

NATIONAL QUALITY FORUM
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CARDIOVASCULAR STEERING COMMITTEE

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FRIDAY,
APRIL 8, 2011

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The Steering Committee met at the Venable Conference Center, the Capital Room, 575 7th Street, N.W., Washington, D.C., at 8:00 a.m., Raymond Gibbons, Chair, presiding.
PRESENT:

RAYMOND GIBBONS, Chair, MD, Mayo Clinic
MARY GEORGE, Vice Chair, MD, MSPH, Centers for Disease Control and Prevention
CAROL ALLRED, RN, National Coalition for Women with Heart Disease
ROCHELLE AYALA, MD, FACP, Memorial Healthcare System
SUNG HEE LESLIE CHO, MD, Cleveland Clinic

DIANNE JEWELL, PT, DPT, PhD, CCS, American Physical Therapy Association*
DANA KING, MD, MS, 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, UAW Retiree Medical Benefits Trust
ANDREA RUSSO, MD, Cooper University Hospital

PRESENT: (Continued)

MARK SANZ, MD, The International Heart
Institute of Montana

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

ROGER SNOW, MD, MPH, Commonwealth of
Massachusetts

CHRISTINE STEARNS, MS, JD, New Jersey Business
and 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

KAREN PACE, PhD, RN

ASHLEY MORSELL, MPH

KATHRYN STREETER, MS

REVA WINKLER, MD, MPH

ALSO PRESENT:

SUSANNAH BERNHEIM, MD, Yale/YNHH Center for
Outcomes Research and Evaluation (CORE)*

ROBERT O. BONOW, MD, American Heart

Association

LEIN HAN, PhD, Centers for Medicare & Medicaid
Services*

MAI HUBBARD, PhD, Mathematica Policy Research*

ROBERT J. SCHMITZ, PhD, Mathematica Policy
Research*

SAMANTHA TIERNEY, MPH, American Medical

Association

*Present via telephone

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

2 8:06 a.m.

3 CHAIR GIBBONS: I think what we're
4 going to do this morning is -- and for the
5 benefit of everybody on the phone, we did not
6 quite finish yesterday's agenda. We have two
7 measures yet to consider in the inpatient
8 heart failure measures from yesterday before
9 we move on this morning to the outpatient
10 heart failure measures.

11 So, our task is to complete
12 yesterday, then complete the outpatient heart
13 failure measures before we move on to some of
14 the important follow-up issues dealing with
15 disparities and with the retirement of
16 measures that we referred to several times
17 yesterday. And then the real task, which is
18 competing measures, which Jon asked about
19 yesterday right near the close. We're going
20 to face the biggest challenges. And I hope
21 all of you looked at the grid from Phase I and
22 gave this a lot of thought because that's when

1 it's going to take a lot of collective wisdom.

2 Are there any questions about what
3 we're going to do today before we get started?
4 This is all a holding action to get David
5 organized.

6 MEMBER MAGID: You know, Ray, I
7 have a present for you here -- Fauxpology is
8 your word and it -- I don't know if you've
9 heard of it before; I'm hoping you haven't, it
10 says when a person makes it sound like they
11 are apologizing when in fact they are just
12 shifting the blame or using twisted logic to
13 argue their way out of responsibility for
14 their actions. You said you wanted a new
15 word.

16 CHAIR GIBBONS: That is a great
17 one. I think we'll get the staff to put that
18 on a slide for us so we all get it spelled
19 correctly.

20 MEMBER MAGID: F-A-U-X-P-O-L-O-G-
21 Y. I'll take care of that, too.

22 CHAIR GIBBONS: All right. I do

1 think that it's going to be hard to top that
2 in the course of today. So, thank you for
3 starting us off in a positive direction.

4 So, David, are you ready to start
5 on Measure 330?

6 MEMBER MAGID: I am. I am. You
7 know, I was really kind of hoping that we
8 would do this measure at the end of the day
9 because with all the energy drained out of us
10 we moved so quickly through Ray's measure, but
11 he wisely said no we have to wait until this
12 morning.

13 So, let me just give you a little
14 bit of the background on this measure.

15 So, heart failure is the number
16 one cause of hospitalization among Medicare
17 members, which I think Ray mentioned, but it's
18 also the number one cause of readmission. So
19 it's both the number one cause of
20 hospitalization and readmission. Readmission
21 following hospital discharge for heart failure
22 occurs in over 20 percent of Medicare patients

1 within 30 days and in half of patients in the
2 coming year. So it's very common. So,
3 readmissions and adverse outcome from a cost
4 perspective and a patient perspective, because
5 readmission is typically driven by symptoms
6 and that typically represents worsening
7 quality of life.

8 Now, I think it's important to
9 acknowledge that many readmissions are
10 appropriate, particularly when the alternative
11 to readmission is worse.

12 So, the key question for this
13 outcome measure is not whether any individual
14 readmission may be unavoidable or beneficial,
15 okay, because clearly a bunch of them are, but
16 whether hospital-level variations and
17 readmission rate are driven by preventable
18 events. That is the key thing we have to keep
19 in mind.

20 So, while truly unavoidable
21 readmissions may be common, they are also by
22 nature invariable. I mean, the proportion of

1 patients who get readmitted for appropriate
2 reasons should be about the same so they
3 shouldn't contribute to differences in risk
4 standardized readmission rates. So, the goal
5 of this readmission measure is to reward
6 processes of care that decrease preventable
7 events and therefore reduce overall
8 readmission rates.

9 So, there's a more than a twofold
10 variability in risk standardized readmission
11 rates between institutions so on face value
12 that's a strong argument that many
13 readmissions are preventable. Moreover,
14 studies have consistently identified a high
15 proportion of readmissions that are
16 attributable to modifiable factors such as
17 medication errors, non-adherence with
18 recommended therapies and failure to obtain
19 timely outpatient follow up. So, in a variety
20 of existing interventions to improve the
21 process of hospital transitions, right; so the
22 transition from hospital to home, including

1 interventions like medication reconciliation,
2 transition coaches and early follow up have
3 been shown to decrease overall readmission
4 rates.

5 So, just to summarize, some
6 readmissions are unavoidable, but that should
7 be pretty much the same across institutions.
8 We see high variation in readmission rates;
9 over twofold. We know that certain
10 readmissions are due to modifiable factors and
11 that interventions to reduce readmission rates
12 have been a success.

13 So, that's sort of the background
14 for the measure. So, in terms of the -- this
15 is clearly a high-impact thing. Number one
16 cause of hospitalization, number one cause of
17 hospital readmission. There's clearly a
18 performance gap, there is over a twofold
19 variation, there is outcome for the fact that
20 readmissions are due to modifiable factors,
21 and there are interventions that have been
22 shown that can reduce readmission rates. So

1 I would say the answer to this is yes.

2 CHAIR GIBBONS: Okay. And I think
3 you've really nicely summarized the whole
4 issue of hospital variation, the fact that
5 some individual patient readmissions are
6 clearly beneficial. We mentioned several
7 points in yesterday's discussion, the way some
8 of the measures, although their intent is very
9 different, get misinterpreted and applied to
10 individual patient situations, and that's part
11 of the push back from the clinical community.
12 I think we somehow need to be mindful of that
13 and the NQF needs to be mindful of that
14 because certainly for this particular measure,
15 as there's more and more attention on
16 readmission, I at least hear a lot of
17 misstatements, both at a private level by
18 clinicians and at a public level as people
19 comment on them.

20 Now, I erred already this morning.
21 I made my first error because I didn't allow
22 the folks from Yale who are on the phone as

1 the developers here to comment. So, now that
2 they've listened to your summary, I'll ask
3 them whether they want to add anything in
4 terms of their overview of the measure.

5 So, anybody on the phone from Yale
6 want to add anything at this point?

7 DR. BERNHEIM: Hi, Susannah
8 Bernheim. We are here at Yale and I think we
9 -- David did a beautiful job.

10 CHAIR GIBBONS: All right. Thank
11 you. So, obviously we have some folks from
12 Yale if anybody has any questions for the
13 developers.

14 Are there any further comments or
15 questions or discussion about the importance
16 of this measure?

17 OPERATOR: And again, for the
18 phone audience, that's star 1 if you would
19 like an open line.

20 CHAIR GIBBONS: We don't need
21 questions just yet from the public.

22 All right. If there are no

1 questions or discussion, we're going to go
2 ahead and vote on the importance.

3 DR. WINKLER: Dianne?

4 MEMBER JEWELL: Yes.

5 DR. WINKLER: Okay. Devorah?

6 MEMBER RICH: Yes.

7 DR. WINKLER: Thank you.

8 CHAIR GIBBONS: So, the vote is
9 unanimous; 19 yes, no no, or no zero.

10 So, we'll move on now to
11 scientific acceptability. David?

12 MEMBER MAGID: So, the application
13 -- I think did a excellent job with this area.
14 I think that it is well-specified. The data
15 about -- all of the factors that are described
16 here I thought are well-described. The one
17 thing I would comment on; maybe two things --
18 one is that there doesn't appear to be
19 significant disparities in the same way that
20 we saw for the hospital mortality measure.
21 So, they look at disparities in this case, not
22 so much at the individual patient level, but

1 they looked at hospitals and they looked at
2 the characteristics of those hospitals in
3 terms of the demographics of the patient
4 populations that come to those hospitals. So
5 for instance, hospitals that had higher
6 proportion of minorities might have had
7 slightly higher rates of readmission, but the
8 confidence intervals were such that they
9 overlapped, so there weren't any statistically
10 significant differences.

11 The other thing that came up in
12 the comments that George had about
13 socioeconomic status, that is not built into
14 the risk models, but that is done on purpose
15 and Reva clarified that instead of actually
16 controlling for socioeconomic status, they do
17 stratified analyses. So, I think that across
18 all of the measurement properties the folks
19 who filled out this application did a nice
20 job.

21 CHAIR GIBBONS: Thank you. Are
22 there other comments at this point about

1 scientific acceptability?

2 (No audible response.)

3 CHAIR GIBBONS: I hope everybody's
4 awake.

5 (Laughter.)

6 CHAIR GIBBONS: At least got a
7 laugh on the phone. That's good.

8 All right. We will go ahead and
9 vote on scientific acceptability.

10 DR. WINKLER: Dianne?

11 MEMBER JEWELL: Completely.

12 DR. WINKLER: Devorah?

13 MEMBER RICH: Completely.

14 DR. WINKLER: Thank you.

15 CHAIR GIBBONS: So, the responses
16 are 18 completely; 1 partially.

17 So, we'll move on now to
18 usability. David?

19 MEMBER MAGID: So, I think the
20 measure does meet the criteria for usability.

21 It's been in place now for a short time, but

22 I don't think people are having any troubles

1 with it. So, I feel it meets the criteria for
2 usability and also adds value to existing
3 measures. I think there's a important domain
4 of quality that's not captured in the
5 mortality measure or any other measures we're
6 looking at.

7 CHAIR GIBBONS: And the
8 application did include as a supplemental
9 document the publication and circulation
10 outcome.

11 Are there other comments,
12 concerns, questions about usability?

13 (No audible response.)

14 CHAIR GIBBONS: If not, let's go
15 ahead and vote on that.

16 DR. WINKLER: Dianne?

17 MEMBER JEWELL: Completely.

18 DR. WINKLER: Thank you. Devorah?

19 MEMBER RICH: Completely.

20 DR. WINKLER: Thank you.

21 CHAIR GIBBONS: So, the summary
22 responses is completely 18; partially 1.

1 And now feasibility. David?

2 MEMBER MAGID: So, the data is
3 generated during care. It could be obtained
4 from electronic health records or paper. I
5 think that the -- it's not particular
6 susceptible to inaccuracies and the data can
7 be implemented. So, I do feel like it's
8 feasible.

9 CHAIR GIBBONS: Discussion or
10 questions about feasibility?

11 (No audible response.)

12 CHAIR GIBBONS: If not, let's go
13 ahead and vote on this.

14 DR. WINKLER: Dianne?

15 MEMBER JEWELL: Completely.

16 DR. WINKLER: Thank you. Devorah?

17 MEMBER RICH: Completely.

18 DR. WINKLER: Thank you.

19 CHAIR GIBBONS: So, the summary of
20 responses is 18 completely and 1 partially.

21 Now, before we have the final vote
22 on this measure, I just want to make sure --

1 there was some discussion with the previous
2 mortality measure and then some offline
3 discussion at the end of the meeting about
4 this issue of racial disparities and
5 socioeconomic status. As people thought about
6 this issue overnight; and Reva did clarify
7 what the issues were offline from an NQF
8 standpoint, are there additional thoughts or
9 questions about this that we can discuss with
10 the developer as a committee before we take
11 the final vote on this? George?

12 MEMBER PHILIPPIDES: I just have a
13 question. How will socioeconomic status be
14 dealt with moving forward or reported?

15 CHAIR GIBBONS: Okay. So, can I
16 direct that question to developers? Did you
17 hear George's question? How will
18 socioeconomic status be dealt with from the
19 standpoint of reporting going forward in the
20 future for this measure?

21 DR. BERNHEIM: Yes, hi, this is
22 Susannah Bernheim from Yale. So, as was

1 mentioned, socioeconomic status is not built
2 into the measure. We, as part of our work
3 with CMS, have ongoing surveillance of the
4 measure. So the way that this is primarily
5 handled from our standpoint; and I think Lein
6 Han may be on the call and can speak more from
7 CMS' perspective, is from a surveillance
8 perspective. We each year look at how
9 hospitals that have high proportions of
10 African-American patients or high proportions
11 of low-SES patients and spacing at hospitals
12 are performing on the measure, so it is a way
13 to surveil for concerns about disparities.

14 CHAIR GIBBONS: And is that
15 surveillance publicly reported anywhere?

16 DR. BERNHEIM: It is not
17 currently, but my understanding is that CMS'
18 intention is to make that public.

19 DR. HAN: This is Lein Han. I
20 think it's on our website, cms.gov. I can
21 provide the URL of the website later.

22 CHAIR GIBBONS: Okay. That would

1 be great. Now, when you say on your website,
2 is it on Hospital Compare.

3 DR. HAN: Oh, no, no, no. It's a
4 separate site. I mean, it's surveillance
5 system. Actually we put the analysis together
6 and put -- published in what we call a chart
7 book. So, it's a chart book. In this chart
8 book we monitor several measures; performance,
9 hospital performance by disparity, but at the
10 national level. So, this is how -- I think
11 Susannah describe one of the analysis that we
12 have done. That's about safety net hospitals,
13 right, Susannah?

14 DR. BERNHEIM: Right.

15 DR. HAN: Yes. And we have also
16 -- can you tell a little bit more? We have
17 also monitor in addition to the safety net
18 hospital and also what else you're in?

19 DR. BERNHEIM: So, there are a
20 number of things we look at in there. We look
21 at hospitals based on the socioeconomic status
22 of the patients based on where they live,

1 based on proportions of African-American
2 patients in the hospital space, on safety net
3 status. We also look at teaching hospitals
4 versus non-teaching hospitals. We look at
5 geographic regions.

6 You know, the idea here is that we
7 don't want to stratify the measure, but CMS
8 does want to be aware if there are indications
9 of changes from what we're currently seeing in
10 terms of how well sub-groups of hospitals are
11 able to perform on the measure.

12 CHAIR GIBBONS: Well, I'm going to
13 ask for any comments or any other comments
14 from the Committee. Sid?

15 MEMBER SMITH: Yes, Sid Smith. I
16 think the data that you described would be --
17 are important and very helpful. I'm a little
18 concerned about -- it seems to be obscure in
19 terms of how to find them. Is there a link on
20 the Hospital Compare website, or is there any
21 way that the public could have -- or we even
22 would know how to take a look at it?

1 DR. HAN: Oh, yes. This is a
2 public information. The Hospital Compare, we
3 -- mostly is to publish these information for
4 the consumers. So this is a type of analysis
5 to monitor, you know, the effect of our
6 implementation of our program initiative and
7 the measures. So, it's a separate analysis.

8 MEMBER SMITH: Yes.

9 DR. HAN: If your question is
10 whether you can have access to it, definitely.

11 CHAIR GIBBONS: No, I think the
12 real question is not -- I mean, and I think
13 Sid's trying to bring this out, is we sort of
14 think of this as intrinsically linked to the
15 data that you're showing on Hospital Compare
16 so that it shouldn't require a whole separate
17 effort on the Internet to locate a separate
18 body of publicly-available knowledge. If the
19 group at Yale has got to go to all this
20 trouble, it would seem that I think we're
21 trying to convey a sense that it should be
22 easier for people to find it either through a

1 direct link from Hospital Compare or actually
2 by putting it on Hospital Compare, because I
3 think it would be of equivalent public
4 interest.

5 Is that the sense of the
6 Committee? I see a lot of nods yes.

7 So, I think we want to kind of
8 convey back as our sense that it's great that
9 these analyses are being done and they should
10 be more visible to the public if we're ever
11 going to effectively deal with the issue of
12 disparities in the country and maybe consider
13 a simple thing like a direct link from
14 Hospital Compare to this alternative site.

15 DR. HAN: Yes, this request is
16 reasonable. We will consider that. I just
17 never thought about that because this -- I
18 think it was -- this year was the first time
19 that we put together the chart book.

20 CHAIR GIBBONS: Okay.

21 DR. HAN: So, yes.

22 CHAIR GIBBONS: Well, we just

1 offer that as a quality improvement
2 suggestion.

3 DR. HAN: Yes.

4 CHAIR GIBBONS: All right. Are
5 there any other questions or comments from the
6 Committee before we take this vote?

7 (No audible response.)

8 CHAIR GIBBONS: If not, let's go
9 ahead and vote on whether the measure meets
10 criteria for endorsement.

11 DR. WINKLER: Dianne?

12 MEMBER JEWELL: Yes.

13 DR. WINKLER: Devorah?

14 MEMBER RICH: Yes.

15 CHAIR GIBBONS: So the vote is
16 unanimous, 20 votes yes in favor of
17 endorsement.

18 Before we move onto the next
19 measure, I did want to reflect the fact that,
20 as David said, we went through the mortality
21 measure relatively quickly yesterday. We
22 spent a little bit more time here this

1 morning, but not a whole lot of time more.
2 And I don't want anybody to misinterpret that
3 as being a lack of attention to these
4 particularly important measures. I think
5 instead it reflects how completely the
6 application was submitted. When submitted all
7 the data was there to answer any particular
8 concern so there really wasn't much
9 discussion. I think we reflected at the last
10 meeting for the previous AMI mortality measure
11 how well that submission was completed, and
12 these two were in the same category. David
13 and I had an offline discussion about what
14 more we were going to have to say because it
15 was all there.

16 So, I thank the folks at Yale for
17 being available again this morning and sorry
18 we had to inconvenience them over two days.
19 And thank you for your effort in completing
20 the application so well.

21 So, we're going to move on to now
22 the next measure. Andrea?

1 (No audible response.)

2 CHAIR GIBBONS: Developer on the
3 phone for the next measure?

4 Give me the number.

5 PARTICIPANT: Nine-sixty-two.

6 CHAIR GIBBONS: Nine-six-two.

7 DR. HUBBARD: Yes, we're here for
8 Mathematica Policy Research.

9 CHAIR GIBBONS: You want to make
10 any brief comments before we start
11 consideration of the measure?

12 DR. HUBBARD: I think we'll have
13 Sophia Chan from CMS speak first.

14 Sophia, are you on the line?

15 MS. CHAN: Yes, I'm on the line.
16 Good morning. This is Sophia Chan from the
17 Office of Clinical Standards and Quality of
18 CMS. Let me explain the purpose of CMS
19 developing this heart failure composite
20 measure and also the major characteristics of
21 the methodology of the measure.

22 CMS developed this heart failure

1 composite measure because we feel that it is
2 important for consumers to have a summary
3 measure that helps them evaluate the overall
4 quality of inpatient care for heart failure.
5 And the primary objective of this measure is
6 to summarize measures for the heart failure
7 focus area into a single composite that's
8 useful, understandable and acceptable to a
9 wide range of stakeholders. So as a result,
10 it's a so-called formative measure and CMS
11 hopes to publish composite measures of
12 inpatient hospital quality on Hospital Compare
13 together with the underlying process and
14 outcome indicators which are already publicly
15 reported. And we believe that providers in
16 addition to consumers will find the composite
17 useful as they can examine the values of each
18 component indicator to understand how they can
19 improve future performance.

20 And also, based on feedback from
21 the NQF Steering Committee meeting on the CMS
22 AMI composite measure back in February, we

1 have made two important changes to the heart
2 failure composite. But firstly, the measure
3 was redefined in a manner that makes it easier
4 to understand. And secondly, we implemented
5 a requirement that every hospital for which a
6 composite is computed have observations for
7 each of the component indicators.

8 So, the measure we present here
9 contains no imputation. And in addition,
10 imputing the measure we have tried to balance
11 the need to have a composite available for as
12 many hospitals as possible and at the same
13 time a need to ensure accuracy by setting an
14 appropriate minimum number of observations.

15 So, overall the composite measures
16 compute entirely from information already
17 available on Hospital Compare and we at CMS
18 believe that the reporting of this measure
19 will add a valuable dimension of hospital
20 quality for consumers and providers without
21 adding any additional reporting further.

22 So, I would now let Mai Hubbard

1 from Mathematica present some additional
2 remarks about the measure.

3 DR. HUBBARD: Thanks, Sophia. Hi,
4 I'm Mai Hubbard from Mathematica Policy
5 Research. I'm actually one of the developers
6 of this project, along with Bob Schmitz,
7 Marian Wrobel and Jessica Roth also from
8 Mathematica, and Jim Burgess and Gary Young
9 from Boston University.

10 And as Sophia mentioned, we've
11 revised our composite methodology following
12 the issues that were raised in February
13 regarding our AMI composite measure. And
14 overall we've computed the composite as a
15 simple average of the process and the outcome
16 domain scores at the hospital level. And each
17 domain score is computed then at a rate of
18 some of the actual to expected scores.

19 And we've made three significant
20 changes. The first is the minimum sample size
21 for the possible care indicators that we've
22 increased. Previously we had that hospitals

1 were included in the composite as long as they
2 had one patient. Now we've increased that to
3 a minimum of at least five cases.

