within the CathPCI registry and they certainly
12 demonstrated a gap in care. The risk of
13 bleeding, at least the mean risk of bleeding
14 was 5.5 to 5.6 percent. That may not seem
15 that all impressive. It is significant to me.

16 Although I don't expect that risk
17 to be zero we really have to strive to be as
18 close to less than 1 percent as possible.

19 The concern there though is the
20 variation in the risk of bleeding where they
21 clearly said that the distribution of
22 hospitals show that there are some sites with

1 excellent performance and other sites with
2 rates of bleeding that were 80 percent or
3 greater than expected risk of bleeding. So
4 with this information in mind I think that
5 there is certainly a significant gap in care
6 and a tremendous opportunity for improvement.

7 With regard to the disparities
8 question also the developer highlighted that
9 there were some statistically significant
10 differences by gender, race, insurance status,
11 but that the absolute rates after patient-
12 level adjustment were clinically marginal
13 except for gender which is a strong risk
14 factor for bleeding. So hopefully this could
15 be reported at least by gender as a
16 performance measure.

17 DR. GEORGE: Any comments?

18 Performance gap. Hearing none we'll move --

19 DR. JAMES: And this is more of a
20 question. Because I think of this as being
21 analogous to the CLABSI and the CAUTI types of
22 things. Do we have standards that would

1 preclude -- that would help push us down to a
2 zero rate of bleeding?

3 DR. AL-KHATIB: That's what we
4 discussed under evidence in terms of like are
5 there any processes of care that can help us
6 lower that risk.

7 And as I said they actually cited
8 a lot of papers where several risk factors
9 have been identified that you could base --
10 knowing about those risk factors you could be
11 extra cautious, extra careful. Talking about
12 like personalized medicine and what have you.

13 Maybe even question whether that
14 patient -- what kind of anticoagulation you
15 need to give them, things like that to try to
16 go for the medications that are associated
17 with the lowest risk of bleeding and things
18 like that. So certainly there are things that
19 can be done to lower the risk.

20 I'm not aware of a checklist.

21 DR. MASSOUDI: Maybe not a
22 checklist but there are tests of approaches

1 underway where one could personalize the use
2 of bleeding avoidance strategies like the use
3 of bivalirudin closure devices and radial
4 access based on a patient's individualized
5 bleeding risk. So there are sort of
6 approaches in place where that could be
7 integrated into care. That's obviously not
8 the goal of this measure here but that's been
9 tested and performed. And published, yes.

10 DR. GEORGE: Any other comments on
11 the disparities and gaps in care? If not
12 we'll move to a vote.

13 MS. LUONG: The timer starts now.
14 One is for high, two is for moderate, three is
15 for low and four is for insufficient.

16 Nineteen voted high, two voted
17 moderate.

18 DR. AL-KHATIB: Moving onto
19 priority. Yes, I believe this addresses a
20 significant health problem. As I mentioned
21 when I talked about the initial measure
22 related to PCI, you know, CAD is a very

1 prevalent condition. PCI is very commonly
2 done associated with high costs. And I
3 believe that this measure fulfills the
4 priority criterion.

5 DR. GEORGE: Any discussion on
6 priority? If not we'll move to a vote.

7 MS. LUONG: The timer starts now.
8 One is for high, two is for moderate, three is
9 for low and four is for insufficient.

10 Seventeen voted high and three
11 voted moderate.

12 DR. AL-KHATIB: Okay, so moving
13 onto scientific acceptability specifications.
14 So the numerator is all patients 18 years of
15 age and older undergoing PCI and developing
16 post-PCI bleeding.

17 The definition of bleeding was
18 very specifically provided, bleeding event
19 within 72 hours. And all definitions use a
20 greater than or equal to 3 grams per deciliter
21 drop in hemoglobin or transfusions, or an
22 intervention to stop the bleeding, or

1 hemorrhagic stroke, or tamponade, or post-PCI
2 transfusion.

3 And then the exclusions were NCDR
4 registry patients who did not have a PCI
5 obviously. And patients who died on the same
6 day of the procedure. Patients who had CABG
7 during the admission. Patients with pre-
8 procedure hemoglobin of less than 8.

9 And the denominator were all
10 patients 18 years of age and older undergoing
11 PCI. And as was described by Fred this also
12 uses the CathPCI registry.

13 I personally think that the
14 construct of the measure is very reasonable.
15 This definition of major bleeding is very much
16 in line with the accepted definitions in the
17 field. I personally don't have any concerns
18 about the specifications, definitions, or
19 coding.

20 DR. GEORGE: Leslie?

21 DR. CHO: As a practicing
22 interventionalist one of my pet peeves is this

1 bleeding criteria. And I just want to, you
2 know.

3 And my number one thing is that
4 this excludes bypass patients, but it doesn't
5 exclude patients who have had, you know, for
6 example, go onto have TAVR. Go onto have
7 structural, you know, balloon valvuloplasty
8 and things like that.

9 Because the criteria, I go through
10 this with my NCDR registry nurses all the
11 time. So if I do a PCI and then two days
12 later they go for a balloon valvuloplasty I
13 get dinged on my PCI. Or, if they go for a
14 permanent pacemaker I get dinged on my PCI.

15 So, there's all these sort of
16 scenarios in which I think it's not a trivial
17 amount of patients only because as we're doing
18 more and more valvuloplasties on older and
19 older patients I think this exclusion criteria
20 -- bypass is good, but I think we need to
21 think about other ones too.

22 DR. GEORGE: Any comments, Fred?

1 DR. MASSOUDI: Yes, I mean, I hear
2 what you're saying. And we're doing more and
3 more TAVRs as well. And I'm sure that it will
4 disproportionately influence centers that are
5 doing those sorts of things.

6 I think that that's good feedback
7 and certainly something that could be
8 accommodated in future iterations of the
9 bleeding model.

10 DR. CHO: I think if you're doing
11 PCI and then you're going onto have other
12 procedures I think that there should be some
13 amount of leeway for that.

14 Especially centers like ours at
15 the Cleveland Clinic, or Mayo, or Duke, or
16 wherever. I mean I think those are big
17 issues.

18 MS. SLATTERY: So, we would agree
19 and that is noted for our version update. It
20 necessitates us updating the data set which we
21 don't do without a lot of pain and
22 trepidation.

1 Specifically with TAVR I mean
2 that's one of the challenges also when you
3 have a rapidly adopted procedure. How can our
4 registries keep pace and also while we're
5 evolving appropriate use criteria and a whole
6 lot of other things going on.

7 The other reminder. We do intend
8 this for public reporting. It is a voluntary
9 public reporting program. So for -- that may
10 still be isolated to specific sites. And so
11 there's the chance that they will choose not
12 to voluntarily report that data.

13 We don't intend that to be a
14 judgment on a hospital. That doesn't mean
15 that we are ignorant to the perception of if
16 a hospital chooses not to it's then left to
17 them to explain why they chose not to which
18 can include their program is at a different
19 place with where the measure is able to
20 reflect the care they're providing.

21 DR. CHO: I mean, I think it's
22 important for the measure to be accurate only

1 because insurance companies like Anthem are
2 now going to start their payment based on the
3 bleeding criteria.

4 And centers, big centers like ours
5 and other centers across the country will be
6 dinged because we do these high-risk
7 procedures and we do combine, piggyback on
8 each other. So I think it is important.

9 DR. MASSOUDI: Point well taken.
10 Thank you. A risk adjustment for a lot of the
11 characteristics might underlie that. So that
12 may account for some of the variability.

13 However, at the end of the day the
14 point is well taken that there are procedures
15 like, you know, again an exclusion for bypass
16 surgery is done specifically because the
17 bleeding definition includes blood
18 transfusions. So the point, as I said, point
19 is well taken.

20 DR. HOLLANDER: I had a process
21 question. Is this a composite outcome since
22 it's a bunch of bleeding from different

1 sources? Or is bleeding one thing? And so I
2 raise that.

