

NATIONAL QUALITY FORUM
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CARDIOVASCULAR ENDORSEMENT
MAINTENANCE STEERING COMMITTEE
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WEDNESDAY, FEBRUARY 16, 2011
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The Cardiovascular Endorsement Maintenance Steering Committee met at the Conference Center of the American Immigration Lawyers Association, 1331 G Street, N.W., Washington, D.C., at 8:00 a.m., Mary George and Raymond Gibbons, Co-Chairs, presiding.

PRESENT:

MARY GEORGE, Co-Chair, MD, MSPH Centers for Disease Control and Prevention
RAYMOND GIBBONS, Co-Chair, MD Mayo Clinic
CAROL ALLRED, RN, National Coalition for Women of Heart Disease
ROCHELLE AYALA, MD, FACP, Memorial

Healthcare System

SUNG HEE LESLIE CHO, MD, Cleveland Clinic
ANN DE VELASCO, RN, National Coalition for Women of Heart Disease
DIANNE JEWELL, PT, DPT, PhD, CCS, American Physical Therapy Association
DANA KING, MD, MPH, Medical University of

South Carolina

BRUCE KOPLAN, MD, MPH, Brigham and Woman's Hospital
THOMAS KOTTKE, MD, MSPH, HealthPartners
DAVID MAGID, MD, MPH, Colorado Permanente Medical Group
GEORGE J. PHILIPPIDES, MD, FACC, Boston

Medical Center

JON RASMUSSEN, PharmD, Kaiser Permanente - Colorado

DEVORAH RICH, PhD, Greater Detroit Area
Health Council

ANDREA RUSSO, MD, Cooper University Hospital

MARK SANZ, MD, The International Heart
Institute of Montana

SIDNEY C. SMITH, JR., MD, University of
North Carolina at Chapel Hill

ROGER SNOW, MD, Commonwealth of
Massachusetts

CHRISTINE STEARNS, MA, JD, New Jersey
Business & Industry Association

KATHLEEN SZUMANSKI, RN, Emergency Nurses
Association

SUMA THOMAS, MD, FACC, Lahey Clinic Medical
Center

NQF STAFF:

HEIDI BOSSLEY, MSN, MBA

HELEN BURSTIN, MD, MPH

ANN HAMMERSMITH

ASHLEY MORSELL

KAREN PACE

KATHRYN STREETER

REVA WINKLER, MD, MPH

ALSO PRESENT:

SUSANNAH BERNHEIM, MD, Yale/YNNH Center for

Outcomes Research & Evaluation*

JOHN BOTT, MSSW, MBA, AHRQ*

DALE BRATZLER, DO, MPH, Oklahoma Foundation
for Medical Quality, Inc.*

SHERYL DAVIES, MA, Stanford University -
AHRQ QI Development Team*

SUSAN FITZGERALD, RN, MBA, American College

of Cardiology

JEFFREY GEPPERT, EdM, JD, Battelle Memorial
Institute*

MARJORIE KING, MD, FACC, FACCVPR, American
Association of Cardiovascular and
Pulmonary Rehabilitation

HARLAN M. KRUMHOLZ, MD, Yale/YNNH Center for

Outcomes Research & Evaluation*

ALSO PRESENT: (CONT.)

STEVEN LICHTMAN, EdD, FACCVPR, American
Association of Cardiovascular and
Pulmonary Rehabilitation*

KAREN R. LUI, RN, MS, FACCVPR, American
Association of Cardiovascular and
Pulmonary Rehabilitation*

KRISTYNE MCGUINN, MHS, American College of
Cardiology

FREDERICK MASOUDI, MD, MSPH, American
College of Cardiology

MATTHEW T. ROE, MD, MHS, Duke University
Medical Center

ROBERT J. SCHMITZ, PhD, Mathematica Policy
Research

RANDY THOMAS, MD, FACCVPR, American
Association of Cardiovascular and
Pulmonary Rehabilitation*

MARIAN V. WROBEL, PhD, Mathematica Policy
Research

*Present via telephone

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2 8:01 a.m.

3 CO-CHAIR GIBBONS: I presume
4 everybody had an excellent evening pondering
5 all the measures we'll be considering today.
6 I don't see a lot of nods. Okay. So we're
7 going to start off completing the measures
8 dealing with AMI that we didn't get to
9 yesterday, and I think much of our discussion
10 around the measures towards the end of the
11 afternoon has set the stage. So, hopefully,
12 your memory will work short term overnight to
13 recall most of the elements of that discussion
14 as we proceed through these this morning.

15 So the first one is 287, median
16 time to fibrinolysis, and I just want to point
17 out that this came up in the discussion where
18 Dr. Masoudi pointed out, I believe, that the
19 elements involved in this one were very
20 similar, if not identical, to 164,
21 fibrinolysis therapy within 30 minutes. And
22 as Kathleen goes through this maybe we can

1 take that into account. Kathleen?

2 MS. SZUMANSKI: I think we were
3 beginning where we left off yesterday.
4 Essentially, there is no significant
5 difference between this measure and the other
6 two that we discussed. And I know that David
7 was interested in putting a proposal on the
8 table that --

9 DR. MAGID: That we don't have to
10 re-vote on each of the data elements because
11 it's identical.

12 MS. SZUMANSKI: It is.

13 DR. MAGID: The data that goes
14 into the measure is absolutely identical to
15 what we've already voted on, and maybe we can
16 just vote on the last one because really the
17 only difference is they want to have an
18 opportunity to present it as a median as
19 opposed to a percentage. So it's just a
20 different way of looking at the same data.

21 DR. WINKLER: Could I just hear
22 from the committee your thoughts on do we need

1 both measures, is one preferable, is there an
2 added value for having both measures if really
3 you're taking the same data and just
4 presenting it two different ways? Is there
5 really a justification for having both?

6 DR. MAGID: Maybe we should ask
7 the measure developer.

8 DR. BRATZLER: This is Dale
9 Bratzler. Are you able to hear me? So, I
10 mean, that's a conversation that came up in
11 the initial development process, and I think
12 the same issue applies to the inpatient
13 setting.

14 CO-CHAIR GIBBONS: I'm sorry.
15 You're breaking up a bit.

16 DR. BRATZLER: The median times
17 are sometimes more actionable in terms of
18 doing improvement. So I think that's the
19 primary reason to have two separate measures,
20 just reporting it two separate ways.

21 CO-CHAIR GIBBONS: We're having a
22 little trouble. You're breaking up. If you

1 could think configuring your phone differently
2 or whatever.

3 DR. BRATZLER: Yes, is this
4 better?

5 CO-CHAIR GIBBONS: Yes.

6 DR. KOPLAN: I think Dr. Masoudi
7 submitted this so maybe he --

8 DR. MASOUDI: Well, no, Dale can
9 speak to it just as well. But I think what
10 he's trying to say is that users have found
11 the median time an easier target for quality
12 improvement purposes and that the proportion
13 facilitates comparisons among sites. And this
14 is how it's been reported on Hospital Compare
15 now for many years, and I think users find
16 both of them useful based on our
17 implementation.

18 CO-CHAIR GIBBONS: Sorry. Could
19 you clarify that, Fred? Which is reported on
20 Hospital Compare? Both?

21 DR. MASOUDI: Yes, both are
22 reported on Hospital Compare, I believe.

1 DR. KOPLAN: You can't do both for
2 one. You can't have one measure that says you
3 collect both pieces of information.

4 DR. MASOUDI: No, it's the same
5 exact measure, but what is recorded out for
6 one -- so you have the whole population of
7 people who got either PCI or fibrinolysis, and
8 there are a group of times, and you can
9 calculate those times either as a median of
10 those times or the proportion of those times
11 that fall under a certain threshold, and
12 that's how it's done.

13 DR. RUSSO: Or I think maybe you
14 mean like have one measure saying, like you
15 could pick or, so you did this and you had it
16 less than such and such or and make it one
17 measure, so when you're reviewing it every
18 time you're not reviewing two separate
19 measures?

20 DR. KOPLAN: Yes. So like measure
21 287 collects both the median time and the
22 proportion under 30 minutes. Like, say,

1 you're collecting your information but it's
2 within one measure, or is that not something
3 that gets done?

4 DR. WINKLER: I think that's
5 something we can certainly recommend. Just
6 hearing the discussion, it sounds like perhaps
7 the median time is more useful to the audience
8 who are actually on the ground looking at
9 quality improvement and maybe less useful for
10 the public reporting where the proportion
11 might be more easily understood by broader
12 audiences. And realizing that NQF's focus is
13 really on the public reporting, you know, the
14 question is, again, do we have more measures
15 than we really need? Of course, your
16 suggestion to combine them is another
17 alternative to try and focus these and reduce
18 the confusion.

19 CO-CHAIR GIBBONS: Can I ask the
20 question and perhaps Dale on the phone can
21 answer it? What would be the consequences of
22 simply sunsetting the median time and just

1 reporting the percent?

2 DR. BRATZLER: So I think it has
3 been pointed the data elements collected are
4 identical. It's simply a matter of
5 calculating the performance two different
6 ways. So the hospitals actually do not
7 collect two separate measures. They collect
8 it once, and then we just calculate it two
9 separate ways. I can't speak for CMS. I
10 don't know if CMS is available on the call or
11 anybody from the Hospital Quality Alliance
12 that uses the data for public reporting. I
13 think Fred and I have both pointed out that
14 the median time was felt to be more useful for
15 quality improvement, helping hospitals work on
16 their targets for improvement. So I can't
17 speak to CMS, though, what might happen if
18 only one were, quote, endorsed.

19 CO-CHAIR GIBBONS: Well, for the
20 moment, I think we have a proposal that we
21 have the same voting pattern that we had
22 yesterday and we'll have to come back to

1 reconcile the competitive nature of these two.
2 Are there any objections to basically
3 duplicating our votes from yesterday on the
4 proportion measure for this median? Anybody
5 who has an objection, please voice it at this
6 time or --

7 DR. AYALA: Well, I think we may
8 be able to decide on whether or not to drop
9 the median one, especially because the
10 healthcare system is going to make that
11 calculation themselves and if they're only
12 using that for operational purposes for
13 process improvement then I don't know that it
14 needs to be an indicator. So some of us might
15 vote differently on the last question.

16 CO-CHAIR GIBBONS: Okay. I don't
17 think they can make that calculation
18 themselves, so we're clear. They would just
19 then have the proportion as the target for
20 quality improvement. Fred?

21 DR. MASOUDI: And the reason that
22 it's not quite so simple for the institutions

1 to make the calculations themselves is that
2 they can't necessarily know what the exact
3 denominator is of their population, vis a vis
4 the specifications, because that's coded off
5 of billing data as opposed to all people who
6 get fibrinolysis, for example. So you can't
7 necessarily develop apples to apples
8 comparisons off the same denominator. Again,
9 I would just say emphatically this measure is,
10 in terms of the institution, is absolutely no
11 additional work, you know, in terms of the
12 data collection. There's absolutely no
13 difference in terms of what goes into this
14 measure. It's just a difference in terms of
15 how the output is reported in two different
16 ways that have been found to be, in testing,
17 useful in different ways.

18 CO-CHAIR GIBBONS: So I'm going to
19 go back to the issue of can we duplicate the
20 voting and let everybody ponder whether we
21 want to return to this competitive issue as we
22 deal with the whole issue of harmonization and

1 competitive issues because, otherwise, we're
2 not going to get people on their planes today.
3 So are there any objections to duplicating the
4 vote?

5 (No response.)

6 CO-CHAIR GIBBONS: Okay. Hearing
7 none, I think we will simply do that. And
8 now, Kathleen, we've taken away most of your
9 work. I'm sorry. We're going to now move the
10 next measure, 290, median time to transfer.

11 MS. SZUMANSKI: This is another
12 time-sensitive measure, and it relates to the
13 time from recognition of MI to transfer to a
14 facility that can provide acute coronary
15 intervention. From the get-go, I think that
16 we would recognize that this is probably
17 important to measure, the fact that we would
18 like to assure that patients get the level of
19 care that is necessary, and if it cannot be
20 provided in the facility that they first
21 present at that they be transferred
22 appropriately to the next site for appropriate

1 intervention. So the question is is this
2 measure important enough to measure? I would
3 recommend that it probably is.

4 CO-CHAIR GIBBONS: Questions?
5 Discussion on this? Yes?

6 DR. BRATZLER: This is Dale. Can
7 I make just a couple of just real quick points
8 about this measure?

9 CO-CHAIR GIBBONS: Absolutely.

10 DR. BRATZLER: I think it's a very
11 important measure. So it's important to
12 remember that this is a really strictly
13 defined denominator, but we think this has
14 been one of the most important measures we've
15 rolled out in the emergency department. So it
16 is limited to patients with a diagnosis of
17 acute myocardial infarction, ST segment
18 elevation, or new left bundle branch block,
19 just as the other acute MI measures are
20 defined, only for patients who are transferred
21 for cardiac intervention, so we specifically
22 look at the record to see if they're being

1 transferred for acute cath lab, PCI
2 angioplasty, words like that in the record.

3 So it's a limited population, and
4 it's reported to the hospitals two different
5 ways. We look at the overall median time to
6 transfer so they can keep track of kind of how
7 long it takes them to transfer all of their
8 patients. But then we have a reporting
9 population which is even more closely defined,
10 and that is a patient who, again, has an acute
11 MI transferred for acute coronary intervention
12 and has no contraindications to fibrinolytic
13 therapy. And the reason for that is, you
14 know, I'm in Nebraska today so if there was a
15 big snowstorm and a small facility has a
16 patient that clearly has a contraindication to
17 fibrinolytic therapy and so they make the
18 decision to transfer the patient for PCI, we
19 don't want to hold them accountable for the
20 fact that it takes the ground ambulance a lot
21 longer to get there than a helicopter in a
22 snowstorm. So the reporting measure looks at

1 those patients for which the hospital had the
2 choice of either giving fibrinolytic therapy
3 or transferring the patient for PCI, and that
4 is the reporting measure. It's a well-defined
5 population.

6 DR. WINKLER: Just to clarify,
7 Dale, this is Reva. I just want to clarify
8 the specifications that you've presented to us
9 are which of the two measures you've just
10 described?

11 DR. BRATZLER: I'm sure it's the
12 reporting measure, the one that's publically
13 reported.

14 DR. WINKLER: Okay, thank you.

15 MS. SZUMANSKI: So the question
16 would be is it important to measure.

17 DR. BRATZLER: I guess the only
18 other point I'll make is that, you know, in a
19 study from NRMI a few years ago the median
20 time from arrival at the first hospital to
21 intervention in the cath lab at the second
22 hospital, the median time in NRMI was 180

1 minutes. So we really think that there needs
2 to be a focus on making the transfers more
3 efficiently.

4 CO-CHAIR GIBBONS: And, obviously,
5 there are national projects devoted to that.
6 All right. Let's take our first vote on
7 importance of the measure, please. Are we
8 software-equipped or not?

9 MS. PACE: No.

10 CO-CHAIR GIBBONS: We are not. So
11 this is going to be the old-fashioned way.
12 You'll actually have to raise your hand. Yes,
13 all right. All who think yes for the
14 importance of the measure. So just to make
15 sure you counted correctly, all who vote no?
16 I've been there, done that, and it's taken ten
17 minutes to get the count right.

18 So let's move on to scientific
19 acceptability.

20 MS. SZUMANSKI: I think that one
21 of the challenges with this measure, and it is
22 not particularly scientific, but the issue of

1 arrival time in today's emergency department
2 is a challenge because we actually, in many
3 places, because of the issue of crowding, have
4 more than one time recorded. We may have the
5 registration time, we may have the triage
6 time, and we may have the medical screening
7 exam time, and they are not necessarily the
8 same. One would hope with this population of
9 patients that they would fast track into the
10 medical screening portion, but there is the
11 issue of there may be a gap at the initial
12 receiving end of the patients and the same gap
13 may appear at the other end because of the
14 simple issue of crowding that is touching
15 every ED in the United States.

16 So that being said, I think that
17 there is strong evidence to say that it is
18 important to do this in a timely manner and
19 that the patient should go to a site that can
20 receive and provide the therapy, and there is
21 evidence to show that this is a good thing to
22 do for these patients who are presenting with

1 MI. As was mentioned yesterday, certainly, if
2 you live in Montana and you have to go a
3 distance in bad weather by some means, perhaps
4 by air, perhaps by ground, that time is going
5 to be, the clock is going to continue to tick
6 even as you're arranging transportation.

7 So from a scientific standpoint,
8 it does bear the challenge of evidence that we
9 certainly feel that this therapy is urgent and
10 necessary. Unfortunately, if you happen to
11 have your MI in a location where the PCI is
12 not available, you do have to be moved to
13 another site of care. So that would be my
14 summary kind of of the scientific background
15 of this. There's kind of soft issues and hard
16 issues that occur.

17 DR. BRATZLER: Sir, I'd like to
18 respond just very briefly to that. And I
19 think even if you happen to show up in a
20 facility that maybe isn't quite as remote but
21 there are issues around delays and the
22 transfer or the other thing that we see

1 happening that we think is inappropriate is
2 that the receiving center is telling the
3 transferring center to withhold fibrinolytic
4 therapy in a patient for whom there is no
5 possibility of getting to the cath lab any
6 where near 90 minutes. And so that's why for
7 our reporting population we strictly define it
8 as those patients who have no contraindication
9 documented in the record to receiving
10 fibrinolysis and who are specifically
11 transferred for acute coronary intervention,
12 a population for which the hospital, the
13 transferring hospital has the choice of
14 considering fibrinolytic therapy as the
15 reperfusion strategy when they know there's no
16 chance that they're going to get them to the
17 next hospital within 90 minutes.

18 CO-CHAIR GIBBONS: Okay. Are
19 there any other comments? And I'd just sort
20 of highlight the point that Kathleen made
21 about arrival time. We looked at the data
22 yesterday and found that there was, roughly,

1 a 20-percent error rate in the arrival time
2 when it was audited. Other comments about
3 this before we vote?

4 DR. RUSSO: Just in terms of the
5 arrival time, at least, and it may vary, but
6 isn't that directly to the cath lab in most
7 cases if they're going to have an acute
8 intervention so there's no --

9 CO-CHAIR GIBBONS: No, this is
10 arrival time at the initial hospital. So the
11 outlying hospital, the transferring hospital,
12 whatever you want to call them, this is the
13 arrival time there. And then they're going to
14 discharge, not discharge because they're never
15 admitted, but they're going to then send the
16 patient. So we looked at the arrival times
17 and they're not very solid, as Kathleen --

18 DR. BRATZLER: They're not very
19 consistent, but I think when you look at the
20 variation in the numbers it's usually minutes.

21 CO-CHAIR GIBBONS: Unfortunately,
22 I looked hard in the report, Dale, and I

1 didn't see that. Is that somewhere?

2 DR. BRATZLER: Yes, I think that's
3 something we need to look at, but I'm pretty
4 sure that's the case.

5 DR. SNOW: I'll just make the
6 observation that, if you've got rotten times,
7 one of the best ways to improve them is to
8 have a measure that identifies them.

9 DR. SMITH: Are there demographic
10 disparity matrices built into this? We know
11 that, we're going to know that efforts will be
12 made not only to transfer the mayor of a small
13 town but all genders, ages, ethnic backgrounds
14 promptly? Is that built into this?

15 MS. SZUMANSKI: It is not defined
16 in the measure as such.

17 DR. BRATZLER: It is not defined.
18 It can be. It is captured and can be
19 calculated.

20 CO-CHAIR GIBBONS: All right. I
21 think we want to go ahead and vote on
22 scientific acceptability. Do we at least have

1 a slide that we can remind people what their
2 choices are going to be in case they don't --
3 this is not yes/no now. You got to remember
4 completely, partially, minimally, not at all
5 or not applicable. Completely, partially,
6 minimally, or not at all, all right? So show
7 of hands --

8 DR. SMITH: Are we voting the
9 disparities in?

10 CO-CHAIR GIBBONS: This is the
11 total scientific acceptability, so that
12 includes the disparities element.

13 DR. SMITH: They said it could be
14 included. Will it be included?

15 DR. WINKLER: I think that's your
16 recommendation that it should be included. It
17 sounds like they can do it and you'll
18 recommend --

19 DR. SMITH: So the vote would
20 carry that? If I vote it's okay?

21 CO-CHAIR GIBBONS: Carry that
22 recommendation to them. All right. So with

1 that recommendation to them, completely show
2 of hands. Partially show of hands?

3 MS. SZUMANSKI: Eight.

4 CO-CHAIR GIBBONS: Just in case,
5 minimally? Not at all? Moving on now to
6 usability.

7 DR. WINKLER: I think this measure
8 is currently in use. It is currently
9 calculated and reported. Again, I don't see
10 any additions that may make this measure
11 clearer or not clearer other than the value of
12 identifying discriminatory issues related to
13 the population that is being served. It is
14 harmonized. That's what I can say about it.

15 CO-CHAIR GIBBONS: All right,
16 that's fine. Any other comments about
17 usability? Okay. If not, we're going to move
18 ahead and vote on this one. I'll remind you
19 of your choices: completely, partially,
20 minimally, not at all. So all those who say
21 completely?

22 MS. SZUMANSKI: Thirteen.

1 CO-CHAIR GIBBONS: Partially?

2 MS. SZUMANSKI: Eight.

3 CO-CHAIR GIBBONS: Minimally? Not
4 at all? I just realized we have to make sure
5 no one is voting twice. And then, lastly,
6 feasibility.

7 MS. SZUMANSKI: I think the
8 feasibility issues, it can be collected. I
9 think the challenge, again, is with the time
10 issue and that clarification would certainly
11 help the abstractors who are looking through
12 charts trying to find out really what is the
13 time they arrived and would certainly help
14 this measure in the data collection
15 standpoint. There are no e-specifications
16 currently. Funding is pending, and it is
17 hoped there will be some. It is easily
18 collected. Abstractors will tell you, other
19 than the data time, it's not too bad based
20 upon some of the other measures that they
21 collect.

22 CO-CHAIR GIBBONS: Other comments

1 on feasibility? If not, we're going to go
2 ahead and vote. All those who believe it's
3 been addressed completely? Partially?

4 DR. WINKLER: Twenty-one for
5 partial.

6 CO-CHAIR GIBBONS: Minimally? Not
7 at all?

8 DR. WINKLER: David, were you a
9 minimal? Okay.

10 CO-CHAIR GIBBONS: Got to get
11 those hands down faster. He was just making
12 sure he got counted. All right. So now the
13 final vote is does this measure meet the
14 criteria for endorsement? A further
15 discussion? This is yes/no. All that say
16 yes? No? Okay. So we have now completed
17 that discussion of 290. We're going to now
18 move on to 0160, beta blocker prescribed at
19 discharge. Devorah?

20 DR. RICH: Good morning. Okay.
21 So the measure here is the beta blocker
22 prescribed at discharge, and this would be the

1 percent of AMI patients prescribed beta
2 blocker at hospital discharge, and this is a
3 process measure. This is a really important
4 measure in terms of reducing morbidity and
5 mortality, and the ongoing use of this measure
6 is designed to ensure high performance. When
7 you look at the data on this, there is high
8 performance. That is from looking second
9 quarter '09 through first quarter '10, it
10 ranges from 98.1 to 98.2. So there's high
11 performance, and it does show disparities and
12 even among the disparities, while there is
13 definitely disparities, it's very close. It
14 ranges from a low of 96.3 to a high of 98.3.
15 So it's clustering pretty close together, but
16 this is a strong predictor of overall ability
17 to maintain health.

18 So are there questions? I mean, I
19 think it's an important measure. You know,
20 when I first looked at it, I was like someone
21 said 100 percent, you know, why are we
22 measuring this? But it doesn't show the, we

1 certainly don't know what the whole range of
2 performance is. And in reading this over, it
3 seems to indicate that by putting this forward
4 as a measure it will make sure that it stays
5 on the top of people's minds.

6 CO-CHAIR GIBBONS: Are there
7 comments about importance? We discussed beta
8 blockers quite a bit yesterday afternoon.

9 DR. KOTTKE: Ray, can I ask a
10 quick question?

11 CO-CHAIR GIBBONS: Sure.

12 DR. KOTTKE: On indicators that
13 have been decommissioned because they approach
14 perfection, does anybody ever go back and look
15 at the effect on social entropy on
16 performance? In other words, you know, the
17 old dust to dust, ashes to ashes thing that
18 systems fall apart when you aren't watching
19 them?

20 DR. WINKLER: I think, certainly,
21 we've heard that voiced as a concern, but I
22 don't actually, I'm not aware of any

1 particular, you know, rigorous review of
2 evaluating that. Helen?

3 DR. BURSTIN: I've seen some early
4 work from the VA suggesting that there wasn't
5 an effect when measures were taken out of
6 public reporting, but I've not seen anything
7 else. But, again, it hasn't been published
8 yet.

9 DR. RUSSO: And just for this
10 measure, I think that this is such an
11 important thing. Even if it were 99 percent
12 instead of 98, I would think it might send the
13 wrong message to not measure it at least right
14 now. It's just so important.

15 DR. KING: If I can comment, I
16 think that every one agrees it's important.
17 That's why there's 98 or 99 percent compliance
18 with it, just like with the aspirin of
19 yesterday. And we've heard a plea and in our
20 instructions to reviewers we were told to not
21 maintain measures that were near perfection
22 and yet we are continuing to do it. So if

1 we're trying to reduce the work of quality in
2 the world and abstractors and poor little
3 secretaries typing things into their Excel
4 spreadsheets, it seems like the aspirin at 99
5 percent and this one at 98 and a half are two
6 candidates, you know, to consider. And it's
7 kind of like, when you cut yourself you get a
8 tetanus shot. I don't know. That's not
9 written anywhere and there's no national
10 program, but everyone just still seems to
11 remember that. I don't think there will be a
12 significant problem because you're trying to
13 use this as a quality improvement as something
14 that discriminates, and this is a non-
15 discriminating measure.

16 DR. RUSSO: Of maybe we could, you
17 know, there's some question, I guess. It
18 looks like there's more analysis in terms of
19 disparities. Is there any disparity in terms
20 of -- maybe not. And maybe eventually it
21 should be retired. But I think if we do
22 something like that, we should have some

1 consistent way of doing it and just come up
2 with some standard to say if you're above 98
3 percent and there's no disparities. There
4 should be some consistency in what we do if we
5 start to retire measures. And it would be
6 nice to see. I guess they're going to do some
7 more analysis on the disparities, if there
8 are; but I guess there may not be.

9 DR. RICH: You know, when we go to
10 look at what we want to retire or not, I guess
11 it would really depend on what's on a full
12 plate. So I would recommend at this point
13 keeping it. It's an important measure. I
14 certainly agree with you, Dale, that, you
15 know, it's almost at perfection, but if
16 there's a huge difference between 98 and 100
17 percent. And if we believe we can get to 100
18 percent then maybe we want to keep it up there
19 so people don't get the message that we don't
20 care about it anymore.

21 MS. SZUMANSKI: Another way you
22 might look at this is the percentage. If you

1 say two percent of 105,000 patients, how many
2 patients is that? That's looking at it from
3 a slightly different pair of glasses, but
4 that's a significant number of patients in
5 that cohort.

6 CO-CHAIR GIBBONS: The other part
7 of that, though, is that when you're at 98 and
8 a half percent, you're in the rounding area.
9 Your confidence interval is probably going to
10 put you so close to 100 percent that I don't
11 know if you can claim those patients
12 reliability. If we can't retire a measure
13 when we're at 98 and a half percent, we really
14 need to think about when we can. And if we're
15 not going to do it here, then somebody should
16 sit down and work on that as a problem
17 because, otherwise, the measures just expand
18 and expand, and I think that's a problem that
19 NQF has recognized.

20 CO-CHAIR GEORGE: We do have other
21 beta blocker measures in slightly different
22 areas of care, but perhaps that whole issue

1 surrounding beta blocker measures needs to be
2 harmonized into those that are most important.

3 DR. BRATZLER: This is Dale. I
4 guess where I'm getting a bit confused here is
5 the language that's being used about whether
6 this committee is looking at, quote,
7 retirement of measures or whether they're
8 looking at re-endorsement of measures because
9 I think the entire committee, you know, that
10 I'm hearing feels that the measure is
11 scientifically sound. It's a good measure.
12 There's nothing scientifically wrong with the
13 measure. The question is around
14 implementation about whether it still makes
15 sense to have hospitals capturing the data on
16 the measure. Helen I certainly know is in the
17 room, and Helen is well aware of the
18 conversation extensive with CMS about when
19 they decide to retire measures that are
20 scientifically sound and is there any way to
21 do that intermittent surveillance to make sure
22 that we don't see backsliding.

1 So all those conversations are
2 going on. I think the question for us has
3 been does it make sense to at least keep some
4 library of measures that are endorsed because
5 they're scientifically sound from which, you
6 know, can be used to pull from in the future,
7 if needed. I know, Helen, you've talked about
8 some new category of measure.

9 DR. RUSSO: Or maybe like the one
10 from yesterday, using a composite. Would it
11 make sense to consider the ACE inhibitor plus
12 beta. They both function so well. Doing one
13 of those composite measures, considering that.
14 But this is one that everyone thinks of at
15 discharge, all the guidelines, you know, AHA
16 work. So this one is really high now because
17 I think people have worked really hard, but
18 maybe if we use it, because it is so
19 important, combine it, like the smoking one
20 yesterday with the lipids, so then people
21 don't perform as well when you combine
22 multiple drugs. Just something we might

1 consider.

2 DR. BURSTIN: Hi, Dale. It's
3 Helen. It's something we've actually talked
4 a lot about. We don't really have a category
5 for this yet, although the evidence task force
6 that just completed its work did specifically
7 make a recommendation about measures that were
8 fairly high level performance. You want to
9 just review that, Karen?

10 MS. PACE: Basically, you know, as
11 I said yesterday, they didn't feel they could
12 set a particular threshold that is
13 contextually driven, and certainly you experts
14 around the table know more about this. But
15 one of the key considerations is whether there
16 are associated outcome measures that are being
17 measured so that, you know, if this process is
18 associated with one of the outcome measures we
19 have then if you've got an outcome measure
20 already, you know, very high levels of
21 performance, do you need to continue
22 endorsement of the associated process

1 measures. So I think that's something else to
2 kind of throw into your discussion about that.

3 I don't know, you know, again, as
4 Helen said, we haven't set up a separate
5 category for measures that are sound but are,
6 quote, topped out, but certainly, you know, if
7 we don't continue endorsement, you know, the
8 reason for that could be clearly indicated so
9 that the measure could be used again. But it
10 sounds like it would be used more from a
11 monitoring perspective and quality improvement
12 versus performance measurement, but something
13 else for your consideration.

14 DR. KOTTKE: Ray, can I make a
15 comment?

16 CO-CHAIR GIBBONS: Yes, Tom.

17 DR. KOTTKE: My quick spreadsheet
18 calculations is that going from 98 to 100
19 percent would, in a population of 100,000
20 middle-aged adults, would prevent a tenth of
21 a life lost per 100,000 people compared to if
22 you use that same energy to make sure

1 everybody got the cardiac rehab it would be
2 about 12 lives. And so it's really very
3 marginal impact, so we have to decide how much
4 opportunity cost are hospitals going to spend
5 trying to get from 98 to 100 percent.

6 CO-CHAIR GIBBONS: Okay. Mark?

7 DR. SANZ: One last comment would
8 be from the ground. When we've looked at our
9 misses on this and Plavix after PCI, 100
10 percent were administrative error. So how
11 much effort after a certain point should go
12 into what sounds good as a clinical miss,
13 missing giving someone a beta blocker, but in
14 actuality is it didn't get reported in the
15 discharge summary but when a nurse went back
16 and called the patient they were on the beta
17 blocker. It was an administrative miss. And
18 when you get to these kind of numbers, most of
19 the time that's what you're looking at.

20 CO-CHAIR GIBBONS: Helen?

21 DR. BURSTIN: I just checked, and
22 this measure has already been retooled for

1 EHR, so that's another consideration is the
2 question is how much of the actual searching
3 needs to be done if this is clearly something
4 put in in a discharge electronic system.

5 DR. RICH: Another thing to
6 consider when we think about this for public
7 reporting, you know, when you have a public
8 report you can only put so many variables out
9 there. And so what's of most benefit to the
10 community to be looking at? You know, you
11 want to really pick things that they're going
12 to see, like, "Oh, here's where we stand, but
13 we're stretching. We're trying to move
14 forward," or, "We're doing great. If we all
15 want to feel really good this is something
16 definitely worth keeping in there."

17 CO-CHAIR GIBBONS: Okay. I think
18 we've had great discussion, but we must move
19 on. So we're going to take a series of votes
20 on this one, and I would point out that if
21 you're really concerned about this issue of is
22 there enough room for improvement to justify

1 this effort, I believe, in terms of the way
2 the process is set up, it should be reflected
3 in the first vote on importance. So we're now
4 going to take that vote on importance. So
5 remind you, yes or no. So those who feel yes?
6 Those who feel no? So the vote is 10 yes, 11
7 no. So we are done with this measure.