4 And second, to address the
5 Committee's concerns regarding imputation of
6 the measure, we have eliminated all need to
7 impute by requiring that hospitals have all
8 four of the process of care indicators, as
9 well as two of the outcome of care indicators.

10 And lastly, we combined the
11 indicators in such a way that the final
12 composite scores actually centered around one.
13 This makes it easier for stakeholders to
14 actually see what -- to rate the performance
15 of their own hospital. Furthermore, this
16 mitigates the issue regarding the very tight
17 distribution that the committee members raised
18 concern about previously during the meeting.

19 So, in summary, testing of our
20 measures showed quite strong reliability
21 across year. And furthermore, although we
22 have not argued for an actual reflective

1 composite but rather a formative one, our
2 analysis indicates that there is positive
3 correlation across the constituent indicators.
4 And furthermore the office showed that there
5 was one single underlying construct.

6 And so, we'd like to thank you so
7 much for taking the time to look at our
8 measure. And at this time we'd be very happy
9 to accept any questions that you may have
10 about our composite.

11 CHAIR GIBBONS: All right. Thank
12 you very much. We'll go on.

13 Andrea?

14 MEMBER RUSSO: You know,
15 unfortunately all the changes that they're
16 talking about -- actually when I -- the one
17 that I had reviewed; I'm pulling up the newest
18 one on the disc, is reflective of the changes
19 for this, but unfortunately my initial reviews
20 of it, they made some significant
21 improvements. So, I'm going to run through as
22 I'm discussing this -- the changes, because

1 it's a completely different application than
2 the one I reviewed as I see here.

3 So, basically starting with the
4 first importance of the measure to report,
5 it's -- you know, clearly the whole concept of
6 this composite measure is an important one.
7 This particular measure combines the hospital
8 process and outcome of care measures for heart
9 failure patients, so it's, you know, a
10 disease. And looking at, you know, the
11 composite measure for the disease similar to
12 the MI-1 that was previously reviewed. I
13 think this is, you know, important. I think
14 the whole concept of having a single composite
15 measure for all different stakeholders to look
16 at, for patients to be able to look up on the
17 website is a good concept. I did have some
18 major consideration, major problems with the
19 initial version, but I see that there are very
20 significant changes on the subsequent revision
21 here.

22 So, this would be used for public

1 reporting and, you know, all of the important
2 things. All the individual measures were NQF-
3 endorsed, however, two of those measures were
4 ones that we did review yesterday. One and
5 two that we either -- were retired for two
6 different reasons. One was the particular
7 measure related to discharge instructions.
8 So, the reason that we thought that wasn't
9 such a great measure is that it doesn't say
10 the quality -- as our patient representative
11 here told us yesterday, the quality of
12 discharge instructions is not at all reflected
13 with a piece of paper handed to a patient.
14 So, I would question use of that particular
15 measure in the formula here.

16 And the second one was the left
17 ventricular ejection fraction -- systolic
18 function evaluation. Those were two of the
19 process measures that were being included.
20 Now, we retired that, and this might be a good
21 thing that it's actually incorporated into
22 this composite measure.

1 Then the other two are ACE
2 inhibitor, ARB for left ventricular systolic
3 dysfunction, which is, you know, a good one we
4 reviewed yesterday also. And then the other
5 one was smoking cessation advice and
6 counseling.

7 So, for the process measures I
8 would question, you know, whether or not we
9 would want to consider recommendation of
10 something different for the discharge
11 instructions or perhaps elimination of that
12 one.

13 CHAIR GIBBONS: Can I ask Reva to
14 comment on the smoking cessation?

15 DR. WINKLER: As we mentioned the
16 last time we looked at the AMI composite, the
17 smoking cessation measure was originally
18 endorsed by NQF, but the endorsement was
19 removed several years ago because the measure
20 was found to be invalid. So it is no longer
21 an NQF-endorsed measure. None of the smoking
22 cessation measures are.

1 MEMBER RUSSO: Okay. So, that's
2 an important point to be taken. So, there's
3 two of the four process measures really
4 shouldn't be in there anymore. So, you know,
5 we'd have to ask the measure developers if --
6 you know, how they would deal with that and,
7 you know, would they be willing to eliminate
8 those. I think, at least from my impression,
9 I'm interested to hear what the group says,
10 but the evaluation of LV systolic dysfunction
11 isn't such a bad thing to keep in there. But,
12 you know, because it's retired, but it wasn't
13 -- the reason for retirement was just because
14 everyone was doing so well on it. So, that
15 would be a significant change.

16 And then the outcome measures were
17 -- the one wonderful measure that we just
18 heard about with the -- well, the two with the
19 30-day risk standardized mortality and the 30-
20 day risk standardized readmission, and those
21 seem to certainly be relevant and well-
22 developed, you know, measures that would be

1 included in the formula. And we can go -- I
2 don't know if you want me to go into -- so now
3 there are some changes to the formula.

4 But I think in terms of the first
5 question --

6 CHAIR GIBBONS: Let's not go into
7 the formula just yet. Let's just vote on
8 importance for the measure as submitted. So
9 the measure as submitted which had smoking
10 cessation, discharge instructions, LVEF and
11 ACE or ARB as the four process measures and
12 the two outcome measures. So can we vote on
13 importance of the measure as submitted at this
14 point.

15 MEMBER KOTTKE: Can I ask a
16 question at this point?

17 CHAIR GIBBONS: Yes, Tom. Sure.

18 MEMBER KOTTKE: It's my
19 understanding that composite measures need to
20 comprise NQF-endorsed measures. No? Okay.

21 DR. WINKLER: They don't have to
22 comprise endorsed measures. They need to be

1 -- the components need to have been evaluated
2 need criteria. But they may not be deemed to
3 stand on their own as an individual measure,
4 but they need to meet the criteria, however.

5 MEMBER RUSSO: And before people
6 vote, just so it's clear that in some of the
7 weighting; and again, I'll have to compare the
8 differences between the two, but the weighting
9 can depend on -- the denominator weighting is
10 dependent on the number of patients. So it's
11 weighted -- so you're going to have -- if you
12 have a lot of smoking cessation, that may take
13 more weight. And if you have a lot of, you
14 know, discharge instruction patients in there,
15 that's going to take a lot of weight in the
16 formula.

17 MEMBER MAGID: Yes, I just think
18 it's important before we vote just to make
19 sure everyone understood, because I thought
20 Andrea did a good job, but one of the
21 components is discharge instructions, which we
22 uniformly voted down at this level.

1 And the second component is
2 smoking cessation, which Reva is just telling
3 us in invalid. So, two of the four are ones
4 either we said are bad or are found to be
5 invalid. So, before we maybe go on and spend
6 a lot --

7 CHAIR GIBBONS: Tom?

8 MEMBER KOTTKE: I guess, where is
9 beta blockers in this? And then, and also
10 there's a paper by Piepoli back in BMJ 2004,
11 "Exercise Training Meta-Analysis of Trials in
12 Patients With Chronic Heart Failure," which
13 concludes that for patients with chronic heart
14 failure who CHAIRpate in cardiac rehab, their
15 mortality rates and readmission rates are 0.72
16 compared to those who don't participate. And
17 so, this gets to the issue of, you know, you
18 send them home with an unopened envelope of
19 instructions versus, you know, here's a way of
20 -- here's a randomized trial evidence way of
21 reducing both readmission and that. And I
22 know it's sort of sneaking up on CMS, but

1 perhaps they want to think about that as a
2 part of their measure; did the patient
3 participate in cardiac rehab after their
4 hospitalization?

5 MEMBER SANZ: Ray?

6 CHAIR GIBBONS: Yes, Mark?

7 MEMBER SANZ: So, if we voted no
8 in the past, that means we're done.

9 CHAIR GIBBONS: We're done with
10 the measure as submitted and then we can make
11 suggestions and --

12 MEMBER SANZ: So, we can make
13 suggestions?

14 CHAIR GIBBONS: Yes. Oh, yes.

15 MEMBER SANZ: Because last time we
16 --

17 CHAIR GIBBONS: Well, we'll make
18 conditional suggestions, but we will, you know
19 --

20 MEMBER AYALA: I wanted to ask
21 Reva to define the difference between meeting
22 criteria and being NQF-endorsed. When you say

1 the components only have to meet criteria, you
2 mean just for the first question?

3 DR. WINKLER: No, all four of the
4 components. If you recall yesterday, I think
5 there's a pretty example in the PCI composite,
6 you at the first meeting evaluated all of the
7 components and said they all met criteria.
8 Yesterday you looked at a all or none
9 composite measure. It met criteria. Then the
10 question was do you want to endorse all of
11 them and you said, no, the composite is fine.
12 We don't need to individually endorse as stand
13 alone measures the various components. But
14 all of those meet criteria, but instead of
15 just adding five measures to the portfolio,
16 your decision was to add one. So, that's the
17 difference. They meet the criteria, but they
18 don't have to be individually endorsed --

19 MEMBER RUSSO: And again, remember
20 --

21 DR. WINKLER: -- as standalones.

22 MEMBER RUSSO: -- with this

1 measure if you say yes, then a lot of the
2 weight could be towards measures that we don't
3 think -- or at least from previous voting we
4 do not think are important.

5 CHAIR GIBBONS: Additional
6 discussion here? This is very key.

7 (No audible response.)

8 CHAIR GIBBONS: Okay. So we're
9 now going to go ahead and vote on importance
10 of the measure as submitted.

11 DR. WINKLER: Dianne?

12 MEMBER JEWELL: No.

13 DR. WINKLER: Devorah?

14 MEMBER RICH: No.

15 DR. WINKLER: Thank you.

16 CHAIR GIBBONS: So, the summary is
17 1 yes and 19 no's.

18 So, we will at this point not
19 consider the measure as submitted, but rather
20 try to I think provide guidance to the
21 developer in terms of what we think would be
22 an important measure.

1 So, let me ask Andrea to lead off
2 with that.

3 MEMBER RUSSO: Okay. So, I think
4 the first part of the recommendation would be
5 to include measures which we think are
6 clinically important. So the concept of beta-
7 blocker therapy for our standard therapy for
8 heart failure patients. And the measures that
9 we already have present, beta-blockers should
10 be in there. I would suggest that --
11 elimination completely of the discharge
12 instructions and then also the smoking
13 cessation.

14 And then, the consideration -- I
15 think I was happy to hear actually that you
16 did change -- there was a formula in there to
17 -- if you are missing data. I guess, let's
18 just talk about the general concept of -- and
19 we didn't review what's in there now, but what
20 to do with patients who are missing data. I
21 have some issues with including hospitals that
22 are missing either numerator -- that are

1 missing some of the numerator. And there was
2 a way to take the average of the overall data
3 in the -- I think you eliminated that into the
4 formula. But I would say that if you're
5 missing data, you shouldn't be included in
6 this measure. And I know you're trying to get
7 as many places as possible.

8 DR. HUBBARD: As developers can we
9 make a comment on that?

10 CHAIR GIBBONS: Yes, absolutely.

11 MEMBER RUSSO: Sure.

12 DR. HUBBARD: So, we have no -- we
13 do not have any hospitals at this point with
14 missing data, so we're not calculating any
15 score whatsoever for a hospital if they're
16 missing data.

17 MEMBER RUSSO: So, then I think
18 you need to just state it and just write it as
19 is then and just say that only hospitals who
20 have all of however many measures -- if it
21 turns out to be the six, for a process to
22 outcome measures -- only hospitals that have

1 all of those measures will be included in
2 this.

3 DR. HUBBARD: And I think we did
4 mention that in our final package that we sent
5 to the NQF.

6 MEMBER RUSSO: Okay. And that was
7 the issue, yes, because we just -- we didn't
8 --

9 DR. HUBBARD: Okay.

10 MEMBER RUSSO: -- have all that.
11 Okay. So and then the question is how to
12 weight it. And I don't know; I'm interested
13 to hear what other people think, but if you
14 weight it more heavily to the measures that
15 have more patients, you could say, well,
16 that's good, but then that might lead to more
17 gaming maybe, you know? So why not figure out
18 -- at least to me, weighting should be how --
19 if we're going to weight them all differently;
20 and maybe want to and maybe we don't, but if
21 we're going to do that -- or we should think
22 of what's clinically the most important

1 perhaps, or just say weight them all equally
2 or weight the process equal to the outcome
3 measures. But weighting it by the number of
4 patients, to me, would be the least favorable
5 option. I'm not sure what other people would
6 recommend there.

7 MEMBER KOTTKE: The impact on
8 mortality is the reduction when you provide
9 times the proportion in your population who
10 are not currently receiving it. And so, it
11 does make -- to make it makes sense to weight
12 on the number of patients and the impact of
13 the intervention, that combination.

14 CHAIR GIBBONS: Sid?

15 MEMBER SMITH: Mine is on -- I
16 suppose we ought to deal with this topic
17 first, then I have another --

18 CHAIR GIBBONS: Okay. So, other
19 comments in terms of direction we can provide
20 or thoughts we can provide about weighting?

21 MEMBER RUSSO: Oh, and the other
22 concept in there, too, just is -- and this may

1 be the only way to do it right now, but the
2 outcome measures were on the Medicare-only
3 patients, is that correct? Because that's the
4 way the data's available --

5 CHAIR GIBBONS: Yes.

6 MEMBER RUSSO: -- and the process
7 on both. Is that okay with everyone? I think
8 maybe -- so the process measures -- oh, I
9 guess they're all -- well, that's --

10 CHAIR GIBBONS: They're all --

11 MEMBER RUSSO: They must be all
12 Medicare-only. Is that correct?

13 CHAIR GIBBONS: Yes, I would think
14 so. Dana?

15 MEMBER RUSSO: But there was a
16 comment in there that process indicators will
17 report on all patients and I'm wondering why
18 you divided that out.

19 CHAIR GIBBONS: Maybe I can ask a
20 developer to comment on that.

21 DR. HUBBARD: I think the problem
22 is that given that there are concerns that we

1 have we're unable to distinguish between
2 Medicare patients and non-Medicare patients at
3 this point. So what we are using is what's
4 available on Hospital Compare, which is
5 Medicare patients for outcome and all patients
6 above the age of 18 for process of care
7 measures.

8 MEMBER RUSSO: So they're
9 different?

10 CHAIR GIBBONS: So, now actually
11 that has direct impact on this weighting
12 issue. So, does the weighting of the process
13 measures therefore reflect the larger patient
14 sample?

15 DR. SCHMITZ: Well, the --

16 MEMBER RUSSO: That's what it
17 sounds like.

18 DR. SCHMITZ: -- process measures
19 as a group are weighted equally to the outcome
20 measures as a group, so they have the same
21 weight.

22 CHAIR GIBBONS: Okay. That's

1 helpful. Dana, you had a comment?

2 MEMBER KING: Yes, this was not
3 about weighting.

4 CHAIR GIBBONS: We'll move onto
5 another topic.

6 MEMBER KING: All right. The
7 discharge instruction thing, we shouldn't lose
8 that concept altogether. In other words, it
9 may be important to track perhaps a new thing
10 that's better than just handing them a sheet
11 of paper with six things on it. Like do they
12 have coordination of care or some kind of
13 transition program from inpatient to
14 outpatient, or cardiac rehab specifically for
15 congestive heart failure patients, something
16 that's a little more interactive? So, we're
17 not saying that the whole concept of giving
18 people instructions is bad. What we're saying
19 is to measure it a different way. And if it
20 was measured a different way, like
21 coordination of care, for example, I think it
22 would be a worthy addition to a composite

1 quality measure.

2 CHAIR GIBBONS: Tom?

3 MEMBER KOTTKE: Yes, I agree with
4 that comment, and then want to express my
5 existential angst about tobacco. There are
6 three studies in the literature that basically
7 show that people who quit smoking at the time
8 of an acute cardiac event double their life
9 expectancy compared to those who don't. And
10 the principle of what gets measured gets done.
11 I realize that the tobacco measure is invalid
12 and people game it and we game it in our
13 hospital, too, because everybody gets advice,
14 you know? Like quit smoking, idiot, you know?
15 But if somebody could come up with a valid
16 measure, I'd be grateful.

17 MEMBER MAGID: I don't think you
18 double your life expectancy. I think you
19 double the number of additional years of life
20 you have left.

21 MEMBER KOTTKE: You double your
22 subsequent life expectancy.

1 MEMBER MAGID: Yes, there you go.

2 CHAIR GIBBONS: Yes, the word
3 there is "subsequent."

4 Okay. Sid, you wanted to make
5 another comment?

6 MEMBER SMITH: Just are these all
7 patients with systolic failure or heart
8 failure in -- are we -- I'm confused about --
9 are we adding beta-blockers? And if so, are
10 we addressing patients with systolic failure?
11 What's the population?

12 DR. HUBBARD: This is all patients
13 with heart failure.

14 MEMBER SMITH: So it can be non-
15 systolic failure? It can be diastolic
16 failure, right?

17 PARTICIPANT: Presumably, yes.

18 MEMBER RUSSO: It's just that one
19 of the component process measures looks just
20 at the systolic dysfunction. I guess unless
21 you're restricted to just those with systolic
22 dysfunction for the whole -- all the process

1 measures.

2 MEMBER SMITH: I'm trying to
3 figure out how the therapy that we are
4 measuring relates to the group that we are
5 including.

6 MEMBER RUSSO: Yes, that's a good
7 point. So then you would just -- so you would
8 only have two things in the numerator. You'd
9 have only two process measures and then two
10 outcome measures. That's one way to construct
11 it.

12 MEMBER SMITH: Unless we define
13 the groups based on the ejection fraction.
14 And then ICDs potentially are in there if they
15 have significant systolic dysfunction. I
16 mean, if you want to get a marker for
17 mortality and things that are not being done
18 --

19 MEMBER RUSSO: It needs a lot --

20 CHAIR GIBBONS: I don't think we
21 have time here to create an entire new
22 measure. I think we've kind of given a fair

1 bit of input and had a sufficient discussion
2 of the measure as submitted and I think we are
3 going to need to move on to today's outpatient
4 measures.

5 So thank you to the developers for
6 being available and I hope that that
7 discussion and the guidance is useful to you.

8 MEMBER SANZ: I would just like to
9 say I think that the concept of a composite
10 heart failure measurement is very important.
11 Is this the end of this measure or can they
12 come back before we're done as a committee?

13 CHAIR GIBBONS: I think that's
14 totally up to the developer. If they want to
15 --

16 MEMBER SANZ: Do you want to
17 comment on that at this time?

18 DR. SCHMITZ: The question is is
19 there an opportunity to come back?

20 CHAIR GIBBONS: Ask NQF staff to
21 comment on that.

22 DR. WINKLER: We're willing to

1 talk with the developers and see what their
2 potential timelines are, you know, in this
3 phase. Obviously there's interest from the
4 committee, so within the time constraints of
5 project we could see how flexible we can be.

6 MEMBER RUSSO: And I would second
7 that. I think it's a really important thing
8 to do if done right.

9 CHAIR GIBBONS: All right. So, I
10 think I see a lot of nods around the table, so
11 I think we can convey a sense of the Committee
12 that the concept of a properly designed
13 composite measure is felt to be very
14 worthwhile.

15 So, let --

16 DR. HUBBARD: May I make one point
17 to the Committee about where we have to start?
18 We have to start with the measures that are on
19 Hospital Compare. We do not have
20 opportunities to reconfigure those measures.
21 We can pick and choose what goes into the
22 composite, we can reconsider how they're

1 weighted, but we can't go under the hood of
2 the measures that are there. And I just want
3 folks to understand that as we deal with --

4 CHAIR GIBBONS: So, let me just --
5 isn't beta-blockers on Hospital Compare?

6 It's not a measure? Okay.

7 All right. We need to move on.
8 We've got to move on to the first outpatient
9 heart failure measure, which is 0077, heart
10 failure symptom and activity assessment, but
11 we first need some brief comments by the
12 developers who are present. Dr. Bonow?

13 DR. BONOW: Thanks. Is the
14 microphone on? I'm sorry.

15 So, would you like me to discuss
16 the background for all four measures or --

17 CHAIR GIBBONS: Sort of three to
18 five months, the general background kind of --

19 DR. BONOW: For all four?

20 CHAIR GIBBONS: For all four.

21 DR. BONOW: For all four. Yes,
22 thank you.

1 CHAIR GIBBONS: Is his mic on?
2 Can you double check so people on the phone
3 can hear?

4 DR. BERNHEIM: It's coming in and
5 out, Ray.

6 CHAIR GIBBONS: It's coming in and
7 out?

8 DR. BERNHEIM: Yes.

9 CHAIR GIBBONS: So, Bob, testing,
10 testing?

11 DR. BONOW: Testing, testing, one,
12 two, three. Can you hear me?

13 CHAIR GIBBONS: Can you hear him,
14 Dianne?

15 MEMBER JEWELL: I can hear you.
16 Yes

17 DR. BONOW: I'll hold it very
18 close.

19 MEMBER JEWELL: Thank you.

20 DR. BONOW: Thank you, Mr.
21 Chairman. My name is Robert Bonow, professor
22 of cardiology at Northwestern University

1 representing the ACC/AHA/PCPI for these four
2 measures which are for continuing endorsement
3 of NQF.

4 I will not add to the groundswell
5 of the discussion already about the impact of
6 heart failure in the United States other than
7 to reiterate the 5.7 million patients, the
8 greater than 1 million hospitalizations per
9 year, the fact that an individual at age 40
10 has a 1 in 5 chance of developing heart
11 failure during his or her life span and the
12 annual cost in excess of \$37 billion.

13 The work group consisted of myself
14 as co-chair, but also a family practitioner as
15 co-chair. And we had a multi-disciplinary
16 cross-specialty force including internal
17 medicine, family medicine, hospital medicine,
18 advance practice nursing, palliative care and
19 patient consumer representatives as well, and
20 one payer representative.

21 We reviewed the updated ACC/AHA
22 2009 Guidelines, which has some new Class 1

1 recommendations. We reevaluated and updated
2 data regarding gaps in care, which persist,
3 especially on the outpatient side. We
4 reviewed data regarding feasibility,
5 reliability and exception reporting and made
6 every effort to harmonize our measures with
7 those developed by others, including CMS and
8 Joint Commission. These measures went through
9 a period of 30-day public comment, extensive
10 peer review and are now being presented to
11 you.