3 And the reason I raise that is
4 there's one thing -- and the interventionalist
5 can tell me if I'm thinking about this wrong.
6 Like tamponade being in there I think of as a
7 more mechanical problem than a spontaneous
8 bleeding problem. Is that wrong?

9 DR. AL-KHATIB: Related to the
10 procedure. I mean, so this is bleeding that's
11 related to the procedure. So that's why
12 they've mostly thought about the major
13 bleeding complications that could be related
14 to the procedure.

15 DR. GEORGE: And I don't think
16 this was intended as a composite.

17 DR. MASSOUDI: I mean, that's
18 really a technical question that I'd bounce
19 back to the NQF. I mean, ultimately it's one
20 outcome.

21 DR. WINKLER: Our most recent
22 composite report talks about a type of measure

1 that's a version of the all-or-none which is
2 any-or-none which we often see with
3 complications.

4 And so it's a bit of a change and
5 really it's a matter of how do you tag these
6 measures. A measure is a measure, whether you
7 call it a composite or not. So it does have
8 characteristics of it.

9 ACC would prefer not to call it a
10 composite. We allow them to say no, it's an
11 outcome measure. Fine. So, it's a little
12 fuzzy.

13 DR. VIDOVIICH: I just had a
14 question since we talked about the bleeding.
15 There's a variety of bleeding avoidance
16 strategies, you know, and there's access-
17 related bleeding and non-access related
18 bleeding.

19 Would it be helpful if you maybe
20 differentiated between those two in this
21 measure? Because radial access may impact the
22 access-related whereas use of bivalirudin may

1 impact non-access site bleeding. Would that
2 be helpful in reporting and then outcomes?

3 DR. MASSOUDI: Yes. I mean, it
4 gets to the point of sort of feasibility. You
5 know, trying to identify what one person might
6 consider procedural related bleeding versus
7 non-procedural related bleeding. And so the
8 definition is intended to try and identify
9 with the best sensitivity and specificity
10 possible, acknowledging that there will always
11 be a little misclassification in anything that
12 you do, bleeding that's related to the
13 procedure in one way or other.

14 DR. VIDOVICH: And this will be
15 in-hospital bleeding, correct?

16 DR. MASSOUDI: That's correct,
17 yes.

18 DR. AL-KHATIB: So, we're not
19 voting yet. Let me talk about reliability
20 testing.

21 I thought the reliability testing
22 was excellent because they performed the

1 testing at the level of the measure score as
2 well as the data element. And they really
3 provided a lot of details about how they did
4 that. And I have no concerns about the
5 methodology that they used.

6 They also reminded us of all the
7 quality assurance initiatives that they have
8 within the NCDR program. And so as I said
9 overall I had no concerns about the testing.

10 Given that the testing was done at
11 the data elements level and the measure score
12 level I would rate this as high.

13 DR. GEORGE: Any discussion on
14 reliability? All right, we'll vote on
15 reliability.

16 MS. LUONG: The timer starts now.
17 One is for high, two is for moderate, three is
18 for low and four is for insufficient.

19 Fifteen voted high and seven voted
20 moderate.

21 DR. GEORGE: We'll move onto
22 validity.

1 DR. AL-KHATIB: So compared with
2 the first measure that I presented I think the
3 developer did a better job with the validity
4 here because they actually did some testing.
5 They talked about again the audit of the data
6 and showed how the data elements are valid.

7 They talked about face validity
8 and described it as content validity of this
9 process. And they really provided a lot of
10 detail on how they did that. I felt that they
11 provided a very good argument for the fact
12 that their data and the data elements are
13 valid. The testing was pretty reasonable and
14 convincing to me. Going through all of this
15 here, making sure that I didn't see any
16 concerns. And I actually had no concerns at
17 all about the validity and I rated it high.

18 DR. GEORGE: Any discussions on
19 the validity? If not we'll move to a vote.

20 MS. LUONG: The timer starts now.
21 One for high, two for moderate, three for low
22 and four for insufficient.

1 Seventeen voted high and five
2 voted moderate.

3 DR. AL-KHATIB: Moving onto
4 feasibility. I think we've discussed this now
5 several times with regard to using the
6 CathPCI. I think it's pretty feasible and I
7 have no concerns about feasibility.

8 DR. GEORGE: Any comments on
9 feasibility? If not we'll move to a vote.

10 MS. LUONG: The timer starts now.
11 One for high, two for moderate, three for low
12 and four for insufficient.

13 Nineteen voted high and three
14 voted moderate.

15 DR. AL-KHATIB: And last but not
16 least is usability. So in terms of current
17 use of the measure it's not publicly reported.
18 I think that's what's planned.

19 It is being used within a program
20 called the Blue Distinction Centers for
21 Cardiac Care. Again, the sponsor is Blue
22 Cross Blue Shield.

1 And ACC again mentioned their
2 program that they started in July of 2013
3 where they gave hospitals the opportunity to
4 voluntarily report on some measures.

5 And although this was not the
6 particular measure that they used they said
7 that they intend to incorporate this measure
8 in their voluntary program.

9 In terms of unintended
10 consequences the developer mentioned the most
11 vulnerable aspect of this measure pertains to
12 physician transparency and willingness to
13 report and record adverse events.

14 The one thing that I would add is
15 the potential for physicians to avoid doing
16 PCI procedures on high-risk patients. We did
17 talk about risk adjustment. And although that
18 should alleviate that issue I'm not sure that
19 it would take care of it completely. But I
20 don't see this as a major issue.

21 DR. GEORGE: Discussion on
22 usability?

1 DR. TING: So, quick question.

2 This is at the hospital level and not at the
3 clinician level. So there's probably -- vis-
4 a-vis our first conversation there's probably
5 differences within facilities for individual
6 operators. But this is a valid measure and a
7 feasible measure just for the hospital measure
8 though.

9 DR. GEORGE: Other comments?

10 Judd, did you have a comment? Any other
11 comments? All right, we'll move to a vote on
12 usability.

13 MS. LUONG: The timer starts now.
14 One for high, two for moderate, three for low
15 and four for insufficient information.

16 Sixteen voted high, five voted
17 moderate.

18 DR. GEORGE: All right. We will
19 move to a vote on overall acceptance of this
20 measure.

21 MS. LUONG: The timer starts now.
22 One is for yes and two is for no.

1 One hundred percent voted yes, 22.

2 DR. KOTTKE: Ready for 0133?

3 DR. MASSOUDI: 0133 is the in-
4 hospital risk-adjusted mortality rate in
5 patients undergoing PCI. This is our oldest
6 -- the NCDR's oldest risk-adjusted outcomes
7 measure. It's actually been endorsed in two
8 previous cycles so this is the second renewal.
9 Yes, it's an alum of the process.

10 This measure includes all -- is
11 intended to include all adult patients, i.e.,
12 older than 18. And applies a widely validated
13 and repetitively validated risk adjustment
14 model to assess in-hospital mortality in all
15 comers.

16 The distinction between this
17 parenthetically and the upcoming measures
18 which assess 30-day mortality is that 30-day
19 mortality is restricted to those patients for
20 whom claims data for mortality are assessable.
21 So this measure can be calculated irrespective
22 of the availability of subsequent claims data.

1 DR. KOTTKE: George.

2 DR. PHILIPPIDES: So, this measure
3 basically allows for benchmarking against
4 national aggregates and against other
5 hospitals with similar PCI volumes as your own
6 hospital.

7 And it's basically an effort to
8 analyze best practices and disseminate them to
9 try to improve practice.

10 As Fred mentioned this is derived
11 from the very large and robust CathPCI
12 registry using a big population looking at
13 many variables and after regression sort of
14 paring them down to I think the eight
15 variables that have sort of the most impact on
16 risk of mortality.

17 This is an outcome measure. And
18 the developers did a very nice job of linking
19 different activities and processes of care to
20 this overall outcome.