8 Next, 142, aspirin prescribed at
9 discharge for AMI. George?

10 DR. PHILIPPIDES: We're in danger
11 of having a very similar conversation. So
12 just to jump right through the meat, this is
13 post-MI with the codes of MI percentage of
14 patients who received aspirin at hospital
15 discharge. Exclusions are the ones that you
16 would imagine: people who died before
17 discharge or there were other important
18 contraindications. So, obviously, this is a
19 high-impact area. The point is going to be
20 the one we just discussed: Over the last two
21 years the numbers have really not budged, 98.3
22 to 98.5 percent, and it's hovering at about

1 98.5 percent. So it's not a particularly good
2 discerner at this point, then, theoretically.
3 It's obviously a very relevant outcome. I
4 mean, clinically and scientifically, it's
5 important. So I don't know if you want to
6 have the same discussion and tweak the
7 differences with aspirin or if you have any
8 way in your spreadsheet --

9 CO-CHAIR GIBBONS: I think we're
10 waiting for the Kottke model to do its magic.
11 Dale, do you want to make any specific
12 comments about aspirin at discharge?

13 DR. BRATZLER: No. This is
14 actually Fred's measure. Again, my issue is,
15 just like on the previous measure on beta
16 blockers, if you de-endorse it and then five
17 years from now we have issues around
18 backsliding, you know, do we have to go
19 through the entire re-endorsement process for
20 a measure that's scientifically sound? To me,
21 it's a question of implementation --

22 CO-CHAIR GIBBONS: I guess it's --

1 DR. BRATZLER: -- versus
2 endorsement.

3 CO-CHAIR GIBBONS: I'll take a
4 stab at answering that. I think the point has
5 been made earlier that this is a matter of
6 opportunity and how you apply the resources
7 that you have in a system that we know has
8 limited resources. Where you apply them are
9 where you're going to get the most impact on
10 actually benefitting patients. And applying
11 a lot of resources to this one at this point
12 in time I think is the question. Yes?

13 DR. JEWELL: So it looks like the
14 disparities are the same or very similar in
15 both measures, the one we just considered and
16 the one that's on the table now. And I guess
17 that piece still troubles me a little bit. I
18 mean, if I'm in the Hispanic/Latino cohort,
19 granted, 96 percent isn't a bad thing, but
20 should we be worried about improving even two
21 more percentage points for those people?

22 DR. PHILIPPIDES: That was one of

1 the two issues I was going to bring up before
2 we voted, which is, is there evidence of
3 disparity and if we lose this measure we lose
4 the chance to look into that more closely. I
5 think that, as a general rule, I've seen a
6 greater need for that across many of these
7 measures. The other thing is this one, as
8 Helen points out, lends itself very well to
9 electronic medical record review. It actually
10 changed the way they look at exclusions. If
11 you're given the aspirin, even though you have
12 an exclusion documented, you're still sort of
13 counting the credit, which makes it much
14 easier to do an electronic search for the
15 numbers. So it just makes the whole endeavor
16 fairly easy. So I just want to bring up those
17 two things, as well.

18 CO-CHAIR GIBBONS: Tom?

19 DR. KOTTKE: Yes, it's four times
20 the impact of beta blockers at four-tenths of
21 a life per 100,000 compared to about 14 for
22 cardiac rehab.

1 DR. JEWELL: Starting at 98
2 percent.

3 CO-CHAIR GIBBONS: Four-tenths of
4 a life per 100,000.

5 DR. JEWELL: So if you did 96 for
6 the disparities. I mean, I guess the other
7 thing about the disparities is that we're
8 talking about populations who have other risk
9 factors that are stronger in some cases in
10 terms of their risk for co-morbidity and for
11 complicated disease. So it's not only not
12 getting the aspirin or not only not getting
13 the beta blocker, it's the whole picture of
14 how they present with their cardiovascular
15 disease that, for me, just is troubling.

16 DR. KOTTKE: I think one thing to
17 remember, I don't get what the guidelines or
18 what the ACC registers are going to drop this
19 just because we take it out as a, you know --
20 there's a lot of redundancy in the system
21 besides just being in --

22 DR. SANZ: Well, speaking to

1 redundancy, there's six measures specifically
2 using aspirin in their title, plus composite
3 measures which I didn't go back to look at.
4 So talk about redundancy. Aspirin is the most
5 redundant measure of all of them, so do we
6 really need, can we cut these down? It's not
7 that aspirin is bad, but we have other
8 measures that say if you have any coronary
9 artery disease you should be on aspirin at
10 discharge. Well, I submit that every MI
11 patient has coronary artery disease and should
12 be on aspirin at discharge and measured in the
13 other group, so why do we need to do both? We
14 have IVD, which I had not heard of until this
15 group, but I submit that every one of these
16 patients who's in that group. Why do we need
17 to keep doing this as separate groups?

18 CO-CHAIR GIBBONS: Dr. Masoudi?

19 DR. MASOUDI: I have nothing to
20 say.

21 CO-CHAIR GIBBONS: You're happy.

22 Okay, good. I'm glad you're happy. So the

1 Chair is going to call -- Sid?

2 DR. SMITH: It's quick. Could we
3 reassure that NQF will develop criteria that
4 committees can use to determine whether
5 something should be discontinued and also a
6 plan for how they would be monitored and
7 reinstated? It would be a real service to
8 groups like this if, you know, even if you
9 decide you want a sub task force from this
10 committee, I'd be happy to work on that. But
11 in the future, if we had objective criteria it
12 would be very helpful.

13 DR. BURSTIN: It's a great point,
14 and it's something that Evidence Task Force
15 really grappled with and actually their
16 decision was if there's an outcome measure and
17 this measure is topped out do you need both,
18 and the answer they said was no. So that was
19 a question for you. Is there a clear outcome
20 measure in the AMI realm, I think Tom is
21 essentially doing that already by looking at
22 mortality, that would suggest that if you have

1 the mortality measure and it's sound do you
2 still need the process measure? And what the
3 Evidence Task Force at least said was, no,
4 that that's probably not necessary.

5 Now, the other thing to consider
6 is that even if these are not endorsed as
7 individual measures you will shortly have an
8 opportunity to consider them in a composite.
9 So there are ways to sort of keep it in ways
10 beyond individual lots of measures being
11 assessed regularly in public reporting.

12 CO-CHAIR GIBBONS: Bruce?

13 DR. KOPLAN: Just one last comment
14 along what you're saying, whenever something
15 gets no voted on, there's a clear expression
16 that comes out the reason why, so it doesn't
17 come out as if we as a group felt that it
18 wasn't important. It was clearly expressed
19 somehow that --

20 CO-CHAIR GIBBONS: There's not
21 room for improvement. Okay. So the Chair is
22 calling the question. We must move ahead if

1 we're ever going to get those rehab measures
2 that have the bigger impact on lives that Tom
3 keeps pointing out. So importance, yes, how
4 many say yes? How many say no? Four yes,
5 seventeen no. We're moving ahead to measure
6 137, ACE and ARB at discharge. Jon?

7 DR. RASMUSSEN: This measure is
8 entitled ACE or ARB therapy for left
9 ventricular systolic dysfunction for post AMI
10 patients. It's measuring the percentage of
11 AMI patients with left ventricular systolic
12 dysfunction who are prescribed an ACE or an
13 ARB by hospital discharge, so at any point in
14 their hospitalization. For this measure, LVSD
15 is defined as an ejection fraction of less
16 than 40 or a narrative description of moderate
17 or severe systolic dysfunction. It's a high-
18 impact measure. The level of evidence is
19 quite high with multiple randomized trials
20 showing ACE inhibitors reduce morbidity and
21 mortality in post MI patients with LVSD and
22 ARBs have been shown to be a good alternative

1 for those patients who are not able to
2 tolerate ACE inhibitors.

3 CO-CHAIR GIBBONS: Do you want to
4 comment on the room for improvement issue,
5 given our discussion thus far this morning?

6 DR. RASMUSSEN: Sure. So looking
7 at the last few quarters, the national
8 performance is around 96 percent. And using
9 the numbers that they provide from 2300
10 hospitals, about 20,000 AMI patients, that gap
11 represents about 800 patients.

12 DR. CHO: Can I ask a question?
13 So the other criteria, like beta blockers and
14 aspirin, it was like 100,000 patients. In
15 here it's only 19,000 patients. Why is there
16 such a disparity?

17 DR. RASMUSSEN: First, this is a
18 subset of AMI patients, only those with LVSD.
19 And I believe they have a public reporting
20 program that looked at this measure, and it
21 may be that the groups that reported out,
22 that's where the --

1 DR. CHO: Because the other thing
2 could be that they're not measuring LV
3 systolic function.

4 DR. RASMUSSEN: Actually, that's
5 an excellent point because when we get a
6 little bit farther, looking at the exceptions,
7 of those patients that were listed as having
8 an exception, 64 percent of those were
9 excluded because they couldn't find documented
10 evidence of an EF or a narrative description
11 of symptoms.

12 DR. CHO: So from looking at this
13 data, I don't think this applies to the same
14 argument as the aspirin or the beta blocker
15 because of the lack of LV systolic function
16 measurement for patients with MI.

17 DR. KOTTKE: About 5.2 lives.

18 CO-CHAIR GIBBONS: All right. So
19 we have an estimate of 5.2. Dana?

20 DR. KING: Similar to our previous
21 discussion, in my fog from yesterday I
22 remember us discussing ACE and ARB therapy in

1 people with left ventricular function left
2 ejection fraction of some 40 percent and
3 number 0066. And that was for all people who
4 had CAD that had either diabetes or left
5 ventricular function injection fraction 40
6 percent. So now we have, but if you had a
7 heart attack and less than 40 percent you need
8 to get it, too. In other words, isn't this
9 just a subset of 0066 yesterday which we
10 endorsed and we said was fine and this one is,
11 you know, and we need to consider whether it's
12 necessary in addition to.

13 DR. RASMUSSEN: The anchor for
14 this measure is a hospitalization. The
15 measure 66 is on an outpatient basis, so they
16 may have had an MI years ago. It's just that
17 they were seen in that year. So this is a
18 measure of inpatient performance. That's a
19 measure of outpatient performance.

20 CO-CHAIR GIBBONS: And I would
21 just point out that there is science. It's
22 older science, but there is science that the

1 first three weeks of therapy makes a
2 difference. Sid?

3 DR. SMITH: So I have a question
4 that has just occurred to me, and that is
5 assumptions that we make on samples. And an
6 area of ignorance, that is I don't know what
7 the denominator is for hospitals. But I look
8 at the data here on patients, and there are,
9 roughly, 2,300 hospitals surveyed, and we're
10 told that they're at 96 percent. But when I
11 look at the data for aspirin and beta blockers
12 I see that 3,100 hospitals were surveyed. My
13 concern is, to draw it to extremes to make a
14 point, the 50 hospitals that are really
15 interested in quality improvement show that 98
16 percent of their patients are getting aspirin,
17 you could have 3,000 hospitals out there where
18 only 10 percent are getting aspirin. And I'm
19 concerned about drawing conclusions from a
20 subset of hospitals that may not be truly
21 representative if we really want to
22 universally improve care. So the sample of

1 hospitals from which we draw data, it's very
2 important to define that. And I'm just
3 looking at these two sheets. I don't
4 understand, I can understand why there would
5 be fewer patients that would be candidates for
6 ACE inhibitors than aspirin because not
7 everybody has LV dysfunction. But I cannot
8 understand why 2,300 patients report on ACE
9 inhibitors and 3,200 report on aspirin.

10 CO-CHAIR GIBBONS: Fred, can you
11 help us with that?

12 DR. MASOUDI: In terms of the
13 relative differences in numbers of patients
14 reporting for a different measure?

15 DR. SMITH: Not the differences.
16 It's the number of hospitals reporting, the
17 sampling. Your sampling 2,200 hospitals for
18 ACE inhibitors and 3,200 for aspirin.

19 DR. BRATZLER: Yes. So this is
20 Dale. There is no sampling at the hospitals.
21 The data that you have I'm sure is all
22 hospitals in the U.S. that voluntarily report

1 the metric. So how can I explain the
2 disparity for ACE inhibitors and aspirin?
3 Well, there are a whole lot more hospitals
4 that take care of MIs that have very small
5 sample sizes. Some of those hospitals may or
6 may not have immediate availability of the
7 ability to do left ventricular function
8 testing. So I think I can pull out the data
9 here in just one second and I'll cut in, but
10 I can pretty well tell you that that is the
11 total number of U.S. hospitals that are
12 reporting the measure.

13 DR. SMITH: There's another bias
14 that we got in to research in this area that
15 those hospitals that do quality improvement
16 have a bias to improving quality, and so their
17 results, by definition, would be better than
18 those who have no interest in improving
19 quality or don't have the time or don't want
20 to do it. So we need to know how many
21 hospitals are out there that are not
22 voluntarily involving themselves in this.

1 DR. BRATZLER: So I can tell you
2 that remember that AMI has a much more limited
3 number of hospitals that actually submit that
4 data because they have low volume. They have
5 either low volume or they don't admit the
6 patients. I'm looking at second quarter 2010
7 data that comes into the QIO National Clinical
8 Warehouse, which includes every reporting
9 hospital that participates in the pay-for-
10 reporting program which is about 98 percent of
11 all eligible hospitals. There were 3,100
12 hospitals that submitted aspirin on arrival.
13 There were 2,296 hospitals that submitted data
14 on the ACE inhibitor measure. So this is just
15 a difference in the number of hospitals that
16 have eligible cases for the measures, but it
17 is the total sample of all reporting U.S.
18 hospitals.

19 CO-CHAIR GIBBONS: Sid, if it
20 reassures you at all, to follow-up on the
21 point that's been made, on the ground in
22 southeastern Minnesota, I can make you a list

1 right now of six hospitals that would report
2 the data on aspirin but would not report the
3 data on ACE inhibitors who are within Mayo
4 Health System. So with that as a sample,
5 there's a lot of hospitals like them, and it's
6 because they don't have LV function assessment
7 and they have a very small numbers.

8 DR. SMITH: Well, the criteria for
9 this are either an assessment of LV function
10 objectively or that they had evidence for
11 heart failure.

12 CO-CHAIR GIBBONS: Yes. And those
13 six hospitals in southeastern Minnesota, the
14 moment there's any suspicion, they're shipped
15 to us, so that's what's happening here. You
16 know, that's what happening. I'm saying that
17 the sample, you're concerned that there's
18 some, you know, hospitals that are doing this
19 and not reporting, I don't think that's right.
20 I think, as described, they had very small
21 numbers, so they're falling off for that
22 reason. If you go look at these hospitals on

1 Hospital Compare, there will be no data.
2 They'll have that asterisk or whatever it is.

3 DR. SMITH: I'm concerned that a
4 third of, roughly, 3,000 hospitals don't think
5 it's important to report on a measure that
6 significantly improves outcomes.

7 DR. MASOUDI: I don't think that's
8 the issue. I think it's more the issue that
9 they don't have the capacity to understand
10 what the patients EF is and, therefore, they
11 can't get --

12 DR. SMITH: I qualify that. And
13 I'm also reassured that we apparently are
14 getting 98 percent of the hospitals around the
15 country involved. That's a good thing.

16 CO-CHAIR GIBBONS: Okay. I think
17 we have to get moving, and we're going to vote
18 on this. Importance of the question? We're
19 back? We've got it? We're hoping. Okay.
20 Now we have an opportunity to compare how long
21 it takes to do it this way versus the old-
22 fashioned way. I think we've demonstrated

1 that Ashley has a quick finger. All right,
2 all right. ACE or ARBs, does it meet criteria
3 for importance? Please vote. All right.

4 Jon, any additional comments on scientific
5 acceptability? Don't feel under pressure.

6 DR. RASMUSSEN: Just quickly.

7 Numerator is number of patients prescribed an
8 ACE or an ARB by discharge. Reliability, they
9 select five cases per quarter across a number
10 of measures from hospitals that have at least
11 six discharges. Face validity regularly
12 assessed by a technical expert panel.

13 Exclusions are justified and are consistent
14 with the other measures in the AMI set. I
15 briefly mentioned looking at the exclusions.

16 Almost 62 percent of those excluded were due
17 to the fact that they did not have that
18 documented EF or description of LV
19 dysfunction. No risk adjustment reported.

20 Meaningful differences quarterly benchmarked
21 have been established. We've talked about
22 that. Disparities, very small looking at race

1 disparities. High to low is only 1.4 percent.

2 CO-CHAIR GIBBONS: Other comments
3 on this? All right. We're going to go ahead
4 and vote on this. Okay. Eighteen completely,
5 three partially. Usability.

6 DR. RASMUSSEN: Useful for public
7 performance quality improvement is already a
8 voluntarily reported initiative. Looking at
9 other measures, this is the only inpatient ACE
10 inhibitor. There are a couple of measures
11 that are looking at ACEs and ARBs on an
12 outpatient basis.

13 CO-CHAIR GIBBONS: I think we'll
14 go ahead and vote on this one. Completely,
15 partially, minimally, not at all. Nineteen to
16 two. And, finally, feasibility.

17 DR. RASMUSSEN: The clinical data
18 is generated during the care process. The
19 exclusions do not require additional data
20 sources. Susceptibility to error, they have
21 a standard exclusion criteria added in the
22 other reason for not taking ACEs and ARBs.

1 Trends do not suggest that that's a problem or
2 is being gamed. Data collection, no evidence
3 that it imposes an undue burden.

4 CO-CHAIR GIBBONS: Any other
5 comments? All right. We'll vote on
6 feasibility. We're unanimous on that. All
7 right. And we're now going to move to does it
8 qualify for endorsement. I'm sorry. That was
9 a unanimous yes for those who are on the
10 phone. Completely.

11 DR. RASMUSSEN: Just one comment
12 that I have, and this goes across some of the
13 other medication measures that we've looked
14 at. With one exception, we're looking at 1.4
15 adherence for medications, and I certainly
16 understand that it's a larger burden to track
17 medication use over time, but I would
18 encourage NQF in the future, as we start to
19 see very high performance on these measures,
20 the next step would be long-term adherence,
21 180 days outside of the hospital. As our data
22 sources get better, I think that's a good way

1 to move in the future and a way to get away
2 from we've got people who are 98 or 99
3 percent, stretch it out a little bit more
4 shows better care, and then we can start to
5 see some differences and places to improve.

6 CO-CHAIR GIBBONS: Point very well
7 taken. All right. We're going to vote now on
8 whether the measure meets criteria for
9 endorsement. And that is a unanimous yes
10 vote. All right. Thank you very much, Jon,
11 for that expedited consideration of 137.

12 We're going to now move on to some
13 true outcome measures. We mentioned earlier
14 the importance of these, and we had a
15 discussion yesterday about how you define
16 certain criteria. I think there's little
17 doubt that, from a public standpoint, things
18 like mortality and readmission are the
19 clearest outcome measures that any patient can
20 understand and most of the public can
21 understand and, from my experience, even
22 people on Capitol Hill can understand. So,

1 therefore, we're now moving into that realm,
2 and the first one is 230, AMI 30-day
3 mortality. This is a re-up measure, and it's
4 Tom Kottke. Tom?

5 DR. KOTTKE: Thanks. It's
6 hospital 30-day all cause risk-stratified
7 mortality rate.

8 CO-CHAIR GIBBONS: We're starting
9 on 230.

10 DR. KOTTKE: 230 comes before 961.

11 CO-CHAIR GIBBONS: Okay. I'm
12 sorry. There are too many multiple versions
13 of the agenda, and I'm working off one of
14 them, and we're going to do 230 first because
15 it's the old measure. It would actually be
16 wrong to do it the other way around.

17 DR. KOTTKE: Plus, Ray's the
18 decider. Measure title is hospital 30-day all
19 cause risk-stratified mortality rate, that's
20 RSMR to the
21 cognoscenti, following acute myocardial
22 infarction hospitalization. The measure

1 estimates a hospital-level risk standardized
2 mortality rate defined as death from any
3 cause within 30 days after the index
4 admission date for patients discharged from
5 hospital. Mortality rates after MI are
6 high. It's an important indicator. I don't
7 think it needs more discussion than that for
8 importance.

9 CO-CHAIR GIBBONS: Measure
10 developers on the line?

11 DR. BERNHEIM: Yes. Hi, we're
12 here.

13 CO-CHAIR GIBBONS: Good. Do you
14 want to say anything further at this point
15 before we begin voting on this measure?

16 DR. BERNHEIM: That was so nice
17 and concise. We're happy to. Are there
18 things that people want us to speak about a
19 little bit more?

20 CO-CHAIR GIBBONS: We will see as
21 we move through whether we have specific
22 questions. We're going to start then voting

1 on importance. Don't vote yet. We're not
2 ready.

3 DR. MASOUDI: Dr. Gibbons? There
4 was a request from back here to have the
5 individual who was speaking on the phone
6 identify themselves.

7 CO-CHAIR GIBBONS: Thank you.
8 Could the phone representative from CMS
9 identify herself, please?

10 DR. BERNHEIM: Hi. This is
11 Susannah Bernheim. I work at the Yale
12 Center for Outcomes Research and Evaluation.
13 We're the developer. And I have with me
14 Elizabeth Drye and Kanchana Bhat as well
15 from Yale CMS and Yale CORE.

16 CO-CHAIR GIBBONS: All right.
17 Thank you very much. We're going to vote
18 now on importance of the measure. All
19 right. It's a unanimous yes, 19. We had
20 two technical glitches. All right.
21 Scientific acceptability. Tom?

22 DR. KOTTKE: The measure is

1 precise. It's 30-day all-cause mortality.
2 The steward has demonstrated reliability in
3 split-half analysis. There's a very nice
4 analysis by the Yale group in circulation
5 and some other stuff. Validity has been
6 demonstrated by comparing the measure to a
7 chart-based audit. The denominator
8 exclusions are well defined and well
9 documented. The frequency of the exclusions
10 is documented in the accompanied 2010
11 Measures Maintenance Technical Report. The
12 measure is fully risk adjusted with
13 hierarchical general linear modeling. Risk-
14 stratified mortality rate shows significant
15 geographic variations that are clinically
16 important. There are no comparable methods
17 to measure for identification of disparities
18 by gender and SES, but analysis indicates
19 that these are small at the hospital level.

20 Now, there is one question about
21 why not mortality rates strictly for
22 coronary disease or for heart disease, and

1 the problem there is, one, you have to
2 adjudicate cause of death; and, secondly,
3 you can have changes in diagnosis, cause of
4 death without actually changing death; and
5 then, thirdly, it's pointed out more in the
6 oncology literature the patients who receive
7 chemotherapy within a week or a month of
8 death, if everybody has an out here, they
9 can basically order palliative care and then
10 they're excluded from this measure. And so
11 it will help prevent sort of the heroic
12 interventions on people that are dying from
13 other causes anyway, and so I think it's
14 appropriate to have all-cause mortality
15 rather than disease-specific mortality.

16 CO-CHAIR GIBBONS: Questions
17 about scientific acceptability? I think, as
18 Tom's pointed out, this has been
19 extraordinarily well studied and vetted, and
20 even if I didn't have people from Yale on
21 the phone I would say that this is really a
22 tribute to the group at Yale and the

1 leadership of Harlan Krumholz in doing that.

2 Sid?

3 DR. SMITH: One question. Is
4 this only involving Medicare patients, the
5 database for this? Is there a mechanism by
6 which younger patients are also involved?
7 Are we talking about people over the age of
8 65?

9 CO-CHAIR GIBBONS: Correct. Over
10 the age of 65.

11 DR. SMITH: So it seems like we
12 would be well served by knowing what
13 happened to people under the age of 65.

14 CO-CHAIR GIBBONS: Helen?

15 DR. KRUMHOLZ: Well, Sid, this is
16 Harlan. I mean, I think that's a really
17 good point. We're limited by the data
18 source. We have every reason to believe
19 that this measure would be just as true in
20 younger patients, but we're searching for a
21 data source that allows us to characterize
22 the patients and look 30 days after

1 discharge. The national databases that
2 exist in hospital you can do. Things with
3 the managed care databases, but, of course,
4 those are selected. So we're working very
5 hard. I've talked to Helen about it. We're
6 going to try to see what we can do to
7 provide evidence that would allow a group to
8 consider the expansion of the measure, but
9 it's not for lack of interest or commitment
10 to those groups but more about data
11 availability at the current time.

12 DR. KOTTKE: If I could reinforce
13 that, working for a managed care
14 organization, we don't really know who's
15 dead for at least 18 to 24 months afterwards
16 because we have to wait for the state death,
17 and I know Mayo is the same way. And it
18 would be significant work to call people up
19 and ask them if they're alive.

20 CO-CHAIR GIBBONS: Tom is
21 exposing Minnesota's dirty laundry here.
22 But he's right. It's somewhat

1 disillusioning to discover in our state that
2 you really don't know for two years.

3 DR. KOTTKE: It is difficult, but
4 that doesn't mean it's not important. I
5 understand. I've been involved in similar
6 work looking at heart failure patients.
7 It's hard to get a handle on.

8 CO-CHAIR GIBBONS: By the way,
9 welcome, Harlan. Okay. I think we're going
10 to go ahead and vote on this, please.
11 Scientific acceptability.

12 DR. RUSSO: Just as a quick
13 question, is it Social Security Death Index
14 or National Death Index? What is this?
15 It's probably obvious to everyone, but how
16 do you get the death quickly? Is it through
17 Social Security Death Index or National
18 Death Index? How do --

19 CO-CHAIR GIBBONS: Can somebody
20 on the phone help us, please?

21 DR. BERNHEIM: Yes, sure. We
22 actually get the information about mortality

1 from the Medicare Enrollment Database. As
2 the measures are currently used, they're
3 reporting on three years of data, but
4 they're about a year delayed so we have
5 plenty of time to have the full 30-day death
6 information.

7 DR. RUSSO: So death then, it's
8 not through Social Security Death Index?

9 DR. BERNHEIM: I believe that the
10 Medicare Enrollment Database is updated
11 through a different mechanism that also
12 comes from the Social Security information.
13 It's been shown to be an extremely valid and
14 accurate way of identifying death in
15 patients.

16 CO-CHAIR GIBBONS: Okay. So it
17 was completely 19, partially 1. Moving on
18 to usability. Tom?

19 DR. KOTTKE: The measure is
20 already publically reported. The
21 statistical adjustment method is the same
22 one used for heart failure and pneumonia.

1 HRQ reports in-hospital mortality, but the
2 30-day mortality is independent of length of
3 stay and cannot be influenced by cure
4 decisions like early discharge if they look
5 like they're not doing that well. And so I
6 think it's completely.

7 CO-CHAIR GIBBONS: Comments or
8 questions about usability? All right.
9 Let's move on to vote. Eighteen completely,
10 2 partially. Feasibility. Tom?

11 DR. KOTTKE: The data are a
12 byproduct of routine medical record coding.
13 The data are available electronically. No
14 additional data sources are required. The
15 measure is already in use. It's prima facie
16 evidence of feasibility.

17 CO-CHAIR GIBBONS: Comments or
18 questions about that issue? All right. We
19 will vote on feasibility. Somebody has a
20 clicker that isn't working, but we have 20
21 completely. So now if I see 20 votes, I'll
22 know somebody on this side of this table

1 voted twice. Okay. We'll now move on to
2 the final vote. Does the measure meet the
3 criteria for endorsement? So for those on
4 the phone, that little side discussion
5 reflected the fact that someone was not
6 present, so our vote of 20 was, in fact,
7 unanimous.

8 Unanimous vote of 18 to zero. I
9 think I would like to reflect for the record
10 that we've all recognized and several of you
11 have commented privately to me that the
12 submissions vary a lot in terms of how
13 complete they are or how thorough they are
14 and how easy they are to understand and
15 read. I think this particular submission
16 set an extraordinarily high standard. For
17 those who didn't have the time to read it
18 but want to learn about this methodology, as
19 well as this measure, I would urge you to
20 read the submission. I know that Dr. Kottke
21 did an outstanding job of summarizing it
22 that allowed us to work through it, but the

1 submission itself was truly of high quality.

2 We're now going to move on to the
3 next measure, which is the hospital
4 composite measure, 961, and Suma Thomas is
5 the primary reviewer. Suma?

6 DR. THOMAS: So this is our first
7 composite measure, and excuse me for my
8 voice. So the primary objective is to
9 summarize the measures for acute MI in a
10 single composite that is useful,
11 understandable, and acceptable to a variety
12 of stakeholders. And there are other
13 composite measures that AHRQ has produced in
14 there in the appendix of other framework for
15 composite measures.

16 It uses seven process measures
17 and two outcomes measures for acute MI. The
18 seven process measures we've mostly talked
19 about: aspirin on arrival, aspirin at
20 discharge, ACE or ARB with LV dysfunctions,
21 smoking cessation counseling, beta blocker
22 at discharge, fibrinolytics within 30

1 minutes, and PCI within 90 minutes. The
2 outcome measures are the 30-day readmission
3 and the 30-day mortality. The process
4 measures are in a sub-composite, and the
5 outcome measures are in a sub-composite.

6 The importance of a composite,
7 there are three things that they pointed
8 out: that the information from a number of
9 composite measures can be summarized into a
10 single measure, that the component measures
11 can be aggregated at a level that's useful
12 to consumers and providers, and that it can
13 respond directly to patient-centered
14 questions of which hospital should I go to.
15 And the construct is a formative construct
16 which is a combination of multiple measures
17 intended to provide summary information. So
18 each of the individual measures has been
19 already found to be important, so this does
20 seem to be an important thing to measure and
21 report.

22 CO-CHAIR GIBBONS: Okay. Are

1 there other comments or questions about
2 importance? Did the developers want to
3 comment on this before we vote on
4 importance?

5 DR. SCHMITZ: My name is Bob
6 Schmitz. I work for Mathematica Policy
7 Research. I thought that was a very nice
8 summary, and I wanted to identify myself in
9 case there were questions later. But,
10 indeed, this is intended as a summary
11 measure aimed at consumers. As someone
12 noted just a few minutes ago, there are a
13 multiplicity of outcome and process measures
14 that consumers confront on Hospital Compare,
15 and this is intended primarily as a means of
16 summarizing that for consumers and is aimed
17 primarily at them rather than at providers.

18 DR. RUSSO: And I think this just
19 answers the question in terms of retirement
20 of other measures. This is perfect for
21 solving that problem.

22 CO-CHAIR GIBBONS: Sid?

1 DR. SMITH: I like the idea
2 behind this measure of beginning to think in
3 terms of how the system fits together. I
4 wonder if we're talking to consumers about
5 how you choose your hospital, and you have
6 an MI you don't have a lot of choice in many
7 instances. You go where they take you. And
8 if we're looking at a 30-day mortality, not
9 hospital, there could be elements that
10 relate to what happens after the patient
11 leaves the hospital that is not the result
12 of quality in that hospital. And so if the
13 intent is to advertise to consumers about a
14 hospital, it seems that this measure is
15 pulling in more than what's happening at the
16 hospital. And I will say that I firmly
17 believe and am passionately involved in the
18 fact that hospitals' work do not end when
19 the patients leave the hospital, and a
20 marker for a good hospital system is having
21 relationship with referring physicians and
22 so forth. And, I mean, that's what we do,

1 and compliance with medical therapy at six
2 months and so forth is important. But here
3 somebody drops dead, gets hauled in,
4 resuscitated, gets out of the hospital, I
5 don't know that they're going to be going
6 back to a setting that necessarily reflects
7 that hospital system. And if the intent is
8 to advertise this to the public, I just want
9 to be sure that the hospital that's being
10 advertised actually is in a way to influence
11 all the parameters upon which it would be
12 judged.

13 DR. SCHMITZ: I guess I would say
14 that that 30-day measure is currently
15 reported on Hospital Compare as an endorsed
16 measure of, as one of the endorsed measures
17 of quality. So it's been pulled into this
18 composite on that basis.

19 DR. SMITH: There's probably not
20 that many patients that would, I mean I
21 think most of them live in the area, but I'm
22 just sort of raising a question about that.

1 Again, following my strong statement in
2 favor that this is the type of composite
3 measure we need to be looking at.

4 CO-CHAIR GIBBONS: Others might
5 want to comment, and Tom might want to
6 comment from a data standpoint. But at
7 least from a practice standpoint, I would
8 argue that a lot of what goes on over the
9 next 30 days is, in fact, the hospital's
10 responsibility.

11 DR. SMITH: Well, I said that's
12 for sure.

13 CO-CHAIR GIBBONS: I know, but I
14 think it's reasonable for the public to see
15 a measure that holds them accountable for
16 that first 30 days because they can do a
17 better job throughout our healthcare system
18 of communicating the handoff to the
19 physicians, and that certainly surfaced loud
20 and clear from the heart failure mortality
21 data when it first became apparent where,
22 for the most part, hospitals did not realize

1 how many patients were dying between
2 discharge and 30 days. So I think we have
3 to do a better job as a healthcare system of
4 handoffs and coordination, and there are
5 various reasons, including payment system,
6 why that isn't done. But, Sid, I think this
7 is going to accomplish what it's trying to
8 accomplish.