12 We believe these measures have
13 broad applicability, can be reported via
14 claims but are also easily integrated into
15 electronic medical records. Our exception
16 methodology supports clinical judgment
17 regarding appropriateness of care for given
18 patients. Our measures have been tested in a
19 variety of settings, a variety of data sources
20 and our measures are in wide use already in
21 many settings including PQRS and meaningful
22 use Phase I.

1 The testing has included
2 outpatient data derived from PQRI, the Doc
3 Project, Cardio Hit and the PINNACLE Registry,
4 a large registry from the American College of
5 Cardiology. We have data regarding
6 disparities in addition to the paper in your
7 submission from Chan and coworkers in Journal
8 of the American College of Cardiology last
9 year. There's a paper in the current American
10 Heart Journal by Thomas and coworkers looking
11 at inpatient use of these measures. And both
12 the outpatient PINNACLE data by Chan and the
13 inpatient data from Thomas indicate that these
14 measures actually provide good data regarding
15 equal access to care and quite good care
16 across the disparity spectrum.

17 In addition, there was a paper
18 published online two days ago in circulation
19 from the improved Heart Failure Registry,
20 which is an outpatient registry involving 167
21 outpatient practices nationwide involving over
22 11,000 patients looking at 24-month outcomes

1 and the use of the ACE/ARB and beta-blocker
2 measure led to a significant reduction in
3 mortality. This is among the first if not the
4 only paper demonstrating a connection in heart
5 failure between process measures and a heart
6 outcome such as mortality. The hazard ratio
7 for ACE inhibitor was 0.4; for beta-blockers,
8 0.44.

9 The measures. Specifically for
10 left ventricular ejection fraction we actually
11 considered retiring this measure because it's
12 not the ejection fraction itself which leads
13 to an outcome, but it's the identification of
14 the patient who needs therapy. However, in
15 doing so, by retiring that, we have the
16 concern that this is inexorably linked to the
17 drug therapy. And if we retire the measure,
18 then the drug therapy has to be re-specified
19 to include only those patients with low
20 ejection fractions. How do we identify those
21 patients? And/or we would have a measure in
22 which would be a large number of exclusions

1 because of the large number of patients with
2 normal ejection fractions.

3 So, we did maintain the ejection
4 fraction measure.

5 We made it clear that the ejection
6 fraction does not have to be measured every
7 year. Once the low ejection fraction is
8 demonstrated, it could be a prior echo from
9 several years ago. As long as it is mentioned
10 within a 12-month period the echo itself does
11 not have to be repeated.

12 The concern about overuse was
13 addressed. We can go into details if you'd
14 like, but we actually found that in a large
15 sample of Medicare claims data only 2.5
16 percent of Medicare patients with heart
17 failure received three or more echocardiograms
18 per year. So there does not appear to be
19 overuse of echocardiograms in the outpatient
20 setting.

21 Regarding the symptom and activity
22 assessment, we modified that to become much

1 more quantitative. We believe that we should
2 be either including a New York Heart
3 Association functional class or some more
4 quantitative quality of life measure to allow
5 clinicians to determine whether their patients
6 are improving or not. So it's not
7 satisfactory just to say the patient still has
8 symptoms. We should be more quantitative and
9 that could drive the team, physicians and
10 nurses, to develop a different care plan to
11 try to improve the patient.

12 Regarding the beta-blocker
13 measure, which now includes a discharge
14 recommendation as well, which was not
15 previously in our measures -- and that's based
16 upon the updated 2009 ACC/AHA Guidelines,
17 which now include beta-blockers at discharge
18 for appropriate patients.

19 We believe that these measures
20 focus on accurate and appropriate evaluations
21 in monitoring of disease to guide treatment
22 including a patient-focused measure to improve

1 symptoms and improve function. And thank you
2 for this consideration.

3 CHAIR GIBBONS: All right. Are
4 there questions at all for the developer?
5 David?

6 MEMBER MAGID: Yes, thank you.
7 That was a very nice presentation. I just
8 wanted to ask you a question about one of the
9 things you said. I feel a little
10 uncomfortable --

11 DR. BONOW: Sorry, right behind
12 you.

13 MEMBER MAGID: You said that there
14 was no data to suggest overuse of outpatient
15 echocardiography? I may have misheard you,
16 but --

17 DR. BONOW: In Medicare claims
18 data we actually looked to see whether we
19 could identify evidence for overuse of
20 echocardiography. It's obviously a concern.
21 And in fact, we thought we were going to
22 develop an overuse measure and felt that the

1 data supporting that would be hard to justify
2 based upon the Medicare data we had available.

3 MEMBER MAGID: Doesn't the
4 Dartmouth Atlas suggest variations approaching
5 threefold in echocardiography use?

6 DR. BONOW: There's clearly a
7 variation.

8 MEMBER MAGID: Yes. So either
9 that's --

10 CHAIR GIBBONS: So --

11 DR. BONOW: But I'm not sure you
12 can demonstrate that for heart failure per se
13 --

14 CHAIR GIBBONS: Right.

15 DR. BONOW: -- or just for the use
16 of echocardiography.

17 CHAIR GIBBONS: Right. I think we
18 have to be careful what the universe is of
19 that data, whether it's inpatient or
20 outpatient. There is an existing AHRQ grant
21 to Yale to revisit some of the imaging
22 analysis from Dartmouth that is now 15 years

1 old, because the only previous data on stress
2 imaging was based on 1996 data.

3 Sid?

4 MEMBER SMITH: So, if I heard you
5 correctly, Bob, you looked at a Medicare
6 database. And using a criteria of three or
7 more echos for overuse it was somewhere around
8 2 to 3 percent. And your conclusion was that
9 there was not a great deal of evidence from
10 this database that overuse was occurring in
11 the outpatient setting. Is that correct?

12 DR. BONOW: Based upon that sample
13 from Medicare.

14 MEMBER SMITH: Yes.

15 DR. BONOW: And realizing that in
16 some patients three or more echos may be
17 appropriate. We don't know the
18 appropriateness of those echocardiograms.
19 It's just a sample. But there did not appear
20 to be a large signal of overuse in outpatient
21 heart failure treatment.

22 MEMBER SMITH: I mean, I think it

1 all resides in how you -- maybe Dartmouth is
2 saying two or more a year is overuse. So it
3 depends on how you set your standards for --

4 DR. BONOW: We could spend a lot
5 of time on this discussion.

6 MEMBER SMITH: Yes, so my question
7 though is with the assessment of symptoms and
8 how easy it's going to be how well we are
9 putting forth for the clinician what they're
10 supposed to do. You say no change in some --
11 when folks are going to be in the records
12 looking for were symptoms assessed, what are
13 they going to be --

14 DR. BONOW: New York Heart
15 Association functional class would suffice.

16 MEMBER SMITH: So they just want
17 some for every visit?

18 DR. BONOW: Something more
19 quantitative than the patient has dyspnea.

20 MEMBER SMITH: Okay. Just put in
21 whatever the New York Heart Association
22 classification is?

1 DR. BONOW: That --

2 CHAIR GIBBONS: I think we want to
3 defer this discussion until the details of
4 that measure. So, Dianne?

5 MEMBER JEWELL: Yes?

6 CHAIR GIBBONS: Could you hear Dr.
7 Bonow?

8 MEMBER JEWELL: I did, thank you.
9 And I apologize to him that I'm not present to
10 have the conversation face-to-face. So, I am
11 definitely having one of those existential
12 angst moments with this measure because, you
13 know, somebody who's responsible for
14 overseeing an implementing exercise with
15 patients like this. I absolutely want the
16 medical community to be checking on functional
17 capacity, whether it's with New York Heart
18 Association class or a standardized
19 questionnaire.

20 My struggle is that we had a
21 similar challenge with the measure that
22 AAC/DPR presented in their last meeting

1 regarding the assessment of risk. And the
2 issue that we had with that measure was that
3 we weren't clear what the information would
4 lead to because it was only the process of
5 asking the question.

6 Having said that, I think the
7 testing data indicated that there are some
8 gaps in how frequently the medical community
9 asks patients about their functional status,
10 so I have to say that I voted no on the
11 importance criteria when I did my first review
12 more to prompt a conversation and hear what
13 others on the Committee had to say about this.
14 Because if I'm putting my hat on as a physical
15 therapist, I'm all for this measure. If I'm
16 putting my hat on as an NQF participant in
17 some of the things that we've decided, I'm not
18 convinced that it meets the criteria for
19 importance.

20 MEMBER RUSSO: I would like to
21 comment. I think actually it's a very
22 important thing to assess at each visit, is

1 the way I think it's specified even, because
2 not only does it have ramifications regarding
3 how the patient's feeling, it has
4 ramifications regarding what other therapy may
5 be appropriate, whether it be drug or device
6 therapy for the patient. So I think it's
7 really important and we should document it in
8 some quantitative manner, which is I think
9 what the measure here does, which I think is
10 actually very nicely done.

11 CHAIR GIBBONS: All right. Others
12 who want to comment on importance of this
13 symptom measure? David?

14 MEMBER MAGID: Just, what's -- I'm
15 sure there's a performance gap, but I'm
16 wondering about 1C. Where's the outcome or
17 evidence?

18 MEMBER RUSSO: So, that may be a
19 harder part of it and maybe the developers
20 could give us some data. But I think if you
21 don't have this information, then you can't
22 assess the patient for other therapies. So,

1 although it's two steps away -- so if the
2 patient needs an ICD, there's outcome data
3 with ICDs. But if you don't even get to that
4 step, where are we?

5 MEMBER JEWELL: This is Dianne
6 again. I completely appreciate that
7 perspective. My struggle again is with the
8 consistency of our decision making. I could
9 make the same argument that cardiac
10 rehabilitation programs absolutely need to ask
11 the questions that lead to better risk
12 stratification so they can safely implement
13 whatever program has been prescribed. But at
14 that time our decision making was exactly the
15 question that was just raised. "Where is the
16 link to the outcome relative to the activity
17 in question with the measure?", so hence my
18 angst.

19 CHAIR GIBBONS: Tom?

20 MEMBER KOTTKE: This is just a
21 point of information that I need clarification
22 again, and I think Dr. Bonow mentioned this,

1 but what exactly does quantitative results of
2 an evaluation of both current level of
3 activity and clinical symptoms document? Does
4 that mean a six-minute walk or -- in 77, or am
5 I --

6 CHAIR GIBBONS: Bob, you want to
7 comment on that?

8 DR. BONOW: No, believe me, our
9 committee had many of the discussions I'm
10 hearing right now as well, and that actually
11 came up; should we be forcing more
12 quantitative objective evidence? And we
13 decided this would be really undue extra work
14 for a busy practitioner. The idea though is
15 to move the field forward beyond just a simple
16 statement that I have a symptomatic patient
17 with heart failure. How does the more
18 quantitative measure of the patient's symptom
19 status this month compare to how it looked six
20 months ago? Is the patient improving? Is the
21 patient getting worse? Because that could
22 drive, as we've heard, more therapies.

1 I think the way to put this is
2 let's bring the patient into the discussion
3 here. This is a patient-centered measure.
4 Otherwise, we're talking about tests and drugs
5 based on tests and we're not talking about
6 what really matters for the patient. So we
7 thought that moving a patient-centered measure
8 into a more quantitative field to allow one to
9 assess efficacy of therapy or to move patients
10 toward more advanced therapies would be quite
11 helpful.

12 MEMBER SANZ: Mr. Chair, to your
13 right.

14 CHAIR GIBBONS: Yes, Mark? Sorry.
15 We were trying to discuss the appendix. Go
16 ahead.

17 MEMBER SANZ: I have concerns
18 about this in the same way we had that
19 discussion last time about a study in
20 Australia and asking about chest pain. I
21 can't imagine as a clinician -- I just can't
22 imagine not asking about symptoms of

1 congestive heart failure and how this --

2 CHAIR GIBBONS: Okay. So, our
3 off-line discussion is actually pertinent. I
4 would urge you to look at the attachment that
5 came in with the application, which is a
6 summary of the PCPI performance measure
7 testing, and the median for heart failure
8 assessment was 73 percent in the sample. The
9 median of the spread, whether it was
10 adequately documented, 73 percent. So as
11 David said, there's clear evidence of a gap.
12 Now the question is --

13 MEMBER SANZ: Is that a gap in
14 documentation or a gap in clinically asking?
15 There's a big difference.

16 CHAIR GIBBONS: Well, we don't
17 know. I think we can just look at the
18 documentation. So it is in the --

19 MEMBER JEWELL: This is Dianne
20 again. I guess I'm curious, for the measure
21 developers, if the conversation came up around
22 this measure specifying it to relate to the

1 action that's been described, which is that
2 you've asked the question and documented it in
3 a quantitative way, but it's linked to a
4 response by the clinician, a plan of care of
5 some kind, whether that conversation came up
6 around measure development.

7 DR. BONOW: Yes, actually in our
8 actual document there's a link to this driving
9 a plan of care if symptom status,
10 quantitatively defined, is not improving or is
11 worsening.

12 MEMBER JEWELL: And so that was in
13 the application for the measure? I'm sorry if
14 I missed it.

15 DR. BONOW: I don't believe it's
16 in the application, but it's in the document
17 that the PCPI has endorsed.

18 CHAIR GIBBONS: Tom?

19 MEMBER KOTTKE: Yes, I'm just, you
20 know, one of those general cardiologists, but
21 every patient I see I ask, you know, "Do you
22 have PND orthopnea, edema, dyspnea on

1 exertion, chest pain on exertion? Are you
2 better? Are you worse? How are you limited?"
3 But I don't write down class. And I think for
4 me those other words are more descriptive than
5 class. And I'm not -- we're talking about a
6 lot of primary care docs treating heart
7 failure and, I mean, that's where heart
8 failure is treated. And I don't know if -- I
9 mean, I have a couple of issues. One is, you
10 know, expecting them to start -- we tried this
11 in our practice to get people to stage in
12 class of heart failure and we worked like
13 hell. And then when -- stopped, you know,
14 beating people up over it, I think it
15 evaporated.

16 CHAIR GIBBONS: So, that really
17 dovetails onto Mark's comment. Part of it is
18 documentation and part of it is how you
19 document.

20 Andrea?

21 MEMBER RUSSO: I think that in
22 terms of -- it is somewhat important to be

1 somewhat quantitative. I think we all do
2 that. When we first talk to the patient, we
3 ask them how they're feeling. But then --
4 maybe this will be eventually a composite
5 measure that might make a lot more, you know,
6 clinical sense to tie it to outcome, but in
7 terms of -- again, I don't want to reiterate,
8 but other therapies. So if they have a left
9 bundle and they're class 1 heart failure,
10 you're probably not going to be thinking of
11 other therapies such as, you know, CRT, ICD or
12 pacemaker.

13 So I think quantifying it; and the
14 way they did it I thought was a reasonable
15 thing either by Heart Association class or by
16 other valid tools, which I don't know how many
17 people use, but so I think it is important to
18 not only put all the pieces together and say,
19 yes, you're short of breath, but are you short
20 of breath after walking a mile or short of
21 breath walking, you know, across the room?
22 That's clinically relevant to other therapies

1 that you might consider.

2 CHAIR GIBBONS: Okay. Mary?

3 VICE CHAIR GEORGE: You know, as I
4 was just reading the numerators, it says
5 patient-reported health status as assessed by
6 a structured survey questionnaire offers
7 another more patient-centric approach, but it
8 doesn't say anything about being a valid
9 survey. So, you know, I think the way I read
10 it, it could be interpreted to do exactly what
11 Tom is asking. That's his survey, which is
12 valid in his practice. Then I would ask the
13 measure developer if that would meet the
14 measure.

15 DR. BONOW: The measure really
16 would require a more -- and I suppose you can
17 come up with your own grading system. So, I
18 think the answer is yes if you then put a
19 number on that from 1 to 10. But I'm not sure
20 how tested or valid that may be beyond the
21 single practice. So, the measure really
22 specifies either a New York Heart Association

1 functional class or one of the existing
2 validated tested surveys.

3 CHAIR GIBBONS: Okay. Tom?

4 MEMBER KOTTKE: I hate to be an
5 anti-ACC grinch here, but I'm not sure this is
6 patient-oriented. I mean, I think patient-
7 oriented is "Are you dissatisfied with what
8 you can do in your life right now if you're on
9 the right therapy?" You know, "Do you want me
10 to do more for you?" And if they say no, then
11 the obligation is to not do any more. I mean,
12 it's -- nobody's asking the patient are you
13 satisfied or dissatisfied with how you're
14 doing?

15 CHAIR GIBBONS: Carol? I could
16 see you were just itching to comment.

17 MEMBER ALLRED: That's right.
18 Absolutely.

19 CHAIR GIBBONS: The moment he said
20 that --

21 MEMBER ALLRED: Absolutely.

22 CHAIR GIBBONS: -- you were just

1 jumping out of your chair. Go ahead.

2 MEMBER ALLRED: Yes. Yes. You
3 know, I have to comment on this on several
4 levels, not only my own experience with heart
5 failure, but also being in charge of a patient
6 organization and listening to lots and lots of
7 stories.

8 I'd have to say, Mark, that not
9 everyone out there asks the questions. There
10 are a lot of people out there that are just
11 left hanging and they don't know where they're
12 at in their prognosis. I have that exception.
13 I have a good relationship with my
14 cardiologist, but it took time for us to get
15 to that point where we could take the time to
16 discuss everything. In fact, I had a meeting
17 with him where I actually put my chair in
18 front of the door and said, "Sit down; we're
19 not finished."

20 CHAIR GIBBONS: Do they do that in
21 Montana, Mark?

22 MEMBER ALLRED: We do it in Texas.

1 But I get my questions answered. And I think
2 it's important to have those discussions
3 because it does make a difference to me if I
4 get discouraged because I can't walk a mile
5 without being short of breath. But last week
6 or the last visit I could only walk upstairs
7 and I was short of breath, and now I can walk
8 for 10 minutes. Obviously I'm making
9 progress. So, I think it's an important
10 patient measure.

11 CHAIR GIBBONS: Okay. Thank you.
12 David?

13 MEMBER MAGID: I have one last
14 comment, which is -- well, first of all, I
15 absolutely agree with what you're saying. I
16 think the issue is still 1C. And we had a
17 similar measure that was brought to us by Dr.
18 Spertus when we were at our last meeting, and
19 we had this same discussion. And in that
20 discussion we came to the conclusion that we
21 -- well, we stopped at this point because we
22 felt like there was no evidence for what you

1 requested. So, I just want to make sure we're
2 being consistent across how we handle the --

3 CHAIR GIBBONS: Right, but to be
4 fair, there wasn't the volume of data in that
5 application which there is here, and that's
6 why the appendix I specifically mentioned.

7 MEMBER MAGID: Right.

8 CHAIR GIBBONS: There is an
9 appendix and then the one publication from
10 Fontero is actually in the application. So
11 demonstration of a performance gap is --

12 MEMBER MAGID: Right, it's not 1B;
13 it's 1C.

14 CHAIR GIBBONS: Yes, it's 1C.

15 MEMBER MAGID: Yes.

16 CHAIR GIBBONS: So, it's a little
17 bit of a different discussion for that reason,
18 because the evidence was lacking from the
19 other one.

20 So, I think we've gotten everybody
21 who wanted to comment to comment. And now we
22 have to take the vote on importance of this

1 measure.

2 MEMBER RICH: Ray, if I could just
3 add one more piece of evidence --

4 CHAIR GIBBONS: Sure, sorry.

5 DR. RICH: -- to the conversation
6 before we take the vote. There is a study.
7 It's limited in its design, but there is a
8 study in Heart in 2007 that does speak to some
9 inconsistencies in a cardiologist's ability to
10 consistently classify patients in the NYHA
11 class system. So, I just want to make sure
12 that we're -- for the sake of completeness
13 recognize that there is some contrary evidence
14 out there about the utility of that particular
15 aspect of the measure.

16 CHAIR GIBBONS: Maybe I could as
17 the developer to respond to that.

18 DR. BONOW: Oh, no, I agree. I
19 think if you had -- I mean, essentially it's
20 what Tom suggested, that we first talk with
21 the patient. That's how you come up with the
22 New York Heart Association functional class.

1 And I might differ from Tom with the same
2 patient whether it was a 2 or a 3, but I would
3 be internally consistent in my own judge of
4 this patient, whether the patient is now
5 improving or not improving, going from a 2 to
6 a 3, or a 2 to a 1. So, I think within in a
7 single practitioner there's probably internal
8 consistency.

9 CHAIR GIBBONS: Okay. Any other
10 comments before we vote?

11 (No audible response.)

12 CHAIR GIBBONS: All right. Let's
13 go ahead and vote.

14 DR. WINKLER: Dianne?

15 MEMBER JEWELL: No.

16 DR. WINKLER: Devorah?

17 MEMBER RICH: No.

18 CHAIR GIBBONS: To summarize the
19 votes, we have 8 yeses and 12 nos. So we are
20 done with the evaluation of this measure and
21 I think it's pretty evident that the stumbling
22 block was item 1C.

1 All right.

2 MEMBER RICH: So, if I could at
3 least offer the suggestion that it would have
4 helped me tremendously to have the measure
5 specified with a more -- the measure itself
6 specified with a link to the plan of care
7 because I fully recognize that that is in fact
8 how the information is being used when it's
9 being collected. And I also appreciate that
10 there is a gap in performance, so for what
11 it's worth, that's one person's perspective on
12 how that measure could come back around.

13 CHAIR GIBBONS: Okay. Thank you,
14 Dianne, and thank you for your time in
15 reviewing this.

16 Now, we're going to move onto
17 0079, which is heart failure, left ventricular
18 ejection fraction assessment in the outpatient
19 setting.

20 Rochelle?

21 MEMBER AYALA: Yes. I'm going to
22 read what the description is, but then I'm

1 going to ask for some clarification on the
2 definition. And it says the percentage of
3 patients 18 years or older with a diagnosis of
4 heart failure for whom the quantitative or
5 qualitative results of a recent or prior or
6 any time in the past left ventricular ejection
7 fraction assessment is documented within a 12-
8 month period.