21 And the bottom line here is that
22 by understanding personalized risk of the

1 patient it allows for personalized care and
2 improvement in the care of that individual
3 patient.

4 So, with regards to evidence I
5 thought it was pretty strong and no problems
6 with that.

7 DR. KOTTKE: Mary, any comment
8 additional? Any -- we lost Vy. We have a
9 pinch-hitter here.

10 MS. MITCHELL: I have a process
11 question. So if this is the third time that
12 this measure has gone and been presented to
13 NQF is there any particular reason why we need
14 to go through every single segment? Was my
15 point. And voting on it.

16 DR. WINKLER: Simply because
17 that's just a standard maintenance procedure
18 and we don't really want to treat different
19 measures differently.

20 You're right, the good measures,
21 you know, continue.

22 DR. PHILIPPIDES: I'll use that as

1 an excuse to go really fast.

2 DR. KOTTKE: Right.

3 (Laughter)

4 DR. PHILIPPIDES: Thank you for
5 that.

6 DR. KOTTKE: Can we finish this by
7 5, George.

8 DR. PHILIPPIDES: Let's vote.

9 DR. KOTTKE: So we're up for a
10 vote on evidence.

11 MS. LUONG: So the timer starts
12 now. One is for yes and two is for no.

13 I think we're missing -- we're
14 missing a few. If you can just keep pushing
15 real quick. Thank you.

16 One hundred percent which is 21
17 voted yes.

18 DR. KOTTKE: Opportunity for
19 improvement.

20 DR. PHILIPPIDES: So the
21 developers analyzed a huge database from 2011-
22 2012 with about 1 million patients. And they

1 found a performance gap, 10th percentile
2 performance 0.7 risk-adjusted mortality. And
3 the 90th percentile was up at 2.7 percent. So
4 I think they correctly identified a room for
5 improvement and opportunity there. So we
6 thought that that was pretty strong.

7 In regards to disparities there
8 were some statistically significant
9 disparities in regards to race and gender and
10 other populations. But when it was risk-
11 adjusted those became very, very small.

12 The only thing that did seem to
13 come out and was a little bit more robust --
14 I think you mentioned this too -- were private
15 insurers and suburban hospitals versus urban
16 hospitals.

17 In regards to gender and race the
18 differences were very small when risk-
19 adjusted. So again there was no compelling
20 reason to think about stratifying anything and
21 the disparities shouldn't really get in the
22 way here. So that was okay.

1 DR. KOTTKE: Mary?

2 DR. WINKLER: Just a point to the
3 developers. Since this measure has been in
4 use for such a long time it would be really
5 interesting to know however far back you have
6 data to see trend over, what, the last decade?
7 I mean, is it really something that everyone
8 should really feel good about, that
9 significant improvements in PCI mortality have
10 really improved over the decade?

11 It's a great story to tell if
12 we've got a nice downward trend. So, for a
13 longstanding measure like this it's really
14 nice to have if it's available.

15 DR. KOTTKE: Is there a comment
16 down there? A couple of comments down there?

17 MS. DELONG: Yes, I want to second
18 that. I think that's important for most of
19 these measures. If there is a trend that we
20 can see it will be helpful to track its
21 utility over time.

22 DR. KOTTKE: Where are we? Time

1 to vote for opportunity for improvement.

2 MS. LUONG: The timer starts now.
3 One is for high, two is for moderate, three is
4 for low and four is for insufficient.

5 Eleven voted high, eight voted
6 moderate and two voted low.

7 DR. PHILIPPIDES: Okay, in regards
8 to priority. And my being brief, CAD, MI, PCI
9 - high priority.

10 (Laughter)

11 DR. KOTTKE: Sounds good.

12 DR. PHILIPPIDES: Any questions?

13 DR. KOTTKE: Mary says nothing.
14 Anybody feel the urge to do anything but vote?
15 So let's vote.

16 MS. LUONG: The timer starts now.
17 One is for high, two is for moderate, three is
18 for low and four is for insufficient.

19 DR. KOTTKE: I think you forgot to
20 mention death, George.

21 DR. PHILIPPIDES: Say again?

22 DR. KOTTKE: You forgot to mention

1 death.

2 MS. LUONG: Twenty voted high and
3 one voted low.

4 DR. KOTTKE: Acceptability.

5 DR. PHILIPPIDES: Should I do
6 specifications? The specifications are pretty
7 clear. The numerator statement was, as
8 mentioned, patients 18 or older with a PCI
9 procedure who expired. Denominator are
10 patients 18 years of age or older with a PCI
11 procedure performed during that admission.

12 There were two exclusions. One,
13 if you got cath but didn't have a PCI. So
14 we're looking at basically patients who had a
15 PCI. And secondly, if you were transferred to
16 another facility on discharge you were
17 excluded. And that's pretty much standard
18 fare.

19 In regards to reporting on the
20 data source and specifications I think we sort
21 of went over the model. And are we to
22 reliability? Okay.

1 So, reliability was done here at
2 the data element level and the measure score
3 level. So testing of the performance measure
4 level was conducted with a signal-to-noise
5 analysis.

6 And it appeared overall the score
7 was good, 0.7 or greater. But when it was
8 broken down by high-volume and low-volume
9 centers it was acceptable for the high-volume
10 centers but not so much for the lower-volume
11 centers. And that was something that I think,
12 Mary, you brought up or somebody did during
13 our discussion. So that requires perhaps Fred
14 addressing it.

15 In regards to the data element
16 testing that was conducted with a test/retest
17 approach. Basically anybody who was admitted
18 twice within 2012, during that period, and got
19 two PCI procedures were compared to each
20 other. And basically -- were basically
21 classified. And it looked as though
22 misclassification of data elements was very,

1 very low, less than 3.5 percent across the
2 board. So, actually pretty good.

3 So, I think the only thing to
4 really talk about in regards to reliability is
5 what to make of the data on the low-volume
6 centers. Any comments?

7 DR. KOTTKE: Anything more, Mary?
8 Anybody else have comments? Seeing none,
9 let's vote on reliability and scientific
10 acceptability.

11 MS. LUONG: The timer starts now.
12 One is for high, two is for moderate, three is
13 for low and four is for insufficient.

14 Eleven voted high and eleven voted
15 moderate.

16 DR. KOTTKE: Validity, George.

17 DR. PHILIPPIDES: Okay. No
18 empiric validity testing was conducted. The
19 developers felt that none was necessary other
20 than establishing content validity because the
21 model looking at mortality is of unquestioned
22 importance and is readily assessed.

1 In regards to content validity the
2 developer did describe the same sort of method
3 that you described, Sana, where they basically
4 looked at data that was coming in and if it
5 didn't have -- if it wasn't complete and also
6 didn't have accurate data as assessed by
7 comparison to the medical record it was given
8 a yellow or a red statement.

9 Only if it was complete and
10 accurate based on that comparison did it get
11 a green stamp. And they make the point that
12 only sort of green-stamped data packets were
13 allowed into the EDW. So that was their way
14 of looking over this.

15 I don't know much about the system
16 but it seems like a large number of data
17 packets are checked that way and it's been
18 used for a long time. So it seemed a
19 reasonable way to get a content validity.

20 But overall there were no numbers
21 attached to that, no sensitivity or
22 specificity. And they relied I think on face

1 validity if I'm not mistaken.

2 DR. KOTTKE: Mary, anything?

3 DR. GEORGE: I'll just add that
4 the missing data was imputed with mean or
5 median.

6 DR. MASSOUDI: Yes, generally I
7 think that -- I'd have to look back at the
8 model, but the general approach that's been
9 used is that for infrequently missing values
10 missing data are imputed with the median or
11 most common value for categorical values.

12 Substantially missing data are
13 generally not considered candidates. And for
14 intermediate missingness multi-variable
15 imputation is typically used. Again, I'd have
16 to look back on the specific specifications
17 for the individual variables involved here.
18 But that's the typical approach.