9 DR. BURSTIN: Let me just make
10 one broad comment from the NQF perspective.
11 We have definitely seen a push and a move
12 towards measures of shared accountability.
13 No one expects readmissions are solely on
14 the back of hospitals or the receiving
15 clinicians, but until we have measures like
16 that it's going to be hard to really have
17 that happen effectively. So this has been a
18 measure that's gone forward. I think
19 there's some really strong evidence that by
20 having it be all cause and 30 day and
21 requiring that interaction, we've actually
22 seen some improvement.

1 DR. SMITH: Well, that's
2 reassuring. Again, as I said, I strongly
3 endorse this, passionately am involved in my
4 own practice in what happens outside, but I
5 live in the luxury of a system where I have
6 electronic records that reach out miles, 30
7 or 40 miles to referring physicians. And I
8 think Ray is in similar position. It's a
9 little bit easier for us to really get in
10 and affect that, but maybe that's an
11 argument that other people ought to have
12 that same luxury. And it sounds like you're
13 making progress, so, again, I'm speaking in
14 favor of this.

15 CO-CHAIR GIBBONS: Just for the
16 public record, I really would like to point
17 out that even systems with good electronic
18 medical records, they do have patients who
19 live in very rural locations with no
20 electronic records, and that certainly
21 includes us in Rochester, Minnesota.

22 DR. SMITH: We're linked in out

1 there, but, again, I would agree it takes
2 more than a computer to take care of a
3 patient. So it's the physician involvement
4 that's key.

5 DR. MAGID: I'd add that this is
6 consistent with the whole concept of the
7 accountable care organization.

8 CO-CHAIR GIBBONS: That's an
9 excellent point. Thank you, David.

10 DR. SANZ: I have a question
11 regarding how or who would be reporting this
12 since the purpose is public reporting. I
13 mean, the measures, composites are
14 excellent. Nobody is arguing. But is this
15 going to go on some proprietary website? I
16 don't know who Mathematica is either. I
17 guess that's my question. I mean, am I
18 going to be looking at a Google set of ads
19 or my hospital and your hospital?

20 DR. SCHMITZ: We're CMS'
21 contractor. This would appear on Hospital
22 Compare.

1 DR. SANZ: Okay, okay. Thank
2 you. And by the way, we are fourth lowest
3 heart failure readmission in the United
4 States at our hospital, and we don't have
5 electronic medical records. So it isn't all
6 there is. We do have to call the referring
7 doc immediately after discharge, so there
8 are other ways to communicate.

9 DR. JEWELL: I have a process
10 question for the NQF staff. On a previous
11 panel, I remember you all expressing a bit
12 of concern and the panel was moving not to
13 endorse individual measures that were then
14 later rolled up into composite measures. I
15 didn't hear you express that concern this
16 last go-around, so am I safe in assuming
17 that that has evolved?

18 DR. BURSTIN: I think we'll have
19 to get to, I mean I think there are some
20 differences there. So for example, NQF has
21 a policy that all measures within a
22 composite should be fully evaluated by a

1 committee. They don't have to be endorsed
2 as stand-alone measures, which I think
3 reflects back potentially on our last
4 discussion of a couple of those process
5 measures that are in here didn't reach the
6 level of importance you thought as stand-
7 alone measures. You would need to decide do
8 they add value and should be part of a
9 composite. We will get into some specific
10 issues as you get into the elements within
11 the composite. For example, there's one
12 measure within the composite, smoking
13 cessation, that was removed from endorsement
14 not just because it was topped out, because
15 it was not thought to be a valid indicator
16 of smoking cessation in hospitals. So I
17 think that's a slightly different issue than
18 saying is it okay to have in a composite. I
19 think you'll need to work those issues
20 through as you get into the meat of it, but
21 I think that gets beyond importance.

22 CO-CHAIR GIBBONS: All right.

1 Let's vote on importance to measure, please.

2 All right. That's a unanimous yes.

3 Scientific acceptability. Suma?

4 DR. THOMAS: So for the
5 scientific acceptability, as I mentioned,
6 there are the seven hospital process of care
7 indicators and the two outcome of care
8 indicators, which are sub-composites. In
9 terms of the numerator, the numerator is a
10 sum of all successes for acute MI process of
11 care indicators which is weighted by one-
12 half the reciprocal of the share of
13 opportunities represented by acute MI
14 process of care indicators and total
15 opportunities, plus the sum of all successes
16 for acute MI outcome of care indicators
17 weighted by one-half the reciprocal of the
18 share of opportunities represented by acute
19 MI outcome of care indicators and total
20 opportunities. The denominator is the total
21 number of opportunities for success on all
22 acute MI indicators used in the composite.

1 One comment I want to make is
2 that right away I found this complicated,
3 and the other composite measures that have
4 been endorsed by AHRQ that I looked at in
5 the appendix were, in my opinion, a little
6 bit easier to understand. So I think the
7 group's opinion about the scientific
8 acceptability and the complexity of this
9 will be very important.

10 Some of the decisions made in the
11 methods were that they use values, not
12 ranks, to decrease the likelihood of small
13 differences in performance leading to large
14 differences in the rank composite score.
15 They imputed values for missing indicators,
16 so composites were defining as many
17 hospitals as possible. They adjusted the
18 individual measures for reliability so that
19 they avoided extreme variations for small
20 hospitals due to random variation, and they
21 used denominator weighting so the composite
22 places more weight on measures that are

1 reported for relatively more patients
2 nationally.

3 So the type of scoring that they
4 used was called absolute scoring index with
5 reliability weighting. And I think
6 Mathematica can go into details if we need
7 that probably.

8 And then in terms of missing
9 composite scores, so you had to have at
10 least four out of seven process of care
11 indicators or one out of two outcome of care
12 indicators or you were excluded. In terms
13 of missing scores, if you met that criteria
14 they would use the national mean to estimate
15 the missing process of care or outcome of
16 care value that was missing.

17 One of the things that I found
18 important was that when they did testing of
19 the missing scores, they found that four
20 plus were missing in 35.7 percent of the
21 time. Both outcome of care were missing
22 42.1 percent of the time, and all were

1 missing in 23.9 percent of the time.

2 In terms of reliability, it was
3 based on the reliability of the component
4 scores and they did do validity testing, as
5 well. Another important thing that I found
6 was that CMS has not decided how they will
7 use it. When they talked about
8 discrimination performance, they spoke about
9 the Hospital Compare site and using better
10 than hospitals, no difference than
11 hospitals, and worse than hospitals, but
12 clarify that they were not necessarily going
13 to be using the measure in that way, which I
14 found a little bit concerning not knowing
15 how this measure was going to be used. And
16 I'm not sure if it fits in here, but my
17 general concern about this is that it's
18 great to take things and make them one and
19 make them easy for consumers, but you have
20 to also deal with what that's going to mean
21 to the provider. I know that this is
22 important for consumers, and that's what

1 some of our goal is. But I also think about
2 the providers and how they're going to look
3 at this, and if you did take it and use it
4 in such a basic way what kind of impact is
5 that going to have down the line. We're all
6 judged now more and more and more. It's
7 important, but if it's this complicated can
8 an individual provider out there, Joe
9 Cardiologist, understand this? That's one
10 of my major concerns because you're supposed
11 to be able to break it down yourself and
12 understand it. I'm not sure about that.
13 That's one of my major concerns.

14 CO-CHAIR GIBBONS: Okay. I think
15 we'll refer that question to the developers.
16 Will providers understand this?

17 DR. SCHMITZ: That's the
18 question? Will providers understand it?
19 Well, I think we can put this together in a
20 way that is, in fact, very easy to
21 understand. The issue, there are two
22 elements of the presentation in the form

1 that have a mathematical structure that
2 makes it look quite forbidding, and much of
3 this is done with the reliability weighting
4 component. The reliability weighting is
5 applied to the process measures to put them
6 on the same footing as the outcome measures
7 that were drawn directly from the Yale
8 measures that you considered here. So they
9 all are weighted in such a way that the mean
10 is pushed toward the national mean for
11 smaller hospitals, more so for smaller
12 hospitals and less so for larger hospitals.

13 That said, once that calculation
14 is done, the steps in the process can be
15 made, I feel, quite easy to understand.
16 And, in fact, the use of the national mean
17 rather than other perhaps somewhat more
18 accurate means of imputation was done
19 precisely to make it easier for hospitals to
20 take their own data and construct their
21 value from it so that, in the end, part of
22 the process here is for us to give each

1 hospital a set of instructions that allows
2 them to take their data from Hospital
3 Compare and create their own composite score
4 from it.

5 CO-CHAIR GIBBONS: David?

6 DR. MAGID: So, I mean, it sounds
7 like this is very well constructed and, from
8 a statistical standpoint, very sound, though
9 I'm not sure all of us with our sort of
10 basic statistic background can appreciate
11 that. So I wonder whether our colleagues at
12 NQF can comment and at least say, yes, this
13 is statistically sound. That would reassure
14 me and we wouldn't have to spend as much
15 time on that.

16 MS. PACE: This is Karen, and
17 Helen and Reva had asked me to review the
18 submission, so I have some observations and
19 questions, actually, to pose to you and the
20 measure developer. First of all, you know,
21 I think it was very thoroughly described in
22 terms of the methods and the analyses that

1 were done, so we appreciate the amount of
2 detail and information that was provided.
3 And I think one of the things that I noticed
4 and certainly, you know, the way our
5 criteria are worded would kind of lead us
6 this way about some of the analyses that
7 were done were more from the psychometric
8 analysis, the intercorrelations, and the
9 internal consistency which when you look at
10 those you might question whether it is a
11 sound measure. But I think and I'll pose
12 this to the developers, I think we shouldn't
13 necessarily rely on those to make that
14 conclusion because I think this was
15 constructed from the standpoint of using
16 what's already there and trying to do a
17 summary of it rather than starting with some
18 conceptual model of what quality of care for
19 AMI patients necessarily is and then
20 creating a scale relative to that. And I
21 don't know, Bob, if you want to comment on
22 that.

1 DR. SCHMITZ: If it were
2 appropriate, I would be jumping up. Yes,
3 exactly. The psychometric analyses that are
4 reported there are actually appropriate for
5 a reflective measure that attempts to
6 extract information from the individual
7 measures and come up with a larger measure,
8 similar, say, to the measure of IQ. We have
9 explicitly abjured that in favor of the
10 formative approach, which is make it an easy
11 to understand, with apologies, summary that
12 is explicitly intended as a formative
13 summary of the measures. That's correct.

14 MS. PACE: Okay. So I think then
15 the question for the committee is does this
16 reflect an accurate summary of those
17 measures that are already there and
18 something that would be usable? So is the
19 content basically sound, from your expertise
20 in the area? I think one of the things that
21 was pointed out and that I would have a
22 question about is the seemingly large amount

1 of missing data, and I know this was touched
2 on with earlier discussion. And so I'm not
3 sure what the reason for that is for so much
4 missing data. Is that a function of this
5 being voluntary reporting?

6 DR. SCHMITZ: It is a function of
7 reporting of hospitals to construct the
8 measures that appear on Hospital Compare.
9 So the reasons, the explicit reasons why
10 hospitals might not report data for some
11 process measures are a matter of conjecture
12 to us.

13 MS. PACE: Right. But that's
14 what I mean. It's not really, it's not a
15 function of they've reported but the cases
16 were too small to appear on Hospital
17 Compare. It's that they haven't reported
18 the data at all for the process measures?

19 DR. WROBEL: I'm sorry if Bob was
20 about to answer this, but I'm Marian Wrobel,
21 and I worked with Bob on the composite. For
22 the mortality and readmission measures,

1 Hospital Compare does impose a bar of N
2 equals 25 and, therefore, given that this is
3 a summary of measures on Hospital Compare,
4 we treat those indicators as missing. So
5 one source of missing data is what you
6 suggested: small hospitals being knocked
7 out.

8 MS. PACE: That would be for the
9 outcome measures? Because CMS has all the
10 data they need to compute those outcome
11 measures.

12 DR. WROBEL: Right, right.

13 MS. PACE: But you're saying that
14 even though CMS has a rate for a small
15 hospital that could be reliability adjusted,
16 as you've talked about, you've just gone
17 ahead and put in the mean for that, rather
18 than starting with that base rate for those
19 --

20 DR. WROBEL: Yes. And let me say
21 two things about the reason for that. The
22 first is that if we used rates that weren't

1 publically reported in the composite, a
2 sophisticated user could back those rates
3 back out by taking the composite apart. So
4 if CMS' goal is not to publically report
5 those indicators because they're not
6 reliable, then it's necessary not to use
7 them in the composite. A second thing about
8 missing data is, of course, the other option
9 would be to compute, to raise the standard
10 for how much data must be available in order
11 to compute the composite. And CMS, early in
12 the process stated that an objective for
13 this measure was to have it defined for as
14 many hospitals as possible and we,
15 therefore, needed a method that would define
16 it for the majority of hospitals while still
17 giving accurate signals about what is truly
18 known about performance.

19 DR. THOMAS: Just one quick
20 point. I said a lot, so I'm not sure if you
21 guys caught this. To me, when you're
22 missing, in 23.9 percent we're missing all

1 of the scores, it just seems like maybe this
2 may not be our best, you know, composite if
3 23.9 percent were missing all of the scores,
4 if you guys have some comment to that.

5 DR. SCHMITZ: For hospitals that
6 are missing all the scores, no composite is
7 created. And for those hospitals also no
8 other measure appears on Hospital Compare.

9 DR. THOMAS: Right, I understand
10 that. But to me it seems like it may not be
11 the best composite if we have 24 percent of
12 hospitals essentially not being able to use
13 this to compare to other hospitals. I don't
14 know. Maybe I'm looking at it in a
15 different way.

16 DR. SCHMITZ: Well, there's a
17 tradeoff here between imposing a
18 requirement, which we did impose on
19 ourselves that this was to be a composite of
20 endorsed measures that appear on Hospital
21 Compare, and having perhaps some larger
22 number of hospitals represented with some

1 other measure. We didn't really know what
2 those other measures would be. So our
3 strategy really or our decision was to live
4 with the fact that a substantial fraction of
5 hospitals will be missing, given that that's
6 a result for the endorsed measures in
7 general.

8 DR. KOTTKE: I don't see that as
9 a problem because small hospitals, those
10 kind of things. If they're not graded,
11 they're not graded. It's like you can't
12 grade me on my angioplasties because I don't
13 do them. And for those hospitals that
14 simply don't have a large number of cases
15 throughout, and I think we need to, the
16 composite measure has to include the
17 important variables that when you treat MI,
18 those are important.

19 CO-CHAIR GIBBONS: So I would
20 point out, you know, if you look at the key
21 paragraph, that the outcome variables, the
22 mortality and readmission variables missing

1 on 40 percent of the hospitals. So if I
2 understood correctly, they're going to be
3 imputed at the national mean; is that
4 correct?

5 DR. SCHMITZ: That's correct if
6 one of them is present. If they're both
7 missing, there's no composite to compare --

8 CO-CHAIR GIBBONS: Right. So if
9 one of them is present, the other one is
10 going to be computed, and that's going to be
11 a substantial percentage of the hospitals in
12 this composite.

13 DR. SCHMITZ: Right.

14 CO-CHAIR GIBBONS: Okay. So we
15 could have this discussion forever. I think
16 we want to now vote on the importance of
17 this measure as submitted. Scientific
18 acceptability of this measure as submitted,
19 now that we've had this discussion on
20 imputation and missing variables.

21 DR. JEWELL: If I can, there's
22 also the issue that I think both Suma and

1 Dr. Smith raised earlier about who is it
2 being used for and what's it reflecting. So
3 I appreciate what you said earlier, Karen,
4 about the statistical psychometric approach
5 to developing versus a more theoretical
6 approach, and that's what you've done.
7 You've pulled the endorsed measures, but not
8 all of the elements perform that well. So
9 I'm just curious if you re-examine the model
10 more than once with pulling some of the
11 individual measures out, like say the
12 smoking cessation one which apparently
13 didn't hold up. It's the same one, right,
14 that you were alluding to? So we didn't,
15 apparently NQF didn't or the committee at
16 the time didn't find that one to be valid.
17 So I'm a little concerned about what's in
18 there, even though, theoretically, I get
19 that they're all endorsed -- well, they're
20 not all endorsed measures.

21 DR. SCHMITZ: I would say had we
22 adopted the reflective strategy here, that

1 is a fully psychometric approach, and the
2 approach of trying to develop a measure that
3 was a truly reflective measure with optimal
4 psychometric properties, I think that's the
5 way, that's the kind of strategy we would
6 have followed. But given that we were
7 proceeding with the goal of developing a
8 formative measure and that it was explicitly
9 to summarize the measures that appear on
10 Hospital Compare, that led us to switch away
11 from that approach.

12 MS. PACE: Right. But one of our
13 criteria is that the components either be,
14 whatever approach you're using, either be
15 NQF endorsed or evaluated to meet NQF
16 criteria. So I think it's still a question
17 regarding that.

18 DR. WROBEL: I do want to say
19 another thing about the design of the
20 measure, which is this is really intended to
21 be a flexible methodology so that the
22 composite will evolve as new measures are

1 brought on to Hospital Compare and as other
2 measures are retired. So although we have
3 written it up around the measures that are
4 there now, the intended use --

5 MS. PACE: And another point on
6 that is NQF can only endorse a measure
7 that's specified. So even though this
8 methodology is part and parcel of the
9 measure, we aren't endorsing the methodology
10 separate from the specific measure. So the
11 other thing I just wanted to point out and
12 make sure that I understood that your table
13 2K.3.1 gives the distribution of composite
14 scores. So the 25th percentile score is
15 83.5 and the 75th percentile score is 84.98;
16 is that correct? So that's another thing
17 just for the discussion of the committee.
18 This is a score that could be on a scale
19 from zero to 100, and that's the
20 distribution.

21 DR. AYALA: But isn't that a
22 factor of the fact that they're plugging in

1 the mean for the missing components? That's
2 the part that I don't think we've heard
3 enough to help us understand how accurately
4 that reflects the real performance of the
5 hospitals.

6 MS. PACE: Well, that's the
7 question. Right.

8 DR. SCHMITZ: It does in some
9 regard result from that use of the mean.
10 The use of the mean, to reiterate, was, in
11 part, to make it easy to understand for
12 hospitals and for them to recreate their own
13 and also for us to be consistent with
14 composite measures that have been developed
15 by AHRQ and that were already endorsed by
16 NQF so that part of the strategy here was to
17 maintain some consistency across measures,
18 composites that have already been endorsed.

19 DR. WROBEL: And CMS sought to
20 distinguish between presenting the measure
21 and presenting a strategy for display,
22 although I do understand Dr. Thomas' point

1 about it's a lot easier to think about a
2 measure when you understand how it will be
3 displayed. This type of method, which is
4 the AHRQ method, and this is how the 30-day
5 mortality and readmission measures are
6 treated, too, typically the display is
7 hospitals are grouped into no different than
8 the national mean, better than the national
9 mean, or worse than the national mean so
10 that the imputation process and the
11 reliability adjustment for small hospitals
12 is pulling them into that no different than
13 the mean group.

14 CO-CHAIR GIBBONS: We have nicely
15 had pointed out to us the importance of
16 table 2K.3.1. It's in Appendix A, which I,
17 for one, had a whole lot of difficulty
18 finding, but my co-chair has found it. And
19 if we have a way to show that, that would be
20 wonderful because I think it will influence
21 substantially the committee's view of this
22 measure. It's on Appendix A. What page on

1 Appendix A?

2 MS. PACE: Page 20.

3 CO-CHAIR GIBBONS: Twenty of
4 Appendix A.

5 MS. PACE: One other question for
6 the developers regarding missing
7 information. I know you chose to do
8 denominator weighting, which means that the
9 measures that are reported most often get
10 more weight. So it's not necessarily
11 reflective of items that are most important
12 to patients or that all -- I mean, if most
13 of these things said that all patients with
14 MIs should receive, pretty similar, is
15 weighting it by the amount of reporting
16 really the best way to go, or what was your
17 decision regarding that?

18 DR. SCHMITZ: Well, there are
19 really two choices to make. One was to
20 weight them all equally and another was to
21 weight by denominator, the way we selected.
22 Perhaps, in some ideal world, there would be

1 a means of weighting according to some
2 measure of clinical importance or patient
3 importance, but we wouldn't do that. Using
4 denominator weighting has the effect of not
5 necessarily minimizing the variance, but it
6 reduces the variance relative to equal
7 weighting. So it does tend to create a
8 measure that is somewhat more precise than
9 equal weighting. It is also an approach
10 that's been used by AHRQ, so, again, we were
11 using the principle of consistency.

12 MS. PACE: I think one of the
13 distinctions between the AHRQ measures is
14 that their components are different
15 conditions, so they may have a mortality
16 measure for procedures and those are each
17 different procedures or mortality measure
18 for conditions and those are each different
19 conditions. But this is all for AMI, so it
20 was just a question of decision.

21 CO-CHAIR GIBBONS: So if we could
22 just, I think it will be hard for those at

1 the far end of the room to see these
2 numbers, and I have to get my bifocals out
3 to actually read these numbers. But the 1st
4 percentile is 79, the 10th percentile is 81,
5 the 90th percentile is 84, and the 99th
6 percentile is 85. Thus, the spread from the
7 1st percentile to the 99th percentile is six
8 percentage points.

9 MS. PACE: And just to point out,
10 CMS is proposing the differential weighting
11 so --

12 CO-CHAIR GIBBONS: Oh, so we'll
13 go to the right hand column, which doesn't
14 change things very much. First, the 99th is
15 79 to 86. That's a total of seven
16 percentage points. And 10th to 90th is 82.4
17 to 85.6, a total of 3.2 percentage points
18 with imputation in approximately, as I
19 understood it, 20 percent of the values.
20 That looks like an incredibly narrow range
21 to me.

22 DR. SCHMITZ: It is a narrow

1 range. In part, this compression is due to
2 the way in which the scores were scaled at
3 the very end. I must admit when we started
4 this process we stopped after the initial
5 scaling, and there were scores that went
6 from, because they're normalized they went
7 from minus something to some other number.
8 And we encountered enormous resistance
9 because, for us, having a negative number
10 didn't mean anything in particular. But,
11 obviously, for a hospital, having a negative
12 score would be a terrible thing.

13 So these scores were scaled in a
14 particular way, and they were scaled so that
15 zero represented the worst score you could
16 possibly get. You would have to have zero
17 for everything. None of your patients
18 survive 30 days, all of your patients were
19 readmitted, you didn't do any of the process
20 measures. And 100 represented the best
21 possible score. We did that because those
22 were the upper and lower bounds that were

1 possible to define in a natural way. But no
2 hospitals got anywhere close to being near
3 zero because nobody is doing, nobody has
4 those things happen.

5 The result, though, of that
6 process of scaling to ensure that all the
7 scores would be positive meant that the
8 reported scores would be compressed in this
9 way. There's another way of scaling that
10 would spread them out more. And I should
11 emphasize that those scores that appear in
12 the right two columns are not percents,
13 they're scores. But the compression of them
14 does, in large part, is a result of the
15 strategy we used for scaling.

16 CO-CHAIR GIBBONS: As well as
17 imputation at the national --

18 DR. SCHMITZ: Yes, yes, that's
19 right.

20 CO-CHAIR GIBBONS: -- because the
21 outcome measures are drivers of a fair bit
22 of this spread, and they're imputed in many

1 cases.

2 DR. SCHMITZ: In many cases.

3 Right.

4 CO-CHAIR GIBBONS: All right. So
5 I would like to suggest that we now vote on
6 scientific acceptability. Partially nine;
7 seven minimally; five not at all. All
8 right. We'll now move on to usability.

9 DR. THOMAS: So this measure is
10 currently not in use. CMS proposes a dry
11 run of public reporting in the second
12 quarter of 2011 if this is endorsed by NQF.
13 And there is harmonization within each
14 domain of the process of care and outcome of
15 care domain, and, in theory, this is, of
16 course, additive value if we could have a
17 composite measure for acute MI. It would be
18 very useful to consumers. Again, I do have
19 some concerns about the usefulness to
20 providers.

21 DR. AYALA: Can I ask a question?
22 Because the gentleman who speaks about the

1 mathematical aspects of this keeps referring
2 to the fact that it's created basically for
3 the providers to use to assess their
4 performance, but we're also talking about it
5 being publically reported. So our concerns
6 about the accuracy or the scientific basis
7 for the composite I think becomes even more
8 concerning when you're talking about
9 publically reporting.

10 DR. SCHMITZ: Actually, we have
11 argued really that the composite is aimed
12 primarily at consumers rather than at
13 providers. Most of the providers we've
14 talked to have emphasized that, from their
15 perspective, the individual indicators, the
16 individual outcome and process indicators
17 are the vehicles by which they gauge their
18 performance and it is only by improving on
19 those that they would increase the value of
20 their composite. So we're not really
21 arguing that this is of primary use for
22 providers.

1 DR. RICH: Our experience in
2 Detroit with public reporting is that while
3 we had hoped that it would really be
4 utilized by consumers it's actually much
5 more highly utilized by providers and has
6 improved care by providers looking at it and
7 wanting to improve. So we don't have, we've
8 tried very hard over the last four years to
9 strongly get the consumers engaged, but I
10 think the greater utilizers are the
11 providers.

12 CO-CHAIR GIBBONS: I think we
13 should go ahead and vote on usability.
14 Quite a spread. One completely, nine
15 partially, eight minimally, and three not at
16 all. Feasibility.

17 DR. THOMAS: The data is
18 generated through coding, and there is
19 electronic means to acquire the data.

20 CO-CHAIR GIBBONS: So all these
21 elements are available. Any other comments
22 on that? So feasibility. So seven

1 completely, ten partially, one minimally,
2 and two not at all. So then the final vote
3 for endorsement, does the measure meet all
4 the NQF criteria for endorsement? Seven yes
5 and fourteen no. So we're going to move on
6 now to 282, angina without procedure. And
7 Roger Snow is our primary reviewer. Roger?

8 DR. SNOW: All right. This is a
9 bit different kind of measure. This is a
10 prevention quality indicator which uses
11 hospital data to inform us about something
12 else. The background is that in 1993 the
13 Institute of Medicine published a monograph
14 in which they called attention to ambulatory
15 care sensitive hospitalization. The issue
16 was that there are a lot of quality issues
17 out in the community that have been very
18 hard to measure that might be measured by
19 looking at hospitalization. The argument
20 behind that being that there is a series of
21 conditions that if you're getting good
22 access to good care you won't have to go to

1 the hospital, so that if you are discharged
2 from the hospital with those conditions it
3 argues that you weren't getting that kind of
4 care before. That's the concept. And they
5 argued for this, and AHRQ developed a total
6 of 14 preventive quality indicators, the
7 PQIs, one of which was angina without
8 procedure. The metric is discharge from the
9 hospital where the discharge diagnosis of
10 angina without having had any of a long list
11 of procedures which would include things
12 like PCI and stenting and heart valves and
13 the list is really remarkable. The argument
14 for that being that if you were discharged
15 with that diagnosis but didn't have a
16 procedure, well, you probably had chronic
17 stable angina. Ray has written about that,
18 and it raises the question again of your
19 access to or quality of your ambulatory
20 care. That's the concept.

21 The issue has been around for a
22 while. It's been adopted by several states,

1 it's been in use, we will come to that. But
2 there were some problems, and I'm not quite
3 sure, maybe we should bring it right up now.
4 Very early on, there was a paper published
5 in which they raised the question that --
6 this is the paper in "Health Affairs" --
7 socioeconomic status accounted for a lot of
8 these hospitalizations and that that needed
9 to be somehow embedded in the measure. The
10 measure does have factors for age and
11 gender.

12 And then there was a subsequent
13 paper published titled "No Pain but No Gain"
14 in which the authors noted a sharp decrease
15 in the number of cases where there was a
16 discharge diagnosis of angina. They then
17 dug into that using the control numbers of
18 the SEER Cancer Registry, which is a
19 nationally recognized public registry. And
20 what they found was that there was a
21 reciprocal increase in the discharge
22 diagnoses for coronary atherosclerosis.

1 They then looked at the incidents of AMI and
2 that was unchanged. They then looked at
3 what happens with people who were admitted
4 with a diagnosis of angina and were they
5 discharged with a diagnosis of angina or
6 coronary atherosclerosis, and what they
7 found was, although it's not quite as
8 dramatic in appearance, the same crossover,
9 that there was a significant increase in
10 coronary atherosclerosis diagnoses and a
11 sharp decrease in the angina diagnoses.
12 Well, this makes a real problem because that
13 decrease would normally, as the measure was
14 intended, indicate one of two things, either
15 that everybody was getting a procedure,
16 because that was an exclusion phenomena, or
17 that the care had dramatically improved.
18 And the other data just didn't include that,
19 so their conclusion was this decrease in
20 angina hospitalization discharges was merely
21 due to a change in practice in how people
22 coded the darn thing. So that raises the

1 whole question of the viability of the
2 measure. What started out as a really
3 serious attempt to use this innovative and
4 interesting concept fell apart in this case
5 in the opinion of these authors, and I'll
6 say that I was quite persuaded by that
7 argument.

8 So there were these two separate
9 problems with interpreting the data. And if
10 you're not measuring what you think you're
11 measuring, then you're not measuring
12 anything at all. And I came to the
13 conclusion at the front end that this
14 probably should, even though I think it's
15 been previously endorsed, with the
16 development of this additional information,
17 should not be considered on the basis of
18 importance simply because you can't say
19 something is important if you can't reliably
20 measure it.

21 CO-CHAIR GIBBONS: Are the
22 measure developers on the phone?

1 MR. BOTT: Yes. This is John
2 Bott with AHRQ, and I think I'm joined by a
3 couple of others if they'd like to introduce
4 themselves.

5 MS. DAVIES: Yes, this is Sheryl
6 Davies from Stanford.

7 DR. ROMANO: And this is Patrick
8 Romano from UC-Davis.

9 DR. GEPPERT: Jeffrey Geppert
10 from Battelle.

11 CO-CHAIR GIBBONS: Do you want to
12 comment in response to Dr. Snow's concerns?

13 MR. BOTT: This is John. I defer
14 to one of the other folks on the teams, if
15 they'd like to make any comment.

16 MS. DAVIES: This is Sheryl
17 Davies from Stanford. Yes, his summary is
18 accurate. The measure was endorsed. The
19 study that he referred to has been published
20 and certainly points to a decrease in coding
21 for this procedure -- I am sorry for this
22 condition -- and for a coding for angina to

1 coding for CAD. And regarding the SES, we
2 do have optional socioeconomic data risk
3 adjustment, an indicator for that may be a
4 moot point for the change in the coding.

5 CO-CHAIR GIBBONS: Can I ask you
6 to comment on a statement made in the last
7 paragraph on page three, which says, "This
8 indicator has unclear construct validity
9 because it has not been validated except as
10 part of a set of indicators?"

11 MS. DAVIES: Sure. This refers
12 to the fact that most of the prevention
13 quality indicators, when they've been
14 studied in the literature, they've been
15 looked at as a set. So all of the
16 information that we have about their
17 relationship with measures to access, the
18 relationship with measures of access to care
19 or proxies of access to care, socioeconomic
20 status, are based on the relationship with
21 the prevention quality indicators as a whole
22 or similar set as a whole. There's little

1 information looking at angina by itself and
2 its relationship to access to care.

3 DR. ROMANO: This is Patrick
4 Romano. I would just add there are some
5 exceptions to that. So, for example, there
6 is robust literature looking at heart
7 failure separately, looking at asthma
8 separately, looking at diabetes separately.
9 But the less common PQIs generally have not
10 been looked at separately in a research
11 context to establish a construct validity.

12 CO-CHAIR GIBBONS: Okay. That's
13 very helpful. Are there other questions or
14 comments from the committee? David?

15 DR. MAGID: Yes. I have two
16 comments. One is with regard to the
17 diagnosis of angina in the setting of
18 troponin. So we know that, over time, that
19 the proportion of patients with this
20 diagnosis has gone down for a couple of
21 reasons. One is there has been a decline in
22 coronary artery disease. But separate from

1 that, there have been dramatic changes in
2 coding practice with the advent of more
3 sensitive biomarkers for acute MI. I also
4 think that, unlike primary hospital
5 discharge diagnosis of 410, which has a
6 pretty high positive predictive value, that
7 angina is not considered to be a hospital
8 discharge diagnosis that has good
9 performance characteristics. There's quite
10 a bit of variability and, in fact, it's
11 often hospital coders, not clinicians, who
12 actually assign this diagnosis. So that's
13 the first concern I have, and I think that's
14 a major concern, just to be clear. And the
15 second concern I have is this assumption
16 that patients discharged in the hospital
17 somehow should be getting procedures.

18 So I think we're trying to live
19 in an era of medical care in which we are
20 good stewards of resources and that there is
21 a general feeling, if you look at the data
22 that's come out of the folks from Dartmouth,

1 that there's wide variation in the use of
2 procedures, specifically cardiovascular
3 procedures, and that all the studies that we
4 know of to date show that increasing use of
5 procedures is not associated with better
6 outcomes in this population.