9 So, I wanted to just clarify, is
10 it that the patient was newly diagnosed with
11 heart failure, or is it a patient that's been
12 carrying the diagnosis of heart failure for a
13 long time? And so, I'm concerned about the
14 situation, for example, where a patient's been
15 carrying the diagnosis for a long time. The
16 physician has documented a couple years ago
17 what the most recent ejection fraction they
18 have for the patient. The patient hasn't
19 changed at all with their symptomatology and
20 now we're in this 12-month period of
21 measurement and the physician has not
22 documented in the progress note the result of

1 that older EF.

2 DR. BONOW: I think you described
3 it. It's both types of patients; the newly
4 diagnosed patient and the patient who's been
5 carrying. So it's every patient you're seeing
6 within that 12-month period. Do you have
7 documentation of an ejection fraction either
8 this year or a prior ejection fraction that
9 was performed years ago demonstrating an
10 ejection fraction in the abnormal range?

11 MEMBER AYALA: Okay. Just, you
12 know, for logistical purposes, I guess the way
13 that the physicians would comply with this is
14 that every time they list the diagnosis in
15 their record, that progress of heart failure,
16 they should put in parentheses what the
17 ejection fraction was just to make sure that
18 they're documenting in a way that whenever
19 that 12-month period hits that they're
20 compliant.

21 DR. BONOW: Well, and I guess you
22 could interpret it -- but sometime in that 12-

1 month period, yes. So, if it's easier for the
2 clinician or the team to be sure that they're
3 going to be, you know, within that window
4 whenever it starts and ends, yes. So, it
5 could be every visit.

6 MEMBER AYALA: Okay. So that's I
7 think important because when I first looked at
8 the information about the performance, the
9 information that's in their main packet
10 actually cites data from 2003 and it wasn't
11 clear whether or not that was inpatient and
12 outpatient or only inpatient, but it was like
13 35 percent compliance. But your more recent
14 data that you have in the appendix shows that
15 for this measure the performance on the DOQ
16 was 85 percent, on the PCPI hit was 23
17 percent, and in the PINNACLE Registry it was
18 64.7 percent. And when I first saw that, I
19 thought, "Oh, there's a big performance gap
20 here. Then we really should be considering
21 this measure."

22 But then after consideration of

1 what we just discussed, I'm wondering how much
2 of this gap that the physician is not
3 documenting every visit what the older EF was
4 and therefore it appears that they never did
5 it. But in actuality they may actually have
6 done it and it would be appropriate for them
7 not to mention it.

8 DR. BONOW: I believe that could
9 explain some of the variation you're seeing.
10 This may drive people to report it.

11 MEMBER AYALA: Okay. In terms of
12 the importance to measure, I think we had this
13 discussion a couple times; we had yesterday
14 and today, and I think everybody agrees that
15 it's important for the physician to know the
16 ejection fraction of the patient to choose the
17 appropriate care for the patient. And as you
18 said, this measure is important because you're
19 using it to base some of your other measures.

20 So, I'm a little bit torn here
21 because I understand the intent of the
22 measure; and I think it's correct, the intent.

1 I'm just concerned that, you know, it may not
2 be so valid because what are we really
3 testing? You know, are we capturing the
4 physician's non-compliance accurately? So,
5 that's the part about this that bothers me.
6 And it just occurred to me when we were
7 talking, when you were giving your
8 presentation, because I had interpreted it
9 that the patient was just newly diagnosed and
10 within one year of diagnosis the ejection
11 fraction had been documented. But after
12 listening to your opening remarks, I was
13 concerned that it may be the situation that we
14 described.

15 CHAIR GIBBONS: Okay. We need to
16 get input from others. Mark or Andrea; I'm
17 not sure who's --

18 MEMBER RUSSO: Yes, I guess I'm
19 starting to have a little bit of concern,
20 because I think, you know, we could talk
21 specifically about how it's measured, you
22 know, when we get to that, but the importance

1 is clear. You need to know -- you see a
2 patient and you're a cardiologist; you need to
3 know what their ejection fraction is.

4 So, and maybe we can make
5 recommendations. You might combine some of
6 these things, this with the last measure. And,
7 you know, there's ramifications in terms of
8 therapy. When you measure it, how you
9 document it. We could talk specifically in
10 the measure, but it's an important thing to
11 know regarding other therapy. And whether --
12 you know, there's for example under-
13 utilizations of ICDs in the United States.
14 Improve heart failure. One of the earlier
15 studies showed that -- and these are highly-
16 motivated practices. Enrolling patients.
17 Fifty percent of these highly motivated
18 practices did not -- fifty percent were not
19 identified or not, you know -- did not have
20 ICDs where they would be indicated based on
21 clinical measures. So we know despite the
22 recent media that there's under-utilization of

1 ICDs.

2 If we don't know their ejection
3 fraction, we don't know their heart
4 association class, we're not going to be able
5 to fix that and there may be some issues with
6 medicines, too. So, how we specify it's one
7 thing, but this is important.

8 CHAIR GIBBONS: Okay. Bruce,
9 you've been dutifully waiting over there, or
10 somebody's dutifully waiting over there.
11 They're not waiting over there. Tom?

12 MEMBER KOTTKE: I know nobody else
13 forgets what the ejection fraction is in their
14 patients they only see once a year in follow
15 up, but I think this is a very important
16 measure to have the physician write it down
17 once a year so they remember whether there's
18 systolic or diastolic heart failure, how bad
19 it is. Have they overlooked -- do they need
20 to have another discussion about a device, all
21 those kind of things. So I think this is a
22 very important measure.

1 MEMBER CHO: I just want to make a
2 comment.

3 CHAIR GIBBONS: Yes, Leslie?

4 MEMBER CHO: The way this reads
5 right now, you know, I appreciate the intent
6 of this measure, but I'm afraid that when
7 somebody reads this, they're going to get an
8 echo on a stable patient every 12 months. And
9 so, I share Rochelle's concern that the way
10 this currently reads in a stable patient with
11 EF of 35 percent, this to me reads like you
12 have to get an echo every 12 months.

13 CHAIR GIBBONS: Okay. All right.
14 We can't have a lot of off lines. Use the
15 mics in fairness to the people on the phone
16 and everybody else. Rochelle?

17 MEMBER AYALA: I understand what
18 you're saying. It is written that you just
19 have to have documented within the last 12
20 months, but I understand what you're saying,
21 that people might misinterpret that.

22 In terms of the importance though,

1 I just wanted to reiterate that it is listed
2 as evidence C, level C, but then there's like
3 a disclaimer about that at the bottom saying
4 that it shouldn't be construed as implying
5 that the recommendation is weak because many
6 important clinical questions are addressed and
7 the guidelines may not lend to study. And
8 it's also a recommendation class 1, so again
9 it is important.

10 My other question that's kind of
11 related to this though is there a guideline
12 that actually says what is the appropriate
13 interval to check, because that's kind of
14 related to this, too. So if you only had it
15 done once, and that was 10 years ago, is there
16 any guideline to say when you're supposed to
17 repeat it?

18 CHAIR GIBBONS: I think the answer
19 is no because there's no evidence. Bruce?

20 MEMBER KOPLAN: Yes, I would
21 actually agree with Leslie that when I -- I
22 understand that it does not tell you to do an

1 echo every 12 months. But when I first read
2 the title of this, that was my first take and
3 I had to think about it.

4 And I would agree that it is
5 absolutely essential to know what somebody's
6 ejection fraction is when they come to a
7 cardiology clinic, when they come to see a
8 consultant. If somebody has a history of
9 congestive heart failure and they show up in
10 an emergency room, it's a very important and
11 helpful thing to know, you know, whether it's
12 diastolic dysfunction, systolic dysfunction,
13 if they're being referred for consideration
14 for a defibrillator, et cetera.

15 So, I wonder if -- it seems like
16 there's a lot of agreement on that. If there
17 was some way we -- you know, sometimes we
18 suggest wording to make things seem more along
19 the intent of what you're trying to achieve,
20 because I do think that there's a concern.
21 And it seems to be one of the future themes
22 that we're going to deal with in medicine,

1 over-utilization of care, and we want to be
2 care not to do something that might create
3 more imaging especially.

4 CHAIR GIBBONS: So, if I can ask
5 the developer, friendly amendment
6 documentation of prior LV function assessment
7 in the title, would that be acceptable?

8 DR. BONOW: Yes, we could change
9 the title, but I'm not sure how to change --

10 CHAIR GIBBONS: Change the title,
11 but none of the specs. It's all in the specs.
12 It's just about the title. Is that correct,
13 Bruce?

14 MEMBER KOPLAN: Yes, that would be
15 -- and I would ask Leslie also, because she
16 brought the issue up. But I would like that
17 better personally.

18 CHAIR GIBBONS: Okay. So, with
19 that friendly amendment, we must move ahead if
20 we're going to get you on your planes, unless
21 you're going to walk home.

22 We now need to vote on importance

1 to measure.

2 DR. WINKLER: Dianne?

3 MEMBER JEWELL: Yes.

4 DR. WINKLER: Devorah?

5 MEMBER RICH: Yes.

6 DR. WINKLER: Thank you.

7 CHAIR GIBBONS: So, we have a vote
8 of 19 yeses and 1 no.

9 We're going to now move on to
10 scientific acceptability. I think some of the
11 discussion has already been about that.
12 Rochelle?1

13 MEMBER AYALA: Yes, it's pretty
14 straightforward. It's just a documentation in
15 the progress note of an LVEF assessment, which
16 is pretty easy if you just do it every time.
17 And the numerator is -- they specify how they
18 get it from the electronic medical record or
19 claims data. And the denominator is all
20 patients age 18 years or older with a
21 diagnosis of heart failure.

22 As I mentioned, the data source is

1 the paper medical record, or electronic
2 medical record, or claims data, or registry
3 data, and they have information for all the
4 different pilot tests that they did.

5 In terms of reliability and
6 validity, we talked about that a little bit in
7 the data that they submitted in the appendix.
8 As I mentioned, there was a variation in the
9 compliance among the three different pilot
10 studies; 23 percent, 64 percent and 85
11 percent. And in the reliability testing it
12 did pretty well where they had two different
13 reviewers reviewing the data.

14 I had a question. I didn't
15 understand what this said. In the DOQ project
16 there was mention that ICD-9 coding was not
17 sufficient in identifying -- patients with
18 left ventricular systolic dysfunction was one
19 of the questions under feasibility testing.
20 But that was in the small study that DOQ -- I
21 didn't know how significant that was.

22 DR. BONOW: Yes, and I just had an

1 off-line conversation with Sam Tierney. It's
2 not clear that the ICD-9 code differentiates
3 inpatient/outpatient.

4 MEMBER AYALA: I'm sorry?

5 DR. BONOW: It's not clear that it
6 differentiates between inpatients and
7 outpatients. Is that correct?

8 MS. TIERNEY: Yes, I think that
9 the ICD-9 code --

10 CHAIR GIBBONS: Closer to the mic,
11 please.

12 MS. TIERNEY: Sorry. The ICD-9
13 codes are very general, so it's just general
14 for heart failure. Maybe that was what that
15 Doc Project was mentioning, that in order --
16 that you need more in order to identify
17 whether they have systolic or diastolic
18 dysfunction.

19 MEMBER AYALA: Okay. So, I
20 thought that -- and there's no exclusions and
21 no risk adjustments, so I thought that it was
22 statistically sound. They didn't really

1 mention much about disparities specifically,
2 but I know you mentioned that you had some
3 disparities data. Did you see any disparities
4 in this indicator?

5 DR. BONOW: No, neither in the
6 inpatient or outpatient side in the data that
7 are our there.

8 CHAIR GIBBONS: It's actually up
9 in section 1 of the submission as well. It
10 deals with a point we're going to deal with
11 later on when we discuss disparities. The
12 forms are confusing in terms of where to put
13 that data and that's why several times
14 yesterday everybody was struggling to find the
15 data. Of course, we have the same problem
16 that the submitters have.

17 Are there any other comments or
18 questions about scientific acceptability?

19 MEMBER RUSSO: I just have one
20 question --

21 CHAIR GIBBONS: Yes?

22 MEMBER RUSSO: -- for either other

1 people on the table here or for the developer.
2 So, does everyone use the mild, moderate,
3 severe designations with the same exact -- is
4 there an echo document that says this is what
5 it is? Because some people say, you know,
6 maybe moderate might be it for -- is that a
7 clearly delineated cutoff for everyone?

8 DR. BONOW: That's a very good
9 question. I mean, the current echo documents
10 indicate one should measure this and report an
11 ejection fraction. Our concern is that not
12 every echo laboratory nationwide does that at
13 the current time. And so what does the
14 clinician do when he or she receives a report
15 with no ejection fraction, which often occurs.
16 Hopefully the field will evolve to a higher
17 level. In fact, there's going to be
18 performance measures on imaging sooner or
19 later, which might drive it faster. But at
20 the current time the poor clinician many times
21 does not have that data and therefore we try
22 to become much more semi-quantitative.

1 And I certainly agree that even
2 though echo ejection fractions are also highly
3 variable, the qualitative assessment of mild,
4 moderate, severe could vary according to the
5 eye of the beholder, but it was an attempt to
6 guide the clinician. If it says severe
7 dysfunction, moderate dysfunction, good, this
8 person is now a candidate for therapies. If
9 it's normal or mildly dysfunctional, probably
10 not.

11 CHAIR GIBBONS: And it's worth
12 pointing out that those particular categories
13 actually have traced through a series of
14 guideline documents extending back to 1998.
15 So, they've been around for awhile. Whether
16 everybody follows them exactly remains to be
17 seen. But moderate, being below 40, you can
18 find an ACC/AHA Guidelines back in 1998.

19 David?

20 MEMBER MAGID: Yes, I was going to
21 say we have a seven-site NHLBI heart failure
22 study and if we couldn't use the qualitative,

1 we would have to drop a lot of patients. So,
2 I think it's really important that you
3 included both.

4 CHAIR GIBBONS: All right. We're
5 going to go ahead. Any questions on the
6 phone?

7 (No audible response.)

8 CHAIR GIBBONS: If not, we're
9 going to go ahead and vote on scientific
10 acceptability.

11 MEMBER JEWELL: No questions.

12 DR. WINKLER: Dianne?

13 MEMBER JEWELL: Partially.

14 DR. WINKLER: Devorah.

15 MEMBER RICH: Partially.

16 DR. WINKLER: Thank you.

17 CHAIR GIBBONS: So, the vote is 12
18 completely, 6 partially and 1 minimally.

19 We'll move on now to usability.

20 MEMBER AYALA: Yes, it's in use
21 with these pilot studies and it doesn't seem
22 like it's causing any difficulty to collect

1 the data. And I think going forward for
2 people to comply, they just would have to make
3 mention of the ejection fraction or the left
4 ventricular systolic function along with their
5 diagnosis, and that wouldn't be too difficult
6 to do.

7 MEMBER SANZ: I have a question.

8 CHAIR GIBBONS: Yes, Mark?

9 MEMBER SANZ: In the pilot studies
10 was there any look at the use of echo or
11 imaging compared to patient, or compared to
12 groups that didn't have to -- did you look at
13 the appropriate versus inappropriate use of
14 imaging after implementing this type of
15 requirement?

16 CHAIR GIBBONS: Tough question.

17 DR. BONOW: No.

18 MEMBER SANZ: If I would guess,
19 echo went way up.

20 DR. BONOW: Oh, I don't -- well,
21 we can look at that. I would bet the other
22 way. I'm not sure, because I think people are

1 already doing this. They may be doing more
2 echos already and this may reduce utilization
3 once they realize they don't have to do it
4 every year.

5 MEMBER SANZ: We're both guessing,
6 right?

7 DR. BONOW: We are.

8 CHAIR GIBBONS: All right. Other
9 questions? Comments?

10 (No audible response.)

11 CHAIR GIBBONS: If not, let's vote
12 on usability.

13 DR. WINKLER: Dianne?

14 MEMBER JEWELL: Completely.

15 DR. WINKLER: Devorah?

16 MEMBER RICH: Completely.

17 DR. WINKLER: Thank you.

18 CHAIR GIBBONS: So, the tally is
19 12 completely, 6 partially, 2 minimally.

20 And let's move on now to
21 feasibility.

22 MEMBER AYALA: It's the same

1 thing. It's feasible the data can be
2 generated as a byproduct of the care processes
3 and you can collect the data electronically.
4 No exclusions and no inaccuracies documented.

5 CHAIR GIBBONS: Okay. Are there
6 comments or questions?

7 MEMBER JEWELL: This is Dianne.
8 The mics are still popping in and out and I
9 actually think it might be because people need
10 to speak right into the mic the whole time.

11 So, I say that only to preface
12 that I don't know where we landed with the
13 unintended consequences over utilization of
14 echos based on the earlier conversation, part
15 of this meeting, clarity --

16 CHAIR GIBBONS: Okay. So, sorry
17 if you didn't hear that. The --

18 MEMBER JEWELL: -- about what the
19 consensus was on that.

20 CHAIR GIBBONS: Right. The
21 discussion was basically a concern over
22 whether collecting this data lead to an

1 increase in the use of echo or a decrease in
2 the use of echo. And there was speculations
3 on both sides, but everybody agreed they
4 didn't have the data to support their
5 speculations. Is that an accurate summary?

6 MEMBER JEWELL: Thank you.

7 CHAIR GIBBONS: I think that's an
8 accurate summary. I'm sorry, we will all try
9 to speak directly into the mic rather than
10 looking down at our notes as we speak, which
11 is what the problem is.

12 All right. So are there other
13 comments or questions about feasibility?

14 CHAIR GIBBONS: Yes, Dana?

15 MEMBER KING: Question? Because
16 this has to be documented and it's annual and
17 now it's in the progress note in our
18 electronic medical record, even though it's
19 electronic. So, now you're saying that the
20 extractors do a text search for the word
21 "ejection fraction," or for the word
22 "fraction," or for the initials "EF," or for

1 the word "heart failure assessment?"

2 In other words, that doesn't sound
3 that easy to me and because I could have
4 looked at it. I could have looked at tab B,
5 which says here's the reports. I looked at it
6 and I said, "Oh, yes, the EF's 48. Yes, that
7 sounds good. They're not having any problem.
8 They're here for a diabetes checkup anyway,
9 not this. They seem to be doing fine.
10 They're not short of breath." Boom. I
11 looked at it. I didn't write down EF in that
12 note. Or some people write down EF. Some
13 people put ejection fraction. Some might put
14 echo 48 percent.

15 This actually seems like a problem
16 to me and there would be multiple ways of
17 documenting it, even if we were so obsessive
18 that we did so every time.

19 CHAIR GIBBONS: All right. That's
20 a good --

21 MEMBER MAGID: I can comment on
22 this.

1 CHAIR GIBBONS: David?

2 MEMBER MAGID: Yes, so, you know,
3 there's a small universe of tests that you do
4 to measure EF, right? I mean, there's echo,
5 there's nuclear stress tests, there's
6 ventriculography, cardiac MRI. I mean,
7 there's not a large number of tests. And so,
8 in our project all the sites have electronic
9 health records and we essentially review the
10 imaging and cardiovascular tabs and find that
11 we can find the EF of well over 90 percent of
12 the patients in those tabs.

13 We do do natural language
14 processing. And the way we did it, we sort of
15 backed into it; and I imagine the developers
16 have thought of this, but we actually looked
17 at about 100 to 200 charts to see all the
18 different ways the text showed up. And then
19 using that we actually did run text searches.

20 We found that we weren't able to
21 really find the information all the time just
22 from the search, but they would point to us

1 where in the record it was, so we could then
2 quickly find it. So, you know, we haven't had
3 trouble finding EF data in our electronic
4 record across the seven sites that are in our
5 project.

6 MEMBER RUSSO: And the other
7 comment is also if you have a registry,
8 obviously the registry I assume would have --
9 this particular PINNACLE Registry has probably
10 a spot for that.

11 DR. BONOW: Well, I think moving
12 into EMRs this will be much easier to capture
13 than going through charts. But, I mean, it
14 has some of its hurdles, but I think they can
15 be overcome.

16 CHAIR GIBBONS: Okay. I think we
17 need to move ahead and vote, please.

18 DR. WINKLER: Dianne?

19 MEMBER JEWELL: Partially.

20 DR. WINKLER: Devorah?

21 MEMBER RICH: Completely.

22 CHAIR GIBBONS: So, the final

1 tally is 7 completely, 11 partially, 1
2 minimally.

3 And now we're going to vote on the
4 final key question, does it meet criteria for
5 endorsement?

6 DR. WINKLER: Dianne?

7 MEMBER JEWELL: Yes.

8 DR. WINKLER: Devorah?

9 MEMBER RICH: Yes.

10 CHAIR GIBBONS: And the vote is 18
11 yes and 1 no.

12 So, we're going to move on to the
13 next measure, 0081, heart failure, ACE and ARB
14 therapy for LV systolic dysfunction.

15 And Jon has been just sitting
16 there quietly on the far side of the room just
17 waiting his turn here for the last day-plus.
18 So, he's now --

19 MEMBER RASMUSSEN: I'm closing out
20 with the last two.

21 CHAIR GIBBONS: He's still awake
22 and we're going to let him spring into action.

1 Jon?

2 MEMBER RASMUSSEN: Well, first I'm
3 gratified that the last measure was approved,
4 because that increases the denominator for the
5 next two measures. The title is, Heart
6 failure: ACE or ARB Therapy in Left
7 Ventricular Systolic Dysfunction. A brief
8 description is the percentage of patients 18
9 and older with a diagnosis of heart failure
10 with a current or prior EF of less than 40 who
11 received an ACE or ARB therapy within a 12-
12 month period outpatient, or at hospital
13 discharge inpatient.

14 So, the importance of this
15 measure. The impact is high. The developer
16 did a nice job introducing all four of the
17 measures.

18 As far as performance gap, on the
19 outpatient side there's a significant gap.
20 When a recent review was done, the average
21 compliance was 80 percent, but a gap between
22 6 and 96 percent. So pretty significant. On

1 the inpatient side it's much better. The
2 average is 92 percent. Outcome in evidence is
3 very strong, 1A.

4 CHAIR GIBBONS: Okay. Any other
5 comments about importance to measure?

6 (No response.)

7 CHAIR GIBBONS: I would just point
8 out that if Tom did one of his little
9 calculations here and you started talking
10 about outpatient heart failure in the United
11 States with that kind of performance gap,
12 there are a lot of lives here.