19 DR. GEORGE: I think there were
20 only two that had any significant missingness.

21 DR. PHILIPPIDES: Yes, that's
22 right. It was GFR and EF. And they did a

1 good job of imputing that, things that would
2 make sense clinically.

3 Exclusions were less than 1
4 percent. And they even went so far as to
5 derive a C statistic which was really good at
6 0.93. So I think all of the threats to
7 validity and validity testing were appropriate
8 for this.

9 DR. KOTTKE: Comments? Hearing
10 none, let's vote.

11 MS. LUONG: The timer starts now.
12 Voting options include one for high, two for
13 moderate, three for low and four for
14 insufficient.

15 Eleven voted high and eleven voted
16 moderate.

17 DR. KOTTKE: Feasibility, George.

18 DR. PHILIPPIDES: So, we discussed
19 the feasibility of using this registry before.
20 Other than the fact that not all of the
21 elements are always in the EMR no matter what
22 anyone says, and the fact that you have to pay

1 a small fee to be in the registry, this is a
2 registry that's been used for a long time with
3 good results. And it's got a long track
4 record. So I think that this is feasible.

5 DR. KOTTKE: Mary? Nada? Let's
6 vote.

7 MS. LUONG: The timer starts now.
8 One is high, two is moderate, three is low and
9 four is for insufficient.

10 Eighteen voted high, four for
11 moderate.

12 DR. KOTTKE: Usability and use.
13 George?

14 DR. PHILIPPIDES: So, as mentioned
15 before this measure is not being publicly
16 reported. It is being used as a feedback
17 mechanism for hospitals within something
18 called the Blue Distinction program. But I
19 guess there are plans to sort of expand that.

20 In regards to improvement over
21 time I heard you guys talking here. There are
22 some papers showing that we have improved our

1 performance over time.

2 The data that was provided by the
3 developer though didn't really show that. It
4 looked like at least within two cohorts, 2011
5 and 2012, I think it was roughly the same as
6 far as performance.

7 Now, it could be that the patients
8 were sicker and that flew under the radar
9 screen, but we didn't see data that showed
10 improvement over at least that one year.

11 In regards to unintended
12 consequences there were concerns in the past
13 that this risk score did not do an adequate
14 job of assessing risk to high-risk patients.

15 And that might lead to sort of
16 risk-averse behavior on the parts of
17 interventionalists who basically say look,
18 every time I do a high-risk patient they don't
19 score it high enough and then I get dinged.

20 But I believe the registry went
21 back and sort of did another analysis and
22 added one or two other risk factors to it. I

1 think getting into cardiogenic shock maybe, or
2 -- something else might have been added later.
3 And now it appears that this is valid at low
4 risk and high risk when looked at. Do I have
5 that right?

6 MS. SLATTERY: We did do an
7 exploratory analysis to validate whether that
8 perception was correct or not, breaking it out
9 into different risk groups.

10 Actually, what we found at the end
11 was the model actually held up fairly well for
12 the in-hospital one. You may be thinking
13 about the pair of models that are about to
14 come up that are harmonized with this measure
15 in terms of breaking it out by shock and
16 cardiogenic shock.

17 DR. PHILIPPIDES: Okay.

18 DR. MASSOUDI: But the variables
19 themselves haven't changed. There's actually
20 pretty strong evidence that the model performs
21 well at all, you know, across the spectrum of
22 risk.

1 DR. PHILIPPIDES: Okay. So no
2 issues there.

3 DR. KOTTKE: Any discussion? I
4 mean, we all know that our patients are sicker
5 than everybody else's.

6 DR. PHILIPPIDES: The ones that we
7 intervene on.

8 DR. KOTTKE: Yes. Let's vote on
9 usability and use.

10 MS. LUONG: The timer starts now.
11 One is for high, two is for moderate, three is
12 for low and four is for insufficient
13 information.

14 Nineteen voted high and three for
15 moderate.

16 DR. KOTTKE: Let's vote on the
17 overall.

18 MS. LUONG: The timer starts now.
19 One for yes and two for no.

20 Can we just re-press your votes
21 again? There you go. One hundred percent
22 consensus, 22.

1 DR. KOTTKE: Thank you, George.

2 DR. GEORGE: Moving onto the next
3 to the last measure of the day, 0535.

4 DR. MASSOUDI: Just very quickly.
5 First of all, I think my patients are sicker
6 than yours, Dr. Kottke, but I could be wrong.

7 So, these last two measures are
8 intended to be used as a pair. I know they'll
9 be discussed separately but it's an important
10 issue to keep in context.

11 And these are 30-day all-cause
12 risk-adjusted mortality following PCI in two
13 distinct groups of patients. The first being
14 patients -- the first one is going to be 0535
15 which is patients without STEMI or cardiogenic
16 shock and 0536 is those patients with STEMI or
17 cardiogenic shock.

18 A few important distinctions with
19 the previous measure that was just discussed
20 to highlight. One of which is that the
21 patients who die and are accounted for in the
22 previous measure are not candidates for this

1 measure. This is death after discharge.

2 And the validation data that are
3 presented are generated from matched claims
4 data. Ultimately these will be matched with
5 broader death records. So with the hopes of
6 making them applicable to broader populations,
7 so a modification of what I said before.

8 And I don't know if -- I think
9 that's pretty much all I need to say. Again
10 -- and they are intended for public reporting,
11 right, and have been, you know, the models
12 have been validated fairly extensively as
13 you'll see in your materials.

14 DR. WINKLER: Fred, I just want to
15 clarify. You said so this does not include
16 the in-hospital deaths. Those patients are
17 removed from this measure.

18 DR. MASSOUDI: Correct.

19 DR. WINKLER: So, this measure is
20 only for patients who are discharged alive
21 from the hospital and whatever else --

22 DR. MASSOUDI: Correct. Yes,

1 that's right. Intended to be complementary to
2 each other and also to the previous measure.

3 DR. TING: Fred, I know my
4 patients are sicker than yours.

5 So, this measure is I think going
6 to be very similar. My secondary discussant
7 is George Philippides. And I think the next
8 measure is, as Fred pointed out, is going to
9 be very similar. So, the methods are -- other
10 than the patient population. So we'll
11 probably have both go pretty quickly.

12 The description of this measure is
13 30-day all-cause risk-standardized mortality
14 rate following PCI for patients without STEMI
15 and without shock. So these are the lower-
16 risk patients.

17 The level is at the hospital. As
18 far as the evidence this is a health outcome
19 risk-adjusted with NCDR CathPCI clinical
20 registry data and linked to the CMS database
21 for 30-day mortality.

22 There's certainly a processes of

1 care that are associated with improved
2 outcomes. So, looking at the evidence
3 algorithm it's actually a pass. Is that
4 right? That means high evidence. It's an
5 outcome measure.

6 Do we even vote on that? We do
7 vote? Okay. But the algorithm says it would
8 be a pass.

9 DR. GEORGE: Any discussion? All
10 right, we'll vote on the importance.

11 MS. LUONG: The timer starts now.
12 One is yes, two is no.

13 DR. WINKLER: This is a vote on
14 the evidence for an outcome measure.

15 MS. LUONG: Can everyone just re-
16 vote there? Thank you. Eighteen for yes, one
17 for no.

18 DR. TING: The opportunity for
19 improvement. The performance on this measure
20 from 2010 and 2011 was 1 percent, 4.2 percent
21 with a mean of 1.8 percent. So, it's 98.2
22 percent are surviving to 30 days but still

1 there is a gap of 1 percent to 4.2 percent.

2 So I think that's a moderate opportunity for
3 improvement.

4 There are no evidence for
5 disparities based on proportion of African-
6 American race or dual eligible patients.

7 MS. DELONG: I'm a little confused
8 about these mortality rates. They seem
9 consistent with the overall mortality rates
10 for PCI. Are these exclusive of inpatient?