7 So I'm a little bit concerned
8 that this could tend to drive practice in
9 the wrong direction in terms of cost
10 effective care. Whereas, I understand how
11 asthma admissions clearly are a sensitive
12 indicator of perhaps poor primary care, the
13 idea that discharges from the hospital for
14 angina without an associated procedure is
15 poor quality of care or indicates poor
16 quality of care but somehow hospital
17 discharge diagnosis associated with a
18 procedure would not be counted in that way.
19 It doesn't make any sense to me. So I think
20 on those two grounds I would strongly say
21 that we do not endorse this measure.

22 CO-CHAIR GIBBONS: Dana?

1 DR. KING: Do we have a measure
2 that I've forgotten about or coming up of
3 just the number of admissions for MI as an
4 indicator of the quality of outpatient care?
5 Do we have that? Does that exist as an
6 outcome?

7 CO-CHAIR GIBBONS: The measure
8 developers can comment. At least I'm
9 unaware of that. That's one of the sort of
10 fundamental issues in our healthcare system.
11 If we do a good job, we should actually keep
12 the patient out of the hospital. That's not
13 measured. That's not measured. Did the
14 measure developers want to comment on that
15 particular issue?

16 DR. ROMANO: This is Patrick
17 Romano. I would say that there's no
18 existing measure that treats hospital
19 admission for acute myocardial infarction as
20 a bad outcome of the healthcare system. But
21 one could certainly argue for such a
22 measure, and perhaps it will be specified as

1 a measure in the future. With respect to
2 the other concern that was raised, I would
3 just comment on one point which is that the
4 diagnosis codes in hospitals are always
5 assigned by coders but they're assigned
6 based, rather strictly, on physician
7 documentation. So the underlying variation
8 that we expose is primarily a variation in
9 physician documentation. But having said
10 that, I think that the point is very well
11 taken that there has been a change in
12 physician practice, and so it is quite
13 unusual now for patients to be admitted to
14 the hospital and discharged with a diagnosis
15 of angina because usually the biomarkers are
16 available in the emergency department and a
17 specific diagnosis is established before the
18 patient is actually admitted to the
19 hospital. So there is that change in
20 practice. And we've seen more recently,
21 looking beyond the period of Saver's
22 article, a further two-thirds decrease in

1 the rate of this indicator since 1999.

2 CO-CHAIR GIBBONS: Tom?

3 DR. KOTTKE: Yes. I'd like to,
4 first of all, express my appreciation of the
5 importance and the positive intent of trying
6 to keep doctors from simply parking patients
7 in the hospital while they try to figure out
8 what to do with them. I'm concerned with
9 the shifting diagnosis because I think we're
10 all, I don't know if they do it in Montana
11 but certainly in Minnesota we are instructed
12 on coding, how to code and like don't use
13 this, use that. And so this is very
14 susceptible to shifts in coding. And like
15 Dave Magid said, I'm concerned, it's
16 probably not happening but driving doctors
17 to do procedures. I mean, it's just much
18 easier to change the code. But this is a
19 very large group of patients that are
20 admitted to the hospital, have negative
21 biomarkers, and they also contribute a large
22 proportion of post-hospital deaths in the

1 subsequent year. They're admitted because,
2 in clinical parlance they smell bad. You
3 don't know what's wrong with them. They're
4 not having an acute infarct. There's a lot
5 of these. They contribute a lot of deaths
6 in the subsequent year, so there needs to be
7 a lot of work to be done. But I don't think
8 this measure is --

9 CO-CHAIR GIBBONS: But as David
10 pointed out, though, the reliability of some
11 of the ICD codes is - I think we've
12 discussed this enough. Yes, Helen?

13 DR. BURSTIN: I just want to make
14 sure people realize this is at the
15 geographic level of analysis. It's at a
16 population level, not the hospital level,
17 not the physician level. So it's intended
18 to be a community indicator of that, so it's
19 a little different measure than we're used
20 to looking at.

21 CO-CHAIR GIBBONS: Thank you for
22 that clarification. So we're going to vote

1 on importance of the measure. It is a
2 unanimous no vote, so we have concluded this
3 measure. We're going to take a break, but
4 before we take a break the Chair needs a
5 little poll so that we're clear on how we're
6 going to proceed for scheduling the rest of
7 the day.

8 So, first, this deals with when
9 people's plane flights are. So how many
10 people anticipate that they will have to
11 leave before 3:30? Okay. And how many of
12 those will have to leave before 2:30? Okay.
13 I need to talk to you three at the break,
14 please. Okay. We will break, and we will
15 try to make it 15 minutes, please. Thank
16 you, everybody.

17 (Whereupon, the foregoing matter
18 went off the record at 10:23 a.m. and
19 resumed at 10:38 a.m.)

20 CO-CHAIR GIBBONS: So we've
21 reviewed the plane flight situation. We
22 will be tight, but I am reasonably hopeful

1 that we can achieve the goal if we move
2 through the measures reasonably
3 expeditiously and if we work through lunch,
4 so there will be a working lunch today. And
5 we will do some on-the-fly last-minute
6 adjustments if we need to. I think that the
7 discussion of the last measure demonstrated
8 that it would be helpful emphasizing the
9 importance of having a brief introductory
10 statement by the developer and that was my
11 error in not doing that the last time. So
12 for this measure, 355, I think we have some
13 AHRQ representatives on the phone. If they
14 could comment in short, three to five
15 minutes, specifically on the intent of this
16 measure, 355, the bilateral cardiac cath
17 rate.

18 MR. BOTT: This is John Bott.
19 I'll make a statement of less than one
20 minute, and if others want to jump in,
21 Patrick or Sheryl go. This is, in this
22 case, a hospital-level measure where the

1 previous one was an area-level measure. In
2 this case, we're looking at the rate of
3 bilateral cardiac cath and in those people
4 who had a cardiac cath in the hospital.
5 Again, this is using an electronic inpatient
6 claims to calculate the measure. I'll let
7 Patrick, Jeff, or Sheryl add anything they
8 think is necessary in here.

9 DR. GEPPERT: Well, this is Jeff.
10 I just wanted to point out the most recent
11 major modification to this measure, which
12 was that the measure underwent our clinical
13 panel review process and one of the
14 recommendations of the clinical panel was
15 that we add to the list of indications,
16 procedure indications. So that was
17 implemented in Version 4.0 of RQI software.

18 DR. ROMANO: And I'm sorry. This
19 is Patrick Romano. I was on mute. I would
20 just contextually sort of clarify that I
21 think this indicator is principally viewed
22 as an indicator of overuse or potentially

1 unnecessary procedure or a component of a
2 procedure when it is performed without
3 appropriate indications. So as time has
4 passed on, we have revised those indications
5 based on input from clinical experts.

6 CO-CHAIR GIBBONS: Thank you.

7 Bruce?

8 DR. KOPLAN: Okay. So this is
9 number 0355. The measure title is bilateral
10 cardiac catheterization rate, and the brief
11 description is that the developer wants to
12 look at the percent of discharges of
13 patients with heart catheterizations in any
14 procedure field who had simultaneous right
15 and left heart catheterization, so how often
16 was the right heart cath also done in
17 addition. This is an outcome measure, as
18 was mentioned.

19 So part one is importance, and
20 there's some interesting data that is
21 provided stating that there appears to be
22 high levels of use of right and left heart

1 cath and there's a significant amount of
2 regional variability. They quote some data
3 from the mid 1990s that reported between 11
4 percent and 50 percent bilateral
5 catheterization rates, and I'm ashamed to
6 say that Massachusetts had a 48-percent rate
7 of bilateral catheterization rates, and that
8 was during my fellowship training, so I
9 learned at some people's expense, I think.

10 But one thing I will mention, not
11 to date myself in any way, but getting back
12 to the point that it is interesting that
13 this data that's from the mid 1990s is
14 rather impressive and almost kind of
15 astounding, but I would wonder about more
16 recent data. It does seem as if later in
17 the submission, because we have the
18 developer on the phone I would ask them this
19 question that it seems like you report in
20 Section 2F and 2H the implication is that
21 the rates are much, much lower now, if I'm
22 reading that correctly. So is that correct

1 that I'm interpreting a less than two-
2 percent bilateral catheterization rate from
3 more recent data? Is that true?

4 DR. ROMANO: Well, partly, that's
5 a result of a general downward trend, which
6 has occurred over the last ten years, and
7 AHRQ reports data from the nationwide
8 inpatient sample on the HCAP web site that
9 can demonstrate that downward trend. But,
10 in part, that's also due to the
11 specification change that we mentioned in
12 the introduction, the inclusion of
13 additional exclusions for indication, the
14 effect of reducing the rate from what was
15 reported in those earlier studies.

16 DR. KOPLAN: Right. And I guess
17 some of this we'll talk about under the
18 scientific part, but in terms of importance,
19 because some of the earlier themes of the
20 day have been, you know, how much bang for
21 the buck do we get if something is a low
22 incidence rate, I just wanted to make sure

1 that we kind of mention that under the
2 importance section. But, nonetheless, I
3 could -- and, also, in talking with some of
4 my colleagues around the room during the
5 break, it seems like, anecdotally, that
6 people seem to notice a much lower bilateral
7 catheterization rate in their hospitals and
8 programs than the 10 to 50 percent that is
9 mentioned before.

10 But, nonetheless, despite this,
11 it's also noted in your report that the cath
12 rate - the bilateral cath rate has been used
13 as a quality indicator for Medicare data and
14 rightfully so. And despite this significant
15 downward trend that's already occurred in
16 percentages, I would still think that this
17 seems to be an important indicator.

18 CO-CHAIR GIBBONS: Other
19 comments?

20 DR. PHILIPPIDES: Was this also
21 reported at a regional level or the hospital
22 level? Because they mentioned, as AHRQ

1 mentioned before, it was regional.

2 CO-CHAIR GIBBONS: I think we
3 were told this was a hospital measure by the
4 developer at the start; is that correct?

5 DR. ROMANO: Yes, that's correct.

6 CO-CHAIR GIBBONS: All right.

7 Thank you. Other questions? Sid?

8 DR. SMITH: Yes. When we start
9 saying, I want to be careful that the
10 message we're sending is not the fewer right
11 heart catheterization you do the better you
12 are. That is, an ideal hospital would do
13 none. What I am seeing, first of all, is a
14 relatively low rate, but there can be a
15 tendency, as someone who is staffing and
16 working in a cath lab, to rush through the
17 right heart cath. The hemodynamics may not
18 be done carefully or even patients with
19 congenital heart disease or valvular heart
20 disease where the information derived from a
21 right heart cath with careful attention to
22 left ventricular hemodynamics would be very

1 important in terms of decisions about
2 surgery and management post-operatively is
3 not done or it can be done hurriedly.
4 Particularly, having worked both in the
5 academic and private community, there can be
6 a major focus on coronary anatomy to the
7 exclusion of everything else.

8 So it seems to me the ideal and,
9 you know, they say that man's reach always
10 exceeds his grasp so maybe I'm asking for
11 too much, but the ideal would not be to
12 reduce catheterization bilaterally to zero
13 but to recognize those hospitals where it is
14 done only in very appropriate circumstances,
15 that is complying with the guidelines and
16 the evidence we have where it is of value.
17 Have we done that here?

18 CO-CHAIR GIBBONS: Bruce?

19 DR. KOPLAN: Actually, your point
20 is very well made because certainly, in the
21 very beginning, the way the description is
22 is that they're just looking at the percent.

1 And so to slightly paraphrase what you said,
2 it seems as if you'd rather, you would like
3 a measure that looked at a way of looking at
4 the percentage of inappropriate or non-
5 indicated right heart cath as a measure.
6 And I think when we get to the scientific
7 part two, the way the developer develops the
8 numerator and denominator, it actually does
9 express that. So I think the title is a
10 little misleading.

11 CO-CHAIR GIBBONS: Okay. I think
12 we should vote on importance. So the vote
13 is 18 yes and 3 no. We'll move on to
14 scientific acceptability. Bruce?

15 DR. KOPLAN: Okay. So this is
16 where it gets a little bit interesting and a
17 little bit of a -- I have a few questions
18 here. So the developer, just carrying on
19 with what we were just talking about,
20 defines the numerator as discharges that
21 have coding for right and left heart cath,
22 and they exclude, it seems as if there's a

1 long list of exclusions that would exclude
2 diagnoses that would lead to an indication
3 for right heart cath. So what it seems as
4 if they're trying to do is eliminate, is to
5 only count what would be perceived as non-
6 indicated or inappropriate right heart cath.
7 So that was my take on the numerator.

8 The denominator looks at heart
9 catheterizations in any procedure field but
10 only to include cases with coronary disease.
11 And I wanted to step back and think about
12 that a little bit because should any non-
13 coronary artery disease type cases be
14 included in the denominator, I don't want to
15 be nit-picky but I just wanted to ask the
16 developer or ask the group if they felt that
17 this type of numerator and denominator
18 actually expressed what they were trying to
19 achieve. That was all. So that's as far as
20 numerator and denominator goes.

21 In terms of, it seems as if
22 reliability and validity testing have been

1 done using large databases, and I think
2 that's all I have to say about the
3 scientific aspect, if anyone has any
4 comment.

5 DR. RICH: I was just looking at
6 the disparities information in this section,
7 and it's kind of interesting we're looking
8 at it by payer. Sorry, I scroll up and down
9 it is around 2 -

10 CO-CHAIR GIBBONS: 2H?

11 DR. RICH: Is it 2H? Thanks.

12 CO-CHAIR GIBBONS: Yes, 2H.

13 DR. RICH: Okay. So what I'm
14 seeing is that you actually have less, like
15 the rate goes down for, it's highest for
16 Medicare and lower for Medicaid and lower
17 for other. I was kind of curious about
18 that. It's a little bit, to me, perhaps
19 counterintuitive but I'm not really sure,
20 but I was wondering if the developers had
21 any comment on that.

22 CO-CHAIR GIBBONS: Did the

1 developers hear that question? It's about
2 Section 2H of the application where you show
3 different rates for Medicare, Medicaid, and
4 other payers. The question is really are
5 they real and have you done anymore analysis
6 on those?

7 DR. MAGID: If they're not age
8 adjusted, you'd expect the Medicare rate to
9 be quite a bit higher.

10 CO-CHAIR GIBBONS: Okay. So I
11 guess we have a follow-up question. Are
12 they age adjusted?

13 DR. GEPPERT: No. The indicator
14 itself is not risk adjusted.

15 MS. DAVIES: But the strata that
16 are reported out --

17 DR. GEPPERT: Strata, yes, yes.

18 CO-CHAIR GIBBONS: So do the
19 difference across payers just reflect
20 difference across ages?

21 DR. GEPPERT: Probably.

22 DR. KOPLAN: And then while we

1 have the developer, the question I asked,
2 can you express why you just did CAD
3 patients in the denominator? I guess that
4 encompasses pretty much everybody, but
5 should anyone else be included in that
6 denominator?

7 MS. DAVIES: So this indicator
8 underwent a clinical panel review, as you
9 see in the documentation. And their
10 recommendation was to stay with the CAD in
11 the denominator, you know, and taking out
12 the indications that are exclusions in order
13 to really hone in on those patients for
14 which right heart catheterization is most
15 appropriate.

16 CO-CHAIR GIBBONS: Yes. And,
17 actually, after thinking about it, I thought
18 that that made sense because any non-CAD
19 patient would probably, as you've said,
20 would be excluded anyways from the
21 numerator. So I think that, I think I'm
22 okay with that.

1 DR. KOTTKE: If you reflect on
2 cath lab burden or, you know, the non-CAD is
3 such a small part that trying to figure out
4 exactly who in that non-CAD ought to be in
5 the numerator and denominator probably is
6 burdensome.

7 DR. PHILIPPIDES: Bruce, you
8 cited some data from your era when you were
9 a fellow, skewing all the numbers. But it
10 appears that in 2F there might be what I'm
11 assuming are more soft of recent numbers,
12 getting 5th, 25th, median, and then 90th
13 percentile results using, I think, the new
14 exclusion criteria. And correct me if I'm
15 wrong, is it varied between 1 percent and
16 about 2.4 percent?

17 DR. KOPLAN: Yes, that's what I
18 kind of alluded to at first is that these
19 data from the 90s are up to 50 percent but
20 more recently the rate of right heart cath,
21 my take on that is that the rate of right
22 heart cath in people undergoing left heart

1 cath is very low.

2 DR. PHILIPPIDES: Right. Now
3 that they've added the new exclusions that
4 take into account the appropriate right
5 heart caths which we think are important, it
6 seems like the discerning capability or the
7 gap is really narrowed quite a bit. So it
8 raises the question as to whether or not
9 we're going to be able to discern as much as
10 initially implied.

11 CO-CHAIR GIBBONS: Right. So
12 George has pointed this out for those who
13 don't have the numbers in front of them, 5th
14 percentile is 0.011, 95th percentile is
15 0.0246. So the 5th to 95th is a difference
16 of 0.013, in other words a 1.3 percent
17 difference in the rate of inappropriate
18 right heart caths, as stated here. Is that
19 correct, developer?

20 DR. ROMANO: That strikes me as a
21 little bit narrow, but that's approximately
22 correct. A little more recent results we've

1 been showing have a variation from about 1
2 to 4 percent from the 5th to 95th, but same
3 order of magnitude.

4 CO-CHAIR GIBBONS: And this is a
5 national number, and you don't have regional
6 variation numbers of this form? Because it
7 seemed like the older data expressed a lot
8 of regional variation, and if you showed
9 these numbers but then followed by a
10 tremendous amount of regional variation it
11 would give more weight to the issue, I
12 guess. But we don't have that.

13 DR. ROMANO: We don't have
14 regional data for the new specification.
15 Under the old specification, the most recent
16 data was 2007. It shows, you know, rates of
17 about 3 percent in the South and the Midwest
18 and about 5 to 6 percent in the West and
19 East Coast. So a doubling of the rate
20 across regions.

21 DR. KOPLAN: So is this a renewal
22 then? It appears that this is working and

1 maybe it raises the question of how much
2 more can be done with it. Just out of
3 interest, I notice that the denominator or
4 the sample comes from 4,000 hospitals, and I
5 remember, I think relatively accurately,
6 that we only had 2,200 hospitals reporting
7 on the use of ACE inhibitors. It's
8 remarkable to me that 4,000 hospitals are
9 doing right heart caths but only 2200 have
10 echos or are able to assess LV function non-
11 invasively. Is that 4,000 number correct?

12 DR. ROMANO: It refers to the
13 total database that AHRQ maintains but for
14 the state and patient databases. The actual
15 number of hospitals in the bilateral cath
16 indicator is a little over 1,900, so it's
17 comparable to the 2,200 number.

18 CO-CHAIR GIBBONS: All right. So
19 I think you've relieved Dr. Smith's anxiety.

20 DR. SMITH: Yes. I was looking
21 at 2F.1, but it sounds like that's a larger
22 sample, that the cath labs are much closer

1 to 3,000?

2 CO-CHAIR GIBBONS: 1,900.

3 DR. SMITH: 1,900. Okay, good.

4 CO-CHAIR GIBBONS: All right. I
5 think we'll vote on scientific
6 acceptability.

7 DR. RUSSO: I think this does
8 overall, though, raise the concern of
9 selecting measures that we see that we might
10 perform better on as part of that
11 possibility and that really may promote the
12 use of more composite measures. So we've
13 eliminated beta blockers because such a
14 small number were in that group, but
15 composite measures may be the way to
16 eliminate any selection bias.

17 CO-CHAIR GIBBONS: So ten
18 completely, nine partially, two minimally.
19 Let's move on to usability. Bruce?

20 DR. KOPLAN: Yes. In terms of
21 usability, the measures appear to be in use
22 in multiple state and some national

1 reporting agencies, and so it seems like
2 they've been demonstrated to be usable and
3 there do not appear to be any particularly
4 harmonization issues that I could see with
5 this measure.

6 CO-CHAIR GIBBONS: Other
7 comments? If not, let's proceed to vote on
8 usability. Fifteen completely, five
9 partially, and one not at all. And now
10 feasibility.

11 DR. KOPLAN: And, once again, the
12 data is generated from coding, which should
13 be easily obtained and should be able to be
14 obtained from electronic record sources. I
15 didn't have any major issues with the
16 feasibility part of things.

17 CO-CHAIR GIBBONS: All right.
18 And we'll vote on that now. Seventeen
19 completely, four partially. And then,
20 finally, we need to vote on endorsement of
21 this measure. Seventeen yes, three no. So
22 this measure is approved for endorsement.

1 We're going to move on now to
2 measure 133. Before we move on to this next
3 set of measures, though, we're going to hear
4 from the measure developer, the ACCF. And
5 demonstrating that he wears many different
6 hats, that's Dr. Masoudi.

7 DR. MASOUDI: Good morning. I'm
8 Fred Masoudi. I'm here as the senior
9 medical officer of the National
10 Cardiovascular Data Registry. The next four
11 measures that you're going to be looking at
12 are those that have been submitted by the
13 NCDR, which is a joint effort of the ACC
14 Foundation and the SCAI. The registry
15 itself collects data on patients undergoing
16 catheterization and percutaneous coronary
17 intervention in approximately 1,100
18 hospitals, which represents about 70 percent
19 of the hospitals that perform PCI. It
20 includes about 80 percent of patients who
21 get PCI nationwide. I won't go through the
22 importance of PCI other than to say it's

1 probably one of the most widely performed
2 invasive procedures in patients with cardiac
3 disease and is associated with substantial
4 expense.

5 The three measures that you will
6 look at, one is an outcomes measure that has
7 already been endorsed and so is up for
8 reassessment. It is a risk-adjusted
9 mortality model. And I'm joined by Matt Roe
10 who is one of the developers at DCRI on the
11 phone, as well as ACC staff, to discuss
12 that, as needed. There are also three
13 process measures that you will look at, one
14 of which is clopidogrel at discharge, one of
15 which is aspirin at discharge, and the third
16 of which is statins at discharge. I would
17 say a few things about these. First of all,
18 these are harmonized in terms of their
19 specifications with the existing CMS
20 measures that look at patients with acute
21 myocardial infarction. This is a different
22 denominator of patients. These are all

1 patients who undergo PCI, only about 30
2 percent of which have acute coronary
3 syndrome. The remaining 70 percent are
4 receiving PCI for elective reasons.

5 As you'll notice, the performance
6 data for the clopidogrel and aspirin are
7 high. You know, you've had prior
8 discussions about some of the other
9 measures. The statin performance is
10 markedly more variable. A couple of issues
11 about this. One is that, again, although
12 this data is collected from the majority of
13 hospitals that perform PCI, because this is
14 a voluntary registry, this isn't necessarily
15 nationally representative. As Dr. Smith
16 pointed out, performance typically tends to
17 be lower in sites that don't voluntarily
18 participate in quality programs like
19 registries.

20 The other issue is one that we
21 can get back to later, which is this issue
22 of the extent to which measures that aren't

1 endorsed can be included in composites, as
2 the ultimate goal of the measurement program
3 is to generate a composite measure for the
4 use in public reporting. So that will
5 become relevant later on, as well, on during
6 these discussions. Thank you.

7 CO-CHAIR GIBBONS: Thank you,
8 Fred. So the primary reviewer of measure
9 133, PCI mortality, is Sid Smith.

10 DR. SMITH: Thank you. And I
11 think you've heard a good description. This
12 is a renewal of a program underway which has
13 been very productive. The risk-adjusted PCI
14 mortality is an outcome measure, and I think
15 you've also heard this is a very frequently
16 performed procedure which can have a major
17 impact on patients' lives to the better if
18 it's done well and very detrimentally when
19 complicated by death. It's very expensive,
20 and so some information and knowledge about
21 how our centers are performing and how we
22 can do better is really very important.

1 It's a frequently performed procedure.

2 The mortality that we're talking
3 about here involves all PCI procedures
4 performed clinically, that is both for acute
5 coronary syndromes and for chronic coronary
6 disease. So it's not separating out there.
7 And I think it's been underway. It has been
8 very productive. There's some really nice
9 publications from the existing registry, one
10 that involved over half a million patients
11 in JACC recently, Journal of the American
12 College of Cardiology.

13 I have some thoughts about the
14 science which would help me in terms of
15 reassurance. But I think this is a very
16 worthy program, so I guess we need to vote
17 on the importance of it.

18 CO-CHAIR GIBBONS: Are there
19 other questions or comments before we vote
20 on importance? All right. Let's go ahead
21 and vote on importance. Okay. The vote is
22 unanimous, 21 yeses. Sid, scientific

1 acceptability?

2 DR. SMITH: Okay. The science
3 here and some of my concerns may just be the
4 problems that are inherent in all
5 registries, but it's the exclusion criteria.
6 I guess the first thing is are all patients
7 reported consecutively, or is it only those
8 patients that the operator sits down and
9 fills out a report or the hospital reports
10 him? Is there a way to be reassured that
11 those hospitals participating in the
12 registry are actually reporting all
13 patients? If they aren't, then it's highly
14 possible that patients where there are major
15 complications, who die, might not be
16 reported, and that could give us an
17 underestimation of the true percentage of
18 mortality. So are consecutive patients
19 reported? Is that a requirement of the
20 registry?

21 And the second thing that
22 concerned me a little bit was that the data

1 submissions that don't pass a data quality
2 and completeness assessment are apparently
3 excluded. So, again, a sloppy report
4 doesn't enter into the assessment, and it
5 would seem that eliminating sloppiness is
6 one of the things we want to do here. So we
7 need to know about the data as a whole, so
8 I'm a little concerned about the effect that
9 excluding reports because of completeness
10 might also aim the - or bias the mortality
11 to be lower than it actually could be.

12 CO-CHAIR GIBBONS: Okay. We'll
13 refer both of those questions to --

14 DR. SMITH: And then there's a
15 third one.

16 CO-CHAIR GIBBONS: Oh, sorry.

17 DR. SMITH: The third one is
18 that, and I've sort of come up with this in
19 other registries, but it's a decision to
20 exclude patients from this consideration if
21 they have more than one angioplasty with an
22 admission. What bothers me there is that a

1 patient who comes in who may have had a
2 stent delivered inappropriately goes back
3 for an operation or for a procedure that's
4 related to poor performance of the first
5 and, because of that, is excluded and dies,
6 so there's no way to really, you lose that
7 population of patients. Do you understand
8 what I'm saying? Okay. So those are the
9 three things.

10 CO-CHAIR GIBBONS: Three
11 questions. Okay.

12 DR. SMITH: Consecutive data, the
13 exclusion of improperly filled out reports,
14 and the idea of how we handle those patients
15 who may have been taken back for a second
16 procedure that was actually an urgent
17 procedure related to a poorly performed
18 first procedure.

19 CO-CHAIR GIBBONS: George?

20 DR. PHILIPPIDES: The people who
21 get involved in registries might have
22 addressed this, but the idea that patients

1 that are transferred to another facility are
2 also excluded. It seems to me, oftentimes,
3 the sickest of the sick or the people that
4 aren't doing well for reasons that are not
5 always captured in these kind of registries
6 get sent out to, it feels like to my
7 hospital when I'm on call. Yet, when they
8 come -- sorry. Mark will take it up from
9 here. All kidding side, and then when they
10 come to us, there's no place else to send
11 them, so those patients stay with us and the
12 mortality becomes part of --

13 DR. SMITH: Yes, you get hit with
14 the mortality.

15 DR. PHILIPPIDES: In this
16 measure, but there are some other measures
17 where they don't take out the transfer
18 issue. So I just wanted to raise that, as
19 well, that the high-risk patients are being
20 sent out.

21 CO-CHAIR GIBBONS: All right. I
22 think we now have four questions for the

1 developers.

2 MS. FITZGERALD: Okay. So the
3 first question is --

4 CO-CHAIR GIBBONS: Please
5 identify yourself.

6 MS. FITZGERALD: I'm Susan
7 Fitzgerald. I'm one of the staff at ACC.
8 Sorry. By contract, hospitals are supposed
9 to submit all records. Now, that's by
10 contract. We police that with our audit
11 just to verify the count of records by a
12 cath lab log or some other independent one.
13 We've tried to do that other ways. It's
14 been logistically difficult, but we do it
15 with an audit. Last year, we audited 25
16 sites, and that's part of the audit. That's
17 the first thing.

18 I don't know if Tony is on the
19 phone, but our data quality program, it's in
20 the very high 90s the percentage of
21 hospitals that submit data that pass the
22 data quality thresholds and are included and

1 get risk adjustment. Many of the hospitals,
2 almost all of them, are in some form of pay-
3 for-performance program, so to get their
4 reports is important to them. If they're
5 not included, we're not going to send their
6 data to, we call them our analytic research
7 service clients. So that's number two.

8 Second PCI, it might be
9 misleading. I don't know if Dr. Roe wants
10 to speak to it, but what we do is we look at
11 there are variables during the PCI that are
12 looked at. So the second PCI, the patient
13 is not excluded, but the procedure is. So
14 we're looking at a patient admission or a
15 patient record not a procedure. So what
16 we're saying is that we're looking at
17 variables in the first procedure within the
18 model but not in the second procedure, so
19 the variables in the second are excluded.

20 And then the patients that are
21 transferred to other hospitals are excluded
22 because we don't know if they lived or died,

1 and we know they probably were sick and
2 something else was happening, so they are
3 excluded in the model.

4 DR. ROE: This is Matt Roe from
5 the Duke Clinical Research Institute, just
6 to follow up on the comment that Susan made.
7 The model is focusing on the first PCI done
8 for a patient during a given
9 hospitalization, and I think there's a good
10 point made before that if that procedure is
11 performed inappropriately or there are
12 problems and the patient had the second
13 procedure and the model may not be
14 accounting for that. In some sense, that's
15 correct, but the patient's hospitalization
16 will still count in the mortality. If that
17 patients dies, it will still count. But
18 it's really hard. You can't re-frame the
19 model on a second procedure after you have
20 already done it on the first procedure. I
21 think that becomes very difficult, and it's
22 also an infrequent phenomenon within the

1 registry. So it would be hard to even
2 develop a model that could do such an aspect
3 there.

4 And then the transfer out part, I
5 think recognized this is an inpatient
6 mortality model, so if a hospital actually
7 does PCI and then transfers a patient out to
8 another center you cannot capture what
9 happens to them after transfer, so we don't
10 know whether they lived or died. So they
11 have to, by nature, be excluded. But we
12 recognize that that's a very infrequent
13 phenomenon as well because when a patient
14 gets transferred out after a PCI it may
15 typically only be for a patient who needs
16 urgent surgery at a center, for example,
17 where the PCI center is doing PCI without
18 on-site CABG facilities. So, again, I think
19 those scenarios are pretty unlikely but
20 difficult to really overcome them with the
21 way the database is structured and the way
22 the model was developed.

1 DR. SMITH: So I'm happy with the
2 explanations. I think the area that, how we
3 handle selective reporting or poor reporting
4 of events would be something to go after in
5 terms of the registry. Those hospitals that
6 have poorly completed reports should be
7 audited in some way in an effort to be sure
8 that all reports are entered and entered
9 correctly. But, again, I think the handling
10 of the transfer out is appropriate. And
11 from the earlier comments, I think they are
12 handling -- the first procedure does get
13 entered, and if the patient comes back
14 because of a complication it's reflected on
15 the first procedure. So my concerns there
16 are handled well, I think.

17 Now, I just, again, have to say
18 that the database here is robust and the
19 observations have provided very important
20 information about PCI. One thing I did not
21 mention in my introduction was there still
22 is a gap in terms of mortality after PCI if

1 you look at it among the different
2 hospitals, and this database allows
3 hospitals a comparable volume to compare
4 themselves against each other and also
5 against a national baseline. So, overall, I
6 think that this project has been very
7 valuable. But I think that there are miles
8 to go before we sleep --

9 CO-CHAIR GIBBONS: Okay. So we
10 need to move on. We're falling behind
11 schedule now. We've got to speed up a
12 little bit. Scientific acceptability?
13 Okay. Completely 13, partially 7. We'll
14 move on now to usability.

15 DR. SMITH: Well, I think however
16 it's said, *res ipsa loquitur*, it speaks for
17 itself. This thing has been used very well
18 by many hospitals, so I think it's
19 demonstrated that it can be done and it can
20 be done with very large enrollment. The
21 major issues that hospitals face is, I
22 think, how to get their data, who's going to

1 enter the data, but it appears that that's
2 been done well here.

3 CO-CHAIR GIBBONS: Okay. Any
4 other comments or questions?

5 DR. SANZ: I'd just like to point
6 out that the usability is based on the
7 accuracy of the data, which I know is self
8 evident. But if you have an institution
9 with an outpatient cath lab and one of the
10 exclusions is transfer to another facility,
11 you will easily have, I shouldn't say easily
12 but almost easily have a zero mortality by
13 transferring a patient who has a
14 complication with CPR to the local nearest
15 bypass surgery facility. And this is an
16 issue, and I think it also comes into some
17 of these other measures where you have an
18 exclusion with something that occurs very
19 infrequently but transfers the mortality to
20 another institution. And I don't agree that
21 you can't find that data. It's a simple
22 phone call to another institution. You know

1 where they got transferred.