13 MEMBER KOTTKE: Our calculations
14 are that if we can just improve care by 10
15 percent that we would have the equivalent
16 impact on mortality as perfecting care for
17 STEMI.

18 CHAIR GIBBONS: I'm the set up
19 man.

20 MEMBER KOTTKE: Yes.

21 CHAIR GIBBONS: You know, STEMI's
22 the gold standard for cardiology.

1 (Off mic comments.)

2 CHAIR GIBBONS: Microphone. You
3 got to be careful.

4 All right. So for those on the
5 phone, the discussion was why we always
6 compare to STEMI, and it's basically because
7 that's been well worked on and is a great
8 systems care issue. So, we're going to go
9 ahead and vote.

10 DR. WINKLER: Dianne?

11 MEMBER JEWELL: Yes.

12 DR. WINKLER: Devorah?

13 MEMBER RICH: Yes.

14 CHAIR GIBBONS: So, the vote is 18
15 yes, 1 no.

16 We're going to move on to
17 scientific acceptability. Jon?

18 MEMBER RASMUSSEN: For the
19 specifications, very nicely specified.
20 Numerator is for a patient who meets a
21 denominator, have an ARB or ACE fill once
22 within 12 months, or if it's inpatient, at

1 discharge. For the denominator, it's an
2 office visit with that code or a principle
3 diagnosis of heart failure as an inpatient.

4 Reliability and validity are both
5 very extensively discussed in the PCPI review,
6 but just in short in the Doc Quality Project
7 there was 94 to 100 percent agreement on
8 reliability. The exclusions are justified and
9 are consistent with the other ACE and ARB
10 measures. Meaningful differences I discussed
11 a little bit earlier. Disparities, black
12 patients are significantly less likely to
13 receive this therapy, but the absolute spread
14 is only 0.5 percent. So it's significant but
15 small. And then men versus women, women were
16 slightly more likely to receive the therapy;
17 2.6 percent.

18 CHAIR GIBBONS: Other comments or
19 discussion about scientific acceptability?

20 (No response.)

21 CHAIR GIBBONS: And we'll come
22 back to the disparities issues in the

1 disparities discussion.

2 I think we'll go ahead and vote
3 then, please.

4 DR. WINKLER: Dianne?

5 MEMBER JEWELL: Completely.

6 DR. WINKLER: Devorah?

7 MEMBER RICH: Completely.

8 DR. WINKLER: Thank you.

9 CHAIR GIBBONS: Vote is 19
10 completely and 1 partially.

11 Moving on now to usability. Jon?

12 MEMBER RASMUSSEN: So, here's
13 where the quick review slow downs a little
14 bit. For meaningful use, certainly
15 appropriate. Adding value to existing
16 measures. This is where I think it gets a
17 little bit interesting.

18 And before I get into my comments,
19 I'd like to ask the developer, when talking
20 about harmonization you mentioned 0162, and
21 that this measure, to avoid duplication,
22 you're requesting endorsement of this measure

1 at an individual clinician level of
2 measurement. Can you explain that, please?

3 DR. BONOW: The intent here, with
4 help from my colleagues, is really to enhance
5 care on the outpatient side. So, we're really
6 looking at individual clinicians on the
7 outpatient performance. So that we're were
8 not competing or duplicating the CMS measure
9 for inpatient discharge.

10 MEMBER RASMUSSEN: So, why did you
11 include the inpatient in the denominator?

12 MS. TIERNEY: I think I can speak
13 to that. And so, I apologize; I think I
14 misled Dr. Bonow just a little bit.

15 So, the measure that we submitted
16 is for the clinical level both inpatient and
17 outpatient, because we do have that piece
18 about at discharge and there are discharge
19 codes for physicians. So I apologize, Dr.
20 Bonow.

21 But we didn't submit the -- we do
22 have a companion measure. It's kind of all

1 one measure that addresses clinician and
2 facility level. But because of the CMS
3 measure and not wanting to compete with that
4 measure, we're not submitting the facility
5 level specifications and not submitting that
6 for your consideration for endorsement,
7 because of that competing measure. Does that
8 help clarify?

9 MEMBER RASMUSSEN: It does, but in
10 fact I'd almost encourage you to put the
11 facility level in there, because in just our
12 group alone over our last two visits this is
13 the 5th ACE/ARB measure that we've reviewed
14 for LVSD. And now, there are different
15 components to that. It's patients who had
16 ICDs, LVSD at discharge, post-MI, chronic
17 stable CAD on an outpatient level and now this
18 measure.

19 Now, this doesn't exactly -- this
20 isn't harmonization, but maybe there should be
21 one to rule them all. And that is, if a
22 patient has documented ejection fraction of

1 less than 40, then we determine an index date.

2 Now, whether that index date is a
3 hospitalization or an outpatient code, that's
4 the date at which we start looking at ACE or
5 ARB therapy. And that can include -- because
6 Fred Masoudi's comments yesterday were well
7 taken. There are some of these measures that
8 may have excluded patients with ICDs. If we
9 can make the measure general enough that all
10 of these patients; post-MI, post-ICD -- we
11 know they're supposed to receive the therapy
12 if they have an ejection fraction less than 40
13 percent. We have one measure, inpatient and
14 outpatient, and we're good.

15 DR. WINKLER: I can respond to
16 that.

17 CHAIR GIBBONS: Okay. We're going
18 to ask NQF to respond to that.

19 DR. WINKLER: Yes. Jon, I think
20 you are very clearly describing what a great
21 many people in the NQF world are asking for
22 and looking for. There are some realities in

1 the world at this point, but I think that that
2 would certainly be the goal.

3 One of the issues when we talk to
4 the measure developers is again broadening the
5 concept and asking them to accept that
6 challenge to figure it out, because there are
7 different data platforms that are used for
8 measures. There are different focuses on why
9 different developers develop measures, you
10 know, whatever their original interest is.

11 And so, your points are absolutely
12 well-taken. I could get you 100 people lined
13 up behind you with a brass band.

14 The reality is moving people
15 along. And so, for whatever recommendations
16 you can make to encourage the development of
17 that kind of a measure, because NQF CEO Janet
18 Corrigan says over and over and over the best
19 measures are one measure addressing a single
20 topic applicable to all settings and all
21 levels of measurement. So, I mean, that's
22 where we want to go.

1 Any recommendations you all can
2 make to help us move towards that would be
3 very, very useful and I would pose the
4 challenge to measure developers that moving in
5 that direction is actually going to benefit
6 everybody.

7 MEMBER SMITH: I'd support what
8 you and Jon have said. Is there any other
9 class of medications that has so many
10 indications as ACE/ARB right now? I mean,
11 really it's interesting to think about the
12 focus that we have on those meds.

13 DR. WINKLER: Later, when we look
14 at some of the competing and related issues,
15 the same issue comes up with multiple measures
16 around aspirin and antithrombotics, statin
17 use, beta-blockers.

18 So any of these -- there's a whole
19 group of things because the denominator
20 populations are very related and they may be
21 subsets or setting-specific or some aspect of
22 it, but it's all really talking about the same

1 sort of secondary prevention for this large
2 group of patients at risk. So, I think it's
3 challenging methodologically, but absolutely
4 the direction everybody needs to go in.

5 CHAIR GIBBONS: And, you know, I
6 think we've had several people comment as
7 we've gone through these; Dana in particular,
8 about this issue. I think we want to come
9 back to it when we talk about competing
10 measures later on. And for the moment, unless
11 there's more discussion here, let's --

12 MEMBER RASMUSSEN: Well, I just
13 want to say I want to make sure I'm not
14 picking on this measure. In fact, I think
15 this is the best of the five that we've
16 reviewed and comes closest to that ideal.

17 CHAIR GIBBONS: All right. That's
18 a comment for the record and for the
19 developer.

20 Let's move ahead to vote on
21 usability.

22 DR. WINKLER: Dianne?

1 MEMBER JEWELL: Partially.

2 DR. WINKLER: Devorah?

3 MEMBER RICH: Partially.

4 CHAIR GIBBONS: The vote is 13
5 completely, 7 partially.

6 And moving on now to feasibility.

7 MEMBER RASMUSSEN: For
8 feasibility, data generated during care, yes.
9 Electronic sources, yes. Exclusions require
10 no additional data sources. Susceptibility to
11 error or inaccuracies, not anticipated. Data
12 collection can be implemented as written, yes.
13 I would place my standard comment when
14 speaking about medication adherence measures
15 that -- hope that you would consider in the
16 future looking at a persistence measure rather
17 than simply a one-time medication use.

18 CHAIR GIBBONS: Other comments?

19 (No response.)

20 CHAIR GIBBONS: Okay. We're going
21 to go ahead and vote then on feasibility.

22 DR. WINKLER: Diane?

1 MEMBER JEWELL: Completely.

2 DR. WINKLER: Devorah?

3 MEMBER RICH: Completely.

4 CHAIR GIBBONS: So, the vote is 16
5 completely and 3 partially.

6 And we're going to move on now to
7 our final vote, does it meet criteria for
8 endorsement?

9 DR. WINKLER: Dianne?

10 MEMBER JEWELL: Yes.

11 DR. WINKLER: Devorah?

12 MEMBER RICH: Yes.

13 CHAIR GIBBONS: The vote is
14 unanimous, 19 yeses. There are no recorded
15 nos. So we've completed that one. And we're
16 moving on; drum roll in the background, to our
17 final measure consideration -- gotten at least
18 some smiles. People are indeed awake -- 0083
19 heart failure, beta-blocker therapy.

20 Jon, you're on again.

21 MEMBER RASMUSSEN: So, this
22 measure is paired with the ACE/ARB measure we

1 just did, so there are some sections that I'll
2 move through quickly because a lot of the
3 information is the same.

4 The measure title is "Heart
5 Failure: Beta-blocker Therapy for Left
6 Ventricular Systolic Dysfunction."
7 Description of the measure: Percentage of
8 patients 18 years or older with a diagnosis of
9 heart failure with a current or prior EF of
10 less than 40 percent who are prescribed beta-
11 blocker therapy either within a 12-month
12 period when seen in the outpatient setting or
13 at hospital discharge.

14 Impact is high. The performance
15 gap between white patient and black patients,
16 only 0.1 percent. Between men and women, 0.5
17 percent with women having a higher percentage.
18 Very low spread between the groups. Evidence
19 is 1A.

20 CHAIR GIBBONS: Other discussion
21 about the importance of the measure?

22 (No response.)

1 CHAIR GIBBONS: Let's go ahead and
2 vote, please.

3 MEMBER RUSSO: I mean, it's
4 impressive the variation between the practices
5 from -- you know, the improved the heart
6 failure trial, too, so clearly important.

7 MEMBER RASMUSSEN: I actually
8 jumped ahead in my notes and talked about
9 disparities too soon. In inpatient care the
10 average is 78 percent at discharge and
11 outpatient it's 86 percent average, but the
12 spread is 9 percent to 100 percent. So, I
13 apologize. I had my notes flipped.

14 DR. WINKLER: Hold on just a sec.
15 For importance, Dianne?

16 MEMBER JEWELL: Yes.

17 DR. WINKLER: Devorah?

18 MEMBER RICH: Yes.

19 DR. WINKLER: Thank you.

20 CHAIR GIBBONS: So, the vote is
21 unanimous; 19 yeses.

22 So, Jon, scientific acceptability?

1 MEMBER RASMUSSEN: Very similar
2 information for the prior measure. The PCPI
3 data was quite extensive. I mentioned
4 disparities in the previous vote.

5 CHAIR GIBBONS: We're going to
6 come back to that. It again reflects the
7 form. It's not your --

8 MEMBER RASMUSSEN: It's not me?

9 CHAIR GIBBONS: It's not you.
10 It's the form.

11 So, other comments or questions
12 about scientific acceptability?

13 (No response.)

14 CHAIR GIBBONS: If not, let's go
15 ahead and vote.

16 DR. WINKLER: Dianne?

17 MEMBER JEWELL: Completely.

18 DR. WINKLER: Devorah?

19 MEMBER RICH: Completely.

20 DR. WINKLER: Thank you.

21 CHAIR GIBBONS: Okay. So, the
22 summary of responses is unanimous; 18 votes

1 for completely and no votes for anything else.

2 Moving on now to usability. Jon?

3 MEMBER RASMUSSEN: Meaningful use,

4 clearly would be useful to the public to be

5 reported. Adds value to existing measures.

6 As a tangent to my previous comments, this is

7 the third beta-blocker measure that this group

8 has reviewed, so same comments about that.

9 CHAIR GIBBONS: Other comments on

10 this?

11 (No response.)

12 CHAIR GIBBONS: Okay. I think

13 we'll go ahead and vote.

14 DR. WINKLER: Dianne?

15 MEMBER JEWELL: Completely.

16 DR. WINKLER: Devorah?

17 MEMBER RICH: Completely.

18 CHAIR GIBBONS: The vote is 18

19 completely; 2 partially.

20 And then finally, feasibility?

21 MEMBER RASMUSSEN: Data generated

22 during care, yes. From electronic sources,

1 yes. No additional data sources required for
2 exclusions. Susceptibility to inaccuracies.
3 None are expected. And data collection can be
4 implemented, yes.

5 CHAIR GIBBONS: Comments or
6 questions?

7 (No response.)

8 MEMBER SZUMANSKI: I have one
9 question.

10 CHAIR GIBBONS: Yes?

11 MEMBER SZUMANSKI: Or just one
12 clarification. You indicate in exclusions
13 that there may be systemic reasons or
14 organizational reasons for excluding someone.
15 Can you tell me what those might be? Those
16 would not be routinely documented in the
17 chart. Is this we don't have enough beta-
18 blockers to go around, or why?

19 DR. BONOW: I think in general we
20 have to talk about patient reasons for
21 exclusion as well as system reasons. And
22 system reasons could be something like that or

1 unaffordability. But I mean, if it's
2 documented, I guess we can hypothesize or
3 speculate as to why there could be a system
4 reason. I'm not sure I can come up with a
5 great example for that, but there certainly
6 could be one related to resources.

7 MEMBER SZUMANSKI: I would just be
8 curious as to where you would look for that
9 information in the medical record.

10 DR. BONOW: I think you would look
11 for that the way you would look for other
12 exclusions, a reason why the patient is not
13 receiving a beta-blocker. Has to be indicated
14 somewhere in the record as to why that patient
15 is not receiving a beta-blocker. So, that
16 person would then be excluded because of valid
17 reasons.

18 MEMBER SZUMANSKI: Thank you.

19 CHAIR GIBBONS: Roger?

20 MEMBER SNOW: Yes, I have a
21 question for the developer that actually goes
22 back a little bit. It has to do with the

1 specific beta-blockers. You specify
2 particular beta-blockers and don't mention the
3 one that is probably the most used one, which
4 is atenolol. And my question is why? It
5 probably reflects my ignorance, but is it
6 because of demonstrated lack of efficacy or
7 because of lack of evidence?

8 DR. BONOW: Lack of evidence for
9 atenolol, but evidence from other beta-
10 blockers that they are not effective and
11 therefore the three drugs which have been
12 shown in clinical trials to be effective and
13 are in the guidelines are metoprolol
14 succinate, carbetalol and bisoprolol, whereas
15 bucindolol, salmeterol, propranolol and
16 metoprolol tartrate have been tested and have
17 not been found to be successful and therefore
18 this probably not a class effect.

19 MEMBER RASMUSSEN: So Roger, when
20 I was reviewing this measure, that numerator
21 is consistent with a previous measure that we
22 approved, 070, the best randomized control

1 trials, looking at mortality, were those three
2 drugs. You can find a meta-analysis that
3 suggests a class effect, but the clearest
4 strongest data is for those three drugs.

5 MEMBER SNOW: I thought that was
6 probably the reason, but I wanted to learn
7 something here. That's why I came here is to
8 learn, and for the coffee.

9 CHAIR GIBBONS: And I would point
10 out parenthetically that at least with respect
11 to disparities issues this did raise a sort of
12 initial confusion because the bucindolol trial
13 which was NHLBI-sponsored had a higher
14 percentage of African-American participants
15 than other trials. So there was a
16 misperception, at least at one point, with
17 regard to potential racial differences in
18 response to the class of drugs, which I think
19 has been largely dissolved given the
20 disparities data we've seen, but nevertheless,
21 did exist for one period of time.

22 All right. I think we need to

1 vote on feasibility.

2 DR. WINKLER: Dianne?

3 MEMBER JEWELL: Completely.

4 DR. WINKLER: Devorah?

5 MEMBER RICH: Completely.

6 DR. WINKLER: Thank you.

7 CHAIR GIBBONS: The vote is 19

8 completely; 1 partially.

9 And then our final vote whether it
10 meets criteria for endorsement.

11 DR. WINKLER: Dianne?

12 MEMBER JEWELL: Yes.

13 DR. WINKLER: Devorah?

14 MEMBER RICH: Yes.

15 DR. WINKLER: Thank you.

16 CHAIR GIBBONS: So, the vote is
17 unanimous; 17 in favor of endorsement and no
18 recorded votes against.

19 MEMBER THOMAS: May --

20 CHAIR GIBBONS: So, I want to
21 thank at this point -- oh, sorry?

22 MEMBER THOMAS: Oh, I just want to

1 make one comment, and part of it may be that
2 I'm not sure about something. In terms of
3 beta-blocker and the other measures that NQF
4 and others have endorsed, are some of the
5 measures specifying those specific beta-
6 blockers and other measures not?

7 And then in terms of that I feel
8 as if that's confusing for clinicians and that
9 we should move towards consistency, either
10 accepting that those three are what we need to
11 think about. But I know that we can't change
12 everything now, but that we should move
13 towards that because it really does affect
14 clinicians. Because once they think that they
15 don't need to have those specified, then they
16 will assume that for the other measures and
17 then not necessarily make that measure.

18 CHAIR GIBBONS: So I think we're
19 going to come back to that in the discussion
20 of harmonization and Jon already referred to
21 it with respect to one other measure with this
22 same spectrum. It is a recurrent theme and

1 one that we have to think about and devote
2 some time to in the subsequent discussion.

3 At this point I want to thank the
4 developers for their participation in
5 consideration of these measures. I also want
6 to point out that we may actually at least for
7 the moment be done voting, so I think we
8 should thank the staff at least for their
9 diligence in making everything work for the
10 votes. Barring yesterday's failure, we would
11 have had perfect performance. And things
12 certainly worked better this time than the
13 last time, and that was not an accident.
14 There are people who are actually plugging
15 away as we go through this process, and we
16 thank them for that.

17 At this point what we're going to
18 do is we're going to first talk about the
19 issue of retirement of measures; which we have
20 alluded to, and Reva's going to discuss that
21 for us. And that will probably take us up to
22 the break. We are a little bit behind

1 schedule, but not terribly. And Jon got us
2 back on schedule; thank you, Jon, or at least
3 closer to schedule, so I think we'll have time
4 to do due diligence for these other important
5 issues.

6 Reva?

7 DR. WINKLER: Thank you. Thanks
8 to everybody for doing the sort of first step
9 of the work that we've done over these last
10 two meetings. As always, there are follow-up
11 activities. Since this is the first approach
12 that NQF has taken towards looking at both
13 maintenance of measures and endorsement of
14 measures at the same time, we are encountering
15 any number of new questions or new challenges.
16 The first one that you all brought to us last
17 time was the issue of measures that have been
18 long in use and that have been topped out, if
19 you will. The current performance is very,
20 very high.

21 And so, you all kind of have this
22 concept of retirement of measures. Well,

1 given that we were a public meeting, I'm sure
2 you can imagine we did get a certain amount of
3 feedback on that discussion. However, it was
4 certainly something that's been discussed
5 conceptually previously in other settings
6 within NQF.

7 And so, we needed to think
8 internally about how we look at these measures
9 because there is -- it's felt to be that the
10 measures that are topped out but are otherwise
11 good measures are different than measures who
12 have issues and no longer meet the criteria.
13 So, we want to be able to make a distinction
14 between those measures that in maintenance we
15 remove the endorsement because there's a
16 problem with the measure as opposed to
17 measures that are good, valid, reliable and
18 still fine. It's just that because usually as
19 a result of their own success there are just
20 such high levels of performance there's very
21 little opportunity for future improvement and
22 so to be able to designate those differently.

1 So, what is currently happening is
2 we took this discussion in a proposal back to
3 CSAC last month and it is not a finalized
4 proposal. It is currently out for NQF member
5 and public comment. And this is a proposal
6 around designation of inactive endorsement.
7 Now, a lot of people have said I'm not sure I
8 like the name. Fine. The name may change.
9 But for right now this is where it's going.

10 So, what we're going to ask you to
11 do is sort of pilot this for us. We're going
12 to do the field test, if you will, to see if
13 using the criteria that we've embedded in the
14 policy speaks to the issues that you've raised
15 and feel are applicable.

16 Now, the two measures that you
17 indicated this for in the last meeting was the
18 160, which is beta-blocker prescribed at
19 discharge after AMI; and the other was 142,
20 aspirin prescribed at discharge for AMI. And
21 so, we'll use those two and then if we want we
22 can talk about perhaps the ejection fraction

1 measure that we talked about yesterday.

2 But in thinking about the concept
3 of topped out, when you looked at your data,
4 you had one data point. What you had was the
5 national mean. And so, when you look at
6 opportunity for improvement, perhaps not on a
7 national level looked at that way, but perhaps
8 there may be opportunities for improvement if
9 you look at the data more differently, if it
10 will.

11 So, what we were thinking about is
12 looking at the data more completely, one for
13 representativeness. I mean, is the data we're
14 looking at that shows very high performance
15 representing, you know, a large spectrum of
16 providers? I think that if we were looking
17 only at data from one state; say from the
18 State of Minnesota, it really wouldn't
19 necessarily reflect what was going on in the
20 rest of the country, even if their performance
21 was very, very high.

22 In this particular case we're

1 looking at national data, we're looking at a
2 large number of participant hospitals. So, I
3 would ask you the question: Do you feel that
4 that data is a representative to say that the
5 opportunity for improvement is limited?