11 DR. MASSOUDI: So, you mean
12 they're consistent with the in-hospital
13 mortality rates?

14 MS. DELONG: Pretty much. And
15 these are exclusive of --

16 DR. MASSOUDI: This is 30 days
17 though after hospitalization. Thirty days
18 after discharge.

19 DR. TING: These patients survived
20 --

21 MS. DELONG: Thirty days after
22 discharge.

1 DR. MASSOUDI: Right.

2 MS. DELONG: And they're as big or
3 bigger than the inpatient. These rates you
4 have here are excluding inpatient. They're
5 after a live discharge.

6 DR. MASSOUDI: Correct. Yes,
7 right.

8 MS. SLATTERY: So, just by way of
9 reminder again. This is where we would like
10 to emphasize the fact that these are always
11 intended to be reported as a pair of measures.
12 But particularly when talking about post
13 discharge. These are always intended to be a
14 pair of measures.

15 I don't know how when they got
16 loaded into NQF's system they got numbered in
17 the sequencing order. So you are looking at
18 the parallel measure that's got the lower gap.
19 But it was designed to avoid drift into the
20 unknown. So patients suddenly not being
21 identified as a STEMI or cardiogenic shock.
22 So just by way of reminder.

1 DR. TING: Lara, was there any
2 consideration just having one measure but just
3 stratifying them as people who are -- just
4 like we could report as one measure and then
5 people who are low-risk versus high-risk as
6 opposed to two separate measures?

7 MS. SLATTERY: Oh, yes. First go-
8 around, sure, that was -- oh yes. And so what
9 you have is two measures. That was determined
10 as the best approach. Always intended to be
11 reported as a pair.

12 DR. TING: Got it.

13 MS. DELONG: So the description of
14 the measure says the numerator is -- the
15 outcome for this measure is all-cause death
16 within 30 days following a PCI procedure. It
17 doesn't say following discharge.

18 DR. MASSOUDI: Well, it may be 30
19 days following the PCI procedure but it does
20 not include patients who -- but it's patients
21 who are discharged alive.

22 MS. DELONG: Yes, but --

1 MS. SLATTERY: So, I think you're
2 correct that that's not as called out in the
3 description. But in the specifications of the
4 measure it does specifically state that
5 patients must be discharged with status alive.

6 DR. VIDOVICH: So, just help me
7 understand. So you're essentially doing
8 landmark analysis, right? You're excluding
9 the patients who died in the hospitalization.
10 Then you restart the clock again.

11 Is there a specific reason to
12 change the denominator to reduce?

13 MS. SLATTERY: So these pair of
14 measures were developed after the in-hospital
15 measure had been developed. The in-hospital
16 measure was being reported systematically
17 already. We are close to being able to start
18 to implement these systematically.

19 There are some other
20 considerations. It is not trivial to get at
21 the post-procedure component. And so they
22 were harmonized that way to pull it out and

1 allow them more specificity in the post
2 procedure, knowing that the in-hospital
3 procedure was already being reported out.

4 There are also again as you'll
5 note in here some slight variables,
6 particularly with STEMI and cardiogenic shock
7 that were more significant in the post
8 procedure than what we were seeing in the in-
9 hospital.

10 MS. DELONG: So, I'm so confused.
11 Is this 30 days post procedure or 30 days post
12 discharge which could be 60 days post
13 procedure if somebody were in the hospital 30
14 days.

15 MS. SLATTERY: It's 30 days post
16 procedure assuming the patient was discharged
17 with a status of alive.

18 DR. MASSOUDI: So it's parallel to
19 what's used with the -- Joe, you can speak to
20 this. But it's what's used -- is a similar
21 process for what's used with STS for their 30-
22 day post-bypass mortality. If I'm not

1 mistaken, Joe.

2 MS. DELONG: But those differences

3 --

4 DR. MASSOUDI: It's discharge.

5 MS. DELONG: -- are very small.

6 Post discharge to 30 days is usually very

7 small from what I used to see in those

8 databases.

9 DR. CLEVELAND: I'm not even sure

10 we stratify post discharge. I think we just

11 look at 30-day data.

12 DR. MASSOUDI: So, I'm not sure,

13 Dr. DeLong, what the issue is. Can you please

14 -- I mean, if the time from procedure to

15 discharge is small I'm not sure what the --

16 MS. DELONG: When we looked at it

17 I believe it was in the STS data set. And we

18 looked at the difference between 30-day and

19 in-hospital. It was minuscule. It was almost

20 indistinguishable from in-hospital. So, what

21 I'm saying is if you only look at that

22 increment you may not get much signal.

1 DR. MASSOUDI: If you look at --
2 I'm sorry, which increment is that?

3 MS. DELONG: So, you've got a site
4 that has a 2.1 percent in-hospital mortality.
5 Their 30-day mortality might be 2.3. The
6 increment that you're looking at, 0.02, or 0.2
7 is very, very small.

8 DR. MASSOUDI: But the increment
9 is what you see in the data that are
10 presented.

11 MS. DELONG: That's --

12 DR. MASSOUDI: The data that are
13 presented exclude -- these are real data and
14 they exclude the patients who died in
15 hospital. That's the increment.

16 MS. DELONG: But they're almost
17 the same numbers as we saw in the in-hospital
18 mortality.

19 DR. MASSOUDI: That may be the
20 case, but that is the incremental difference
21 between the two. They happen to be similar
22 but that is the incremental difference between

1 the two. They're not overlapping numbers.

2 DR. HOLLANDER: So, I want to
3 follow up on that. Because in effectively
4 every study ever published the event rates,
5 the beginning are like this and go down. And
6 so I know that's what the report says, but I
7 question whether that's actually right.

8 Because I think Liz's take on it
9 is probably right and consistent with every
10 post-PCI study that's ever been done. Your
11 events are early on and the further out you
12 get the less likely events are.

13 It seems to me incredibly unusual
14 to have near-similar event rates post
15 discharge and in-hospital. And I just wonder
16 if it's --

17 DR. MASSOUDI: Remember, though,
18 that the time of ascertainment differs as
19 well. So in-hospital tends to be a relatively
20 short time frame. Right? And we're talking
21 about 30 days. So it may be a declining rate,
22 but it's over four or five times the period of

1 time of ascertainment.

2 And again, early is sort of in the
3 eye of the beholder. In that yes, event rates
4 may drop after the early period, but 30 days
5 is relatively early in the context of an MI.

6 MS. SLATTERY: When they developed
7 the measure initially for the last go-around
8 also they actually looked at it all the way
9 out to 45 days. You're right, most of the
10 event occurred probably more around 21 days.
11 But they made the decision that it was
12 probably to go with the 30-day cut point than
13 all the way out to 45 days.

14 DR. JAMES: I'm the sole vote that
15 said no on this. And I know that right now
16 that particularly with CMS the use of 30-day
17 all-cause mortality or readmission rates or
18 whatever is very popular.

19 But a number of us have had
20 concerns about that it really should be a
21 measure of something related to the procedure
22 or the disease entity.

1 And I still have a problem with
2 something. When you're getting to these small
3 numbers, these incremental numbers of people
4 who are discharged from the hospital, that's
5 where the rate of being struck by an
6 automobile, struck by lightning, or having
7 something completely unrelated starts to go up
8 as a percentage.

9 And so that's why I've got
10 concerns with this one. And I'm sorry, also
11 with yours.

12 DR. MASSOUDI: Yes, I think it's a
13 reasonable point. I mean, there are a couple
14 of issues to address there.

15 One of which is that it's a great
16 idea to think about well, let's just look at
17 procedurally related deaths. Put that in
18 front of a committee of people and there's
19 absolutely zero agreement on what constitutes
20 procedurally related or not. I mean, short of
21 an automobile accident. But even then, maybe
22 someone had a syncope from a reinfarction.

1 And they drive their car into a tree and they
2 die. So there's obviously, you know, it's
3 sort of in the eye of the beholder in one.