2 CO-CHAIR GIBBONS: Dr. Masoudi?

3 DR. MASOUDI: Just to speak to
4 that, so you wouldn't have a zero mortality
5 if you don't submit any patients to the
6 registry. It's only the patients you
7 submit. So a site that does not participate
8 that's an outpatient site, which generally
9 wouldn't be submitted to the registry anyway
10 because it's an outpatient site, simply is
11 not captured in this data. And you could
12 say it is true that this doesn't capture
13 data on outpatient cath labs, but it does
14 capture data on a large number of hospitals
15 and is useful for hospital reporting. But
16 just to clarify, a transfer out is excluded,
17 so that would not count towards your
18 denominator, for which you would have a zero
19 in the numerator. Those patients are simply
20 excluded.

21 CO-CHAIR GIBBONS: David?

22 DR. MAGID: So I think Sid

1 brought this up as an issue. I think it is
2 a little bit of an issue, probably not a lot
3 of an issue, in the sense that institutions
4 that don't have complete capabilities may
5 transfer out patients for CABG or for other
6 major procedures. And, you know, Matt, this
7 is a suggestion and you might consider
8 looking at within the data set at the sites
9 that don't transfer out and the
10 characteristics of those people that
11 transfer. You could probably build a
12 propensity model that imputed mortality on
13 those transfer people and run the analysis
14 both the way you're doing it now and
15 estimating mortality in those transferred
16 out for the institutions that do it with
17 some regularity just to see if there are any
18 difference. So just a suggestion.

19 DR. ROE: That's a great
20 suggestion, and we'll certainly take that
21 under advisement. Again, I don't have data
22 in front of me right now, but I think the

1 transfer out rate is pretty small, but I
2 think in centers that do it more frequently
3 it's a good idea to see how that comes out.

4 DR. STEARNS: My concern would be
5 that for consumers looking at these numbers,
6 if the patients that are getting transferred
7 out, if the mortality is not included,
8 aren't we giving them a false sense of
9 security if they're looking at these
10 numbers?

11 DR. MASOUDI: You know, again,
12 the transfer out percentages are quite
13 small. And, generally, the bottom line is
14 that you really cannot reliably identify
15 them, and part of this has to do with a lack
16 of a national patient identifier. There's
17 no reliable way to identify what happens to
18 a patient after they've been transferred.
19 You could say it's just a phone call. The
20 fact of the matter is if there's anything
21 that could be gamed it would be that. So
22 because you can't reliably identify what

1 happens to a patient after their
2 transferred, they can't be eligible for
3 inclusion in the measure. And this may
4 affect a small number of centers. That is
5 correct. But the overall, the proportion of
6 transfers as a group of the entire data set
7 is quite small. We have the numbers, 0.7
8 percent.

9 CO-CHAIR GIBBONS: Okay. We have
10 to move ahead. We're going to vote on
11 usability. Eight completely, twelve
12 partially. All right. Now we have to move
13 ahead to feasibility.

14 DR. SMITH: I think some of my
15 comments on feasibility I made in the
16 usability. The data are available. They
17 are retrievable. The major limitation is
18 being sure that someone enters it
19 accurately, and I think the size of this
20 registry, if I'm not incorrect, looking at
21 the JACC article now, over 500,000 patients
22 suggests that it is doable by a number of

1 hospitals. So I would say it appears to be
2 quite feasible.

3 CO-CHAIR GIBBONS: All right.
4 We're going to vote on feasibility. Twenty-
5 one completely, a unanimous vote. All
6 right. We'll move ahead and vote on
7 endorsement. Okay. A unanimous vote in
8 favor of endorsement.

9 We're going to move on to 1495,
10 but I would point out that for the next
11 three we really have to keep to schedule.
12 If at all possible, 15 minutes each because
13 the more we fall behind the less time we
14 will have for the rehab measures before our
15 reviewers leave. So Mark?

16 DR. MAGID: Can I just ask one
17 question? And I'll be quick. Dr. Masoudi
18 brought up this issue that they're looking
19 to put these measures into a composite and
20 that some of them may have high rates but
21 that if NQF, if we don't endorse each of
22 them separately it's hard to make them into

1 a composite. Is that correct?

2 DR. BURSTIN: They have to each
3 be evaluated for endorsement. You can make
4 the argument that a non-endorsed measure
5 should be part of a composite for balance or
6 something like that, but it has to be
7 evaluated but not necessarily endorsed.

8 DR. MASOUDI: So would that
9 evaluation occur here then?

10 DR. BURSTIN: Yes, right.
11 Exactly. But they could still be in the
12 composite if you can make the argument they
13 should live in a composite, even if they
14 wouldn't be stand-alones.

15 DR. MAGID: And after we are done
16 if we say, well, we like these individually
17 but they have high rates, we'd rather see
18 them in a composite, we can say that at the
19 end or --

20 MS. PACE: Right. But one thing
21 to keep in mind, I think part of what you
22 saw in that composite that we talked about

1 earlier with the CMS, besides the missing
2 and imputation issues, part of that lack of
3 variability was because all those component
4 measures had high rates. So, you know, do
5 you accomplish anything is another question.

6 CO-CHAIR GIBBONS: We must move
7 on. We must move on. I'm sorry. The Chair
8 has got to start getting tough here, or
9 we're not going to get done. Mark, you're
10 on.

11 DR. SANZ: Okay. Measure 1495 is
12 Plavix post PCI at the time of discharge.
13 This is like one of those ten commandments.
14 It's just something that every
15 interventional cardiologist knows and does.
16 I will quote 1C14, which is this guideline
17 is the most widely-recognized professional
18 guideline in the U.S. for cardiovascular
19 medicine in the area of PCI care, so
20 importance is not in doubt.

21 I will say I believe that this
22 should be a composite score with the next

1 one, and much of the comments I'm going to
2 make relate to both. I understand -- side
3 discussion with Fred that we have to somehow
4 vote on these separately, but, in the end,
5 they should be combined because nobody
6 should go home in the United States off of
7 both aspirin and a P2Y12 inhibitor. So in
8 my opinion, it does not make sense to look
9 at them as independent, but if we have to do
10 that to get them together that's fine.

11 All I'll say is a lot of the data
12 that's quoted really doesn't pertain to PCI.
13 It doesn't change the value of the measure,
14 but there's a lot of stuff in here about
15 unstable angina, STEMI, et cetera, which has
16 little to do with this measure, and it's
17 repeated over and over. But the measure
18 itself stands.

19 CO-CHAIR GIBBONS: Other comments
20 vis-a-vis importance? Dana?

21 DR. SANZ: Is this where we talk
22 about the gap, the performance gap?

1 CO-CHAIR GIBBONS: Yes.

2 DR. SANZ: Well, I'll just say
3 the performance gap is extremely low, but I
4 was going to talk a little bit about that
5 under the next one. I will say that this
6 concept that exclusions are not a problem, I
7 disagree with. The gap here is trivial, 98
8 percent or so, and everybody is about the
9 same. Of that, I would estimate personally,
10 based on my institution and the local area,
11 half or more is administrative miss. When
12 you go back and look at each patient, they
13 actually went home on it; it just didn't get
14 documented appropriately.

15 Finally, to say that transfer to
16 other hospitals isn't important, I did.
17 Thanks, Tom. Back of the napkin
18 calculation. If 0.5 percent of the one
19 million PCI are excluded, which is what is
20 in the data of the Plavix one, 0.57 I
21 believe it was, which was the second largest
22 exclusion, and half of those will get

1 subacute thrombosis, that's a pretty big
2 number. You end up with about 1,500 deaths
3 or infarcts. So I think that these
4 exclusions, while small, if you look at the
5 benefit to be gained, which is only one
6 percent, if you keep measuring this, it's
7 about the same.

8 So this may be one of those
9 things where the performance gap gets low
10 and then why not just get rid of the
11 exclusions. Obviously, death has to remain.
12 If you're doing this and the patient ends up
13 in hospice, there are some issues as to what
14 you're doing. Maybe you didn't know they
15 were going to go to hospice, but I question
16 that all of those are appropriate. Maybe
17 it's because of what you did that they ended
18 up in hospice.

19 CO-CHAIR GIBBONS: Developer?
20 Dr. Masoudi?

21 DR. MASOUDI: Yes. Just in terms
22 of these exclusions, again, the attempt here

1 was to harmonize these measures to the
2 extent possible with existing CMS measures,
3 which use these very selfsame exclusions.
4 And so in order to minimize burden on
5 practitioners, these are specified
6 identically to the CMS measures. I guess
7 the argument that was made about, you know,
8 a 0.5 percent miss in exclusions could have
9 this immense impact is more of an argument
10 to accept this measure even though
11 performance rates are high because even
12 marginal increases then in improvement would
13 lead to substantial improvement in health
14 outcomes.

15 But I think the key factor is in
16 terms of the exclusions these are completely
17 concordant with those that are used for CMS
18 for all of its inpatient measures. That was
19 done intentionally as a means of trying to
20 reduce provider burden.

21 CO-CHAIR GIBBONS: Okay. We need
22 to vote on importance. Okay. Unanimous

1 vote in favor of importance. Let's move on
2 to scientific acceptability.

3 DR. SANZ: I have one concern
4 under 2A.3, which I suspect is only an
5 English problem, but it says that it should
6 not be there if PCI is attempted. Frankly,
7 if PCI is done and there's no stent placed,
8 you don't need Plavix. So this should be
9 with a successful stent implantation and
10 remove angioplasty itself. I think it's
11 just an English language thing that needs to
12 be changed because right now we're going to
13 include angioplasty without a stent. Does
14 that make sense?

15 Under 2A.4, it's actually stated
16 correctly. I'll just stop there. I think
17 that, otherwise, it's very good.

18 CO-CHAIR GIBBONS: So does the
19 developer accept that correction?

20 DR. MASOUDI: Yes, that's
21 intended that way. We accept the
22 correction. I'll put it that way.

1 CO-CHAIR GIBBONS: Thank you.

2 All right. Any other comments or questions?

3 So our vote is in light of that correction,

4 accepting that correction. Nineteen

5 completely, two partially. Moving on to

6 usability, Mark.

7 DR. SANZ: It's being used, well,

8 certainly everywhere the NCDR is, which is

9 most places, and used well. Harmonization,

10 there is another measure for drug-eluting

11 stents separately, which I don't really

12 understand. I don't think it necessarily

13 came from ACC, but that needs to be

14 harmonized. There's no reason to have both

15 of these. And then the issue of dual

16 antiplatelet therapy, there really should be

17 one measure which somehow we need to vote on

18 later.

19 CO-CHAIR GIBBONS: Okay.

20 Additional discussion on usability? All

21 right. Let's go ahead and vote on

22 usability.

1 Seventeen completely, four
2 partially. Now feasibility.

3 DR. SANZ: I don't have a whole
4 lot to say here. I do think it's feasible
5 to make a phone call regarding what happened
6 to a patient transferred out. The N is
7 small. The number of those that are going
8 to have a major event is high, so that's it.
9 Otherwise, it's already being done.

10 CO-CHAIR GIBBONS: Okay. Let's
11 go ahead and vote on feasibility.

12 Seventeen completely, four
13 partially. And then, finally, let's vote on
14 does this measure meet criteria for
15 endorsement.

16 All right. So that's a unanimous
17 vote for endorsement.

18 We'll now move on to 1493,
19 aspirin at discharge for PCI. Mark, you've
20 already indicated you think the whole
21 construct here is very similar.

22 DR. SANZ: It's nearly identical.

1 You change the drug, but as far as any -- I
2 didn't see anything specific --

3 CO-CHAIR GIBBONS: David is about
4 to weigh in with his usual motion.

5 DR. MAGID: Yes, I think dual
6 antiplatelet therapy is noncontroversial,
7 and I think I would suggest that we consider
8 the same vote for clopidogrel that we did
9 for aspirin.

10 DR. SANZ: And I want the record
11 for the quickest.

12 CO-CHAIR GIBBONS: Does the
13 developer see any difference in this measure
14 versus the clopidogrel measure?

15 DR. MASOUDI: No. I think you
16 could do a find and replace with aspirin and
17 clopidogrel essentially. Again, the
18 contraindications to aspirin may be somewhat
19 different from those of clopidogrel because
20 it would be an aspirin allergy and not a
21 clopidogrel allergy. But, essentially,
22 there's no difference.

1 CO-CHAIR GIBBONS: Okay. Are
2 there any objections to simply duplicating
3 our vote on this aspirin measure to be the
4 same as we just voted on for clopidogrel?

5 DR. KOPLAN: So just to clarify,
6 this is with the stipulation that it's
7 intended --

8 CO-CHAIR GIBBONS: Well, we're
9 going to have another vote on that issue.
10 This is just to say for this measure,
11 aspirin after PCI, we're going to vote the
12 same as we just voted for clopidogrel. Is
13 there anyone who objects to that? Okay. So
14 Mark will get the record for the fastest
15 turnaround.

16 So now I would propose that we
17 have a separate vote, and that vote is to
18 encourage the developer to combine these two
19 as being aspirin and clopidogrel, i.e. dual
20 antiplatelet therapy. And how do we vote on
21 this? By hand I guess. All in favor of
22 that? Opposed? All right. So I think we

1 will convey to the developer our formal
2 suggestion that those two be combined.

3 All right. Now before lunch we
4 need to do 1498, statins at discharge.
5 Dana, you're the barrier from lunch. Don't
6 feel any pressure.

7 DR. KING: The importance of this
8 is not widely debated. Statin therapy
9 reduces the risk of coronary events and
10 coronary artery disease following PCI. This
11 measure will encourage improvement in the
12 rates of statin prescribing. Unlike some of
13 the other measures we've discussed this
14 morning, there is a performance gap. The
15 prescribing rate actually from the 5th to
16 the 98th percentile was from 72 to 98
17 percent. So there are people achieving the
18 98 percent rate, but there are a significant
19 number of hospitals that are down at --
20 below that, and half of hospitals do not --
21 have over 10 percent of people discharged
22 not on a statin.

1 Interestingly, they did do some
2 stratified analysis, and the lower SES
3 hospitals did as well or better than the big
4 cats. So I just thought it was worth
5 mentioning. So I guess I would not argue
6 with importance of this measure, and there
7 does appear to be a performance gap.

8 CO-CHAIR GIBBONS: Any comments
9 or questions regarding importance? All
10 right. Let's go ahead and vote on
11 importance.

12 DR. KING: Okay. The scientific
13 acceptability measure, the specifications
14 are well done. It has the same reliability
15 and validity as the ones we were talking
16 about with Plavix and aspirin. It's taken
17 from a registry, not from a total population
18 thing. But, otherwise, it has the same
19 reliability and validity as that registry,
20 which was, as we heard, fairly complete and
21 pretty reasonable.

22 As I mentioned, there was some

1 stratification being done, and I think it
2 might be important to continue hearing about
3 that since getting from the 72 to 98 might
4 involve addressing some socioeconomic
5 things, although right now it doesn't appear
6 that they're different. And they did not do
7 anything with other disparities besides SES,
8 but I think the scientific acceptability is
9 there.

10 DR. RUSSO: I have just a
11 question. So on the exclusions for -- so
12 I'm trying to figure out why there's such
13 wide variability in that. Is it possible
14 that some of the patients were -- it says
15 contraindicated as obviously excluded, so an
16 allergy. How about is patient refusal -- is
17 that an acceptable -- or if they're placed
18 on another agent for cost -- or is there
19 some, I guess there's generic. Should there
20 be any more -- is there any other way to
21 figure out why there's such a difference
22 across the country? It's not related to SES

1 so I guess it's not cost. Are there any
2 other exclusions we're missing? Maybe not.

3 CO-CHAIR GIBBONS: Does the
4 developer want to comment on that?

5 DR. MASOUDI: So basically
6 there's a contraindication to statins
7 regardless -- again, it's aligned with the
8 CMS measure criteria where if there's a
9 contraindicated noted that patient is
10 excluded from the measure, unless the
11 medication is given.

12 DR. SNOW: Is that the only
13 exclusion? What about patients who opt for
14 a different lipid-lowering agent? I mean,
15 statins are wonderful and all but --

16 DR. MASOUDI: If the provider --
17 I think that happens in, I would imagine, a
18 vanishingly small group of patients who
19 didn't have an intolerance to a statin. But
20 even if it did, if the provider didn't
21 indicate that there was a contraindication
22 to therapy, they would be indicated as

1 having failed. Again, I think that that is
2 going to be extremely unlikely, but it's
3 hard to know how many of those
4 contraindications represent a situation
5 where a patient who is tolerant to a statin
6 has requested that their doctor not treat
7 them with a statin.

8 CO-CHAIR GIBBONS: Any other
9 comments or concerns about this? All right.
10 Let's vote on scientific acceptability.
11 Eighteen completely, three partially. We'll
12 move on to usability. Dana?

13 DR. KING: Okay. This is
14 currently in use and has been voluntarily
15 reporting this measure. Participating
16 institutions receive an institution outcomes
17 report each quarter with their hospital's
18 results.

19 CO-CHAIR GIBBONS: Any issues
20 about usability? Okay. Let's go ahead and
21 vote. Twenty completely, one partially.
22 And now feasibility.

1 DR. KING: It's obviously
2 feasible. It's being done. It's in use.
3 The electronic sources are used, and even
4 the survey is submitted electronically.
5 They identified several paragraphs of their
6 efforts to reduce inaccuracies and follow up
7 on the process, and I think it was
8 reasonable.

9 CO-CHAIR GIBBONS: Okay. We'll
10 go ahead and vote on feasibility. One
11 clicker isn't working. We have 20 votes
12 saying completely.

13 All right. We'll move on now to
14 the final vote. Does the measure meet
15 criteria for endorsement? Unanimous
16 support, 21 yeses. Okay. We're going to
17 break for lunch, but we're going to have a
18 working lunch, so I'd ask everybody to try
19 to just grab lunch and get back in here, and
20 we will restart on the next set of measures.
21 Thank you to Dana and Mark for putting us
22 back on time.

1 (Whereupon, the above-entitled
2 matter went off the record at 11:47 a.m. and
3 resumed at 12:02 p.m.)

4 CO-CHAIR GIBBONS: So this is a
5 different block of measures and requires
6 everybody to sort of, I think, listen
7 carefully and adopt a somewhat different
8 mind set as we approach these. So for that
9 reason, they were originally allocated more
10 time in the schedule, and we, hopefully, by
11 getting back on time, will permit adequate
12 discussion of these.

13 So we're going to open up by
14 asking the measure developers to concisely,
15 in three to five minutes, give us the intent
16 of this block of measures.

17 DR. MARJORIE KING: Hello, I'm
18 Marjorie King from AACVPR and the AHA/ACC
19 AACVPR writing group for this measure. This
20 group of measures was written when the
21 referral to cardiac rehab measures were
22 written and published back in 2007 to

1 accompany the measures. Those referral
2 measures are NQF endorsed. These measures
3 were written to set safety and performance
4 standards for cardiac rehabilitation
5 programs so that if we hold doctors to
6 referral to cardiac rehab we want to hold
7 programs to a minimum standard of quality.

8 In order to write these measures,
9 we reviewed about more than 30 potential
10 measures that would be appropriate. Not
11 surprisingly, we ended up choosing measures
12 that are very similar to the measures used
13 in the AACVPR program certification process,
14 and that's because the measures that we
15 chose are based on the core components of
16 cardiac rehabilitation and also on ACC and
17 AHA guidelines.

18 You need to know about the AACVPR
19 certification process because we used that
20 process for some of our testing. First of
21 all, it's been in existence since the late
22 '90s. It has been an evolving process. It

1 is linked to standards. It is an all-or-
2 none phenomenon. You either pass
3 certification, or you do not pass
4 certification, and you need to meet all of
5 the specifications in order to be AACVPR
6 certified. It was developed as a mentoring
7 process, not as a pay for performance or
8 anything like that process. And so when
9 programs apply for AACVPR certification they
10 have already attended seminars, had
11 mentoring from their affiliates, and they
12 don't apply unless they think they're going
13 to pass. They wait until the next cycle,
14 and they get all their ducks in a row.

15 The denial level is very low for
16 AACVPR certification. It's about two
17 percent. And when we looked at the denials
18 for the last three years, the reasons for
19 denials were across all four of the
20 measures. They're very low numbers. We
21 didn't put them in the application because
22 they were such low numbers. But, again, you

1 have to understand the data that we had to
2 analyze. Unfortunately, we do not know
3 anything about the programs that are not
4 AACVPR certified, which is probably at least
5 50 percent of the programs in the country.
6 So we don't know what we don't know, and we
7 don't know how to get about knowing the
8 characteristics of those programs. Our
9 measure testing, as I said, is very similar
10 across all four measures because it used the
11 AACVPR certification process for the inter-
12 rater reliability testing, for example, and
13 for the other testing.

14 We also ask ourselves the
15 question, well, is there a relationship of
16 AACVPR certification to what we're really
17 trying to drive, which is improved patient
18 outcomes using these processes that are
19 stated in the measures. And so there is a
20 large registry in Wisconsin with the
21 Wisconsin cardiac rehab affiliate plus the
22 Wisconsin Department of Health. We looked

1 at that data asking the question do
2 certified programs have better patient
3 outcomes compared to non-certified --
4 programs who are not AACVPR certified. That
5 is in the appendix that is probably labeled
6 Report to the Board of Directors of AACVPR,
7 and we found that there were significant
8 differences in body mass index, number of
9 exercising days outside of cardiac rehab,
10 HDL/triglycerides, waist circumference, and
11 diastolic blood pressure in those patients
12 who were in AACVPR certified programs
13 compared to those who are not.

14 So that's kind of the overview of
15 the rationale for these measures and the
16 testing that we did to submit with these
17 measures. I probably have a couple of
18 colleagues on the phone, as well, from
19 AACVPR. They probably should introduce
20 themselves.

21 CO-CHAIR GIBBONS: All right. If
22 there are additional representatives on the

1 phone from AACVPR, could they please
2 introduce themselves?

3 DR. MARJORIE KING: They should
4 be joining. There were two numbers that
5 were circulated.

6 CO-CHAIR GIBBONS: Well, we are
7 actually eight minutes ahead of time, so
8 they may be not on the call yet and we may
9 hear them come on. So we're going to move
10 ahead with the first measure, 1496, safety
11 standards. Leslie?

12 DR. CHO: So this is measure
13 1496. It's looking at cardiac
14 rehabilitation program structure base
15 measurement set of safety standards. And,
16 basically, what it's talking about is that
17 there needs to be a medical director
18 present, emergency response team, minimal of
19 BLS and ACLS training by one personnel, and
20 a functional emergency resuscitation
21 equipment.

22 I think the importance is self

1 evident. Patients are getting older.
2 They're at higher risk. They have more
3 comorbidities and medical supervision is
4 crucial for good cardiac rehabilitation.
5 About one arrest occurs in every 100,000
6 patient hours, so definitely safety nets are
7 needed.

8 I mean, I think importance for
9 that, and we can talk about scientific
10 acceptability and whatnot later, but I think
11 the importance is kind of self evident.

12 CO-CHAIR GIBBONS: Questions or
13 comments about importance? Yes?

14 DR. JEWELL: So I think this is
15 going to apply to all three -- all of the
16 measures under this category. Dr. King made
17 an important point that the information in
18 the application, actually, under gap in care
19 actually looks at gross rates of achievement
20 in the certification program and a need for
21 remediation before approval. It doesn't
22 link to any of the specific measures that

1 are in here. So in other words, we don't
2 know if the programs were denied or had
3 trouble getting through the process based on
4 these measures. That being said, I think
5 the significance of all of these in terms of
6 safety and efficacy of programs I think is
7 probably the more salient importance
8 feature, even though, typically, we're
9 looking for a gap in care.

10 CO-CHAIR GIBBONS: All right.

11 Other comments? I think we'll go ahead and
12 vote on importance. All right. So 20 yes,
13 one no. We'll move on to scientific
14 acceptability.

15 DR. CHO: Right. So the
16 scientific acceptability, I think all of us,
17 I think, are aware that all these safety
18 standard has to be in place for a good
19 cardiac rehab program. My only concern, and
20 maybe the representative can speak to this,
21 is there's a growing trend for non-
22 traditional cardiac rehabilitation, number

1 one; and that there's going to be also CMS
2 funding for something called intensive
3 cardiac rehab. And my greatest fear is is
4 that those programs will have patients who
5 are high risk enroll in them, and there will
6 be no safety standards. And currently,
7 because only 40 percent of the cardiac
8 rehabilitation programs in the U.S. are
9 certified, there's no real way to measure,
10 as we've all alluded to. I think things
11 like this have to be in place so that when
12 home rehabilitation, non-traditional
13 rehabilitation, and those intensive cardiac
14 rehab/Dean Ornish kind of place -- things go
15 into effect they still adopt a safety
16 standard.

17 Just one comment. In your packet
18 of all this scientific acceptability, you
19 had listed for non-traditional CR that
20 medical director will create a program for
21 safety standards for those patients. Are we
22 endorsing some kind of risk stratification

1 for certain patients going to home rehab
2 versus hospital rehab in this document?

3 DR. MARJORIE KING: That addition
4 of the phrase that the medical director
5 would be responsible for setting safety
6 standards for home programs was added in --
7 to answer your fears. I have similar fears
8 in heart failure patients, for example, and
9 the very sick and the elderly and the ones
10 who have troubles getting in. I have very
11 similar fears as a practicing cardiologist.
12 And that was added so that there would be
13 safety standards for home programs. One may
14 say you do not do a home program for people
15 who are at high risk, but you're not
16 endorsing a specific risk stratification.
17 You'd be endorsing the responsibility for
18 setting up those policies and procedures.
19 The responsibility is the medical director
20 of the cardiac rehab program.

21 MS. LUI: This is Karen Lui. May
22 I speak?

1 CO-CHAIR GIBBONS: Certainly.

2 MS. LUI: Okay, thank you.

3 There's also, as far as the Medicare
4 population, regulations in place for both
5 ICR and standard cardiac rehab that require,
6 as Marge said, the medical director
7 requirements, the medical supervision
8 requirements, the ACLS certification, and
9 staff requirements as far as safety. So ICR
10 is held to the same safety standards as
11 standard cardiac rehab. And home setting is
12 not supervised early outpatient setting
13 currently.

14 CO-CHAIR GEORGE: Can the measure
15 developers comment on how this data is
16 selected, whether it's the physician in the
17 facility that's saying, yes, I do have a
18 procedure in place, or exactly how that data
19 is collected.

20 DR. MARJORIE KING: The policy
21 and procedures would be submitted online.
22 The AACVPR certification process is an

1 online submission process to submit evidence
2 that you are meeting the standards.

3 CO-CHAIR GEORGE: So the only way
4 to attest that the standard is being met is
5 through the certification organization?

6 DR. MARJORIE KING: Right. There
7 is currently only one certification
8 organization. It's not a money making
9 phenomenon.

10 DR. CHO: You actually hit upon
11 this major problem, which we'll come to in
12 every single one of these measures, is that
13 the only way we know is through the
14 certification process for which only 40
15 percent of cardiac rehab programs are
16 certified, so we have no idea. And this
17 outcome study in Wisconsin between the
18 certified program and the non-certified
19 program, there is no hard outcome. There's
20 no mortality outcome, MI outcome. It's all
21 soft endpoints. It's a huge problem. I
22 mean, I feel like we should be able to get

1 the data because CMS pays for cardiac rehab,
2 regardless of whether you're certified or
3 not.

4 DR. MARJORIE KING: Right. There
5 is mortality data from CMS from the Brandeis
6 group that there's a significant -- there's
7 about 20 percent improved mortality in
8 patients who attend and at least, I don't
9 remember if it's 20 or 24 outpatient cardiac
10 rehab --

11 DR. CHO: But that's not for
12 certified versus non-certified, which is the
13 main question here. You're measuring a
14 group of patients. Your measurement is
15 wholly dependent on AACVPR certification,
16 but the question is is that certification --
17 can a program be just as good without being
18 certified? Do you know what I mean? If you
19 just don't want to do or you don't want to
20 go through the paper certification process
21 but you still follow all the guidelines, are
22 you just as good?

1 DR. MARJORIE KING: And it's
2 similar to the questions that were asked
3 before. It's kind of a cart before the
4 horse. If we don't have measures, then CMS
5 won't test them, and then there's less
6 likelihood for them to be tested, so it's
7 something we're struggling with.

8 DR. RICH: I'm just thinking
9 about this from a public reporting point of
10 view, and I'm not exactly sure how we're
11 going to report it. I know that in Michigan
12 we tie our public reporting either to -- we
13 do physician organization reporting or
14 health system, but these can also be
15 standalone. So I'm not sure, are we looking
16 to do this just as a population measure?
17 Because I think that's an important
18 question, as well.

19 DR. MARJORIE KING: It's a per
20 program measure, so per cardiac rehab
21 program, whether they're standalone, based
22 in a hospital or physician's office. So

1 it's --

2 CO-CHAIR GEORGE: Can NQF comment
3 on whether you have other program measures
4 in your other measure sets?

5 DR. WINKLER: We don't have a lot
6 of them, but we certainly do have measures
7 that are of similar nature. These are more
8 structural measures. You know, do you have
9 certain characteristics, yes or no, within
10 your program. And while they're not large
11 numbers, there are a few, so it's within the
12 type of measure we have.

13 DR. RUSSO: And a similar
14 question, too. Can you expand, I'm not
15 familiar with the lit, that one study, how
16 large a study was that comparing the
17 certified programs versus non-certified, and
18 then is there any way to even consider
19 expanding the measure, to bring up the point
20 to not just be at the certified centers so
21 that we could measure that? Do we really
22 know right now that the certified -- I mean,

1 it makes sense. It should be. And will it
2 be required soon? Is CMS going to reimburse
3 only the certified programs?

4 DR. MARJORIE KING: I will defer
5 the question about CMS to Karen Lui, who is
6 on the phone. It was 70 programs, 21,000
7 records analyzed for the Wisconsin data.
8 There are plans for an AACVPR registry which
9 will begin in 2012. But, again, that will
10 be self-selecting for programs that want to
11 participate in outcomes data collection.

12 DR. CHO: Maybe the CMS
13 representative can answer this, but CMS pays
14 for cardiac rehab, regardless of whether you
15 are certified or not, and you have to have
16 certain standards in place. Isn't that
17 correct?

18 DR. MARJORIE KING: Karen
19 actually is in AACVPR, but she knows the --

20 DR. CHO: But isn't that correct,
21 that CMS will pay for that?

22 MS. LUI: At the current time,

1 there's no movement by CMS to reimburse only
2 for certified programs. However, the
3 organization is in the early planning stages
4 of attempting to get dean status and moving
5 that direction, but that's as far as it has
6 gone to date.

7 DR. CHO: Right. So I guess what
8 I'm asking is is there a way for us to get
9 data from CMS to look at outcomes between
10 people who are certified versus non-
11 certified cardiac rehab programs to see if
12 there's really a difference? You guys know
13 who you certify, so everybody else is non-
14 certified; isn't that true?

15 DR. MARJORIE KING: Yes. Does
16 CMS do that for free?

17 DR. CHO: I mean, I guess the
18 question is -- you know, I fully believe
19 that you have a wonderful standard and I
20 feel like everyone in America should adopt
21 it. I am completely in agreement that these
22 are excellent, and we're, at the Cleveland

1 Clinic, AACVPR certified, thank God. But
2 the question is is that for these safety
3 standards and for other standards, because
4 you are only looking at people who are
5 certified --

6 DR. MARJORIE KING: I know. We
7 struggled with this. I don't know if Randy
8 Thomas or Steve Lichtman are on the phone or
9 can help me out, but we struggled and
10 struggled and struggled and I hear you.
11 And, unfortunately, you know, it went
12 through my head we'll ask the Brandeis
13 people, but the Medicare data they had for
14 that was a decade ago.

15 MS. LUI: This is, this is --

16 DR. THOMAS: This is Randy
17 Thomas. Can you hear me? This is Randy
18 Thomas. I was just going to answer very
19 quickly it would be ideal if we could work
20 with the Brandeis investigators to answer
21 that question, and we'd be very interested
22 in doing that. Because we had a very short

1 time frame to put together the data that
2 were presented to you, we weren't able to
3 pull that off with the Brandeis
4 investigators, but it certainly would be
5 more accurate than looking just at certified
6 program definitely.

7 And likewise when we presented to
8 you the data from the registries from
9 Wisconsin and Montana, those data are also
10 somewhat limited because it's still a self-
11 selecting group, even if they're not
12 certified by AACVPR, but they've taken the
13 initiative to be part of a registry, they
14 get regular feedback, they work on quality
15 improvement, et cetera.

16 So it would clearly be better to
17 have from a Medicare general population of
18 data to answer that question. We'd be more
19 than happy to pursue that. We don't have
20 the funds that would be necessary to do this
21 on our own, but we're definitely interested
22 in working with the Brandeis folks to see if

1 they would be interested.

2 DR. LICHTMAN: Yes, hi. This is
3 Steve Lichtman. Can everybody hear me also?
4 Okay. Yes, I think Drs. King and Thomas hit
5 the nail right on the head. When you look
6 at the evidence presented now, it presents a
7 picture that you have to infer from. We
8 have a published study from the Brandeis
9 group we've all been talking about, and
10 actually Dr. King understated the benefits
11 of general standard cardiac rehab. It
12 actually, depending on which regression
13 model you use and which co-variate model you
14 use, five years out after cardiac rehab,
15 patients who attended cardiac rehab of the
16 28, a 54 percent decrease in mortality as
17 compared to those patients who did not.
18 Additionally, there's a clear dose effect
19 with one visit being better than zero, 12
20 being better than one, 24 being better than
21 12. And what's kind of the standard full
22 program of 36 being statistically better

1 than 24 in terms of morality/morbidity
2 endpoint.