6 The other questions that we asked
7 in terms of data was the range. We know the
8 median may be at 98, 99 percent, but what do
9 we know about the decile, the lowest decile,
10 the lowest quartile? What's the range? And
11 so, I was able to ask CMS's contractor and
12 they provided the data in terms of how it
13 breaks down in deciles for these two measures
14 after AMI. And in the memo that I gave you on
15 inactive endorsement, if you go down to the
16 attachment, the first attachment actually is
17 their spreadsheet where they talk about --
18 this is in your -- it's on your thumb drive.
19 It was sent to you. I don't know. It's the
20 memo on inactive measures.

21 And if you scroll past four pages
22 of actual words, you'll get to the first

1 spreadsheet. And what this is is the broken
2 down by -- or, well, different percentiles.
3 We see the 5th, the 10th, the 25th, 50th,
4 75th. So, for the measure for aspirin at
5 discharge, the 10th percentile is 90 percent.
6 The 25th percentile is 96 percent. And the
7 beta-blocker, it's similar.

8 MEMBER RUSSO: Can I just ask a
9 simple question that's even a step back from
10 this, and this is just maybe me and it's clear
11 to everyone else. So although there's a lot
12 of hospitals who obviously this represents,
13 there are hospitals that are not included in
14 this, correct? Because this is all -- right
15 now is not required? Correct me if I'm wrong.
16 Are we still thinking of making these
17 inactive? Once this is required for everyone,
18 are we still seeing right now the best people
19 who did this voluntarily and might we even
20 want to even take a step back and wait because
21 we're taking the more highly-motivated.
22 Granted, there are a lot of hospitals, but

1 still more highly motivated. And when we get
2 it out to everyone, we may see even more
3 variations.

4 DR. WINKLER: I think these are
5 exactly the questions we're asking you to help
6 us think through, because the criteria 1B,
7 opportunity for improvement, given that
8 limited data that you had, you know, yes, it
9 looked great, nothing more to do. But I think
10 we need to probably look at that criteria more
11 completely or with sort of a different lens
12 for this particular concept of topped out.
13 What do we mean? And the questions you're
14 asking I think are exactly the things we'd
15 like you to help us think through in terms of
16 that.

17 So, given the conversations we may
18 want to revisit those recommendations. And
19 today gives you an opportunity to do that as
20 we think about this maybe a little bit more
21 broadly in terms of what does it mean when we
22 say there's no opportunity for improvement?

1 Aside from this data on the
2 percentile so that you can look at the range,
3 the other question was the disparities data.
4 Is there data that demonstrates an issue among
5 certain disparities population that could
6 demonstrate an opportunity for improvement?
7 And I think that that kind of data, all of
8 these pieces I think are important to consider
9 when you are thinking about whether a measure
10 truly has very limited or minimal opportunity
11 for further improvement.

12 So, your thoughts would be helpful
13 as we're trying to put this kind of together
14 to help guide steering committees in making
15 these decisions.

16 MEMBER KOTTKE: Yes, I'm concerned
17 that -- say that an n of 1, terror of the
18 numerator, you know -- say I'm out in a small
19 hospital and I'm arguing, you know, you have
20 to -- beta-blockers, you have to measure
21 ejection fraction, you have to -- and it
22 doesn't show up on the active list. And they

1 say, well, you know, they misinterpret it.

2 And so, and I know that the beta-
3 blocker story came from NCQA retiring it, and
4 individual organizations I think can retire
5 it. Mayo can decide they're not going to
6 measure something because they know they do
7 very well, but a particular organization may
8 not. And I think if there are measures that
9 we know are strongly associated with outcomes,
10 that somehow we have to preserve that
11 information for the casual reader who may
12 misread the intent of the retirement.

13 MEMBER RUSSO: And in addition, in
14 terms of, you know, my passion for beta-
15 blockers, I think just looking at what you're
16 showing us here is a minimum of 28 percent.
17 I mean, and then even the 5th percentile --
18 again, granted that's a lower -- but 85
19 percent -- beta-blockers are standard therapy.
20 And these are -- to me that's not acceptable,
21 85 percent, without saying what you're -- you
22 know, exclusions you can include. So to me,

1 85 percent, even for 5 percent or the 5th
2 percentile would be unacceptable.

3 MEMBER SNOW: Which raises the
4 point that somewhere we need to provide
5 guidance to users as to when they can pull the
6 trigger on use of a measure that in some
7 places such as the Mayo or like that may have
8 been topped out and have little utility.

9 I mean, up until somewhat recently
10 most people that I've talked to haven't really
11 thought of that issue, that you -- you know,
12 it doesn't make much sense to worry about
13 mammograms because everybody gets one, or that
14 kind of thing. Everybody's getting Pap
15 smears. So, now we should put our energy
16 someplace else, but when and what's the line?
17 And being able to talk and think about that so
18 that when it gets out into the community
19 hospitals, the folks working on it have
20 guidance. That's what we really, really need.

21 MEMBER CHO: Reva, is there a data
22 on beta-blocker use throughout the last three

1 years? Has it stayed this way?

2 DR. WINKLER: I probably could
3 have asked for it, but didn't, so I don't have
4 it at hand. I'm going to guess they've got
5 it, but I don't have it to give you.

6 MEMBER CHO: The second question
7 is, is you guys have retired other measures in
8 the past?

9 DR. WINKLER: Not in this way.
10 This was kind of a first because it's part of
11 the maintenance activity and we've really done
12 maintenance in a very casual way in the past,
13 more if there were issues around a measure, as
14 opposed to really systematically, like you've
15 done, look at it against the criteria. Many
16 of these measures have been endorsed for many
17 years and have not undergone that kind of a
18 thorough review. You know, time moves on.
19 Sometimes, you know, measures just are no
20 longer particularly useful in the portfolio.
21 So, this truly is our first go at
22 this. So, not really. So, that's why this

1 whole concept about retirement, if you will;
2 although that won't be the term that's used,
3 but acknowledging that measures may be topped
4 out is the sort of term people talk about.
5 But the question is what do we mean by that?
6 What does it take to be that? And then do we
7 want to somehow designate them differently
8 than just saying, oh, keep it on the endorsed
9 list versus -- because it really doesn't meet
10 that criteria for opportunity for improvement
11 perhaps.

12 MEMBER CHO: Right. I guess all
13 of us are struggling that when we retire or
14 when these become legacy measures or whatever,
15 that we would fall off, the standard of care
16 will fall off.

17 DR. WINKLER: Well --

18 MEMBER CHO: But I think the other
19 way to look at it is, is for years the U.S.
20 has recommended vaccination. And at certain
21 point the vaccination has been steady; and
22 Mary could speak for this from the CDC point

1 of view, mainly because some people don't want
2 to get vaccinated or whatever, but the level
3 has been steady. The recommendation is there.
4 So, I wonder in the light of measure fatigue
5 the amount of measures coming down the true
6 impact that you want to make. I mean, it's
7 difficult I think.

8 DR. WINKLER: The tension is, you
9 know, measures that are good -- if it's a good
10 measure, what's the problem keeping it in the
11 portfolio? The issue is resources, and as you
12 say, measure fatigue or just how many can
13 anyone cope with, as well as maintain them, or
14 have the expectation that people will use
15 resources to collect data for the limited
16 information that's going to drive further
17 improvement. So these are the tensions that
18 are involved. But I think we have to look in
19 a world where we don't want an endless library
20 of measures that aren't looked at carefully
21 against, you know, the criteria, the
22 usefulness, the value added, you know, the

1 opportunities associated with them.

2 Karen, did you want to say
3 something? Karen helped develop this with
4 Helen and the rest of us.

5 DR. PACE: Yes, I just wanted to
6 mention the evidence task force also addressed
7 this a little bit last year. And one of the
8 things that keeps coming up is, well, what's
9 the threshold? What's the definition of being
10 topped out or no opportunity for improvement,
11 et cetera? And they really -- it kind of
12 revolves around some of the discussions you've
13 made, that there is no one threshold. It kind
14 of depends on the population at risk, the
15 consequences involved in the particular
16 quality topic in terms of impact on patients,
17 and that's what we need. So we can't just
18 say, you know, if it hits this number it's
19 gone. We need you as the people with
20 expertise to help weigh those factors.

21 But I think the other thing is in
22 terms of, you know the discussion about when

1 should providers stop using a measure, we're
2 talking about measures that have NQF
3 endorsement. So, these are often used in
4 public programs, in required reporting
5 programs. And so, individual providers may
6 not have that particular choice if it
7 continues to be an active NQF-endorsed
8 measure.

9 And just one other thing about the
10 percentile chart that you have. Just keep in
11 mind that that's the percentile on the
12 hospitals, so we don't know exactly how many
13 patients are represented in each of those
14 percentiles. So, that's another kind of slice
15 of the data that we don't have for you right
16 now.

17 MEMBER SNOW: One thing that might
18 get at a little bit of this; not completely,
19 but might make it more manageable, is if you
20 could for topped out good measures, in light
21 of the concern that if they sort of go away
22 that performance will fade; we don't know that

1 will happen, but everyone will worry about it
2 -- if you have a protocol for rotating some of
3 these measures. So, put them in the
4 background with the understanding that they
5 will come back after some period of time, you
6 know, on a schedule. That won't solve it, but
7 it might make it more malleable.

8 VICE CHAIR GEORGE: Reva, you
9 know, I think in terms of our voting, and
10 particularly on this issue, if this first
11 question were split so that we could actually
12 vote on performance gap, that might provide
13 some additional information as we go through
14 this process.

15 MEMBER KOPLAN: Have you actually
16 come up with a way to express the designation?
17 Would that be helpful to come up with
18 something like that?

19 DR. WINKLER: Well, that's what
20 the proposal around the term inactive
21 endorsement is. It remains endorsed, but
22 again it's sort of in an inactive way.

1 Because NQF doesn't implement the measures,
2 Roger, the idea is that it's still sitting on
3 our shelf and should. Programs that do a lot
4 of measurement want to rotate them every
5 couple of years to maintain surveillance and
6 all that. They're still using an endorsed
7 measure, though. It's not one we're
8 advocating being actively used on a regular
9 basis.

10 MEMBER KOPLAN: Right. And would
11 it be reasonable to use something along the
12 lines of like reflecting what some of the
13 comments were, like legacy due to high
14 compliance achieved, or something like that?
15 Because then it tells you why -- this
16 designation -- it sounds like is clearly only
17 because of high compliance achieved. It's not
18 because of anything else. So this just
19 implies that we think it's important, but
20 that's why.

21 DR. WINKLER: That's correct.

22 MEMBER RUSSO: And I think what

1 Leslie was alluding; or maybe I don't want to
2 put words, but when do you do that? Is it
3 after just one year of good performance? Do
4 you need five years? Maybe the duration of
5 great performance should be in that formula
6 somehow.

7 MEMBER KOTTKE: Can I make a
8 comment? Minnesota has had 12 cases of
9 measles in the last week after years of none
10 at all. At ICSI in Minnesota we had this
11 issue of guideline fatigue, where we kept on
12 -- we got the important guidelines and started
13 getting down. And I think what we recognized
14 is at some point you don't need guidelines on
15 trivial stuff. And I know NQF has thought
16 about this, but making sure that if there are
17 measures, they're measures about important
18 things. And I think that's why we rejected
19 the amiodarone ALT thing yesterday.

20 I would personally like to see
21 that all of the guidelines stay in the list of
22 endorsed, but perhaps you just asterisk it and

1 at the bottom say, you know, think -- you
2 know, there's very high performance with this
3 measure. You know, one should think carefully
4 before asking people to collect data on it or
5 something. But I'm worried that they don't
6 look at a second list and there are some very
7 important things on this second list that
8 people don't look at. They just look at
9 endorsed measures.

10 CHAIR GIBBONS: Yes, I agree. I'm
11 a little concerned about the separate list
12 concept and whatever you call them. I would
13 rather see them flagged as, you know, no
14 longer active. And I guess I want to put on
15 the table something that I think is inherent
16 in some of the comments, which is there's an
17 opportunity cost here regardless of the cost
18 of actually collecting the data. And I think
19 Tom referenced this in some of his comments
20 yesterday.

21 The reality is there's just so
22 much energy and so much focus that a given

1 practice, physician, hospital, system,
2 whatever can put on quality improvement. And
3 really it boils down to where is all that
4 energy best directed? And I really doubt that
5 it's best directed getting aspirin from 98.5
6 percent to 100 percent because most of that's
7 actually going to turn out to be a
8 documentation problem.

9 So, I think we want to be mindful
10 of that and somehow flag it. And I like Tom's
11 idea, which is I think individual systems
12 should decide to some degree what they're
13 going to retire, quote/unquote, but it should
14 still be on the same list with some sort of
15 flag saying we think overall performance is
16 well enough that the healthcare system ought
17 to move onto other things.

18 DR. WINKLER: We can take that as
19 sort of an implementation feedback on how we
20 would designate, portray, title or whatever.
21 We're still talking more the concept as
22 opposed to how exactly we're going to call it.

1 MEMBER RASMUSSEN: Reva, you made
2 a comment that worries me just a little bit,
3 and that is that NQF endorses a measure and
4 that's as far as their influence goes. So
5 that CMS could say this is an endorsed measure
6 and require organizations to report it, even
7 though that they may be in the 99th
8 percentile. So they have to spend some of
9 that energy reviewing that data. Even though
10 they're very good and we've said it's
11 endorsed, CMS can do whatever they want with
12 it.

13 DR. WINKLER: That actually is
14 pretty much always the case with the endorsed
15 measures.

16 MEMBER RASMUSSEN: Right.

17 DR. WINKLER: Okay?

18 MEMBER RASMUSSEN: Yes.

19 DR. WINKLER: I mean, it's
20 guidance, but it's something that's taken very
21 seriously, which is why this is a very
22 significant issue. There are considerable

1 concerns mentioned both here and elsewhere
2 that these are good measures. They measure
3 important things. And the only issue we've
4 got is the opportunity for improvement, the
5 high current levels of performance.

6 So, the question is what do we do
7 with this kind of a measure? If you take it
8 off the list, is it going to be interpreted
9 that this is a bad measure such as -- because
10 we're going to take off, you know, five others
11 off the list because they do have problems.

12 So, that seems to be an
13 uncomfortable place. I see you guys express
14 discomfort with doing that. But essentially
15 your votes heretofore have done exactly that.
16 What we're trying to do is open the door up to
17 considering another way of looking at these
18 measures as opposed to either a yes/no. It's
19 kind of like the third way, if you will.

20 MEMBER RASMUSSEN: How about an
21 NQF hall of fame?

22 CHAIR GIBBONS: Yes, right.

1 Carol?

2 MEMBER ALLRED: I was just going
3 to suggest how about just leaving it on the
4 list but with a designation of high
5 compliance?

6 DR. WINKLER: Again, I think that
7 that kind of feedback are the suggestions in
8 terms of how we might implement it. But the
9 issue at hand for this group right now is
10 currently you've taken those measures off the
11 list. So, the question I've got to come back
12 to now is do you want them back on the list
13 with some designation?

14 I mean, so far because these two
15 measures, very rightfully, reading the
16 criteria, you've voted them not to meet the
17 importance criteria, but that takes them off
18 the list. Clearly that poses a relatively new
19 problem that we're trying to work our way
20 through at NQF. You're the pilot study.
21 You're helping us figure this one out.

22 MEMBER SNOW: Yes, but there's

1 something that's a little unclear to me. Have
2 you created and identified another place for
3 us to put them?

4 DR. WINKLER: Well, this is the
5 proposed policy that we talked about,
6 inactive. That's the proposal that's
7 currently -- you know, that NQF currently has.
8 It's out for comment. It's been, you know,
9 gone through CSAC. It will go to the Board.
10 You're helping us by giving us the feedback
11 and we're also looking about how it might
12 actually be applied with some real measures.

13 MEMBER SNOW: So, could we vote
14 this morning to use that bucket?

15 DR. WINKLER: Yes, that's exactly
16 what is on the table right now is to --

17 MEMBER SNOW: So, I move it.

18 CHAIR GIBBONS: Okay. So, and it
19 gets back to Mary's point earlier. We never
20 voted 1B separately, but we would have I think
21 voted. You know, had we had that separated
22 out, it would have been clear what the issue

1 was. Rochelle?

2 MEMBER AYALA: Well, I just wonder
3 if we had a designation like that should we be
4 more specific than saying high performance?
5 Should we have like a quantitative cutoff
6 point beyond which we said it's --

7 MEMBER KOPLAN: The problem with
8 that is that you're going to have to
9 individualize, you know, in terms of -- some
10 things are more important at certain levels
11 than others, I would think. So I think one of
12 the problems sometimes, as happened this week
13 and the last time, or these last two days, is
14 that sometimes people say, oh, we're
15 inconsistent. We did this on this measure and
16 that on this measure, but I do think you kind
17 of have to individualize sometimes.

18 MEMBER AYALA: Well, my concern
19 with that is that if we don't put it very,
20 very high, like 98 percent, for example, then
21 the next question we have to say is at a
22 certain level we have to look at disparities

1 because if you get it really, really high, by
2 definition you're eradicating disparities.
3 But if you start having a gap between where
4 you think it's acceptable and 100 percent,
5 then you're opening yourself up to
6 disparities, like a gap.

7 VICE CHAIR GEORGE: No, but I
8 think it also depends not just on what that
9 mean or median is, but what your range is.
10 So, two measures could be 98 percent for the
11 median, but have still a different lower end.

12 MEMBER AYALA: Oh, I didn't
13 realize that we were talking about median here
14 for the --

15 CHAIR GIBBONS: Well, you know, to
16 get back to the question Leslie asked, for
17 example, you know, the medians for these
18 measures have been persistently high for
19 years. We're looking at at least three years
20 and maybe five years the medians have been
21 particularly high, or have been consistently
22 high, because that's what's shown in most of

1 the data sets. But I don't know that I've
2 ever seen the 10th percentile applied over
3 time to see what's happened to that during the
4 same time frame.

5 MEMBER RASMUSSEN: As a point of
6 clarification, I'll --

7 MEMBER JEWELL: This is Dianne.
8 It's a little hard to know how to participate
9 in the conversation since I can't see the
10 slides, but I would offer this: It seems to
11 me that part of what we do when we consider a
12 measure the first time -- well, consider a
13 measure is we ask about importance.

14 And so, if we have an inactive
15 class of measures and there's some regular
16 schedule that's enacted for revisiting them,
17 rather than waiting for a trigger, like an
18 arbitrary sort of drop below a certain
19 performance level -- but maybe there could be
20 criteria for reactivating that could be
21 developed and those criteria could fall along
22 the lines of, you know, this issue of how much

1 of a drop in performance are we seeing, but
2 also what impact that translates into along
3 the lines of some of the calculations that
4 have been offered up in our discussions. So,
5 I guess I would just offer that.

6 MEMBER RASMUSSEN: So, a question:
7 For example, if CMS is using this measure, how
8 do they grade an organization? Is it based on
9 median? Is it based on percentile? The
10 reason I ask; with this beta-blocker measure,
11 if we get credit, if we're in the 90th
12 percentile and I miss one patient, I'm in the
13 50th percentile. That's not existential
14 angst, that's just plain angst. You know, if
15 you're chasing one person. So, it's a
16 clarification question more than anything.

17 DR. WINKLER: And honestly, I
18 don't want to speak for CMS because they
19 actually make the rules of their
20 implementation and their payment programs, and
21 I just don't know the details.

22 MEMBER RASMUSSEN: So, it may vary

1 by accrediting organization.

2 DR. WINKLER: The implementation
3 programs are -- you know, use these measures,
4 but the rules on how they do it and whatever
5 incentives that may go along with it are
6 really specific to that program.

7 CHAIR GIBBONS: And obviously
8 that's a numbers issue. And I'll just reflect
9 that in the discussion of imaging efficiency
10 measures that loomed very large because at
11 least one of the developers was going to put
12 in something that would be a major problem at
13 the low end of numbers with respect to whether
14 the performance changes were due to chance
15 alone, and it was a major struggle in the
16 process.

17 Yes, Karen?

18 DR. PACE: Just one other comment
19 on the disparities issue; and it kind of
20 relates to why we've asked that question under
21 importance, is that if there is data that
22 there are disparities issues, we would kind of

1 consider it doesn't matter what the median and
2 mean and percentile rankings are, that that
3 would be justification that there are
4 opportunities for improvement and in
5 eradicating disparities. So --

6 CHAIR GIBBONS: Yes, and I think
7 as we -- we should though reflect that that's
8 in itself a complex issue.

9 DR. PACE: Right.

10 CHAIR GIBBONS: Because what is
11 the socioeconomic group that you're looking
12 at? Is it left-handed Finnish-Americans that
13 have a disparity? And because it came up in
14 part of our discussion yesterday, you can get
15 into an awfully small sector of the population
16 and is it worth the opportunity cost in the
17 other 99.85 percent of the population?

18 So, okay. I think we've had a
19 good discussion on this. Reva, anything else
20 we can provide?

21 DR. WINKLER: Yes, in fact I need
22 some action from you because --

1 CHAIR GIBBONS: Action? Well,
2 Roger has moved that we're going to put these
3 two measures in the inactive category.

4 DR. WINKLER: Okay. Hold on. I
5 need a couple other things. Because you
6 stopped your evaluation at importance and it
7 failed on your first vote, we didn't do the
8 evaluation of the other criteria. And in
9 order to keep them on the endorsed list,
10 they've got to meet all the criteria. So,
11 yes, it's a process issue, but it's one we
12 want to keep nice and crisp and clear.

13 CHAIR GIBBONS: Okay. So, let me
14 try and take a stab at a suggestion. We
15 figure out who the original reviewers were and
16 ask them to re-consult that particular
17 application with the notion that their scoring
18 will be distributed to the committee for
19 either an email ballot or a telephone ballot
20 subsequently regarding the criteria so that we
21 move the process along here today. And we
22 probably I think should do the same thing for

1 EF.

2 DR. WINKLER: Okay. That's what I
3 was going to ask, do you want to include the
4 EF in that?

5 CHAIR GIBBONS: Yes.

6 DR. WINKLER: That's fine. We can
7 do that. We did --

8 CHAIR GIBBONS: I think EF boiled
9 down to performance gap versus unintended
10 consequences in the discussion.

11 DR. WINKLER: Given the
12 discussion, I think that what we've learned is
13 we're going to have to ask the questions of
14 the committee somewhat differently,
15 particularly in this topic area. So certainly
16 we can approach it differently. And I think
17 we'll parse that out in the questions we ask
18 you as we do this final evaluation on these
19 three measures.