4 And the other issue is that there
5 are statistically distinguishable differences
6 amongst sites. And so even though there's
7 noise there there's reason to believe that
8 there is variability, meaningful variability
9 in mortality that is beyond the play of chance
10 when you look at these at a site level.

11 DR. JAMES: There's also
12 statistical arguments counter.

13 DR. MASSOUDI: Yes, of course. I
14 mean we can -- yes.

15 MS. MITCHELL: I'm good. I was
16 going to beat a dead horse. I just wanted
17 clarification on the 30-day post procedure
18 versus 30-day post discharge. And the
19 clarification is that it's post discharge.

20 DR. GEORGE: Any other discussion
21 before we vote on importance and
22 opportunities?

1 MS. LUONG: The timer starts now.
2 One for high, two for moderate, three for low
3 and four for insufficient.

4 DR. WINKLER: You're voting on
5 performance gap opportunity for improvement.

6 MS. LUONG: We have eight for
7 high, six for moderate, five for low and two
8 for insufficient.

9 DR. TING: So, priority is next.
10 And so this cohort actually includes some sick
11 patients, patients with non-acceleration
12 myocardial infarction, patients with left main
13 complex three-vessel disease, heart failure.
14 The only people who are in 0536 that are
15 actually STEMI and shock. So, it wouldn't --
16 I'm not surprised there are some deaths here.

17 As far as priority I mean I think
18 we've talked about PCI multiple times already.
19 This is a common procedure and mortality I
20 think is an outcome that patients care about.

21 DR. GEORGE: Any discussion on
22 importance? Priority.

1 MS. LUONG: For high priority the
2 timer starts now. One is for high, two is for
3 moderate, three is for low and four is for
4 insufficient.

5 We have 15 for high, 3 for
6 moderate, 2 for low and 1 for insufficient.

7 DR. TING: So for scientific
8 acceptability we've talked about the numerator
9 being -- this is an outcome measure for all-
10 cause death within 30 days following the PCI
11 procedure in patients without STEMI or shock.

12 At the time of the procedure the
13 denominator includes all inpatients and
14 outpatient hospital stays with a PCI procedure
15 for patients at least 18 years of age.

16 Includes outpatient observational
17 stay, patients who have undergone PCI but have
18 chosen not to be admitted.

19 There are several denominator
20 exclusions which all seem appropriate based on
21 multiple procedures in the hospital, transfer
22 patients, or low-volume sites. So, the -- and

1 the calculation of expected versus predicted
2 mortality, observed versus predicted mortality
3 is really based on 18 clinical variables
4 within the NCDR database. So that seems solid
5 in terms of scientific validity.

6 DR. GEORGE: Any discussion on
7 that? If not we'll move onto reliability.

8 MS. LUONG: Reliability. Sorry.

9 DR. TING: So reliability testing
10 was done both at the level of the performance
11 measure score as well as the data elements.

12 It was the test/retest you've
13 heard before. Each hospital had their data
14 sets randomly selected into two data sets.
15 The intra-class correlation coefficient was
16 0.256 which indicates fair or moderate
17 agreement on reliability testing.

18 DR. GEORGE: Any discussion on
19 reliability testing?

20 MS. DELONG: Did you look at the
21 correlation between this and the previous
22 measure? Is this not an appropriate time to

1 talk about this and the previous measure?

2 Because it would be good to see how this one
3 fares and actually -- it should be fairly
4 consistent.

5 MS. SLATTERY: So, when they
6 originally developed the measure, yes, they
7 looked at correlation between the in-hospital
8 and this measure being developed. I don't
9 know that we revisited it for purposes of this
10 measure project.

11 MS. DELONG: So, who developed
12 this measure actually?

13 MS. SLATTERY: So, it was
14 originally developed under contract with the
15 Centers for Medicare and Medicaid Services.
16 And then Yale Centers for Outcome Research and
17 Evaluation was the analytic center. And then
18 American College of Cardiology was also a
19 partner on that.

20 When the measures originally went
21 through the endorsement cycle CMS was listed
22 as the measure steward. ACC is now taking

1 over measure stewardship with this project.

2 And so we allowed Yale access to
3 all data to be able to take a look at and
4 harmonize it with what was going on with the
5 in-hospital measures as well.

6 MS. DELONG: Because I just
7 recalled that we worked on a similar measure
8 at DCRI.

9 MS. SLATTERY: At the time that
10 measure actually was -- the in-hospital
11 measure that you just discussed was originally
12 developed by DCRI and as evidenced by it being
13 the published papers coming out the lead
14 authors are from DCRI.

15 But ACC is the steward and owner
16 of those measures. So for purposes of
17 development of this pair that information was
18 provided to Yale.

19 DR. JAMES: I'm sorry to be so
20 negative here. On page 38 the graphic there
21 looks like a non-correlation. But am I
22 looking at this thing wrong? I mean, I'm just

1 a country doctor.

2 (Laughter)

3 MS. ISIJOLA: We probably have
4 different pagination because we don't have
5 access to quite the same documentation that
6 you have. So if you could give us a little
7 more of a landmark.

8 DR. TING: I think, Tom, that is
9 why it's fair to moderate. You know, the ICC
10 of, what is it, 0.256 shows. It's not great,
11 perfect, strong. Fair to moderate.

12 DR. MASSOUDI: I don't hunt
13 squirrels so I don't know.

14 (Laughter)

15 DR. GEORGE: Any other discussion
16 on reliability? If not we'll move to a vote
17 on reliability.

18 MS. LUONG: The timer starts now
19 for reliability. And it's one for high, two
20 for moderate, three for low and four for
21 insufficient.

22 Can everyone just point towards me

1 one more time? There we go. Thank you. So,
2 4 voted high, 11 voted moderate and 6 voted
3 low.

4 DR. TING: So moving onto validity
5 testing. This was done at the level of the
6 data elements only. Overall agreement
7 statistic was a median agreement 92 percent at
8 the data element level.

9 I did have a question regarding
10 was the validity testing done for all the data
11 elements, or just the 18 that were in the
12 model? That wasn't clear to me.

13 DR. MASSOUDI: Well, there's been
14 broader validity testing of NCDR elements that
15 goes through various cycles. But I think the
16 validity testing that's addressed here is
17 pertinent to the variables that are included
18 in the model.

19 DR. TING: So there are 18
20 variables. And the median agreement was
21 reported at 92 percent. And again, the
22 measure is risk-adjusted using a hierarchical

1 logistic regression model with 16 risk
2 factors.

3 And the calculated score is the
4 ratio of predicted deaths to number of
5 expected deaths multiplied by the national
6 mortality rate. So it's very much like the
7 AMI or CHF RMSR.

8 And let's see. The C statistic
9 which is the area under the receiver operating
10 curve was 0.807 for the validation sample
11 which is considered acceptable. Anything
12 above C statistic, anything above 0.7 is
13 considered acceptable. So this was 0.8.

14 DR. GEORGE: Any discussion on
15 validity?

16 MS. DELONG: So, Fred and I
17 actually had -- Dr. Massoudi and I actually
18 had a conversation awhile back.

19 And it would really be helpful I
20 think, Fred actually suggested this, that
21 there would be some templates for developers
22 to use when they're reporting things like

1 this.

2 And one of the things that would
3 be helpful. When they report percent
4 agreement it's not necessarily meaningful.
5 For example, on a data element -- I mean, you
6 want to see data element-wise. But they could
7 mostly be nos. So your agreement could be 80-
8 90 percent. But where they disagree they
9 almost disagree entirely. So you really want
10 to see that 2 by 2 table of did they agree
11 entirely. The problem is you need repeat
12 measures for that.

13 DR. MASSOUDI: Again that's sort
14 of a larger policy issue in terms of how the
15 NQF wants to provide direction to measure
16 developers.

17 But I concur that a certain degree
18 of consistency around realistic standards that
19 could be achieved and greater guidance, we're
20 all for it.

21 DR. WINKLER: We're certainly open
22 to the conversation to make things as

1 standardized and as easily understood for
2 everyone as possible.