3 So we have that data to start
4 with. Then we have the data for
5 programmatic issues, certified and non-
6 certified programs, why programs are
7 certified, why programs are not. But,
8 again, as Dr. Thomas said, that's a self-
9 selected group. Certification is intended
10 as a self-study process. We don't want to
11 turn down folks for certification. We want
12 people to go through the certification
13 process to improve their performance
14 measures so that, indeed, they do get
15 certified and they have what we believe is a
16 top quality program.

17 Then we looked at a database of
18 20,000 records, albeit from one or two
19 states or a few states, that showed some
20 differences between certified and non-
21 certified programs. There were some
22 differences with certified programs having

1 some outcomes that were better. Some
2 outcomes everybody improved in. And, again,
3 Dr. Thomas said that is a self-selected
4 population, but even within that self-
5 selected population there was some
6 differential improvement for certified
7 programs.

8 None of these hit the nail on the
9 head. They're all inferential data where we
10 can conclude cardiac rehab is good,
11 certification is good, there's evidence that
12 shows certification is better than non-
13 certification. But, clearly, if we could
14 identify certified programs, all of them,
15 which we can, give Medicare those center
16 identification so that we know where data is
17 coming from and where bills are coming from,
18 you can certainly construct a research study
19 to look at Medicare endpoints, just as the
20 Brandeis group did, mortality and morbidity
21 data, looking at certified and non-certified
22 programs, but that's going to take a while,

1 and we would have to get the buy-in from the
2 research group at Brandeis also.

3 DR. JEWELL: So I think that that
4 gets us in the right direction, that kind of
5 approach. We're still challenged by the
6 notion that even if there are significant
7 differences between certified and non-
8 certified, we may or may not know whether
9 those differences are linked to the measures
10 that are being submitted in front of us.
11 And for me, that's one of the biggest
12 challenges here. And, again, I want to
13 disclose, as a member of that organization,
14 this is an enormous struggle for me because
15 I'd like to see them succeed. But when I
16 put on my measurement hat, this is where I
17 really am struggling.

18 CO-CHAIR GEORGE: Is there a cost
19 to certification?

20 DR. MARJORIE KING: Yes, it's,
21 roughly, \$600.

22 CO-CHAIR GEORGE: Is that annual

1 or one time?

2 DR. MARJORIE KING: You then get
3 re-certified every three years, so a couple
4 of hundred dollars a year to a hospital.

5 DR. SMITH: So just a point of
6 information, we are being asked to certify
7 the certifiers, in a sense. So this process
8 would result in ordaining the AACVPR with
9 credibility. In order to do that, it would
10 seem that we need the evidence mentioned to
11 have some reason for doing it. I mean, I
12 say I'm a strong supporter of rehab,
13 underutilized, of major importance, but what
14 are the criteria that will best allow us to
15 say it is safe and where is the evidence
16 that these criteria are valid? This process
17 could be used to do that if it were modified
18 in some way.

19 CO-CHAIR GIBBONS: Do the
20 developers want to attempt to answer that
21 point?

22 DR. MARJORIE KING: Well, we

1 don't own these measures. We wrote them.
2 They're published, but anybody can use them
3 once they're NQF endorsed. If someone wants
4 to say, oh, I'm going to make money on
5 endorsing cardiac rehab programs they can go
6 out and do it. So it's not like --

7 DR. CHO: Right. But I guess the
8 question, you know, I really want to say how
9 much I'm in favor of cardiac rehab and all
10 this stuff and how much I think the AACVPR
11 does a wonderful, fantastic job. I think
12 the thing that all of us are struggling with
13 is because the measurement relies on
14 certification, it is a completely circular
15 process. Do you know what I mean? So what
16 you really want to know is is, you know,
17 somewhere in Alaska, non-certified CR
18 program, are they doing -- do they have the
19 safety in place? You will never know
20 because they're non-certified. Do you know
21 what I mean?

22 DR. THOMAS: This is Randy

1 Thomas. I was just going to answer very
2 quickly. I agree with what you're saying.
3 I think Dr. Lichtman had mentioned this that
4 really the use of the certified data and the
5 certified program data was really a
6 surrogate to try to answer the question that
7 you're talking about. And, clearly, the
8 purpose of the measures are not to promote -
9 - to promote the delivery of effective
10 cardiac rehabilitation. And so the intent
11 is to make this, these measures widely
12 applied whether or not the programs are
13 certified.

14 Unfortunately, with the
15 relatively quick turnaround time that we had
16 to put together data to show this committee,
17 the best available data that we had was
18 through the certification process. But
19 we'll agree completely that that's really
20 not the issue. Really, the issue is trying
21 to implement these into programs, whether or
22 not they're certified. So the tricky part

1 is try to identify the programs that are
2 using the measures. The best surrogate we
3 could find was certification.

4 DR. MARJORIE KING: Could I just
5 say one thing? When we chose the measures
6 back in 2005, I mean, I remember my heart
7 sinking when the group said you have to
8 write measures for cardiac rehab, thinking,
9 oh, my gosh. And when we chose those
10 measures, I was pleasantly surprised that
11 the measures we came out with independently,
12 independently came out with were very
13 similar to the then existing AACVPR program
14 certification measures, and it's because
15 they're based on the core components of
16 cardiac rehab, which are based on the
17 ACC/AHA guidelines. You know, it's kind of
18 mom/pop/apple pie that processes to do all
19 these safety standards and these other
20 things are kind of mom/pop/apple pie
21 standards. So that part is circular, too,
22 that the AACVPR certification process is

1 based on these measures because they're all
2 based on common guidelines.

3 DR. LICHTMAN: Yes, hi. This is
4 Steve Lichtman again. And just to echo what
5 Marge just said in maybe a different light,
6 I don't think we should also forget or
7 disregard other measures of validity other
8 than measurable quantitative data points.
9 You know, these measures did go through an
10 extreme process of content, context, and
11 face validity analysis, and a lot of them,
12 unless you did a very, very large scale
13 nationwide study of the type we've been
14 talking about, and even that might not show
15 conclusive results, but a lot of these are
16 really the result of committees, peer review
17 processes, expert opinion, consensus, NQF-
18 like scoring for each one of the points
19 where measures were eliminated, measures
20 were altered. So there was this multi-
21 process, rigorous process of looking at the
22 content, the context, and the face validity

1 of these measures. And as Dr. King said,
2 you know, it was actually a marvel that
3 these came about and that there was such
4 good consensus on the final set.

5 CO-CHAIR GIBBONS: So my sense of
6 the various comments made by the committee,
7 if I can try to bring this to a halt and
8 move to a vote, is that the concern is not
9 about the measures but the linkage of the
10 measures to certification by a particular
11 group.

12 DR. CHO: Right. So if you have
13 to be certified to -- in order -- if you
14 have these safety standards and you're
15 certified, you're going to be 100 percent.
16 So if we go out and measure these people,
17 it's going to be 100 percent because those
18 people are the ones who got certified. So
19 the goal of NQF is to identify people at
20 gap, right? So you want to bring the rest
21 into 100 percent. But if they're already
22 100 percent because they got certified

1 because there was four of these, then what
2 have we accomplished?

3 CO-CHAIR GEORGE: And I'm
4 struggling with how a rehab center that does
5 not want to be certified for some reason,
6 how do they report this data?

7 DR. CHO: CMS, you have to have
8 certain minimal criteria in order to get
9 reimbursement from CMS. So even if you're
10 not certified, you have to have some kind of
11 individualized planning, you have to have
12 the code card and things like that. I mean,
13 we should bring this to a vote because I
14 think, you know, the issues are pretty
15 evident.

16 CO-CHAIR GIBBONS: So we're going
17 to vote first on scientific acceptability of
18 the measures, okay? Scientific
19 acceptability.

20 DR. JEWELL: Just to clarify,
21 even though we've been talking about all of
22 them, we are still just voting on --

1 CO-CHAIR GIBBONS: Safety. We're
2 voting on safety standards.

3 DR. JEWELL: Right. But on this
4 measure specifically.

5 CO-CHAIR GIBBONS: Right. This
6 measure, 1496. David is getting ready. All
7 right. We have 3 completely, 11 partially,
8 3 minimally, and 4 not at all. So now let
9 us move to usability.

10 DR. CHO: Well, I think for
11 usability you have to be certified in order
12 -- it's currently in use for those programs
13 that are currently certified. So if other
14 programs want to join, then it would be in
15 use. But then, again, they would be 100
16 percent.

17 DR. SNOW: Is there any way we
18 could remove the need to be certified from
19 this proposal and just look at how the
20 various programs are doing with regard to
21 safety measures?

22 DR. MARJORIE KING: You do not

1 need to be certified to use these measures.
2 These measures were just -- the only way we
3 had to test the measures was by testing the
4 certification process. These measures could
5 be used by anybody anywhere.

6 CO-CHAIR GIBBONS: They can be
7 used, but where's the data which we have
8 been requiring as part of the process for
9 their use outside of certification? That's
10 the dilemma we have.

11 DR. MARJORIE KING: Where's our
12 competitor? Where's AACVPR's,
13 quote/unquote, competitor.

14 CO-CHAIR GIBBONS: You're
15 misunderstanding the point. Where's the
16 data for the 60 percent of programs that are
17 not certified. We don't have any.

18 DR. LICHTMAN: Right. But that's
19 almost the point. The point is that
20 programs choose to be in certification. If
21 performance measures that set the standard
22 for cardiac rehab were passed, and the goal

1 of AACVPR and everybody in cardiac rehab is
2 to have quality programs across the country,
3 it would at least -- it would provide
4 standards for programs that choose not to be
5 certified to be able to achieve to set their
6 standards to, so it would actually increase
7 the number of quality programs, we believe,
8 across the country. We're not looking at
9 certification as part of these performance
10 measures. These performance measures stand
11 alone, and they hopefully will provide the
12 standards that cardiac rehab centers have to
13 achieve.

14 MS. PACE: Just one comment. We
15 do have measures that have been endorsed
16 that come in initially from a particular
17 program. Registry measures are an example.
18 The goal is that by the time of maintenance
19 review they're publically reported and more
20 widely used. So that, in itself, shouldn't
21 prevent it from going forward. But then the
22 question would be are these appropriate

1 performance measures? Structural measures
2 have other issues.

3 CO-CHAIR GIBBONS: At a minimum,
4 presumably, time limited endorsement to
5 demonstrate collection of data outside of
6 the program.

7 MS. PACE: Our testing doesn't
8 require widespread national testing. Even
9 other measures do it on a sample, and so
10 that wouldn't necessarily limit it. I think
11 the broader issues are the structural
12 measures.

13 CO-CHAIR GIBBONS: I think we
14 have to have a vote on usability. The vote
15 is 2 completely, 12 partially, 4 minimally,
16 and 3 not at all. And now feasibility.

17 DR. CHO: So I think it's very
18 feasible if they're certified. It's not
19 that feasible if they're not certified,
20 unfortunately.

21 DR. MARJORIE KING: But there's
22 nothing that precludes, I'm sorry for

1 butting in, but there's nothing that
2 precludes a non-AACVPR member from applying
3 for certification.

4 DR. CHO: I'm so with you on the
5 certification. I feel that, you know, the
6 thing is is I have existential angst about
7 this thing because I totally believe in the
8 certification process. But the point is not
9 the certification. Do you know what I mean?

10 DR. MARJORIE KING: I know, I
11 know. And we struggled with this, Randy and
12 I and Steve and Karen struggled with it.

13 DR. JEWELL: So you made a
14 comment earlier that I just want to revisit.
15 You will be the measure -- if we were to
16 endorse this you would be the measure
17 stewards, as opposed to anybody else using
18 them. That's a different issue. You would
19 be the measure stewards. So the testing
20 that they're talking about and the ability
21 to gain data, whether it's from CMS or
22 wherever, on the currently non-certified

1 programs falls to AACVPR to do.

2 DR. THOMAS: Excuse me. This is
3 Randy Thomas. Actually, this is a measure
4 that's jointly developed by the American
5 College of Cardiology, American Heart
6 Association, and AACVPR. Just like with
7 some other measures we developed together,
8 we'd be joint stewards.

9 DR. JEWELL: Okay. And thank you
10 for that clarification. I think my point
11 was simply to make sure. You've talked a
12 lot about the challenges you face with
13 testing on the front end of this. I want to
14 make clear that everybody -- that you all
15 understand that if were to conditionally or
16 in some way endorse this and require testing
17 that that means that it's up to you to go to
18 CMS or wherever else you think you can get
19 the data in order to come back and
20 demonstrate that this measure has utility.
21 So we hadn't touched on that yet, so I just
22 wanted to be clear that you understood that

1 that's the implication of a decision like
2 that.

3 DR. MARJORIE KING: We know.

4 DR. AYALA: I have a question,
5 too, for those that are not certified. With
6 the first point of the numerator statement,
7 is there a set of standards that, like I'm
8 just trying to understand how a reviewer or
9 how the institution would prove that they
10 actually have appropriate policies and
11 procedures. You know, it's a very broad
12 term. I was just wondering how specific is
13 that in terms of the content of those
14 policies and procedures, and how would the
15 institution report that and how would it be
16 monitored and audited?

17 DR. MARJORIE KING: So you're
18 saying if it's outside of the AACVPR
19 certification process which has trained
20 reviewers with templates and best practices
21 and all that sort of thing. Somebody else
22 help me out within the group. I mean, it

1 would be like any process when you're
2 looking at data.

3 DR. THOMAS: This is Randy Thomas
4 again. I would think it would depend on the
5 application of the measures. For example,
6 if a health care system implements these or
7 a third-party payer institutes these
8 measures, they would be the ones who would
9 be collecting and auditing the information.
10 If Medicare, for example, were to adopt
11 these as part of their evaluation of
12 reimbursement for cardiac rehabilitation, we
13 would assume that there would be a process
14 in place to help audit and identify the
15 adherence to the measures. The
16 certification process through AACVPR is one
17 mechanism to make that happen, but it would
18 really depend on the organization that is
19 using the measures.

20 DR. MARJORIE KING: And as I look
21 at this numerator statement, it's fairly
22 explicit about policies and procedures

1 consistent with evidence-based guidelines,
2 safety standards, regulatory standards.
3 Those are in the literature.

4 DR. AYALA: Right. I understand
5 that. I'm just thinking of the feasibility
6 of reporting on the details of that and on
7 the auditing process.

8 DR. MARJORIE KING: Right. It
9 would require similar to the AACVPR process
10 with training and --

11 MS. SZUMANSKI: I think there is
12 one piece in here that is missing from the
13 safety standpoint, and that is the concept
14 of hand-off communication which has been
15 shown nationally to be a major problem.

16 DR. CHO: It comes up at
17 different --

18 DR. MARJORIE KING: We have a
19 specific measure for that.

20 CO-CHAIR GIBBONS: Okay. I think
21 we need to vote on feasibility. Okay. The
22 vote is two completely, seven partially,

1 eight minimally, and three not at all. Now,
2 the final vote: does the measure meet all of
3 the NQF criteria for endorsement? The vote
4 is six yes, fifteen no.

5 So we'll now move on to 1494,
6 cardiac rehab response to therapy. And I
7 presume that the construct here is very
8 similar. Ann, why don't you guide us
9 through this one?

10 MS. DE VELASCO: I sort of feel
11 like I'm trying to guide you through the mud
12 because I'm kind of befuddled and muddled by
13 all of this anyway. But this program
14 actually, this measure is related to the
15 monitoring response to therapy and
16 documenting the program effectiveness. It
17 has to do with written procedures and
18 policies, and it is a patient-centered and
19 structure-management type of program.

20 The importance, I think, was
21 alluded to in the comments prior to this.
22 Obviously, the effect of cardiac rehab on

1 the patients' survival and quality of life
2 is well documented. And the only thing I
3 saw was that there was some performance gap
4 when they referred to the people who were
5 AACVPR certified that it wasn't, you know,
6 the proportions were disproportionate. The
7 other thing that I saw that was, the
8 percentage of patients to referral, it said
9 that 55 percent are referred but only 19
10 percent actually enroll. So there was a
11 performance gap, at least at that level.
12 However, the importance of the measure seems
13 to be solid. There are some disparities,
14 though, that it is less prescribed for the
15 elderly, the women, and minorities. And,
16 obviously, in order to implement all the
17 procedures, you have to have some type of
18 recording process and documentation, which
19 this measure specifically addresses.

20 CO-CHAIR GIBBONS: Are there
21 additional comments before we vote on
22 importance? Okay. Let's go ahead and vote.

1 Twenty yes, one no. Okay. So now we'll
2 move on to scientific acceptability.

3 MS. DE VELASCO: Okay. As far as
4 scientific acceptability, it has been
5 precisely specified. The numerator has four
6 components that are listed on the measure to
7 document the percentage of patients who have
8 received a formal request to cardiac rehab;
9 also document the standard plan to access
10 completion of the prescribed course of
11 cardiac rehab; document for the patients a
12 standard plan to access certain outcome
13 measures at the initiation and at the end of
14 the completion of cardiac rehab, and the
15 outcome measures are actually outlined in
16 the AACVPR performance measures; and also to
17 describe the programs' methodology to
18 document program effectiveness and initiate
19 quality improvement strategies. This is per
20 reporting year, and the denominator is all
21 cardiac rehab programs, male and females, 18
22 years or older. Again, the time element is

1 per the performing year. There were no
2 exclusions and no variables. There appeared
3 to be no risk adjustment, and the data
4 source can be paper medical records or
5 computer provided. It also has relations to
6 the organizational plans and policies that
7 are implemented by the cardiac rehab program
8 using their departmental records. For the
9 people that are AACVPR certified, there is
10 an outcomes data registry that is going to
11 be collecting and analyzing the data, as
12 well.

13 So that, basically, reliability,
14 the reliability testing has been done
15 through the AACVPR, which, again, is this
16 kind of circle of things that we did before.
17 And AACVPR is an all-or-none phenomenon.
18 You are not partially certified. And they
19 have an extensive review program in place so
20 that they can remediate people who are not
21 approved and can come back for
22 certification.

1 Validity testing was done through
2 peer review and extensive record review.
3 And validity testing was also completed
4 without any obvious outliers that I could
5 tell.

6 So in February 2011, they were
7 going to make additional testing records
8 available to us. I don't know. I didn't
9 see those records. But there were no
10 exclusions in this section.

11 Again, the difficulties I had
12 with the scientific acceptability was the
13 circle within the AACVPR certification, if
14 we were just basically certifying a
15 certifier. But that's been addressed
16 before, so I don't have any new insight on
17 that.

18 CO-CHAIR GEORGE: When I looked
19 at this, there's four components in the
20 numerator and three of those are really
21 patient level, one is a system level. And
22 I'm wondering if it wouldn't be possible to

1 go back with the patient level components
2 and construct measures that really address
3 each of those items on patient level.

4 DR. MARJORIE KING: Are you
5 referring to does the patient get in
6 program, finish program, and improve their
7 outcomes? And then the reason we wrote the
8 fourth component was, okay, so you document
9 all that, but your patients don't get in
10 program, they don't finish program, and they
11 don't improve their outcomes, then what do
12 you need to do about it, have a performance
13 improvement project to improve those. So
14 that was the thought process behind the
15 measure.

16 CO-CHAIR GEORGE: I think, from a
17 measurement standard, the first three could
18 be reconfigured so that you could report on
19 those components individually that go into
20 each one of those and come out with
21 something that is meaningful, perhaps at the
22 patient level, for the rehab unit.

1 DR. MARJORIE KING: And these
2 measures are actually being used in non-
3 AACVPR places, like these registries which
4 are not part of the national registry. The
5 Wisconsin registry is not part of the
6 national registry, and Montana also uses
7 these measures. So these are not, these are
8 used outside of AACVPR.

9 MS. DE VELASCO: One thing that I
10 thought was interesting is that risk factors
11 that influence outcomes should not be,
12 obviously, exclusions, but that patient
13 preference is not a clinical exception to
14 eligibility because it could be influenced
15 by provider intervention. And on a day-to-
16 day basis we certainly see whether patients
17 come to cardiac rehab. There's a huge
18 provider intervention component to that of
19 how attractive you make it to them when you
20 basically sell the program on the phone and
21 how diligently you follow the patient from
22 admission through discharge and then at home

1 to get them back into the system. So even
2 though that's not an exclusion, it certainly
3 does play a part in how many people actually
4 do attend cardiac rehab.

5 DR. MARJORIE KING: And that's
6 another part of why this measure was written
7 is to hold cardiac rehab programs
8 accountable for working with the referring
9 physicians to get the patients from those
10 endorsed referral to cardiac rehab measures
11 actually into and finishing program.

12 MS. DE VELASCO: Right. Which
13 speaks to the hand-off that Kathleen
14 mentioned is interdisciplinary connections
15 with other providers and different
16 disciplines that the patient would be
17 subjected to after their diagnosis.

18 DR. MARJORIE KING: Right. Our
19 referral measures do have communication
20 embedded in them.

21 MS. DE VELASCO: Right. And I
22 think that's the key to a successful rehab

1 program, too, is to have the
2 interdisciplinary approach.

3 MS. SZUMANSKI: Your reviewers
4 that you describe in your analytical method,
5 are those individuals permitted to review
6 their own program?

7 DR. MARJORIE KING: Absolutely
8 not.

9 MS. SZUMANSKI: And do you send
10 more than one reviewer for review, similar
11 to what AATB would do for bone marrow?

12 DR. MARJORIE KING: It's a paper-
13 based review currently with plans to do on-
14 site reviews. And if there's any
15 controversy, the chair of the committee does
16 the review as well.

17 MS. SZUMANSKI: So this is
18 strictly a paper review and not an onsite --

19 DR. MARJORIE KING: Or an
20 electronic review. Yes, it's not an onsite
21 review.

22 DR. AYALA: Would it be

1 appropriate to have an exclusion for the
2 first component of the numerator if a
3 referral request was received but that the
4 medical director who reviewed the case
5 decided it was inappropriate to have the
6 patient enroll in the cardiac rehab program?

7 DR. MARJORIE KING: Well, there
8 are medical contraindications to referral,
9 things like very severe aortic stenosis and
10 very severe hypertrophic cardiomyopathy, but
11 they're very rare. And severe dementia,
12 obviously, would not be appropriate with
13 lack of carryover. But there's very few
14 patients who don't benefit from cardiac
15 rehab.

16 MS. DE VELASCO: But I think, in
17 reality, there are certainly cases where
18 patients do not get accepted to cardiac
19 rehab because they don't fit within the
20 construct of an outpatient cardiac rehab
21 program. They may be referred to cardiac
22 rehab and may be totally immobile. They may

1 be in a wheelchair or there may be other
2 things, so they would absolutely --

3 DR. MARJORIE KING: I work in an
4 inpatient rehab hospital, so, to me, no one
5 is not rehabbable. I'm sorry. So I have a
6 different view. There are adaptive
7 modalities and things you can do with
8 people, so I may not be typical. Randy may
9 want to address that.

10 DR. LICHTMAN: Physical
11 disabilities would never preclude somebody
12 from participating in cardiac rehab. In our
13 facility, we even had an individual with
14 quadriplegia who participated using the
15 shoulder muscle, so I think without the
16 extreme medical or cognitive exclusions,
17 I've been doing this 20 years and I've never
18 turned down a patient for physical
19 disability. We work around it. Some may
20 not progress as well as others, but we
21 certainly would enroll them.

22 MS. DE VELASCO: That's good to

1 know. I'm glad to know that. Our
2 experience is a little bit different, but we
3 have something to look forward to then to
4 achieve.

5 DR. MARJORIE KING: Right. We
6 want to drive enrollment and adaptation of
7 programs and that sort of thing.

8 DR. KOTTKE: Yes, the old Kottke
9 back of the spreadsheet analysis here. The
10 impact of getting everybody into cardiac
11 rehab would be about four times the impact
12 of angioplasty and everybody immediately for
13 STEMIs. We talk about setting clocks on ECG
14 machines and all those kind of things, and I
15 think where my angst is about this is that
16 CMS collects all the data on, for example,
17 aspirin, you know. And if we turn this
18 down, you know, we're asking them to find
19 somebody who will collect all the data.

20 It's like this problem of why
21 don't we talk about diet? Because we don't
22 know how to talk about diet. Nobody denies

1 that nutrition is very important. And I
2 don't think we have the answer, but I think
3 we need to, somebody needs to really work on
4 this answer. And I don't know if it's CMS
5 to adopt stricter criteria for payment or
6 something, but I'm very uncomfortable here
7 because the impact is very large. We risk
8 shutting down a very important process that
9 patients clearly benefit from, but I haven't
10 figured out the solution.

11 CO-CHAIR GIBBONS: All right. I
12 think we need to go ahead and vote on
13 scientific acceptability. Okay. Completely
14 three, partially fifteen, minimally three.
15 Usability?

16 MS. DE VELASCO: We didn't have
17 any problem with the usability. It is
18 currently in use, and it's publically
19 available on several websites. Let's see.
20 We have recognized the expected outcome of
21 these cardiac rehab programs. The reporting
22 is done, and it's harmonized with the other

1 measures that we're reviewing for cardiac
2 rehab. We think that it encourages cardiac
3 rehab secondary prevention programs to
4 collect and respond to these outcome data
5 and that to improve enrollment and
6 completion of cardiac rehab. It also
7 stimulates performance improvement
8 strategies for cardiac rehab professionals -
9 sorry, yes, if you are certified. So in
10 agreement to what Dr. Kottke says, of course
11 we heartily endorse cardiac rehab and the
12 benefits to the patient. It's getting to
13 that point that is what we're trying to
14 debate here today, I think. And as far as
15 usability, it appears to be something that
16 definitely meets the criteria of usability.

17 CO-CHAIR GIBBONS: Any other
18 comments before we vote on usability? Okay.
19 Let's go ahead and vote. Seven completely,
20 eight partially, six minimally, reflecting
21 the difficulty of this dilemma for sure.
22 Moving on to feasibility.

1 MS. DE VELASCO: Okay. As far as
2 feasibility goes, the only thing is that if
3 the patient fails to complete the program it
4 may affect the program's ability to capture
5 the individual outcomes and accurately
6 reflect the program effectiveness. But
7 we're aware of the fact that attrition is a
8 challenge in cardiac rehab programs where
9 self motivation is a significant problem.
10 However, the feasibility could be affected
11 by closely monitoring the barriers to
12 completion and not waiting until the very
13 last minute for when you think the patient
14 is going to, for example, complete 36 visits
15 if you try to proactively collect some of
16 the data prior to the end of especially the
17 patient component data that they have to
18 respond to.

19 They conducted this work group in
20 the Wisconsin study, and the refinements
21 were made to all the different completion
22 reasons or the reasons for not completing

1 cardiac rehab. Those things are being
2 tracked.

3 So far as the feasibility, it
4 seems to be a lot of that is already in
5 place. The cost seems to be minimal. We
6 reviewed the costs that belong to AACVPR,
7 which currently is part of a lot of this
8 stuff in this measure. So for a relatively
9 low-cost process, we can have a significant
10 impact on the outcome in patients who
11 require cardiac rehab as far as their
12 quality of life and morbidity and mortality.
13 So we think that it's feasible as it is
14 right now, although it's dependent on the
15 AACVPR and how that works out.

16 CO-CHAIR GIBBONS: Okay. I think
17 we'll go ahead -- oh, sorry.

18 DR. JEWELL: Just to clarify,
19 this measure is asking whether or not a
20 program has a policy to do all these things,
21 yes? It's just simply a yes/no question.

22 MS. DE VELASCO: Yes.

1 DR. JEWELL: Okay. Because the
2 way you're describing it it sounded like
3 more than that, and I was thinking, God, I
4 really missed something when I re-read it.

5 MS. DE VELASCO: No. I was just
6 adding, that's sort of the endorsement of
7 cardiac rehab stuff I was adding, but it
8 basically just refers to the policies and
9 procedures.

10 DR. JEWELL: Okay. So just to be
11 clear, it's a measure that says does the
12 program have a policy or not, and it's
13 verified through certification, as was the
14 prior measure. Okay.

15 CO-CHAIR GIBBONS: Tom?

16 DR. KOTTKE: I'm just trying to
17 figure out the logic here of this. Let's go
18 back to 30-day mortality post-MI discharge.
19 CMS only has data for Medicare, and we
20 didn't put the kibosh on their indicator
21 because they couldn't tell us anything about
22 people under 65. And so if this indicator

1 or this measure is for cardiac rehab
2 programs that participate in AACVPR
3 certification then it seems to me that it's
4 okay. I mean, yes, we don't know about the
5 other half of the glass, but other measures,
6 too, we don't know the entire universe of
7 patients with the condition.

8 DR. JEWELL: Yes, but just to be
9 clear, we actually chose not to endorse or
10 re-endorse measures because there was no
11 demonstrated gap in performance. Based on
12 your math that was 98 to 99 or 100 percent
13 wouldn't save many lives or do many things
14 for other measures. We have no idea if
15 there's a gap in performance here because we
16 don't have beyond the remediation efforts of
17 the overall certification whether this
18 particular issue is a problem.

19 DR. KOTTKE: But we have no idea
20 whether there's a gap in performance between
21 Medicare age and non-Medicare age and 30-day
22 mortality.

1 CO-CHAIR GIBBONS: Dana?

2 DR. KING: Tom, point very well
3 taken. I see a bit of a difference between
4 those two things. One is if we were talking
5 about cardiac rehab and we said, well, we
6 only have information in 33 states out of
7 the 50 and we're working towards getting all
8 50, or if we said we only have information
9 on people over 50 years of age but not under
10 50 because of some unusual thing. But it
11 would be a difference if we said we only
12 have information in PCI mortality on people
13 that didn't die but not on the ones that
14 did. And so that is not the same thing. We
15 can't say we only get information on the
16 ones that are doing good and not on the any
17 of the ones that are doing bad. I mean, all
18 of us are like throwing ourselves onto
19 knives, but right now it's bad data in and
20 bad data out. I mean, the measure is good,
21 but one of the requirements of NQF, and
22 everyone is up there shaking their head, is

1 that you have to have some data to show the
2 utility of the measure and we don't have the
3 utility to show the good and the bad and we
4 don't have a good picture. So that's the
5 difference. It's not an arbitrary or a
6 sampling problem. You have to meet the
7 measure before you enter data, and it's not
8 the same.

9 CO-CHAIR GIBBONS: I think we
10 should move on to a vote on feasibility. So
11 we have one completely, twelve partially,
12 four minimally, and four not at all. So
13 final vote for this measure, 1494, response
14 to therapy, does it meet criteria for
15 endorsement? Okay. We have three yeses and
16 seventeen nos.

17 So we're going to move on to
18 1497, which is cardiac rehab risk for
19 adverse events. And, Dianne, you're the
20 primary reviewer.

21 DR. JEWELL: I am. So this is a
22 measure that looks to assess the presence of

1 two assessments of risk for adverse
2 cardiovascular events in newly-enrolled
3 patients in cardiac rehabilitation. All the
4 previous comments, at least that I've made,
5 stand here. It's essential to know not only
6 because we don't want our patients blowing
7 up on our treadmills but also because we
8 want to optimize the effectiveness of the
9 care they get, and part of that optimization
10 depends on understanding their risk for
11 events.

12 So absent data that links a gap
13 or demonstrates a gap on this measure, I
14 would urge us to vote yes on the importance
15 because I think, at a minimum, that needs to
16 be stated somewhere in the record that we
17 think that this is, in fact, important for
18 all programs to do.

19 CO-CHAIR GIBBONS: I would
20 suggest that much of the discussion for the
21 previous two measures does apply here, as
22 well. So any other comments about

1 importance before we vote on importance?

2 Let's go ahead and vote. Nineteen yes, two
3 no. Scientific acceptability.

4 DR. JEWELL: I am torn because,
5 you know, the cardiac specialist in me
6 definitely wants to see a higher standard of
7 performance in the programs and wants to be
8 able to reflect that in the quality
9 measurement efforts. The measurement person
10 in me says that all the things that we've
11 talked about make this measure not ready for
12 prime time across all three domains. That's
13 just the frustrating part. That's where I
14 am.

15 CO-CHAIR GIBBONS: Anybody else
16 want to share any additional existential
17 angst or otherwise? Leslie, it's a term I'm
18 now going to carry with me and I'm going to
19 associate with you. It is a perfect
20 succinct summary of the problem.

21 CO-CHAIR GEORGE: I would just
22 say that this measure, again, allows itself

1 to be easily reworked into something that I
2 think would be much more usable and would
3 encourage the measure developers to continue
4 to work on that.

5 DR. AYALA: I'm going to ask the
6 question that if we had data that showed
7 mortality and stratified it by whether or
8 not an institution were certified or not and
9 if that showed a difference, a significant
10 difference, would we even need these
11 measures if we know that those that got
12 certified would meet all these measures? So
13 if we had that one measure of mortality
14 stratified by, you know, whether or not the
15 institution was certified, then wouldn't
16 that be enough for CMS, for example, to say
17 you've got to be certified and then these
18 measures wouldn't even be relevant because
19 they would all be met by the certification
20 process?