20 Are there any others that seem to
21 fall into that category?

22 CHAIR GIBBONS: Roger?

1 MEMBER SNOW: List the three
2 measures for me again so that --

3 DR. WINKLER: It was aspirin after
4 discharge for AMI --

5 MEMBER SNOW: One-forty-two, one-
6 sixty and what's the other one?

7 DR. WINKLER: Oh, let me look at
8 -- it was yesterday's. One-thirty-five.

9 MEMBER SNOW: Thank you.

10 CHAIR GIBBONS: So, Kathleen,
11 you're not done yet with 135.

12 DR. WINKLER: But I would
13 recommend that we have outlined the proposal
14 in this memo. You have received it. Before
15 you do register your final votes, we'll send
16 around the survey to do that. Just please
17 look this over because it does have the
18 details in it.

19 MEMBER SZUMANSKI: Reva, I just
20 have one comment --

21 CHAIR GIBBONS: Yes?

22 MEMBER SZUMANSKI: -- on this, if

1 I can.

2 DR. WINKLER: Yes.

3 MEMBER SZUMANSKI: I would ask
4 from the application standpoint and the
5 hospital end it would be extremely helpful if
6 NQF could create some recommendations or
7 guidelines for a quality department to say,
8 you know, you're falling for the last rolling
9 12 months or quarters. You're in the 100th
10 percentile. Please consider, as Tom
11 indicated, selecting other measures that might
12 be on your dashboard. I don't know that
13 people know how to do this out there and it
14 just might be helpful if you can give them
15 some overall general guidance on how to retire
16 a measure or how to bring a new measure into
17 their dashboard.

18 And secondly, these measures that
19 reach that top level of performance are used
20 routinely by hospitals for public relations
21 reasons. And I think it would be very much of
22 a challenge for them to say, well, we're going

1 to now not give you as much information as you
2 had. They need this to maintain their day-to-
3 day operations from a public satisfaction
4 perspective unfortunately.

5 MEMBER SNOW: I hear that, but the
6 concept that I will point to is not giving
7 them less information, but giving them
8 different information. If the total effort
9 remains the same, then they'll just be talking
10 about different things are being improved.
11 And I would avoid the term "retire." I would
12 use the term "rotate," if we think of it as
13 something that can come back when needed. If
14 it's a good measure; that is, the structure of
15 the thing is good, it measures something
16 that's real, then it won't get bad. It's not
17 like cheese.

18 MEMBER SANZ: The other thing is
19 you shouldn't be -- you're right that a lot of
20 this is used for public marketing, but
21 marketing and measure where everybody has 99
22 percent I would argue is not a useful use of

1 this tool and all the effort required to
2 capture it. You ought to be marketing your
3 congestive heart failure composite score if
4 you're that good.

5 MEMBER SZUMANSKI: And I don't
6 disagree with that, but I'm not sure they know
7 how to do that. And by giving them some
8 structured guidelines on measurement -- and
9 that might be helpful, because they always
10 fall into, well, we're looking really good.
11 Here's our number. So, and I don't disagree
12 with what you just said.

13 CHAIR GIBBONS: Christine?

14 MEMBER STEARNS: But and that I
15 think though that we should also think about
16 trying to find something other than inactive
17 perhaps to call high performers that have been
18 rotated out or something so that -- to express
19 because that will better communicate.

20 DR. WINKLER: As I mentioned, this
21 is out for public comment. I'm sure we're
22 going to get all sorts of suggestions. We'll

1 add yours to the list.

2 CHAIR GIBBONS: Okay. We're going
3 to take a 20-minute break right now and then
4 come back for a discussion of disparities.

5 (Whereupon, the above-entitled
6 matter went off the record at 10:50 a.m. and
7 resumed at 11:11 a.m.)

8 CHAIR GIBBONS: So, we're going to
9 take a little time discussing and reviewing
10 the data which we requested on disparities.
11 And NQF went back to developers, and in
12 particular CMS. And there are two separate
13 documents and the one that I propose that we
14 discuss is just entitled, "Disparities, CMS."
15 It's an Excel spreadsheet and it's now up on
16 the screen. Disparities analysis for 26
17 performance measures.

18 The other one is the emergency
19 department measures, which, you know, we did
20 also discuss the last time, but are far
21 smaller numbers because they largely reflect
22 smaller hospitals that are then transferring

1 the patient on. And we went through a
2 discussion of those. It's not to say they're
3 not important, but simply in terms of the
4 overall numbers and impact I think we'd be
5 best to focus on this analysis.

6 And I mentioned that this issue
7 surfaced because several of you mentioned it
8 to me at the break the last time, that it was
9 obvious that the disparities blank in part 2
10 of the form was not being taken seriously and
11 expressing concern over that. So, that's why
12 we then had a discussion about the issue and
13 asked the staff to revisit it with the
14 developers.

15 So, I think I'd ask everybody --
16 make sure everybody gets the right spreadsheet
17 open. And one of the people who did discuss
18 it with me at the break last time was George.
19 So, I've asked George to just take a look at
20 what's here and make a few comments and
21 inspire some comments from everybody else to
22 this important issue. And then we'll discuss

1 what other guidance we might give NQF going
2 forward. George?

3 MEMBER RICH: Yes, this is
4 Devorah. Can I just ask a question? On the
5 thumb drive I don't see the spreadsheet. I'm
6 not sure where I'm supposed to be finding it.
7 I just don't see it.

8 DR. WINKLER: It's a PDF file on
9 your thumb drive.

10 MEMBER RICH: Under -- okay.
11 That's helpful. But -- and it's under --

12 DR. WINKLER: Do you have a
13 disparities slide?

14 MEMBER RICH: Under the competing
15 measures form?

16 DR. WINKLER: There should be a
17 disparities folder.

18 MEMBER RICH: Oh, fine. Okay.
19 Thanks. Thank you so much.

20 CHAIR GIBBONS: Okay. So, has
21 everybody found it?

22 (No audible response.)

1 CHAIR GIBBONS: I see a bunch of
2 nods yes. I don't see any nos.

3 So, George, you want to make a few
4 comments?

5 MEMBER PHILIPPIDES: Yes, just a
6 few comments. So, this is in fact some of the
7 data that we had requested. It's CMS data
8 from a 2009 clinical data warehouse, and
9 depending on the parameter, they have up to
10 have 400,000-plus patients they've looked at.
11 And they break them down by race, ethnicity in
12 the first few pages, and later on there's also
13 some data on gender. And I think broad
14 strokes, there still are small differences,
15 but they're small in many, many cases. Okay?
16 So, not as problematic as, you know, we
17 initially had been thinking.

18 There are a few things that you
19 might want to sort of focus on. One is, if
20 you look at PCI and time to reperfusion, there
21 is still a small but significant difference
22 between Caucasians versus Hispanics or versus

1 Native Americans in some of those parameters
2 that I think sort of jump out. Similarly, on
3 page 4 there are some differences as far as
4 flu vaccination at discharge. And I'll give
5 you guys a moment.

6 DR. WINKLER: CMS has included
7 measures on pretty much everything they put up
8 on Hospital Compare, so they gave us data
9 beyond the cardiovascular measures that you
10 guys discussed. They were bountiful in their
11 response.

12 MEMBER PHILIPPIDES: And then
13 again, you should probably peruse this in your
14 own time period, but on page 7 there are also
15 some small but again significant differences
16 in regards to reperfusion therapy, both PCI
17 and fibrinolysis between males and females.

18 So, overall I think this is
19 helpful. This is the kind of data that in the
20 future we'd like to have sort of up front
21 imbedded in our paperwork so we can comment on
22 these at the appropriate time. It really is

1 very, very helpful in helping us guide the
2 developers as to what we want.

3 And we also should discuss, as Ray
4 brought up, when in our future discussions,
5 you know, time 1 or item 3 or 4, do we want to
6 sort of bring this up. And that sort of gets
7 at the issue of what do we think the valence
8 is for this kind of data. Should it be
9 something that's discussed up front as part of
10 the initial impact and scientific importance?

11 CHAIR GIBBONS: Sure, Tom?

12 MEMBER KOTTKE: You know, we were
13 having this discussion with Bob Bonow at the
14 break about, you know, what part of town you
15 live in in Chicago depends on whether you get
16 PCI and not looking at -- I mean, the
17 disparities may be hidden in the ZIP code of
18 residents rather than in race or ethnicity.

19 CHAIR GIBBONS: Yes, for sure.
20 David?

21 MEMBER MAGID: Yes, so I think
22 that it's important to do that -- the sort of

1 hierarchical modeling that helps you separate
2 out what's going on. So, you mentioned the
3 reperfusion work, George, and I've alluded a
4 couple times to the -- I think a seminal paper
5 by Betsy Bradley that was in JAMA that looked
6 at -- it basically -- first it showed that
7 African-Americans were -- had significantly
8 longer door-to-balloon times than non-African-
9 Americans. But then it said, okay, well, how
10 can we sort of apportion this disparity in a
11 way? What is it about -- is it that providers
12 take care of these patients differently, or is
13 it that the hospitals where these patients
14 receive care are of lower quality?

15 And what she found was is that the
16 majority, probably about two-thirds of the
17 longer door-to-balloon time could be
18 apportioned to the fact that African-Americans
19 receive care in hospitals that overall had
20 worse door-to-balloon times. So, I think if
21 we're going to, you know, look at these
22 measures, we need that type of hierarchical

1 analysis that helps us understand what's
2 better than just sort of saying it's worse in
3 African-Americans than whites.

4 CHAIR GIBBONS: So, I certainly
5 wholeheartedly agree. And now the question is
6 now that that analysis has been done and
7 published, is anybody doing anything about it?

8 MEMBER MAGID: Yes, that's a good
9 question. That's a good question. Yes, how
10 are they acting on it?

11 CHAIR GIBBONS: Is the world --
12 you got to use your microphone, Tom.

13 MEMBER MAGID: I don't think he
14 wants that recorded.

15 CHAIR GIBBONS: So, I mean, you
16 know, I think there's a message there. If
17 we're going to collect these data and look at
18 them and then, as in that case, extensively
19 analyze them. All right? And what?

20 MEMBER MAGID: Well, I mean, I
21 think the thing about the disparities
22 literature is largely study after study after

1 study that shows that, you know, certain
2 groups of patients; be they, you know, women
3 compared to men, or African-Americans compared
4 to non-African-Americans, have worse outcomes.
5 But we really have very little understanding
6 as to why that occurs. And so, this was sort
7 of one of the first studies that began to help
8 us understand that. I mean, to the extent
9 that, you know, CMS and other agencies report
10 out, you know, their results by hospital and
11 hospitals see how they do compared to others,
12 that's one way that you can affect change.
13 I'm not sure exactly beyond that, you know,
14 what we're suggesting. Did you have some
15 specific ideas?

16 CHAIR GIBBONS: Well, I mean, for
17 example, I happen to know that there's a
18 leadership group meeting today as we're
19 meeting for a mission lifeline for the
20 American Heart Association. It would seem to
21 me that hopefully within the context of that
22 QI project that someone's looking at this

1 specific issue and saying, okay, what can we
2 do? And likewise, I would hope within the ACC
3 efforts at QI that somebody's thinking about
4 it, because I don't think there's any issue
5 about which physicians feel more consistently
6 together about than the fact that people ought
7 to receive the same care regardless of their
8 ethnicity, or gender, or anything else. I
9 mean, I think there's a uniform commitment to
10 that concept and we ought to try to figure out
11 from a system standpoint what we can do.

12 Mary?

13 VICE CHAIR GEORGE: Yes, just a
14 couple of things. Actually, HHS today
15 released two new initiatives, "HHS Action Plan
16 to Reduce Health Disparities." Second one is
17 the "National Stakeholder Strategy for
18 Achieving Health Equity." And I think, you
19 know, it clearly emphasizes how important this
20 is on a national level.

21 In terms of what level of data we
22 have here as we go through our meetings may be

1 different than all that is needed to do the
2 fine research, but we can certainly keep a
3 certain level of maybe high-level disparity
4 data in what we do and it should be there to
5 stimulate others to look further.

6 MEMBER MAGID: I mean, the folks
7 from Yale gave us that information on both the
8 mortality and readmission rate, so maybe
9 asking for that kind of data across all the
10 measures would be good.

11 MEMBER RICH: Hi, this is Devorah.
12 I see that there's also opportunities here to
13 collaborate with Robert Wood Johnson. I know
14 they just put out a parcel of proposals mostly
15 looking at the county health statistics and
16 how to do some work there. But they're very
17 interested in this and this could be the area
18 that they'd want to do some piloting profiling
19 around.

20 MEMBER SMITH: Ray?

21 CHAIR GIBBONS: Yes?

22 MEMBER SMITH: To answer your

1 question, we published a paper just a few
2 months ago in circulation that Mauricio Cohen
3 is the first author on; Bob Bonow and I are
4 co-authors, looking at close to 450 hospitals,
5 150,000 patients in AHA "Get With the
6 Guidelines" for acute myocardial infarction
7 showing that the racial differences exist,
8 that when patients were entered into these
9 quality improvement programs, that those
10 differences improved. So there are people
11 doing something about it. Specifically, the
12 American Heart Association in "Get With the
13 Guidelines" and the use of quality improvement
14 programs has been shown at least in 150,000
15 patients, 450 hospitals to narrow these
16 differences.

17 MEMBER AYALA: One other --

18 CHAIR GIBBONS: Yes, other
19 comments? Rochelle?

20 MEMBER AYALA: Yes, that just
21 echos what I mentioned in the first phase, and
22 that is that when you put quality and

1 eliminating disparities together, it's very
2 powerful because you first have to collect the
3 data and look at it and analyze it before you
4 can actually do anything about it. And then
5 you create your own quality improvement
6 program to eliminate any existing disparities.
7 But if you don't know you have them there,
8 then you're not going to do it. And a lot of
9 times institutions are not going to collect
10 this data unless it's a part of a mandated,
11 you know, indicator, quality measure. And
12 you're looking at it at multiple levels.

13 So you're right, there may be
14 hospitals where all the care is bad and they
15 happen to have a lot of minorities there. And
16 you might not have any disparities within that
17 hospital's data, but that hospital's
18 contributing to a higher level of data. So,
19 if you're combining the quality part, that
20 hospital's goal is going to be just get our
21 quality up because we have to report that.
22 And it may in the future actually be tied to

1 reimbursement.

2 So, if you link them together this
3 way, you're getting a lot of data, you're
4 having a lot of incentives for improving
5 quality which will ultimately narrow the gap
6 and eliminate disparities or decrease
7 disparities.

8 MEMBER RUSSO: And similar to that
9 the data was also for improvement. Linking
10 the two with improved heart failure showed the
11 same thing.

12 The other thing, and related to
13 the last discussion right before the break,
14 you know, I'm wondering if somehow the formula
15 to put some of the measures aside might also
16 incorporate some of the disparity issues such
17 as, for example, the beta-blocker one. So, if
18 you look in here, although most of them I --
19 George summarized, most of them do not look
20 that different. But on the beta-blocker acute
21 MI measure there is, you know, 96 versus 98
22 percent. I mean, we're talking about, you

1 know, Hispanic patients, you know, whether
2 it's hospital-related or whether it's related
3 -- you know, whatever the reason for it is,
4 there clearly is this disparity in care, you
5 know, identified with beta-blocker use, some
6 with gender, too. But, so, should that be in
7 the formula maybe before -- or should -- as
8 long as beta-blockers are in a composite
9 measure, maybe that's enough. But those two
10 things in the formula for retirement.

11 DR. WINKLER: Actually, it's in
12 there.

13 CHAIR GIBBONS: So, other -- I
14 guess I'm going to put the interventionalist
15 on the spot. Mark, any discussion in the
16 interventional community about this issue of
17 door-to-balloon time differences?

18 MEMBER SANZ: First of all, I
19 don't know any specifics on disparities. But
20 as someone has already pointed out, we are
21 rapidly reaching the limits of what we can do
22 from the standpoint of infrastructure. People

1 are pretty much down to less than 90. Some
2 are down to less than 60. If you're inner
3 city, you're -- or if you're in a city, you
4 know, you're pretty much there and it's
5 dependent on, as I think Bob Bonow said,
6 something like where your ambulance is going
7 to take you, and that's more of the disparity
8 issue than anything that providers have
9 control over. If you're in a rural
10 environment, there are simply limits to what
11 you can do. I don't think that there's a lot
12 of room within the medical community to effect
13 change. It's now an infrastructure issue.

14 CHAIR GIBBONS: Right, it's a
15 systems of care issue probably.

16 Well, I think we can at least make
17 sure that the necessary -- I guess one
18 question in my mind is we're seeing these data
19 and obviously CMS went through a process
20 before they agreed to release them to us. Are
21 they posted publicly anywhere?

22 DR. WINKLER: We actually have

1 them posted on the Web site for this project
2 with the meeting materials. So, but I'm not
3 sure that they actually post them anywhere on
4 CMS' world.

5 CHAIR GIBBONS: I mean, I --

6 DR. PACE: What was Lein talking
7 -- were these data in the chart book she was
8 referring to, or was that just specific --

9 DR. WINKLER: Lein was talking I
10 think about more of the analysis they did.
11 So, I don't know to what degree there may be
12 some of this data replicated. It's possible.

13 CHAIR GIBBONS: So, it would seem
14 to me to be helpful, period, if these were
15 more widely disseminated and more widely
16 available for people interested in quality
17 improvement to see. So, if the committee
18 agrees with that, I think we could give CMS
19 some feedback to encourage them to release
20 them more than just on our committee Web site,
21 which to be honest people aren't going to find
22 or look at, because I do think there would be

1 broader interest. We can direct people to our
2 Web site from efforts like Mission Lifeline
3 and ACC, similar efforts, to try to make them
4 aware of this as far as the systems issues.

5 Moving forward, I think we had a
6 sense the last time that we wanted to make
7 certain that disparities data was required for
8 the submissions, and I think clearly conveyed
9 that message to the staff and the staff will
10 convey that to the developers.

11 But we did have this confusion
12 repeatedly, I think, about where the data
13 appears in the form, because there's a section
14 in section 1 and then there's another section
15 in section 2. Can I get a sense of people as
16 they reviewed this where do they think it
17 should be so we can give the staff some
18 guidance moving forward as to where this
19 should be on the form? George alluded to it;
20 should it be, you know, fundamentally
21 considered as part of the importance rather
22 than the scientific acceptability?

1 Others want to comment? Roger?

2 MEMBER SNOW: Yes, I just want to
3 vote for importance. And we talk about
4 rotating or retiring measures. I don't think
5 we should consider a measure for rotation if
6 there's a significant problem of disparities.
7 It's just too important an issue broadly and
8 in terms of care. So I think it belongs at
9 least in one.

10 MEMBER AYALA: I agree with that.
11 I think it should be close to the performance
12 gap. And I like what Reva had put together in
13 that document we looked at just now, where you
14 had those different levels of the total number
15 of patients, the range; because that came to
16 me when we were talking just now. We don't
17 want to look at just the median; we want to
18 see the range of the data and the disparities
19 in terms of opportunities for improvement.

20 CHAIR GIBBONS: Other thoughts
21 about this issue? Mary?

22 VICE CHAIR GEORGE: Yes, I guess

1 this really pertains to maintenance measures,
2 but in looking at the disparity data with a
3 maintenance measure, it would be helpful to
4 know what the previous -- when it was
5 previously up for review what the disparities
6 data showed in the past compared to where it
7 is with the current submission.

8 CHAIR GIBBONS: In other words, to
9 specifically ask the measure developer to
10 indicate whether they're tracking disparities
11 so that the updated submission; be it three
12 years or five years or in yesterday's case
13 twenty years later, we'll be able to provide
14 data in terms of this important issue. Does
15 that sound reasonable to everybody?

16 MEMBER AYALA: Just thinking about
17 the types of information that the developers
18 gave us under the disparities. A lot of times
19 it was just a simple statement or a little
20 paragraph that really didn't give us data, but
21 rather said that they didn't have any evidence
22 of it. Is it too hard or too much to ask of

1 the developers to actually in their pilots
2 when they're giving us their information back
3 how they developed the measure and what their
4 reliability, validity and all that was, to
5 actually ask them to include disparities,
6 include race, ethnicity, language, whatever we
7 decide on and that they report those back to
8 us as well?

9 DR. WINKLER: We can certainly
10 communicate that as an important aspect of
11 information in part of the testing, you know,
12 to what degree it's feasible and doable for
13 the different types of measures on different
14 data platforms. But we can certainly add that
15 to guidance. And we certainly get questions
16 all the time about, well, what kind of
17 testing? What all do we need to do to, you
18 know, provide a good solid testing basis. And
19 so, we can add that and be sure that that's
20 emphasized as well.

21 Karen?

22 DR. PACE: And I would just add --

1 and your comments are great and we need to do
2 some more clarification, but that actually is
3 the intent of having disparities information
4 in both places. The one is kind of is there
5 a problem whether you know it from your
6 measure or from research or whatever? And in
7 section 2 it was about testing that -- you
8 know, part of the testing, but that definitely
9 needs more work. And appreciate your
10 comments.

11 CHAIR GIBBONS: Any other thoughts
12 of those who have looked at these data that we
13 as a committee want to convey back to either
14 CMS or NQF?

15 DR. WINKLER: Or other developers.

16 CHAIR GIBBONS: Or others. By the
17 way, you realize now, since this is posted on
18 the committee proceedings, if you are
19 discussing this issue with any other group,
20 you can at least point them to that location
21 for these data. They're in the public domain,
22 so there's nothing confidential here.

1 MEMBER PHILIPPIDES: I have one
2 other small tweak.

3 CHAIR GIBBONS: Yes, George?

4 MEMBER PHILIPPIDES: Just looking
5 at this now that they have age, region, urban
6 versus rural. There's no mention; it's
7 probably a difficult parameter, of
8 socioeconomic status, which is probably moving
9 forward going to be an important thing to look
10 at. So, we might ask whenever there is such
11 data to include that and have the details in
12 true detail so we can look at it.