3 DR. GEORGE: Any other comments on
4 the validity? If not we'll move to a vote.

5 MS. LUONG: The timer starts now.
6 One is for high, two is for moderate, three is
7 for low and four is for insufficient.

8 Ten voted high, nine for moderate
9 and two for low.

10 DR. GEORGE: Feasibility.

11 DR. TING: So for feasibility the
12 data source again is the NCDR CathPCI clinical
13 registry which we've talked about for the
14 other performance measures. For PCI the --
15 over 90 percent of hospitals that do PCI
16 participate in this registry so I think it's
17 quite feasible, consistent with the other
18 measures that we've already looked at,
19 endorsed.

20 DR. GEORGE: Any comments on
21 feasibility?

22 DR. WINKLER: One comment that

1 always comes up and that's matching it to the
2 CMS data. Is that a time lag in terms of
3 being able to calculate the measure? What
4 logistical issues do you encounter putting
5 those data together?

6 MS. SLATTERY: So, just as a
7 reminder, when we go to implement it will be
8 based on CDC data, not CMS data.

9 But yes, there are some lag time
10 issues, particularly in this instance because
11 we are limited to going with CDC data.

12 That's the only avenue currently
13 available to us. We are tracking regs to see
14 if we will be able to get access to Social
15 Security Administration vital status data
16 which could be a significant game-changer in
17 terms of timeliness of being able to report
18 this out as well as frequency of being able to
19 report this back to our sites.

20 When we initially put this measure
21 forward and expressed the desire to be able to
22 report it on all patients we did have access

1 to Social Security Administration master death
2 file. During that time there have been some
3 changes but there are new regulations being
4 introduced to potentially create the
5 opportunity that we could get access to that
6 data.

7 So right now we're dealing with
8 CDC data and there is a time lag there as
9 well. We just sent off our data files for
10 2011 and 2012 so those will be able to be
11 matched.

12 One of the other challenges. We
13 had one time previously gone through the CDC
14 process for applying. And it was for a
15 different registry.

16 This is our first time sending off
17 PCI data for the match. We are hoping that we
18 don't encounter some of the same questions.
19 Because we do find that different reviewers at
20 CDC come back with different questions. So,
21 there are challenges.

22 DR. GEORGE: Any other comments on

1 feasibility? If not we'll go to a vote.

2 MS. LUONG: The timer starts now
3 for feasibility. One is for high, two is for
4 moderate, three is for low and four is for
5 insufficient.

6 Twelve voted for high, eight for
7 moderate and one for low.

8 DR. GEORGE: Validity.

9 DR. TING: Use and usability. I
10 don't want to go back to validity. So,
11 usability and use.

12 This measure as I understand is
13 currently not in use. But as far as
14 historical trends or secular trends, from 2006
15 to 2008 the 30-day mortality rate was 1.4
16 percent as a median. Now it's from 2010 to
17 2011 that has increased to 1.8 percent. So,
18 there would be some use to continuing
19 following those trends and seeing if we can
20 improve.

21 DR. GEORGE: Any comments on
22 usability? If not we'll vote on usability.

1 MS. LUONG: The timer starts now.
2 One is for high, two is for moderate, three is
3 for low and four is for insufficient
4 information.

5 Can everyone just do it one more
6 time? Thank you. Nine for high, ten for
7 moderate, one for low and one for insufficient
8 information.

9 DR. GEORGE: All right. Any final
10 comments before we vote on the overall?

11 DR. TING: Will we talk about
12 competing measures? Or that's after this
13 vote? Thank you.

14 DR. GEORGE: All right, we'll go
15 to an up or down vote.

16 MS. LUONG: The timer starts now.
17 One is for yes and two is for no.

18 Seventeen voted yes and four for
19 no.

20 DR. TING: Terrific. The last
21 comment I had was about competing measures.
22 There are four other measures that look at 30-

1 day all-cause mortality. So that's for heart
2 failure, acute myocardial infarction, COPD and
3 pneumonia. So if any of those patients happen
4 to get a PCI they would be in both sort of
5 measures.

6 DR. KOTTKE: You get to vote
7 twice. 0536, 30-day all-cause risk-
8 standardized mortality rate following PCI for
9 patients with STEMI or cardiogenic shock.

10 DR. MASSOUDI: Right, so this is
11 sort of the teammate of the other measure.
12 And I will say that probably the largest
13 difference is the higher event rates in this
14 population not surprisingly because it's STEMI
15 and shock.

16 Just a small footnote. I have to
17 catch a flight and will have to leave at 6:15.
18 So I'm obviously not empowered to put anyone
19 on the clock but I will have to leave at 6:15
20 which is fine. You have able representation
21 here. But if I depart that's why. Thank you.
22 Hopefully it won't be necessary.

1 DR. CLEVELAND: My nickname is Ted
2 Cruz so I'll filibuster Fred for the next 23
3 hours.

4 (Laughter)

5 DR. CLEVELAND: Kidding. I thank
6 Henry for taking a lot of the headway on this
7 because this really is -- I'll be brief.
8 Again, this is 30-day all-cause risk-
9 standardized mortality following PCI. Really
10 the difference between the previous measure is
11 just these are sick patients, they truly are.
12 So I think we can use the word "death" because
13 it involves STEMI and cardiogenic shock.

14 Data source. Again, the NCDR,
15 CathPCI. And again, the evidence or to skip
16 ahead quickly to that. It's an outcome
17 measure. There are data provided by the
18 measure developer associating increased
19 survival with the use of periprocedural
20 clopidogrel, GP2B3 inhibitors. Participation
21 continues quality improvement. So I found the
22 evidence to basically meet the criteria to say

1 yes.

2 DR. KOTTKE: Kristi?

3 MS. MITCHELL: I have nothing to
4 add.

5 MS. DELONG: Does the evidence
6 speak to post discharge, or is it just 30 days
7 post procedure?

8 DR. CLEVELAND: I guess the
9 evidence is 30 days post procedure.

10 MS. DELONG: Within 30 days.

11 DR. CLEVELAND: Yes. Fred, do you
12 want to amplify on that?

13 DR. MASSOUDI: Right. You mean in
14 terms of the evidence-based therapies? Yes,
15 correct, as Dr. Cleveland says.

16 DR. JAMES: In this case my
17 objections are attenuated significantly
18 because this is a group where the population
19 at risk is much sicker, is more likely to have
20 a cardiac event. So I'm going to reverse
21 everything that I said on the prior one. I
22 still believe in what I said before.

1 DR. KOTTKE: Any further
2 discussion? So, vote on the evidence.

3 MS. LUONG: The timer starts now.
4 One is yes, two is no.

5 Nineteen voted yes and one voted
6 no.

7 DR. KOTTKE: Okay. Opportunity
8 for improvement.

9 DR. CLEVELAND: So again, this --
10 as Tom pointed out, the spread here is quite
11 high. The mean mortality in this is 12.6
12 percent, range 10.8 to 14.4. These are
13 obviously 10 times what we saw in the two
14 prior measures. So I think that there is a
15 significant chance for improvement in those
16 types of numbers.

17 DR. KOTTKE: Nothing? Any
18 discussion? Okay, let's vote.

19 MS. LUONG: The timer starts now.
20 One is for high, two is for moderate, three is
21 for low and four is for insufficient.

22 Sixteen voted for high, four for

1 moderate and one for low.

2 DR. KOTTKE: Priority.

3 DR. CLEVELAND: Again, we can
4 discuss what we said earlier. Coronary
5 disease, PCI, STEMI and cardiogenic shock.
6 I'd argue those are compelling priorities.
7 Death.

8 (Laughter)

9 DR. KOTTKE: Well, anybody vote
10 low priority or want to change their vote?
11 Sorry. Okay, we'll just roll the vote over
12 from the last one.