21 DR. RICH: Maybe you would want
22 that measurement, that certification in

1 conjunction with the composite score so the
2 patients would have some idea of
3 differentiation between places.

4 MS. SZUMANSKI: One could use
5 that same argument related to the Joint
6 Commission that if you are accredited you
7 must be meeting all of the elements of
8 performance that they define and, yet, we
9 know nationally that is not the case. So
10 while it sounds good, it ain't so.

11 DR. RICH: That's why throwing in
12 a composite score would give people a little
13 bit more information.

14 CO-CHAIR GIBBONS: I think
15 Kathleen's point is an outstanding one. It
16 gets to the heart of what we all know goes
17 on in terms of certification processes.

18 DR. JEWELL: Sure. Although that
19 being said, at least to the extent that
20 these measures are structural so the
21 presence or absence of the policies, as
22 opposed to the actual effect of them. And I

1 agree with you, having lived through the
2 Joint Commission myself a few times, it
3 probably would be more true perhaps but
4 still with its limits.

5 CO-CHAIR GIBBONS: Okay. I think
6 we want to vote on scientific acceptability.
7 Okay. One completely, thirteen partially,
8 six minimally, one not at all. Moving on to
9 usability. Any additional comments on
10 usability?

11 DR. JEWELL: Sorry, no. I've
12 meant my comments to address all three.

13 CO-CHAIR GIBBONS: Okay.

14 DR. JEWELL: Because the same
15 issues apply.

16 CO-CHAIR GIBBONS: We'll go ahead
17 and vote on this one. Okay. So two
18 completely, ten partially, seven minimally,
19 and one not at all. And feasibility. I
20 propose we just go ahead and vote. Okay.
21 So we have eleven partially, eight
22 minimally, one not at all. And now can we

1 move to the final vote on endorsement? We
2 have two yes and nineteen no.

3 All right. So now we're going to
4 move to 906, the cardiac rehab composite.
5 And Leslie is once again the reviewer. And,
6 Leslie, I guess my first question to you is
7 whether we should follow David's previous
8 motion here with respect to the voting on
9 this measure since it's a composite of the
10 three we just talked about?

11 DR. JEWELL: I think we should
12 follow David's example.

13 DR. CHO: Can I just make one
14 comment, and that is I think all of us in
15 this room are truly angst-ridden because of
16 the fact that we're voting this down. But I
17 just want to commend the AACVPR for all
18 their hard work. I think if somehow these
19 were all aside from the certification
20 process, we would wholeheartedly endorse
21 them 21 to zero. And I think that just
22 because we voted this down does not, in any

1 way, shape, or form, reflect the fact that
2 there has to be standard in America for
3 cardiac rehab programs.

4 CO-CHAIR GIBBONS: Well stated.
5 The Chair would suggest that we take the --
6 the votes were slightly different, so the
7 Chair would suggest that, for the record, we
8 take the last vote on 1497 and enter it on
9 the composite, if there is no objection.

10 DR. AYALA: I just had a question
11 on the math on the composite. Is this
12 pretty straightforward, or does this got
13 some weird math in it?

14 DR. CHO: Unfortunately, it's got
15 a little bit of weird math, but it doesn't
16 have the composite like in the AMI. So what
17 it is is that you have to fulfill 11 of
18 these or 10 of these composites. And it's
19 purely based on the certification process.
20 They have to come up with an assessment.
21 Depending on some of the composite, the
22 compliance is anywhere from 60 to 90

1 percent, like, for instance, LDL and all
2 this other stuff. I think that there are
3 some questions with composite only because
4 the blood pressure definition has changed,
5 as Dr. Smith had alluded to, and also the
6 waist circumference is purely Caucasian
7 based and not ethnically based like for
8 Asians and whatnot. But I think that the
9 problem with this is so similar to the other
10 ones that I think the voting should be the
11 same.

12 CO-CHAIR GIBBONS: Okay. So
13 hearing no objection, we'll enter the vote
14 for 1497 for this measure. Now, my sense of
15 this is that everybody is as uncomfortable
16 as I am at the fact that we have voted these
17 four measures down, so I think we need to
18 record something for the record for the
19 measure developers and for others that we're
20 not against cardiac rehab. And I would
21 encourage others to weigh in, but the issues
22 I see are, one, linkage to certification

1 and, two, absence of data for centers who
2 are not certified with respect to
3 performance gap and validity of the data,
4 that those two are the fundamental flaws and
5 that if they could be addressed by the
6 measure developer the likelihood of
7 favorable review would be greatly enhanced.
8 They are structural measures, but I think
9 Leslie has nicely outlined the need for
10 quality improvement in cardiac rehab in the
11 United States.

12 Are there other fundamental flaws
13 that we should mention?

14 DR. KOTTKE: My feeling is that
15 they could, it would take some time and I
16 think there would be foundation money
17 available to look at CMS data for outcomes
18 by certification, and that would satisfy the
19 panel that there's a problem and that the
20 attributes of certification are important to
21 promote.

22 CO-CHAIR GEORGE: I would also

1 stress that I think that it's important that
2 we have some patient-level measures in this
3 set for cardiac rehab, in addition to
4 structural measures, to consider.

5 DR. SNOW: Question. How long do
6 you think that process might take? Well,
7 yes, just a guess, you know, getting
8 foundation --

9 DR. KOTTKE: I would have to ask
10 somebody who has actually worked with CMS
11 data. I don't know.

12 DR. SNOW: Well, okay. That kind
13 of answers the question. That could be a
14 slow process because it probably won't come
15 back to this committee is what was in my
16 thoughts, even though --

17 CO-CHAIR GIBBONS: It would be
18 highly unlikely to surface in this year's --

19 DR. SMITH: So the proposers
20 should be encouraged to be more inclusive of
21 programs in this project and not link them
22 specifically to one form of certification,

1 right? That's what we're saying.

2 CO-CHAIR GIBBONS: Helen?

3 DR. BURSTIN: Just one point. In
4 the spring we actually did endorse two
5 cardiac rehab measures, our first ones,
6 which was patient referral from an inpatient
7 setting for cardiac rehab and patient
8 referral from an outpatient setting for
9 cardiac rehab, both of which were endorsed
10 at the patient level. So we do have two
11 relatively new ones, so I think there's
12 something to build on. But, again, agreed.
13 Particularly, patient-level measures, I
14 think, as Mary has pointed out, would be
15 ideal. We just had discussion about sort of
16 rules of the road for measure construction,
17 and yes/no structural measures about
18 specificity are just not going to make it
19 through any panel kind of going forward. So
20 it's good to start thinking about how to
21 make those measures more robust as long as
22 you have the time.

1 CO-CHAIR GIBBONS: Okay. So I
2 think we want to, I'm trying to get a crisp
3 sort of message back to the developers that
4 this committee is comfortable with, and I
5 think we've outlined four components: the
6 absence of data on patients who are not
7 certified or the linkage of these measures
8 to certification, the absence on data of
9 patients who are not certified. Tom has
10 highlighted the absence of outcomes,
11 favorable outcomes related to certification,
12 and then, finally, the need for patient-
13 level measures.

14 I think that's a pretty
15 comprehensive message with those four
16 components to indicate that we believe that
17 if they can be addressed that rehab measures
18 are important. Can I have a show of hands
19 in favor of that? Okay. Hands down and any
20 nos? Okay. Is there anything else that
21 anybody can think of to satisfy their
22 existential angst before we take a brief

1 break at this point?

2 DR. WINKLER: Public comment
3 first.

4 CO-CHAIR GIBBONS: Public
5 comments. I'm sorry. Public comment?
6 Okay. We will take a 15-minute break. And
7 those who need to leave, thank you for your
8 diligent service during these two days.

9 (Whereupon, the foregoing matter
10 went off the record at 1:23 p.m. and resumed
11 at 1:45 p.m.)

12 CO-CHAIR GIBBONS: So --

13 DR. SMITH: Ray, Ray?

14 CO-CHAIR GIBBONS: Yes.

15 DR. SMITH: I have some
16 information, if I could.

17 CO-CHAIR GIBBONS: Absolutely.

18 DR. SMITH: It turns out that
19 existential angst is defined, and I'll just,
20 within a minute, I'll let you know. It's
21 one of the three corners of the existential
22 triangle, along with People as Scenery

1 theory and the Anthropic Fallacy. People
2 suffering from existential angst are either
3 not convinced that they exist, unsure why
4 they exist, or not at all convinced that
5 anything really exists. It goes on with
6 other information, but I thought that would
7 reassure you.

8 CO-CHAIR GIBBONS: I think that's
9 terribly reassuring, Sid. I feel so much
10 better already. I think we ought to send
11 Leslie an e-mail. Staff, you're hereby
12 directed to send Leslie an e-mail that this
13 was defined in her absence.

14 DR. SMITH: I talked to her
15 before she left. I confronted her. In
16 fact, that may be why she left. I'm not
17 sure.

18 DR. MAGID: You know, I was also
19 thinking that since Bruce is done with his
20 training maybe we could go back and say that
21 measure is not necessary.

22 CO-CHAIR GIBBONS: All right. So

1 we are now faced with a series of difficult
2 issues. We will not get through them today.
3 We will just get started on them today. But
4 they deal with sort of insights that I think
5 we've now gained from this process, from the
6 difficult issue of competing measures that
7 we've identified in several constructs, and
8 from the issue of harmonization.

9 So several of you have spoken to
10 me about this one, and I must admit, as I
11 read through the applications, it truly
12 bothered me, and that is just healthcare
13 disparities. It was my feeling, as I looked
14 at the applications, that a number of
15 applications sort of chose to disregard that
16 field. One or two has listed it as not
17 applicable, which I found unbelievable.
18 Others just put minimal, if any, answer in
19 that field. And in response, several of our
20 developers stated something to the effect of
21 they had that data but had never looked at
22 it.

1 I think we all work in
2 environments that pride themselves on trying
3 to deliver the same care to every American,
4 regardless of race or gender, and this
5 notion that disparities are not important
6 when they've been documented in our
7 healthcare system for at least 30 years and
8 been the subjects of two IOM reports I just
9 find totally unacceptable.

10 So what I would propose are two
11 things. Number one, in the short term, we
12 can ask the staff to convey and measure back
13 to the developers that we actually expect to
14 see that data that they said they have and
15 they're going to get because I think now is
16 the time to sort of push them to actually
17 look at the data with respect to this issue
18 and we make it clear that we expect to see
19 that back because I just don't think we can
20 let it fall through the crack.

21 So that's the short-term first
22 step we can take and invite discussion or

1 comments about other short term things we
2 can do in the next few months before I
3 address the longer term issues. Are there
4 other things that have occurred to people
5 that they are concerned about?

6 DR. RUSSO: Just to clarify that
7 one, are you implying that the initial
8 application should include any literature
9 that's currently available regarding
10 disparities, plus when --

11 CO-CHAIR GIBBONS: That's the
12 long term because we can't change the
13 initial application for this round. It's
14 already happened, so that's the long term.
15 But in the short term, for the people that
16 said, oh, we have that data but we haven't
17 analyzed it, which I find just unacceptable,
18 totally unacceptable for somebody who works
19 for an agency of the United States
20 Government. And I don't think they would
21 want that in the public domain on the front
22 page of the Washington Post. We have the

1 data but we haven't looked at it after three
2 years? Come on. I mean, I know there are
3 limited resources, but this is so obvious.
4 And that's one of the reasons that
5 disparities persist is people don't shine
6 the light on them.

7 So any other ideas about what
8 feedback we can give in the next few months?

9 DR. THOMAS: You know, another
10 thing I noticed was some of them just said
11 no disparities, so there were those that
12 said, you know, we have it and, you know, we
13 just haven't addressed it and there was
14 others that said no, so just to make sure
15 that those organizations, as well, address
16 that issue because that's unlikely, you
17 know.

18 CO-CHAIR GIBBONS: Right.

19 DR. AYALA: And in addition to
20 the race, ethnicity, and gender, I would add
21 payer source because I see that they
22 actually have that data, as well. And age,

1 someone mentioned age, as well.

2 CO-CHAIR GIBBONS: Other
3 thoughts?

4 DR. MAGID: Yes. I would just
5 encourage the measures that, and we talked
6 about this, the measures that talk about
7 prescription of a medication at discharge,
8 to really think about the possibility of
9 going beyond that, because we know that a
10 fair number of patients, you know, they may
11 write that the patient is going to get this
12 at discharge but then we find out later they
13 either don't pick it up even the first time
14 or refill it. There's a huge drop off at
15 the second. So being able to look at these
16 medications, which are really intended for
17 chronic use over a time, make sure that they
18 actually receive it and that they take it
19 for longer. I know it may not be something
20 that we can request them to do right now,
21 but the next time they come around that's
22 probably where they need to go.

1 CO-CHAIR GIBBONS: Okay. So I'd
2 like, I think there will be more authority
3 in this if there's a vote. So in terms of
4 the short-term communication regarding the
5 need for data regarding disparities, can I
6 have a show of hands as to all of those who
7 are in favor? Okay, all right. And in
8 terms of David's suggestion that we
9 encourage measure developers to look at
10 medication issues over time rather than a
11 single point in time, those who are in favor
12 of that? Are there any nays?

13 You know, unless you prod them
14 they're never going to try. All right. Now
15 I want to move to the --

16 DR. BURSTIN: A quick follow-up
17 question as long as you're being so
18 decisive. So on the disparities piece, so,
19 yes, you want to see that they include data
20 on known disparities. The second thing is
21 if you guys come forward and say this is a
22 measure of known disparities, part of what

1 we're struggling with is should the measure
2 we currently tag it as disparity-sensitive
3 and indicate it's a measure that should be
4 stratified, would you like to see that
5 stronger --

6 CO-CHAIR GIBBONS: Okay. That's
7 the longer term so that's about the next
8 part of this.

9 DR. MAGID: Actually, I think the
10 interesting thing about disparities would be
11 to look at to what degree the disparity
12 occurs because patients of certain
13 characteristics go to hospitals that perform
14 worse versus actually within a hospital
15 whether they receive it, so sort of Betsy
16 Bradley's work where she showed that the
17 disparity between, say, African-Americans
18 and whites was more due to the hospitals
19 that African-Americans got cared for than to
20 actual disparities within a given hospital.

21 CO-CHAIR GIBBONS: Yes?

22 DR. RUSSO: Just another comment,

1 since you're asking for other, is there
2 someway that there could be some mention of
3 what expectations would be if the
4 performance, as they're resubmitting, if the
5 performance on the measure was greater than,
6 it's being considered for retirement so it's
7 greater than a certain percentage and
8 there's no variation across anymore, is
9 there some way we could suggest before it's
10 submitted, some standard that maybe --

11 CO-CHAIR GIBBONS: Well, there's
12 another group already tasked with that. So
13 I think that already exists. Dr. Masoudi?

14 DR. MASOUDI: Yes, I was just
15 going to say I completely agree with what
16 you're saying, and I think the measures that
17 I discussed actually include it, and that's
18 not the point. The point is, from a
19 developer's perspective, it would be good to
20 know in the submission form exactly what is
21 being expected. People are interested in
22 age, people are interested in gender, if

1 they're interested in race, whatever the
2 stratification variables are, it would be
3 good for developers to know that that is
4 being mandatory as part of the submission
5 and what the stratification variables are.

6 CO-CHAIR GIBBONS: I
7 wholeheartedly agree, and that was going to
8 be my longer term suggestion that the blank,
9 and help me what field it is, 2G, H? 2H.
10 That that blank is going to be given high
11 priority and that the submitter needs to
12 supply data regarding race, gender, age,
13 payer. What else did we mention?

14 DR. AYALA: You have to include
15 ethnicity because the OMB --

16 CO-CHAIR GIBBONS: Ethnicity.
17 And if they can't supply that data, indicate
18 why. But that's a requirement. I would
19 suggest we go on record empowering the staff
20 for the future applications that unless that
21 blank is adequately detailed we will not
22 consider the application. That's the only

1 way I think we can drive the process. And
2 as I said, I think this is an important
3 societal issue that somehow or other is
4 getting lost in the field of measurement,
5 and I think that's appalling.

6 DR. SANZ: I wish to add
7 rural/urban since, according to our Chair,
8 25 percent of the people in the United
9 States are in a rural area. And these
10 measures, many of them have significant
11 differences in rural areas.

12 CO-CHAIR GIBBONS: Now, sometimes
13 all of these things won't be available, but
14 we'll at least hold people's feet to the
15 fire to try to get them. Dr. Masoudi, do
16 you have other suggestions?

17 DR. MASOUDI: Just one other
18 quick thing, which is that all the measures
19 for this cycle have already been submitted.

20 CO-CHAIR GIBBONS: Oh, yes.

21 DR. MASOUDI: So they won't --

22 CO-CHAIR GIBBONS: No, they're

1 not affected. This is for the future. This
2 is for the future.

3 DR. MARJORIE KING: Easily go
4 back to those who have --

5 CO-CHAIR GIBBONS: Oh.

6 DR. WINKLER: Measure developers
7 can expect that measures that will be viewed
8 in phase two we'll be back at you.

9 DR. AYALA: I mean, in answer to
10 Helen's question, there were three specific
11 indicators that we talked about here where
12 people raised the question about race and
13 gender, and they were 0289 median to ECG,
14 0163 primary PCI within 90 minutes, and 0290
15 median time to transfer to another facility.

16 CO-CHAIR GIBBONS: I think it's
17 wonderful that you kept track of that. I
18 really do. I commend you for keeping track
19 of that. So now we get into this question
20 that Helen raised, which is not actually
21 about blank 2H. It's about the earlier
22 blank.

1 DR. BURSTIN: It's still about
2 disparity. So the question would be we
3 currently can tag them with the three that
4 you just read off. We'll say these are
5 disparity sensitive, and we would encourage
6 these measures to always be stratified.
7 Should it be stronger? Should it be that
8 these measures should not be publically --
9 I'm just throwing this out, just curious
10 here, you know, should measures like that
11 where there are known disparities always be
12 stratified so that you don't ever just look
13 at a lump without being able to see what's
14 underneath it?

15 CO-CHAIR GIBBONS: Thoughts about
16 that issue?

17 MS. ALLRED: I would say
18 absolutely yes because we already know from
19 our experience that there are a lot of
20 disparities that exist, and it isn't just
21 women versus men. Sometimes it's young
22 women versus older women. Young African-

1 American females, we know the first thing
2 that is looked at in them when they go to
3 the emergency room is cocaine use and
4 instead of, you know, chest pain being heart
5 attack. So I think there are a lot of
6 issues that could be looked at, and that
7 information ought to be readily available on
8 any of these that are coming off the medical
9 records.

10 DR. KOPLAN: I think everything
11 that's been said is extremely important, but
12 we just want to be a little bit careful not
13 to be viewed as, I would think, as a group
14 where that's like our only first priority
15 because there's some other aspects to
16 measure development.

17 DR. BURSTIN: There's a whole
18 disparities group that's beginning in a
19 couple of months. I was just really, since
20 Ray brought it up, picking your brain
21 because that's exactly what they're going to
22 have to figure out.

1 DR. KOPLAN: Yes. But to make it
2 a requirement across the board is a little -

3 CO-CHAIR GIBBONS: Well, the
4 requirement is that they not blow the blank
5 off, which many of the submissions clearly
6 did. They put nothing in there and, yet,
7 when questioned here said, well, we have the
8 data, we haven't analyzed it. I'm sorry.
9 They should have analyzed it and put it in
10 the blank. So that's the driver, Bruce.
11 And sometimes they didn't have the data.
12 It's not a field that they're capturing but,
13 hopefully, it will inspire them in the
14 future to add that in the next round or in
15 the next update or whatever because, you
16 know, we've struggled for too long as a
17 country without very much progress, and I
18 think we need to start to make some
19 progress.

20 DR. AYALA: You know, one
21 positive thing about linking quality
22 measures to disparities is that it's been

1 shown, at least in the Robert Wood Johnson
2 Foundation's Expecting Success Excellence in
3 Cardiac Care, I was one of the project
4 directors for that program, that when you
5 use quality improvement you can actually use
6 it as a non-controversial solution to
7 eliminating disparities because, as people
8 focus on getting as close to 100 percent
9 compliance with the quality indicators as
10 possible, any disparity that existed prior,
11 it shrinks, it goes away, it vanishes just
12 by definition because people aren't so
13 focused on all the qualitative and emotional
14 aspects of disparities but they're focusing
15 on the right thing, and that is providing
16 the high quality evidence-based medicine to
17 every single patient regardless of their
18 background. And when they do that and they
19 start achieving really high compliance rates
20 with the quality indicators, their
21 disparities disappear. And we saw that in
22 that project, and so I'm an advocate for

1 using quality improvement to actually
2 eradicate disparities.

3 CO-CHAIR GIBBONS: Thank you for
4 bringing that up. I'd actually forgotten
5 about that. I was present at the
6 presentation of that at the national NQF
7 meeting October 2009 perhaps, maybe 2008,
8 one of those wonderful years, and I can
9 remember that graph which was pretty darn
10 clear with respect to the gap narrowing. It
11 was very, very impressive. Thank you for
12 bringing that up.

13 Okay. So, Helen, do you need any
14 more guidance about this issue? Okay, good.
15 Now, should we look at the portfolio?

16 DR. WINKLER: A couple sort of
17 big picture questions that go along with
18 your role as providing guidance for
19 evaluating the portfolio. The first one is
20 three measure developers have asked for
21 measures that were previously endorsed by
22 NQF to be retired, and mostly these are not

1 supported anymore. The question we would
2 just ask you is do you have any particular
3 feedback, questions, concerns? Does it give
4 you heartburn that these are going away? We
5 just want to take advantage of your
6 expertise and the fact that you're kind of
7 looking in this context, as we, you know,
8 kind of look at the whole portfolio.

9 The measures are, the first one
10 is 72. This is beta blocker treatment after
11 heart attack from NCQA. This is a HEDIS
12 measure that they actually stopped using
13 because performance rates became very, very
14 high.

15 The second one is an AMI
16 inpatient mortality. This is the measure
17 originally from the Joint Commission. The
18 Joint Commission has taken that out of use
19 in favor of the 30-day mortality that they
20 work with jointly with CMS. So that measure
21 is, I think they've still got it in their QI
22 portfolio, but they're asking it be retired

1 from NQF's portfolio.

2 And the last one is from ACC, and
3 one of the very earliest measures endorsed
4 by NQF back in 2002 or something like that
5 was PCI volume, and that measure has been
6 asked to be retired. So --

7 CO-CHAIR GIBBONS: So why don't
8 we take these in order. The first one, the
9 beta blocker, Rochelle, you were the primary
10 reviewer on the PCPI measure related to
11 this. Thoughts about this?

12 DR. AYALA: Now, is this the one
13 --

14 CO-CHAIR GIBBONS: This is not
15 the measure you reviewed. This is a
16 potential competing measure that's being
17 retired.

18 DR. AYALA: Now, is this one in
19 the hospital or when they get discharged?

20 DR. WINKLER: No, this is a, this
21 is a health plan level measure, and it is
22 looking at patients who have had a heart

1 attack but in the outpatient realm. So
2 they're looking at usually prescription
3 data.

4 DR. RASMUSSEN: So this measure
5 was actually a beta blocker prescription
6 within seven days of discharge, so, again,
7 one of those single point adherence
8 measures. And now the measure we discussed
9 yesterday is that more of a long-term
10 adherence measure. So really peg the needle
11 on this one that we're talking about and now
12 extend it out to 180 days medication
13 adherence.

14 DR. RUSSO: The only comment, as
15 we retire them, and it certainly makes sense
16 to do so, and, obviously, I like beta
17 blockers, but if you're retiring all of the
18 beta blocker measures I guess the only thing
19 I would wonder is, number one, should we
20 look back in a few years to make sure that
21 now people don't focus on something else and
22 that slips off and make that a standard, or

1 do we just promote when we retire, if we
2 retire all the beta blocker measures, do we
3 say we have a composite measure that somehow
4 we can get at it in the future or some other
5 long-term beta blocker treatment that may be
6 more important than initial treatment.

7 DR. WINKLER: One of the issues
8 with these measures is they're no longer
9 supported by their measure steward, so they
10 won't be available for future use. That's
11 different than, you know, keeping them out
12 of NQF's portfolio.

13 DR. AYALA: I just want to
14 clarify that we retired the beta blocker
15 prescription at discharge but not the one
16 for persistence of beta blocker use after --

17 DR. WINKLER: Well, just to
18 clarify, you haven't done anything final
19 yet, all right? That's why we've got the
20 rest of this agenda. You've made initial
21 steps, as I've described in the beginning,
22 step one, the initial evaluation. We still

1 have a bunch of work to do before your final
2 recommendations, okay?

3 CO-CHAIR GIBBONS: This is to
4 make sure you stay awake for the remainder
5 of the meeting. Other questions about the
6 beta blockers? I think we feel we're in a
7 better place with the measure we have.
8 That's the sense. Okay. AMI inpatient
9 mortality. Tom, do you want to speak to
10 this since you reviewed the 30-day one?
11 Retiring this one? Do you have any angst
12 over this?

13 DR. KOTTKE: No, I guess not.
14 There have been arguments that there are
15 important lessons from inpatient mortality,
16 but I think 30-day mortality is probably
17 more consistent with the systems that are
18 needed for good outcomes for patients.

19 DR. WINKLER: Just to mention,
20 trying to keep things simple but it does get
21 complicated, is currently there is another
22 inpatient measure from AHRQ on inpatient

1 hospital mortality that is at the very end
2 of the endorsement process. We don't lose
3 it all together.

4 CO-CHAIR GIBBONS: Any other
5 concerns about retiring inpatient mortality?
6 I'm sorry. The Joint Commission's version
7 of inpatient mortality. All right. And PCI
8 volume, Sid, do you want to comment on that
9 and any of the other interventionists?

10 DR. SMITH: Well, I'm not sure
11 who decided to retire the PCI volume.

12 CO-CHAIR GIBBONS: The ACC.

13 DR. SMITH: So I haven't seen the
14 thinking behind that. Initially, the
15 concern to which PCI volume addressed
16 itself was our need to identify quality of
17 outcomes, and there had been some data to
18 suggest that the more frequently the
19 procedure was performed the more likely it
20 was to be performed well. And volume
21 criteria had been submitted both for
22 hospitals and for operators. In addition,

1 there had been some data to suggest minimal
2 volumes for hospitals and operators that
3 were performing PCI for STEMI, and those had
4 been written into the guidelines with the
5 clear statement that they were only a
6 partial method to really assess outcomes and
7 that, when other approaches to assessing
8 outcomes were available, that the centers
9 were encouraged to participate in them. And
10 along the way there have been many, many
11 criticisms. It's very difficult with low
12 volume to really determine quality. The
13 fact that people are doing a lot of PCIs
14 doesn't necessarily mean that they are doing
15 them well and, in fact, there's been one
16 really notable problem in California where
17 angioplasties were being done for the wrong
18 reason. And then we have issues about
19 people starting up, issues about people that
20 are injured while they're skiing, and 75
21 year-old medical reasons.

22 So there are a lot of problems

1 and there's been a lot of controversy about
2 this. I think that the reason that it's
3 being recommended that this be retired was
4 what we talked about today. We have a new
5 program here to look at mortality associated
6 with PCI, and I think that probably is being
7 retired because it's felt that there are
8 better ways to assess outcomes than just
9 look at the number of procedures.

10 In many hospitals now, that has
11 been done by the hospital committees
12 themselves. So speaking from a level of
13 ignorance about why it's being retired,
14 that's why I would think it is, and I think
15 it's a reasonable suggestion.

16 CO-CHAIR GIBBONS: David?

17 DR. MAGID: Yes. I published two
18 articles, and there's one in New England
19 Journal and one in JAMA, so I think --

20 DR. SMITH: Yes, I've quoted your
21 articles, and we've used them. They're
22 good.

1 DR. MAGID: Thanks. I would say
2 that, first, so we looked at institutional
3 volume, not provider volume, and the
4 threshold is fairly low. And my guess is is
5 that, and Fred can speak to this, that the
6 number of institutions that are below that
7 threshold that report to the ACC NCDR PCI is
8 very, very small. And then the other thing
9 is, I agree, I think mortality is a better
10 outcome measure because it's obviously the
11 ultimate outcome that we're interested in,
12 so I would say you can probably get rid of
13 it.

14 DR. SMITH: Yes. I think
15 everybody has wanted to move beyond a number
16 of procedures to a better assessment of
17 quality, and we've seen examples here that
18 we're on the way to that.

19 DR. WINKLER: I think this is
20 just a reflection of how things have evolved
21 over time. And as better measures come
22 along, it can measure more important robust

1 aspects of care, such as outcomes. Some
2 measures have just outlived their
3 usefulness. So thank you. We wanted your,
4 I don't know, reactions to those before we
5 recommend them to the Board that they are
6 permanently removed from the portfolio.

7 Okay. A couple of other follow-
8 up things. I think, at this point, I just
9 want to mention to you what the next steps
10 are before we talk about just how we're
11 going to look at the whole portfolio. But
12 during the course of your conversations over
13 the last two days you've raised a lot of
14 questions that were either partially or not
15 totally answered, to say nothing of the fact
16 you've raised the disparities to the top of
17 that list of questions. What we're going to
18 be doing over the next few days is preparing
19 a series of questions to go back to the
20 measure developer to get responses for you.

21 This is an iterative process.
22 It's a dialogue. They gave you the

1 submission, you've responded to it. We're
2 going to go back. We're going to volley a
3 few times so that, as we move through time,
4 you will have greater understanding of what
5 the measures' strengths and weaknesses are.
6 So just be aware that that's an ongoing
7 process.

8 Once a steering committee has met
9 like this, our dialogues with the measure
10 developers are sort of on a very frequent
11 basis. We become the very best of friends
12 and regular e-mail buddies. So just realize
13 that that's really what's going to go on.
14 This does not stop. It really is part of a
15 fluid ongoing process. So we will be
16 bringing back some of these responses.

17 In that, some of the answers and
18 some of the information that may be added to
19 the mix that you haven't seen before will
20 help in terms of the final resolutions.
21 Probably the biggest question of information
22 we're going to need to approach the

1 developers about is this issue of
2 harmonization. In addition to
3 harmonization, you all have identified and
4 raised issues of measures that are so
5 similar that they're really competing. You
6 know, they're measuring the same thing. Is
7 there a point of having two, or does that
8 really become every confusing out in the
9 world?

10 So that is a huge task,
11 particularly with this set of measures, so
12 we did not want you to really get embroiled
13 in that at this setting. Now that you've
14 had your first pass through the measures, we
15 will want to be going back through that.

16 Let me just show you something
17 that I have not yet shared with you but we
18 will get there. And this is an additional
19 sort of embellished spreadsheet. We've
20 shared this with you at the beginning. This
21 is the portfolio of measures. They're
22 organized along the episode of care

1 framework. The measures that are
2 highlighted in yellow were the ones that you
3 looked at. They were either from a review
4 or new submissions.

5 What we've also done is begun
6 looking at them in terms of the measures
7 that are competing or require harmonization.
8 If you noticed, as we've scroll through, it
9 is not a short list. And you've raised this
10 issue many times. One of the more complex
11 issues about harmonization is sometimes we
12 need to harmonize the numerator with a group
13 of measures and then the denominator with a
14 different group of measures. The
15 inclusions, the coding for things like AMI,
16 CAD, ischemic vascular disease are amazingly
17 off by two or three or five little
18 inclusions and codes when you put them side
19 by side.

20 So we will be doing these
21 multiple side-by-sides, and there are not
22 just one or two. There are a large number

1 of them.

2 The first thing we're going to do
3 for harmonization purposes is we will be
4 taking it back to the measure developers and
5 get them together and say, look, you both
6 are trying to measure ischemic vascular
7 disease, you code it this way and you code
8 it this way; what is the deal here, you
9 know, why aren't they the same, and see if
10 we can get that harmonization to occur. It
11 is really their job to do. It's your job to
12 reflect and evaluate how well they did it
13 and whether they've actually done it well.

14 When it comes to actual competing
15 measures, this is an area that has become
16 very much a current topic. In one of our
17 projects that's recently trying to come to a
18 conclusion, the Board of Directors has sort
19 of pushed back on us and said, look, these
20 sound so much alike, it sounds like they're
21 competing, you need to help us, you know,
22 understand this issue of very, very similar

1 measures. As a result, policy is evolving
2 as we speak, and Helen will be happy to
3 share with you a decision tree that is
4 almost final that we will be using.

5 DR. BURSTIN: So this actually is
6 pretty hard to see. We'll make sure you get
7 this individually, but we've been working
8 and literally have a call next week with our
9 board to finalize this, some guidance on
10 competing measures. And so, essentially,
11 trying to define clearly what is and what is
12 not a competing measure. So same measure
13 focus, i.e. target process, condition,
14 event, or outcome, and same target
15 population. So you want to just be really
16 clear on what we're talking about in terms
17 of which ones are actually competing.