13 MS. LUONG: The timer starts now.
14 One is high, two is moderate, three is low and
15 four is insufficient.

16 Seventeen voted high and four for
17 moderate.

18 DR. KOTTKE: Acceptability.

19 DR. CLEVELAND: So in regards to
20 the acceptability the numerator statement
21 again, all-cause death within 30 days
22 following PCI. That's what's stated here in

1 the measure development. When patient with
2 STEMI or cardiogenic shock at the time of the
3 PCI.

4 There are some exclusions in the
5 denominator. The denominators are exactly as
6 what we saw in the last measure. The
7 exclusions are PCI that follows a prior PCI in
8 the same admission. That seems reasonable.

9 Patients with inconsistent or
10 unknown vital status or other unreliable data.
11 For example, someone who has a date of death
12 preceding the PCI. Subsequent PCIs within 30
13 days to avoid double counting. And lastly,
14 PCIs in patients with more than 10 days
15 between the date of admission and the date of
16 the PCI.

17 The argument was made that this is
18 a rare, fairly heterogenous unusual situation,
19 not well characterized. And I think I can
20 accept that. So I think the exclusions are
21 reasonable.

22 Again, the data source is the NCDR

1 linkage to this PCI registry with Medicare
2 data.

3 I guess, we touched it on a little
4 bit but I wouldn't underestimate the
5 challenges in that linkage as we've already
6 raised in discussion. So I really have no
7 issues or concerns with the reliability.

8 I guess we can move onto
9 reliability testing. So this was tested for
10 reliability, both at the data element level
11 and the measure score level.

12 Again, the reliability was
13 actually -- the ICC for this was actually
14 fairly low too, 0.122, slight agreement. So,
15 when I follow it all the way, being a surgeon
16 I can follow algorithms pretty well, I think
17 what I arrived at was box 6B of the algorithm
18 2 which gives us a moderate reliability score.

19 DR. KOTTKE: Comments? Kristi,
20 anything? No other motions? Vote.

21 MS. LUONG: The timer starts now.
22 One is high, two is moderate, three is low and

1 four is insufficient.

2 Three voted high, seventeen for
3 moderate and one for low.

4 DR. KOTTKE: Validity.

5 DR. CLEVELAND: In regards to
6 validity, validity was tested at the data
7 element level only. Again, data element
8 validity so with the CathPCI as we've seen
9 previously is fairly robust. Hospitals are
10 audited, cases reviewed, the methodology is
11 appropriate for that.

12 The only agreement statistic that
13 was reported was a median agreement.
14 Obviously there's no sensitivity or
15 specificity around that.

16 However, in terms of potential
17 threats this measure is risk-adjusted. It has
18 a hierarchical logistic regression model with
19 13 risk factors. The C statistic for that was
20 0.83 with a validation sample which is quite
21 acceptable.

22 There were a total of about 3,000

1 exclusions of the 40,000 patients or 48,000
2 patients looked at in calendar year 2010 to
3 2011 data set. Again, the exclusion criteria
4 seemed appropriate.

5 So, I think that regarding
6 validity -- oh, missing data. Less than 1
7 percent of the values are missing. And
8 similar to the last discussion these values
9 were imputed in a reasonable way. So validity
10 I would rate as moderate as well.

11 DR. KOTTKE: Kristi, anything?
12 Nothing. Any other? Seeing no action, let's
13 vote.

14 MS. LUONG: The timer starts now.
15 One is for high, two is for moderate, three is
16 for low and four is for insufficient.

17 Seven voted high, thirteen for
18 moderate and one for low.

19 DR. KOTTKE: Feasibility.

20 DR. CLEVELAND: Feasibility.

21 Similar to the last discussion the data
22 sources are registry elements with the CathPCI

1 and administrative data. I think we similarly
2 discussed some of the challenges for that. I
3 think it is feasible.

4 DR. KOTTKE: Kristi? Anybody
5 else? Nobody? Let's vote.

6 MS. LUONG: The timer starts now.
7 One for high, two for moderate, three for low
8 and four for insufficient.

9 Can everyone just -- just keep
10 pushing. Thank you. Ten for high and eleven
11 for moderate.

12 DR. KOTTKE: Usability and use.

13 DR. CLEVELAND: In regards to
14 usability this measure was originally NQF-
15 endorsed in August of 2009. It is not
16 currently in use. It is not publicly reported
17 but there are plans for a phased
18 implementation of public reporting. I think
19 this is part of a rollout of kind of overall
20 PCI mortality in the public reporting sphere.

21 One interesting note in terms of
22 improvement. There's -- just as we saw with

1 the last data set when you looked at the 2006-
2 2008 data set the mean risk-standardized
3 mortality rate was 11 percent. That has
4 increased to 12.6 percent in the 2010-2011
5 data set. So I think it does bear keeping an
6 eye on the signal too as well.

7 Again, reasons for that a lot of
8 things in terms of case mix, new addition to
9 hospitals, et cetera, et cetera.

10 I suppose unintended consequences.
11 This might be the one patient population that
12 high-risk PCI patients would not receive PCI.
13 It's always hard to know how people behave in
14 a risk-averse type of thing with this. But I
15 think the possibility does exist. I think we
16 just need to be cognizant of that.

17 DR. KOTTKE: Kristi, anything?
18 Nada? Any other comments? Let's vote on
19 usability and use.

20 MS. LUONG: The timer starts now.
21 One is for high, two is for moderate, three is
22 for low and four is for insufficient

1 information.

2 Ten for high and eleven for
3 moderate.

4 DR. KOTTKE: Let's vote on
5 overall.

6 MS. LUONG: The timer starts now.
7 One is for yes and two is for no.

8 For overall NQF endorsement 19
9 said yes and 2 said no.

10 DR. KOTTKE: So we're two minutes
11 ahead of schedule.

12 (Laughter)

13 DR. WINKLER: The point you raised
14 about intending to pair these measures.
15 Actually, NQF can pair them in our system.
16 And you could have chosen that when you
17 submitted them but you didn't. But that's
18 okay, we can retroactively do that. If the
19 committee agrees that these are measures that
20 should be paired.

21 And what pairing implies is that
22 you do both of them. You don't do one or the

1 other or pick or do whatever you feel like.
2 It's really the two together is a single
3 entity. And in fact, we'll vote them that
4 way. We'll put them out for vote. So they
5 rise and fall together. They travel together.
6 You report them together. And that's what
7 pairing implies. And so it sounds like that's
8 what the developers want. Does the committee
9 agree that that's the way you would want to
10 see these go forward?

11 I see --

12 DR. KOTTKE: Anybody disagree?

13 DR. WINKLER: Tom disagrees.

14 Reason?

15 DR. JAMES: The reason is if the
16 latter is a stronger measure and I think that
17 it becomes weaker because of the statistical
18 issues that I'm concerned about with the
19 former one that would drag this one down.

20 DR. WINKLER: Is Tom the outlier?
21 Does everybody else agree they should be
22 paired? Anymore or Tom's our one outlier?

1 That's fine. That's fine. Okay, then we can
2 put it forward that way.

3 DR. KOTTKE: We have a public
4 comment period.

5 DR. WINKLER: Yes, we do want to
6 do public comment.

7 MS. TIGHE: Cathy, if you could
8 check and see if anyone on the line wants to
9 provide a comment. And anyone in the room.

10 OPERATOR: Okay, if you would like
11 to make a comment please press * then the
12 number 1. There are no public comments from
13 the phone line.

14 MS. TIGHE: Thank you.

15 DR. WINKLER: So, we will
16 reconvene tomorrow morning to begin at 8
17 o'clock. We will have a continental breakfast
18 available at 7:30. So we will be here and see
19 you all tomorrow. Have a great evening.
20 Thanks so much for your work today.

21 (Whereupon, the foregoing matter
22 went off the record at 5:59 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Cardiovascular Measure Endoresment
Project Standing Committee Meeting

Before: National Quality Forum

Date: 04-21-2014

Place: Washington, D.C.

was duly recorded and accurately transcribed under
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