18 We then go through a process
19 where we say if they're competing measures
20 how would you assess superiority? And
21 that's going to be the next step here after
22 we get some clarity on this. So, for

1 example, importance to measure and report,
2 probably not going to be much of a
3 difference there as based on the evidence,
4 probably the same gap if they're competing
5 measures, etcetera. So it really comes down
6 to the next set of them. So for scientific
7 acceptability, for example, untested
8 measures of which you don't have, I think,
9 very, very few, cannot be considered
10 superior to tested measures, for example, as
11 one point we put forward.

12 We would also ask you to look in
13 terms of the specifications and the methods.
14 Can you pick the measure with the broadest
15 possible applications, settings, target
16 populations, compare on reliability and
17 validity, if you have that data. And then
18 usability, all else being equal, if
19 something is being publically reported it's
20 preferred. If a measure has got the widest
21 use, settings, number of entities, etcetera,
22 it's preferred. And measures that are in

1 use are preferred over those that are just
2 newly done and have never put out there at
3 all.

4 And then on feasibility, again,
5 measures of electronic sources, of course,
6 given the feasibility concerns, are
7 preferred. And measures that are freely
8 available are preferred, as well.

9 But, finally, we recognize, even
10 if you go through all that, and that's the
11 situation we're in with the three measures
12 we're going back to the Board on next week,
13 sometimes you're going to come to the point
14 where they're competing measures and there's
15 no clear superiority based on those
16 criteria. And so there we've been trying to
17 come up with some guidance to say if there's
18 not clear superiority can you justify having
19 endorsement of multiple measures? And does
20 that added value offset any negative impact?

21 So, for example, if perhaps the
22 measure allows you to move more easily

1 towards and EHR-based measure, is that
2 something to consider? Or if the additional
3 measure is applicable to an additional
4 setting or significantly increases the
5 number of entities that you could capture,
6 is that another reason to do it? But then
7 the key thing there would be those two
8 measures that have to be harmonized.

9 So we'll bring this to you in
10 final form as you go through your next
11 process, but we want to, you know, going
12 back to Dr. Smith's comment earlier, we're
13 trying to give you as much guidance as I
14 think you're going to need to go into this
15 brave new world for us in this next phase of
16 work. So more to follow, but if you have
17 any thoughts please let us know. And we'll
18 share this with you on e-mail.

19 CO-CHAIR GIBBONS: So, Helen, can
20 we put this little flow diagram to a little
21 test?

22 DR. BURSTIN: Sure.

1 CO-CHAIR GIBBONS: Do you think
2 it's ready for that?

3 DR. BURSTIN: It's almost cooked.

4 CO-CHAIR GIBBONS: All right. So
5 we had this discussion earlier today about
6 the median time to fibrinolysis and
7 fibrinolytic therapy received within 30
8 minutes. The percentage versus the median.
9 Can we sort of help me, those who discussed
10 these, to try to apply these criteria to
11 that situation.

12 DR. MAGID: Can I just ask a
13 question about that? I thought that the
14 issue was it wasn't extra work to provide
15 the --

16 CO-CHAIR GIBBONS: No, wait,
17 wait, I know. But we're just trying to
18 apply, these are the criteria --

19 DR. MAGID: No, no, but I know.
20 But I thought we heard that there were
21 constituents who preferred it one way versus
22 another, and if there's not any extra work

1 is that a problem to present it more than
2 one way?

3 MS. PACE: Right. But I think
4 that may ultimately be your conclusion, but
5 we're starting with the idea they're both
6 trying to measure the therapy given at the
7 right time in the same population. So the
8 question is, you know, they're trying to do
9 the same thing and do we need both.

10 DR. AYALA: And one other
11 question. So this is the issue at hand with
12 things that we already have and even looking
13 forward. So you're going to have new
14 measures. We're assuming that people who
15 developed them have looked at everything
16 that's out there. Should there be something
17 on the application that says if you see this
18 might be a competing measure let us know the
19 pluses and --

20 CO-CHAIR GIBBONS: It's there.

21 DR. AYALA: It is. So you have a
22 lower chance of getting approved because

1 it's competing, but show us why it's better
2 and what might be --

3 CO-CHAIR GIBBONS: But until this
4 process plays out to actually, you know,
5 identifying or choosing between competing
6 measures, I think we saw in this round of
7 applications that a number of applications
8 just chose to politely ignore that blank.
9 They really did not give much credibility,
10 their answer wasn't credible. I'll say
11 that. I suspect they just didn't think that
12 blank was important.

13 MS. PACE: So we are on the next
14 version of the measure submission, being
15 even more directive about that. We're
16 asking measure developers to attest that
17 they've actually identified and worked on
18 these harmonization and competing measures
19 issues. Otherwise, it will not be accepted
20 for consideration.

21 CO-CHAIR GIBBONS: I hear tough
22 love works very well. Okay. So for those

1 in the back of the room, why don't you read
2 the first box and then we'll try to apply it
3 to this group because I think they're having
4 trouble. To be honest, I'm having trouble
5 with my bifocals in the front of the room.

6 DR. WINKLER: Well, the first one
7 is does anybody disagree that those would be
8 competing measures? They're measuring the
9 same measure focus, same target population.
10 So it brings us into importance to measure
11 and report. You should have the same
12 information on opportunity for improvement
13 and the evidence base for the measure. So
14 that should be a wash. So we move into
15 scientific acceptability, and both of the
16 measures are tested, so that does not give
17 us any discrimination. And then we're
18 looking at measures with the broadest
19 application or comparison of reliability and
20 validity on the overall criterion.

21 DR. KOPLAN: Sorry to interrupt.
22 In this particular instance, the reason why

1 David maybe had a little issue with this
2 example, if you go all the way to the top of
3 the -- oh, sorry. Where it says numerator.
4 The numerators are different, right? If
5 we're just using this example, you would --
6 in other words, you would stop right there.
7 That's why it might have been better to do,
8 like as an example, use aspirin and MI
9 versus aspirin and ischemic vascular disease
10 because the numerators are the same and the
11 other stuff is different.

12 DR. WINKLER: Yes, but I think
13 what Karen would say to you is that the
14 numerator, though, is you're measuring the
15 same, you're measuring the same thing: time.
16 So I don't know if it has to be that
17 identical.

18 CO-CHAIR GIBBONS: If you just
19 took numerator out of there and just said
20 same measure focus -

21 DR. KOPLAN: But in this example,
22 in this example, that is the only issue. So

1 the whole rest of the stuff, you are going
2 to get to the end - so it didn't work.

3 CO-CHAIR GIBBONS: It would be
4 worse if she was crying.

5 MS. PACE: Some people don't
6 understand what we mean by measure focus
7 because they're totally focused on
8 terminology of the numerator, so that's the
9 reason for the parens. But we can just as
10 easily take it out. But the idea is we're
11 not looking for measures that are exactly
12 the same because if that's our criteria then
13 we would not have any competing measures
14 because they always differ by something. If
15 they were exactly the same it would be the
16 same measure. So we're really looking at
17 measures conceptually first that are really
18 trying to measure the same clinical
19 phenomenon or condition or --

20 CO-CHAIR GIBBONS: Well, I'm
21 going to keep driving this because you've
22 got this draft. So if we come down and say

1 compare usability. Now, there's a statement
2 that measures that a publically reported are
3 preferred, but these are both publically
4 reported, measures with the widest use are
5 preferred, same, you know. So I don't know.
6 So then we get down to -- yes.

7 MS. PACE: But I want to go back
8 because I think that perhaps one of the
9 things that we have to deal with and it
10 needs to be discussed further, if we go back
11 up to scientific acceptability. So they
12 have different methods of getting at the
13 same issue. And should we talk about is
14 there some bullet point or some way to look
15 at which is the more valid way to measure
16 that? And then on the usability side, which
17 one gives you better information on which to
18 drive improvement? So we're probably
19 missing some things, but that's what we'd
20 like to -- I mean, how would you compare
21 them? Do you think it's a methodology
22 issue? Is there one that's a better

1 methodology in terms --

2 MS. SZUMANSKI: I think if you
3 talk to people in the trenches, they're
4 going to say that the percentiles that you
5 see in median time to fibrinolysis are very
6 usable to them, which may be different than
7 the other measure. The question is who are
8 you producing this information for? And I
9 think that is the splitting difference
10 between these two particular measures on the
11 same topic.

12 CO-CHAIR GIBBONS: I think it
13 really does boil down to that. I mean, I'm
14 surprised they're both publically reported,
15 to be quite honest. I'd love to see the
16 survey of Americans as to what percentage of
17 Americans know what the word "median" means.
18 So from the public, you know, patient
19 perspective, that one is virtually
20 worthless. On the other hand, for quality
21 improvement, that one is better than the
22 point estimate or percentage below the

1 cutoff. So you have an argument both ways
2 on this.

3 DR. MAGID: You know what would
4 be interesting to see would be whether
5 institutions really are ranked in a
6 different quartile on the different
7 measures. If you find that they're really
8 ranked in the same quartile across both
9 measures then they're really not providing
10 any additional information, whereas
11 something like mean, where you could have
12 one outlier that pulls things up, it
13 wouldn't be surprising to see a difference
14 in ranking.

15 CO-CHAIR GIBBONS: Since we had
16 an extended discussion about this one
17 earlier today, while it's fresh in
18 everybody's mind, I really think we should
19 come to a decision on this one. That is, as
20 we understood it, no incremental work of
21 having a second measure, and we have one
22 measure that's, I would argue, more patient

1 friendly and another measure that's more
2 provider friendly with respect to quality
3 improvement. How does everybody feel about
4 continuing both measures? Does that seem
5 reasonable, given that construct? And then
6 we'd invite comments from the public.

7 DR. RUSSO: The only comment I
8 would have, although it's no additional work
9 to collect it, we are reviewing two separate
10 measures each time. It's minimal additional
11 work for us, I guess every three years, or
12 is it even an option to say go back to the
13 developer and say, hey, listen, can you
14 combine these into one and measure "or" or
15 "and" or one of the other in the same
16 measure so you review just one measure each
17 time, or can they pick? Maybe they have a
18 preference.

19 DR. SNOW: They're so close to
20 each other. They're two elements of the
21 same concept. We just put them together,
22 line one, line two, with one number, one

1 measure with two arms; is that wrong?

2 CO-CHAIR GIBBONS: Well, there
3 are two different lines on Hospital Compare,
4 I believe. Somebody can help me. Fred, is
5 that right?

6 DR. KOPLAN: When people compare
7 medians, I worry. I'm not as experienced
8 with this kind of thing, but, you know, if
9 there's some standard you have to meet where
10 there's a cutoff, a percentage, like
11 everybody is greater than 90 percent of X,
12 of some standard, then hospitals can be
13 equivalent when there's a median. If one
14 has a number of 87 and another has a number
15 of 86, and it's on Hospital Compare and
16 people look at that, they're going to say,
17 some people will say that one is better than
18 the other one, even though the difference
19 may not be significant. So don't you tend
20 to usually always say, okay, if you meet
21 this cutoff you get a passing grade and
22 that's kind of a better way to approach

1 quality, or am I wrong about that?

2 MS. PACE: I think that there's
3 differences of opinion about that. I mean,
4 the phenomenon you're talking about also
5 kind of gets into the reporting issue and
6 whether you identify the amount of error
7 around a point estimate to show that there's
8 no difference between 91 and 90. You know,
9 so some of this kind of gets over into how
10 the data are displayed versus the actual
11 measure construction, but it's a good point.

12 CO-CHAIR GIBBONS: There is an
13 unforeseen kind of consequence which we have
14 to, at least theoretically, consider, which
15 is that, in the course of taking care of an
16 individual patient, somebody realizes
17 they're already past the threshold. They'll
18 be less likely to hurry if they know they've
19 already failed, whereas a median will
20 capture that data so they'll presumably have
21 an incentive to keep hurrying. I have no
22 idea how often that happens, but I'm sure it

1 happens because everything happens.

2 DR. AYALA: In terms of
3 operational, I'm wondering how the median
4 impacts the quality improvement process more
5 than the percentage. Because in the median
6 process you can actually throw out your
7 outliers, but those are, you know, those are
8 included when you're looking at your
9 percentage of compliance.

10 CO-CHAIR GIBBONS: Fred, do you
11 want to try to answer that question?

12 DR. MASOUDI: I mean, these are
13 just things we've heard in implementation.
14 I can't tell you why people, you know,
15 necessarily like these things but --

16 DR. AYALA: I'm just going to
17 share my experience for a moment. I was
18 actually asked, when I was doing the Robert
19 Johnson Foundation project, to serve as the
20 chairperson as the PCI task force, and every
21 time we had a fallout, even if it was just
22 like by one minute, oh, my gosh, you should

1 have seen the angst that everyone went
2 through, and we had to look at every single
3 time segment along the process. And we
4 really took everything really seriously. My
5 feeling about the median is that it might
6 actually cause a bit of a more relaxed
7 approach to the quality improvement process
8 because then you can get rid of your
9 outliers. And outliers are really important
10 because, in our situation, the outliers
11 tended to be the patients who came with
12 atypical chest pain or no chest pain at all,
13 you know, the atypical presentations where
14 we had to cast our net wider to capture
15 those early so we got that EKG within,
16 actually ten minutes is a good estimate but
17 less than ten minutes.

18 So, to me, the real true
19 attention to the indicator itself, which is
20 evidence based, to me, it's more pressing
21 when it comes to your operational quality
22 improvement process. That's just my

1 experience.

2 DR. BURSTIN: I just checked on
3 Hospital Compare, and, at least currently,
4 only the two threshold measures are
5 reported, not the median. So one could make
6 the argument this is probably reported and
7 very useful for internal QI, so maybe these
8 should continue to be the ones publically
9 reported. So consideration for you.

10 CO-CHAIR GIBBONS: By your
11 criteria then, the proportion would win.
12 We've just gone through it. Everything else
13 is equal, so the proportion would win
14 because it's publically reported.

15 DR. KING: I have a question.
16 Have you considered that this might be what
17 we call a technicality? The measure is the
18 time to get fibrinolytic therapy. You can
19 express that as a time, a percent that gets
20 it under a certain number of minutes. You
21 can express it as the number of people 50
22 and over that get it. You can express it as

1 the number of males or females or blacks or
2 whites or Hispanics that get it. Each of
3 these measures, and there has been no
4 restriction that I've heard thus far, has
5 multiple ways of displaying. And we, just a
6 few minutes ago, President Chairman,
7 encouraged, indeed demanded that they use
8 the measure and report it in more ways. So
9 I say, sir, in the sake of harmony, that we,
10 by fiat, declare that this is, in fact, one
11 measure, it already is, and the consumers of
12 it can see the data however they'd like.

13 CO-CHAIR GIBBONS: Well, that's
14 going to be hard for anybody to say anything
15 after that. So we'll just vote on that
16 proposal, which would, in essence, leave
17 both of them as is as different expressions
18 of the same data regarding time to
19 fibrinolysis. All in favor? Opposed? All
20 right.

21 DR. BURSTIN: That's why I think
22 coming back and actually presenting this to

1 you a little more thoughtfully with tables
2 would be nice just because --

3 CO-CHAIR GIBBONS: Well, I think
4 we had a volunteer to try a second example,
5 if you're willing.

6 DR. BURSTIN: I think a second
7 example, if you guys are willing, would be
8 great. I'm just saying that the first one
9 is a little complicated because one of the
10 measures is only, I think, for transfer
11 patients. So we just want to think about
12 this. It's a little nuanced, though.

13 DR. MAGID: That's the issue with
14 the aspirin, so it's going to be hard to
15 harmonize.

16 CO-CHAIR GIBBONS: Actually, no,
17 both of those are on transfer patients, I
18 believe.

19 DR. WINKLER: Yes. The pair is
20 for the transfer measures, the percentage is
21 the only one for hospital measures.

22 CO-CHAIR GIBBONS: Okay. So I

1 think the other eager volunteer to try this
2 framework -- well, we want to test the
3 framework -- occurred earlier in the day
4 yesterday. Now, I know this has been a
5 wonderful experience and you probably have
6 difficulty remembering that, but we did
7 consider vascular disease use of aspirin or
8 anti-thrombotics and CAD antiplatelet
9 therapy back to back, okay? And Bruce had
10 the first one.

11 DR. KOPLAN: I remember mine said
12 the CAD antiplatelet therapy, or mine was
13 aspirin and vascular disease, and then was
14 the person who did -- okay.

15 CO-CHAIR GIBBONS: George had the
16 other one.

17 DR. KOPLAN: So in terms of going
18 through this, the competing measures, so the
19 measure focus appears to be the same. Would
20 you agree, George?

21 DR. PHILIPPIDES: I think one was
22 vascular disease --

1 DR. KOPLAN: Oh, that's right.

2 Mine is --

3 CO-CHAIR GIBBONS: That's going
4 to be the target population --

5 DR. KOPLAN: So mine is more
6 encompassing, I shouldn't say mine. The
7 aspirin in ischemic vascular disease. No, I
8 don't want to be, I'm already responsible
9 for all the right heart caths in the 1990s
10 in Massachusetts. So ischemic vascular
11 disease is a wider net than CAD. That's the
12 denominator, and the numerators are the
13 same.

14 CO-CHAIR GIBBONS: So, Helen, per
15 this construct, does it end there? Because
16 there were other major differences in these
17 measures when we were discussing them.

18 MS. PACE: Well, one of the
19 things that we didn't include here was
20 actually a discussion before we get to the
21 competing is whether something like that
22 should be combined into one measure.

1 DR. BURSTIN: So for example,
2 could it be IVD with a strata for CAD, if
3 you think it's important enough to have CAD
4 separate. Just an example of perhaps ways
5 to approach that.

6 CO-CHAIR GIBBONS: Well, as I
7 recall, one of the dilemmas of having those
8 two back to back was that the exclusions
9 were different and were much more carefully
10 defined, as I recall, from a clinical
11 standpoint in the second measure that George
12 reviewed. Is that right, George?

13 DR. KOPLAN: Agree, yes. I
14 remember that, too.

15 CO-CHAIR GIBBONS: Yes.

16 DR. KOPLAN: And people had the
17 issues with the lack of exclusions in the
18 aspirin in ischemic vascular disease.

19 CO-CHAIR GIBBONS: So I think
20 that that experience would suggest there's a
21 potential to broaden perhaps, I mean I think
22 there was a solution for that one.

1 DR. KOPLAN: The decision tree is
2 a tree you have to go down even if you stop
3 at one branch. You still have to go down
4 the tree anyway.

5 MS. PACE: I mean, because, you
6 know, you point out a good thing. I mean,
7 strictly speaking, those were different
8 denominator populations, but the question is
9 should they be? I mean, does the evidence
10 indicate that aspirin is really indicated
11 for the broader population? Then if there's
12 some way to work through that, either
13 combining or --

14 CO-CHAIR GIBBONS: So we're now
15 starting assignments for the next
16 interaction of the meeting. And you guys
17 were which group?

18 DR. KOPLAN: Three.

19 CO-CHAIR GIBBONS: Three. So I
20 would suggest, hearing no objections, that
21 group three be tasked with looking at those
22 two, 0068 and 0067, with respect to

1 suggestions for reconfiguring those into a
2 single measure and then which framework,
3 which measure developer gets that feedback
4 and tasked with doing that. Because it
5 would seem to me that that's an example of
6 something where we could conceivably
7 eliminate a measure by creating one very
8 good one.

9 DR. RASMUSSEN: What are the
10 implications if we have two measures that we
11 harmonize that have different developers?

12 CO-CHAIR GIBBONS: If they can be
13 harmonized using the same platform, in terms
14 of criteria, I would suggest that it can go
15 forward that way. But in this case, if we
16 were to favor, for example, the exclusions
17 listed in the AMA proposal, the NCQA process
18 would not allow them, as described by their
19 staff yesterday.

20 DR. RASMUSSEN: So to frame it
21 even more specifically, there can be one
22 owner and one developer. If we harmonize

1 two measures, one of the developers would
2 have to give up ownership.

3 DR. BURSTIN: We actually do have
4 some examples of co-ownership, but they
5 would need to come together and agree. But
6 it takes a long time I'll warn you, having
7 just spent about five months trying to get
8 one C-spine measure combined. It takes a
9 long time.

10 MS. PACE: The other thing, and I
11 think what Reva said is that for the ones
12 that are clearly harmonization issues versus
13 competing, you know, she's going to go back
14 to the developer to ask them to harmonize.
15 Now, when they're competing and you're
16 trying to make a decision of one or the
17 other, that's why if you can identify one
18 that's clearly superior, that's the more
19 efficient route because trying to get two
20 developers, after they've invested in a
21 particular measure, as Helen said, is quite
22 lengthy.

1 CO-CHAIR GIBBONS: Okay. What
2 group were you in? What group number?
3 Four? So I would suggest a similar task for
4 group four with respect to measures 0075 and
5 0074 on lipid control, which Mary discussed
6 both of those yesterday. And as we went
7 through those, I think there were
8 discernable differences in the way they
9 approached exclusions that potentially offer
10 an opportunity for us to take a position.
11 And I think it best done not on the spur of
12 the moment here but after careful due
13 deliberation with whatever kind of wine in
14 hand you want for that evening.

15 DR. WINKLER: And side-by-side
16 tables from us, so we'll make it easy for
17 you to see the similarities and differences.

18 CO-CHAIR GEORGE: With these
19 being both outpatient measures, do you see a
20 need to try to harmonize with similar
21 discharge measures from the hospital
22 setting?

1 DR. WINKLER: I think we will ask
2 you that question and, you know, add that
3 into the mix. I think Mark was the one who
4 noticed, what is it, five measures for
5 aspirin use? So I do think that is a
6 question for you to address. You may decide
7 that it's okay to have some differences
8 based on setting, but I think it's important
9 that you consider it explicitly and be able
10 to provide the rationale for that. So as I
11 said, this is very complex how we're going
12 to have to make these multiple comparisons.

13 MS. SZUMANSKI: I think there are
14 two other variables that are not listed up
15 here that we've mentioned today. One is on
16 diversity, the impact on diversity, diverse
17 populations. And the second one, as
18 difficult as it is to think about, is the
19 financial impact of the monitoring of that
20 measure or what impact does it have on the
21 institution in terms of their reimbursement,
22 etcetera. So I think those are not listed

1 here and may or may not be important, but I
2 think they're worth being said at least.

3 CO-CHAIR GIBBONS: I think
4 they're more than worth being said. Thank
5 you, Kathleen. I think they're both very
6 important points for this process. And
7 Helen is intensively revising the grid as we
8 speak. It's just become two pages or else
9 it's one page of impossible to read print
10 under any circumstances.

11 MS. PACE: You actually didn't
12 get the actual algorithm and other things.

13 CO-CHAIR GIBBONS: All right.
14 We've talked about the antiplatelet issue.
15 We've talked about the lipid issue. I think
16 the other issue that repeatedly surfaced in
17 various ways is blood pressure. And we've
18 given a clear message back to the Minnesota
19 Community Measurement Project and,
20 hopefully, we'll see a revised submission
21 from them, but the NQF has already endorsed
22 a blood pressure measurement for diabetes,

1 blood pressure measure I should say for
2 diabetes. DR. WINKLER: And you
3 will see the measure for blood pressure
4 control for hypertension in phase two.

5 CO-CHAIR GIBBONS: So what I
6 would respectfully suggest here is that
7 everybody put their thinking caps on because
8 we can't have potpourri of confusion for the
9 remainder of 2011, pending the release of
10 JNC 8. And I do think we want to take a
11 position that seeks to have a uniform blood
12 pressure standard. And this is another big
13 topic but I would like people to think about
14 it. I would throw on the table a strawman
15 which is that all of these developers should
16 be told in very clear terms that they have
17 to comply with JNC 8 pronto to avoid
18 confusion in the practice community because
19 I think that's one thing that drives docs
20 nuts is to see different "guidelines" from
21 different groups, and blood pressure, it
22 seems to me, should be driven by the

1 national process that NHLBI has directed for
2 years. Mark?

3 DR. SANZ: So having said that,
4 how quickly and what's the mechanism so that
5 15 busy people don't have to come together
6 to approve some change in the measure?

7 CO-CHAIR GIBBONS: Staff, help.

8 DR. WINKLER: Well, Mark, what
9 are you asking? In terms of what level?

10 DR. SANZ: Well, I think the
11 guideline is --

12 DR. WINKLER: Right, okay. All
13 right. Whenever evidence changes, major
14 guideline changes, NQF has a process of
15 having an expeditious ad hoc review that
16 doesn't require the entire world to come
17 together and talk about it that we would put
18 into play for these measures.

19 CO-CHAIR GIBBONS: We were
20 thinking about a simple site visit to
21 Montana to discuss it.

22 DR. WINKLER: But this is not an

1 infrequent thing. If you recall the ACCORD
2 trial, I mean, lots of things happen on a
3 regular basis, so we have had to deal with
4 this issue previously. It's not a new
5 problem.

6 CO-CHAIR GIBBONS: Are there
7 other issues of harmonization that were
8 mentioned as we went through, particularly
9 now for the primary reviewers, remembering
10 that blank, that we need more extensive kind
11 of prep for for our next meeting? Those are
12 the three that I identified as we went
13 through. Mark?

14 DR. SANZ: I don't know if it's
15 another issue, but maybe you covered it and
16 I just don't remember. Why does it start,
17 like 67 and 68 are two different
18 organizations, why can't they be asked in
19 the next 30 days to review their own
20 criteria before we come back in April and
21 say what they can or cannot accomplish
22 rather than we have to do it for them? I

1 mean, we have other things to do.

2 DR. WINKLER: Mark, I'm sorry if
3 I wasn't clear, but that's exactly what I
4 said we were going to do.

5 CO-CHAIR GIBBONS: But I do think
6 it's worth pointing out that, as Helen has
7 politely indicated, this is a sometimes
8 difficult and long process. So she is still
9 dealing with the directives from the last
10 committee I served on when I had more hair,
11 so you can tell that it's taken a while for
12 this to play out.

13 DR. WINKLER: One of the things
14 that, having listened to you over the last
15 couple of days, for our meeting in April,
16 which I'm going to remind you we're going to
17 be looking at an additional 23 measures and
18 looking at a different topic area, this is
19 sort of the etcetera group, the
20 hypertension, atrial fib, heart failure that
21 fall into this cardiovascular bucket. There
22 are only 23 measures. Most of them are

1 maintenance measures. But in preparation
2 for that, we are going to go back to the
3 developers who've submitted their measures
4 and first we're going to go back and review
5 their submissions for things like
6 information on disparities and some of these
7 other questions you guys have raised. And
8 if it looks like they really have not
9 submitted appropriate information, we'll go
10 back to them and say, you know, it would be
11 in your best interest to fill in the blank
12 because the committee is not going to see
13 this favorably with no information. So it
14 will be an opportunity for them, as opposed
15 to a requirement. But we can certainly do
16 that for our April meeting.

17 We will need to get back with you
18 to finish the work on these measures. We
19 are going to have to schedule a couple of
20 conference calls. Hopefully, we can do a
21 bunch of this by e-mail. But as you can
22 see, this is a complex task as we try and

1 sort through all of these various issues,
2 particularly the competing measures and
3 harmonization issues. This is the first
4 project where we've had this level of so
5 many measures being involved in the need for
6 harmonization. Usually, it's a one or two
7 kind of thing, not every measure you've
8 looked at practically. So that provides its
9 own sets of new challenges.

10 CO-CHAIR GIBBONS: All right. So
11 the other thing that we want to briefly deal
12 with is the question of gaps in measures
13 that adequately describe the clinical care
14 process. This deals with, if you remember,
15 I don't know how to describe that diagram
16 across the board with the different process
17 steps. We had that at one point for an
18 imaging conference, and we all called it the
19 Masoudi diagram because Fred drew it on an
20 envelope and we ended up using it in the
21 publication. But in any case, that's sort
22 of, whatever that's called -- DR. WINKLER:

1 The bubble diagram.

2 CO-CHAIR GIBBONS: The bubble
3 diagram. And I would suggest that there
4 were actually examples that several of you
5 cited during these discussions, and so this
6 is the time to sort of put them on the table
7 for staff to mull them over and put them
8 into some sort of comprehensive form for the
9 developers. So one, for example, is the
10 point that Dana raised, which was do we have
11 a measure for people not going in the
12 hospital that reflects, basically, the goal
13 of good outpatient care, which is to keep
14 people from going in the hospital. That's
15 actually part of the continuum of care at
16 this point in time, as we heard from, I
17 think it was from, AHRQ, quote, could be
18 measured but isn't being measured.

19 The other one was the universe of
20 hospitals, which Sid kept us pointed towards
21 because he kept counting up the hospitals
22 and trying to figure out what happened to

1 them all. And I think that alludes to sort
2 of the whole issue of what is happening in
3 those, be it hospitals, practices, whatever,
4 who aren't participating in the voluntary
5 submission of data or the various registries
6 that are the sources of some of these
7 proposals.

8 But I'm sure some of you thought
9 about this as you looked at your individual
10 measure and thought about what needs to be
11 improved. So are there ideas that you want
12 to offer at this time, this is just free-
13 floating to sort of get them on the table
14 while they're fresh in your mind of things
15 where measures might really be needed. It
16 isn't to say there's a data source right
17 now, it isn't to say there's a track record,
18 but just to say this is something worth
19 doing. So I throw it open for ideas.

20 DR. RUSSO: Is it even a
21 possibility to even consider, so people
22 don't just pick a measure, I mean they

1 obviously can pick measures, but if there's
2 a group of measures they need to pick all
3 three as opposed to picking one that might
4 prevent some cherry-picking of measures that
5 they know they'll perform well in? I don't
6 know if that's --

7 DR. WINKLER: One of the
8 techniques that NQF has used through the
9 years has been pairing of measures, and
10 pairing is often a bad word when we're
11 talking about more than two, but grouping
12 measures such that the recommendation with
13 the endorsement is you don't use one, you
14 use all of them. So a paired set is they're
15 paired for use as endorsed measures and you
16 do them both. We have groups of three and
17 ten and whatever, if necessary.

18 The one thing I heard you all say
19 was use of composites. There seem to be a
20 couple of opportunities for composites, say
21 AMI discharge medications or PCI discharge
22 medications, all of that. And you also

1 seemed to like the idea of some of the all-
2 or-none composite approaches, did that
3 individual patient get the three medications
4 they were supposed to, as a way of
5 continuing to promote those processes of
6 care, even though right now the current
7 individual measures are kind of pretty much
8 topped out and unlikely to promote a whole
9 lot more improvement as is. So things like
10 that.

11 CO-CHAIR GIBBONS: So is that
12 really what you were thinking of, Andrea?

13 DR. RUSSO: It would be easier
14 than to have to create a whole composite
15 measure and put more work into it. If we
16 have the separate measures, then we'd have
17 to -- it's not exactly the same thing,
18 obviously, but at least you're going to
19 require people to report. You can't pick
20 something you didn't do well in and not
21 report that.

22 CO-CHAIR GIBBONS: The one

1 advantage of that is you can then turn it
2 into an all or none where you say, okay,
3 you'll get a score if you do all three of
4 these things. The IOM encouraged that in
5 their original report on performance
6 measures, and it's a hard bar then for
7 everybody, so you take these very high
8 adherence rates and suddenly they don't look
9 so high because the experience in the state
10 of Minnesota was that failure on one is
11 poorly predictive of failure on a second
12 one. Everybody thinks, oh, it must be the
13 same doc or the same patient or whatever.
14 Actually, it's not. They're almost mutually
15 exclusive. So it's a kind of interesting
16 thing where you're 92, 92, 92, 92, you'll
17 actually come down well below 80 on the all
18 or none. So there's some utility in doing
19 that, and I think, as I cited the example
20 which was repeatedly cited in the state of
21 Minnesota when this was being proposed, we
22 don't think you're delivering good care if

1 everything is perfect except the blood
2 pressure and that's 220 over 120. That was
3 a hard argument for any doc to counter.

4 Sid, you had a point.

5 DR. SMITH: Well, just a comment.
6 We're seeing that in China. In Dongbei,
7 they don't use the ACE inhibitors. In
8 Sichuan, they don't use beta blockers. You
9 get this regional variation in China, just
10 like what we're seeing in the United States
11 in terms of therapies. You can't say if one
12 thing is not used uniformly the others will
13 not be well. It seems to be sort of a
14 heterogeneous situation.

15 CO-CHAIR GIBBONS: Yes, yes.

16 Okay. Well, if any other thoughts come to
17 you on the plane where I know you're going
18 to be thinking more about this meeting,
19 please jot them down and get them to us by
20 e-mail. Next steps will be staff
21 communicating with us by e-mail and probably
22 set up a conference call before our meeting

1 in April. I know people are emptying out,
2 but I wanted to thank everybody for your
3 participation.

4 Oh, public comments. It looks
5 like the public is also emptying out. And I
6 just wanted to indicate that the Chair
7 recognizes this as a quality improvement
8 process, so any comments or suggestions you
9 have for me feel free to e-mail or phone me.
10 I'd welcome them. I'm trying to make this a
11 good use of your time and, hopefully, a
12 stimulating few days. So thanks again.

13 (Whereupon, the foregoing matter
14 was concluded at 2:59 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 Endorsement
Maintenance Steering Committee

Before: National Quality Forum

Date: 02-16-11

Place: Washington, DC

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