13 DR. WINKLER: Yes, George, just to
14 tell you that disparities is a conversation
15 that happens at NQF on a regular basis. In
16 fact, we have an upcoming project that's going
17 to address disparities. One of the real
18 challenges that's constantly discussed is how
19 do you describe these elements? What do you
20 mean by socioeconomic status? What data do
21 you use to classify, you know, patients into
22 whatever strata it is you think is important?

1 And there's huge discussions around the proper
2 classification for some of these issues. So,
3 and it's certainly not in any way
4 standardized. So, those are huge issues, but
5 they're being discussed and certainly we can
6 push for more.

7 MEMBER PHILIPPIDES: Well,
8 certainly to have something like Medicaid
9 versus not, or ZIP code, that kind of thing,
10 it might be helpful.

11 CHAIR GIBBONS: Yes, I think as we
12 pointed out; Tom and others pointed out, you
13 know, you can get a fair bit of data from ZIP
14 code. And the Yale folks mentioned that
15 yesterday you can model socioeconomic status.
16 But that data is fairly static because it's
17 only updated by the census process and I don't
18 know actually whether it's updated in between
19 the 10 years.

20 Tom, you may know.

21 MEMBER KOTTKE: There is an
22 ongoing survey; what is it, American Community

1 Survey, yes, which is ongoing and there's a
2 little better -- but I mean, people are
3 mobile, but they're not all that mobile.

4 CHAIR GIBBONS: So, I pointed out
5 in an off-line discussion yesterday that if
6 you look at a particular ZIP code that might
7 actually change quite a bit over a 10-year
8 period of time. There's a problem in terms of
9 updating that and that's why it's only a
10 surrogate because it's a moving target in some
11 areas of the country, more so than others.

12 But I think, George, that's a good
13 suggestion as well.

14 Are there any other thoughts?
15 Rochelle?

16 MEMBER AYALA: Just a follow up to
17 that. When we first came in, I was thinking
18 about disparities more along the lines of
19 race, ethnicity, gender. But then as we
20 talked around the room, these other issues
21 came up, these other areas that are worthy of
22 analysis, including rural versus urban and

1 then socioeconomics. And so, when we ask the
2 developers to give us disparities data, are we
3 going to specify what type of data we would
4 like to get back, like which categories and
5 maybe prioritize them, or, you know, to help
6 people in the future instead of having a
7 fragmented set of data to look at it?

8 DR. WINKLER: Well, you know, what
9 we're trying to do is standardize the requests
10 for everyone so it won't be so much topic or
11 measure-dependent. And we have to look at the
12 -- you know, what's reasonable. That's a lot
13 of the work that Karen does. And so, we'll
14 take all of your feedback in terms of what's
15 desirable. Again, a lot of the push back we
16 get from developers is they don't have data
17 like that and things like that. And there are
18 limitations. But again, constantly asking,
19 constantly pushing, constantly requesting can
20 you know, make progress.

21 CHAIR GIBBONS: Okay. I think
22 this has been worthwhile. I think it was

1 certainly worthwhile to request the data.
2 Hopefully the process will be improved moving
3 forward with respect to this important issue.
4 But I for one was heartened by the data. It
5 was not nearly as bad as I thought it might be
6 except for the PCI issue that we pointed out,
7 which by the way has a long, long history
8 going back into, oh my goodness, the 1980s
9 when Herman Taylor was at the University of
10 Alabama at Birmingham and actually first
11 studying this issue in the Great State of
12 Alabama. So, there have been people pursuing
13 this particular goal for a long, long time in
14 the scientific community.

15 So, let's move on then. There are
16 a few follow ups from our last meeting that we
17 need to deal with before we broach the whole
18 issue of competing measures.

19 So, the first one I think is
20 fairly straightforward. It is that, if you
21 recall, we considered a composite measure for
22 chronic coronary or vascular disease from the

1 Minnesota Community Measurement Project where
2 we all liked the notion of this composite. It
3 was the measure that's been in use in the
4 State of Minnesota. So to remind everybody:
5 Smoking cessation, aspirin, blood pressure
6 control, lipid control. All four. It's an
7 all-or-none measure. But we did not like
8 their threshold for blood pressure control,
9 which had a whole unique history and was not
10 aligned with the national blood pressure --
11 existing blood pressure guidelines.

12 So, we had two separate series of
13 votes. One was that literally rejected the
14 measure as it was, but the second was that we
15 would entertain -- or we did vote approval of
16 the measure if they changed the blood pressure
17 criteria.

18 DR. WINKLER: You know, I'd like
19 to just point -- direct the committee to --
20 this is the memo that's called "Follow Up From
21 Phase I." And we asked the measure developers
22 a large number of questions based on your

1 discussion for follow up. And it's a fairly
2 meaty document, so you can certainly look at
3 it at your leisure. But in those follow up,
4 we can go and look at the one from Minnesota.
5 And basically they agreed to make the change.
6 They went to their committee on March 9 and
7 they approved the change. So, they have
8 adopted the 140/90 threshold and agreed to
9 align with JNC 8 when it becomes available.
10 And if we need to review all the blood
11 pressure measures, that's -- you know,
12 everybody's sort of aware of the desire to
13 align around a single national guideline as
14 opposed to kind of having guideline confusion.
15 So, Minnesota did come back favorably.

16 So, I will interpret your vote to
17 say that you have approved the revised
18 measure. I just want to be sure everybody's
19 aware of that and you're okay with that.

20 CHAIR GIBBONS: Yes, so this is to
21 be transparent. They've come back. They have
22 changed. We told them to change. They did

1 it. We actually voted on this, but just to
2 make everybody aware that this is now --
3 unless somebody has some additional concerns,
4 this is approved with the different blood
5 pressure target. And personally I think it's
6 a big deal, because it's a national composite
7 outpatient measure.

8 Any other discussion or comments
9 about that?

10 DR. WINKLER: Okay. There was one
11 --

12 CHAIR GIBBONS: Now, Reva, you
13 want to take on the other one?

14 DR. WINKLER: Yes, the other one.
15 The other measure was the measure from NCQA on
16 blood pressure management that there were a
17 couple of issues around. And in the follow-up
18 document you'll see their responses. One was
19 -- if you recall, it had two blood pressure
20 targets. It was the less than 140/90 and less
21 than 140/80. And your question was what's the
22 evidence for the 140/80? What's the deal?

1 And so, basically they've removed it. So,
2 there is no second target.

3 The other question I think was the
4 significant issue, was the lack of an upper
5 age limit with concerns about blood pressure
6 control in the elderly or patients without
7 tolerance. We had very similar conversation
8 yesterday on the hypertension measure, so this
9 is not a new issue.

10 I can tell you that their
11 responses, that their advisory committee
12 talked about it, didn't -- hasn't come to any
13 agreement, although they are certainly willing
14 to discuss it, particularly in the realm of
15 harmonization, because this measure is
16 essentially a component of the Minnesota
17 composite and the Minnesota composite has an
18 age limit, an upper age limit of age 75. So
19 we've got a harmonization issue that it think
20 is the way we could tackle this. And NCQA has
21 indicated that they'll also align with JNC 8
22 going forward. And given some of Dr. Smith's

1 comments over the two meetings, it seems
2 likely there might be some additional guidance
3 coming forward from there on some of these
4 issues as well that we will revisit.

5 All of the measures that are
6 endorsed go through annual updates. We look
7 at new ones, and any measures that need to be
8 seriously reconfigured because of new
9 evidence, new guidelines, whatever, we just
10 review them at that time. So, all of these
11 blood -- knowing JNC 8 is out there in less
12 than a year, we know that we'll have to take
13 a serious look at all the blood pressure
14 measures, and we've got several once they're
15 available.

16 So, in terms of this measure from
17 NCQA, it was one of those where we didn't vote
18 it conditionally. We voted it that we didn't
19 like it as submitted. But now that we have
20 these changes, we did not do the second vote
21 like we did with the Minnesota measure. So
22 the question is does the committee want to

1 revote the revised measure from NCQA?

2 CHAIR GIBBONS: Yes, and I would
3 suggest that what it would then take was again
4 identifying somebody to be the reviewer and
5 hopefully the same person who was the original
6 reviewer re-looking at the application in
7 light of these responses and then providing
8 advice to us that would be the basis for a
9 future vote either by email or conference
10 call. And so, the real question is do we feel
11 that these responses are satisfactory to merit
12 that additional work?

13 MEMBER SNOW: Well, we asked them
14 to do a particular thing and they've done the
15 particular thing.

16 CHAIR GIBBONS: No, we didn't
17 actually -- it was not as direct here. We
18 just raised in our -- they were here.

19 MEMBER SNOW: Yes.

20 CHAIR GIBBONS: And they heard all
21 our concerns. And then they came back with
22 these responses. We never got to the details

1 of the measure.

2 MEMBER RUSSO: What is this add --
3 what's the value added of this measurement
4 compared to the hypertension measurements from
5 yesterday?

6 DR. WINKLER: Essentially the
7 denominator populations are different.
8 Yesterday's measure was patients with
9 hypertension. This measure is patients with
10 ischemic vascular disease. So, I think that
11 given that's where we are today, it prompts
12 the bigger question that I think Dr. Gibbons
13 mentioned at the last meeting; why isn't there
14 one measure for blood pressure control for
15 everybody who needs their blood pressure
16 controlled? Excellent question, but I don't
17 think we're quite there yet, though it's
18 definitely a worthy goal. But they are
19 different patient populations.

20 MEMBER KOTTKE: I guess, I mean,
21 people probably know this, but it's a matter
22 of, you know, how the patient gets in the door

1 and how they get identified. That's why
2 there's so many different --

3 DR. WINKLER: So, when we do the
4 follow up, which is likely to be probably by
5 email, would you like to include this as a
6 follow up to revote?

7 (No audible response.)

8 DR. WINKLER: I'm seeing nodding
9 around.

10 CHAIR GIBBONS: You know, is it
11 worth the effort in light of these responses
12 from the developer, is the question? I just
13 need a sense.

14 MEMBER KING: I have a question
15 about that would relate to that. In other
16 words, yesterday we said that everybody's
17 blood pressure should be less than 140/90 and
18 these people should have their blood pressure
19 -- and now they agree that it should be
20 140/90. Aren't they included in that?

21 DR. WINKLER: No, not necessarily.
22 If the patient -- well, you tell me: How many

1 patients carry both the diagnosis of coronary
2 artery disease or ischemic vascular disease
3 and hypertension such that they would be
4 captured in the hypertension measure. That's
5 the difference. Unless you carry a diagnosis
6 of hypertension, you won't get captured.

7 MEMBER MAGID: I'm not really sure
8 that you're going to capture more people. So
9 there are a significant number of people in
10 the United States who have hypertension for
11 which it's not recognized and they don't carry
12 a diagnosis, that's true. But this measure
13 doesn't really address that.

14 DR. WINKLER: No, I guess the
15 question I would ask you, are there patients
16 who have coronary artery -- or ischemic
17 vascular disease primarily --

18 MEMBER MAGID: Right.

19 DR. WINKLER: -- coronary disease
20 that don't carry a diagnosis of hypertension
21 also?

22 MEMBER KING: Not those that don't

1 have their blood pressure -- you would carry
2 that diagnosis if your blood pressure two or
3 more times in a row was over 140/90. If it
4 was below, you already meet this and we don't
5 need to monitor you, judge you and do
6 anything. I would still maintain that now
7 that they have harmonized, this measure may
8 not be necessary at all.

9 DR. WINKLER: That's a different
10 question.

11 MEMBER MAGID: Yes, I mean, I
12 think that you're not going to capture a
13 significant proportion of the people. In
14 other words, those people with known coronary
15 artery disease are the ones we focus on a lot.
16 The people that are largely unrecognized are
17 not in this group.

18 MEMBER KOTTKE: Because they've
19 done the work I think we ought to give them a
20 response. I think that's polite.

21 MEMBER SNOW: I agree with that.

22 CHAIR GIBBONS: No, no. I think

1 we want to -- all we're going to do -- vote
2 today is whether it's worth the effort to have
3 this re-reviewed and fully revoted. That's
4 what this vote is about. Is it worth the
5 effort? Because we can't do it properly
6 without a re-review, etcetera. So, can we use
7 our automated system for this?

8 DR. WINKLER: As long as you -- if
9 you ignore the meet criteria and just use it
10 as a yes/no.

11 CHAIR GIBBONS: Yes/no.

12 MEMBER RUSSO: Can I ask one other
13 question?

14 CHAIR GIBBONS: Yes.

15 MEMBER RUSSO: So, would this open
16 the door; and I'm not saying it's good or bad,
17 for all the other measures that we stopped at
18 that first step for people to come back in the
19 next month or --

20 DR. WINKLER: You didn't stop at
21 the first step. You did the complete
22 evaluation, but during your discussion you

1 talked about being open to revisions to the
2 measures. You didn't do that with all the
3 rest of the measures.

4 MEMBER RUSSO: Okay.

5 DR. WINKLER: And so the follow up
6 of --

7 MEMBER RUSSO: And so we did this
8 for the one we just talked about, so why
9 wouldn't we do it for this person then?

10 DR. WINKLER: Because we did this
11 one first and didn't think about it.

12 MEMBER RUSSO: Okay. No, no, I'm
13 saying, but we should give them -- no, no, I
14 know that we didn't do it that day, but we
15 should --

16 CHAIR GIBBONS: We became more
17 proactive as the day went on the last time.

18 MEMBER RUSSO: That's right. Yes,
19 okay. Give them the same chance, I mean.

20 DR. WINKLER: Yes, that's
21 essentially it.

22 CHAIR GIBBONS: And you could

1 potentially just, as Tom said, just say this
2 is a matter of politeness. They came back,
3 blah, blah, blah.

4 So, is the voting clear as to what
5 we're voting on? It's whether we're going to
6 go to the trouble of re-reviewing this
7 particular blood pressure measure that we
8 rejected the last time?

9 (No audible response.)

10 CHAIR GIBBONS: So, if the vote is
11 now clear, we're going to go ahead and vote.

12 DR. WINKLER: Dianne and Devorah,
13 are you clear with this?

14 MEMBER JEWELL: I think so.

15 DR. WINKLER: Okay. Good.

16 MEMBER RICH: I think so as well.

17 DR. WINKLER: Dianne, Devorah,
18 what do you think? Dianne?

19 MEMBER JEWELL: Yes for me.

20 DR. WINKLER: Devorah?

21 MEMBER RICH: Yes for me as well.

22 DR. WINKLER: Okay. So, okay.

1 CHAIR GIBBONS: So, the vote is 17
2 yes; 3 no. So, we will re-review this and
3 just the same way we're going to re-review
4 those measures slated for rotation the way we
5 said earlier. Okay? All right. Good.

6 Now, we're going to move onto
7 competing measures. Oh, boy.

8 DR. WINKLER: Okay.

9 CHAIR GIBBONS: So first of all,
10 we've got to find the right grid.

11 DR. WINKLER: Right. Okay.
12 Again, it's the third of the other memos that
13 says "Memo to Steering Committee: Competing
14 Related, Final." And I believe on your jump
15 drives it's a PDF and the side-by-sides that
16 go with it are attached. Okay?

17 Okay. And essentially we
18 identified based on where were at before this
19 meeting measures that seem to be competing,
20 topic areas. Some of those have been
21 eliminated by the decisions you've made over
22 the last couple of days, but I think that what

1 we can do is start with the first side-by-side
2 around aspirin use because it brings the whole
3 problem to bear all in one fell swoop.

4 This is not all measures that had
5 aspirin in its title. Aspirin on arrival I
6 did not include. These are more the secondary
7 prevention measures. As you can see --

8 CHAIR GIBBONS: So, let's make
9 sure first before we start, has everybody
10 found the right grid?

11 DR. WINKLER: Right.

12 CHAIR GIBBONS: Or they can see it
13 on the screen, but hopefully the right grid on
14 their computer.

15 DR. WINKLER: Has everybody got
16 the side-by-side for secondary prevention,
17 anti-platelet agents? There are six measures
18 on this side-by-side.

19 MEMBER RICH: I'm sorry, I'm --

20 CHAIR GIBBONS: And it is page 7.

21 DR. WINKLER: Yes.

22 MEMBER RICH: Okay. Fine.

1 Thanks.

2 DR. WINKLER: Okay? Now --

3 CHAIR GIBBONS: Wait a minute.

4 Whoa, whoa, whoa. I really think we need to
5 just make sure we're literally all on the same
6 page.

7 DR. WINKLER: Yes. Are we all on
8 the same page?

9 CHAIR GIBBONS: Do I have nods?
10 Do I have nos? I got a lot of nods. Thumbs
11 up. Far side of the table? Christine?

12 MEMBER RICH: You're talking about
13 the PDF file --

14 CHAIR GIBBONS: She's looking.

15 MEMBER RICH: -- that is in
16 landscape format?

17 DR. WINKLER: That's correct.

18 CHAIR GIBBONS: Christine is
19 looking.

20 MEMBER RICH: Yes?

21 DR. WINKLER: Correct.

22 CHAIR GIBBONS: Suma? Okay. So,

1 we'll give a few more seconds to make sure,
2 because I think it's really -- otherwise it's
3 so hard to catch up on these discussions.

4 DR. WINKLER: Dianne and Devorah,
5 do you have the --

6 MEMBER JEWELL: I'm good.

7 MEMBER RICH: Yes, I got it.

8 Thank you.

9 DR. WINKLER: Great. Thanks.

10 CHAIR GIBBONS: All right.

11 DR. WINKLER: Okay.

12 CHAIR GIBBONS: All right. We
13 will proceed.

14 DR. WINKLER: All right. What
15 I've included here; and six seemed to be about
16 the limit of what we could put on a single
17 page, is the first two measures are measures
18 you reviewed at the first meeting. And the
19 first one is the chronic stable coronary
20 artery disease anti-platelet therapy, and
21 that's from PCPI. You also looked at ischemic
22 vascular disease, use of aspirin or other

1 antithrombotic.

2 Now, we also have in the portfolio
3 another measure that came out of our
4 clinically-enriched administrative data
5 project of secondary prevention of
6 cardiovascular events, use of aspirin or anti-
7 platelet therapy. That project was looking at
8 measures that can be generated primarily with
9 administrative data, primarily claims data
10 with -- enriched by either EHRs or PHRs. So,
11 you will see measures from that project
12 peppered in here.

13 Under related measures I included
14 the Minnesota composite because one component
15 is the same thing. And when you're talking
16 about harmonization -- now, the last two, the
17 142 is the aspirin prescribed at discharge for
18 AMI, and this is the measure you sort of are
19 discussing about its status. So, it's still
20 kind of to be determined, I guess.

21 The last one is the aspirin at
22 discharge for patients with PCI, which was a

1 measure you evaluated last time, but it became
2 a component in the new composite yesterday and
3 you recommended the composite but not the
4 individual measure.

5 So, can't tell the players without
6 a score card.

7 CHAIR GIBBONS: Is everybody
8 tracking that? So in other words, the last
9 column on this grid is the individual measure
10 that yesterday we said because it was rolled
11 into the composite we were no longer going to
12 recommend for endorsement?

13 DR. WINKLER: Right.

14 PARTICIPANT: That's 1493.

15 CHAIR GIBBONS: Because of very
16 high compliance, 1493. So, in essence the
17 last column to some degree has already been
18 wiped
19 off --

20 DR. WINKLER: Yes, right.

21 CHAIR GIBBONS: -- by us
22 yesterday.

1 DR. WINKLER: So, anyway. So, and
2 not all of these measures are on our list for
3 maintenance review. Now, earlier in this memo
4 -- and if you recall at the end of the last
5 meeting, Helen started walking you through the
6 proposed kind of algorithm, policy, whatever
7 you want to call it, that talks about how to
8 evaluate competing and related measures. And
9 I think one of the first things is
10 definitional, and that is which measures are
11 competing and which measures are related? And
12 frankly, I found that difficult because if you
13 look at them, I think that if you look -- the
14 biggest target population is patients with
15 ischemic vascular disease.

16 Now, they may be subset because
17 they either just had an AMI, just had a PCI or
18 they're just the CAD subset, but the target
19 population is still this group. But yet they
20 all kind of look at a different piece of that
21 big pie. And I think this is where Jon and a
22 lot of other people's suggestion that is there

1 some way we can move to, you know, sort of one
2 way of looking at this concept of secondary
3 prevention with the appropriate medications?
4 So, there are -- this just gets, you know,
5 extremely complicated.

6 And the question I would ask you
7 is, given that we can't roll it up into one
8 measure yet, do we need all of them that are
9 here? And I think that's sort of the
10 fundamental question. If you look at the
11 first two measures, you're talking about
12 aspirin and anti-platelet agents in CAD.
13 Essentially the next one, 68, is use of
14 aspirin and antithrombotics in ischemic
15 vascular disease. That's a slightly larger
16 denominator. CAD is the largest portion of
17 it, but it does include peripheral arterial
18 disease and cerebrovascular disease and some
19 other ischemic vascular diseases so that, you
20 know, 67 is a subset of 68. Is there a need,
21 a benefit, a value or does it just add
22 confusion and chaos to have both measures?

1 Since those are both up for
2 maintenance review, that's a fundamental
3 question for this committee in terms of your
4 final recommendations going forward.

5 MEMBER SMITH: Are you saying,
6 Reva, that the Venn diagram for 67 lies
7 entirely within 68? I would wonder about
8 that.

9 DR. WINKLER: Well, the way --

10 MEMBER SMITH: I mean, I'm sure
11 there's overlap, but --

12 DR. WINKLER: Well, ischemic
13 vascular disease is defined as --

14 MEMBER SMITH: -- disease is
15 included in the definition of ischemic
16 vascular --

17 DR. WINKLER: Yes. I mean, it's
18 defined as CAD plus PAD plus CVD. So, I mean,
19 just by purely the definition of the ischemic
20 vascular disease.

21 MEMBER RUSSO: As a separate
22 question moving forward, is there a way as a

1 measure developer that you can query to see --
2 you must have spent a lot of -- or you know
3 the measures, but someone from the outside
4 developing new measures so we don't get three
5 more of these next year that you can query by
6 keywords? Or should we consider requiring the
7 submitters add some keywords so we can use a
8 query search so that new people don't make up
9 the same measures again?

10 DR. WINKLER: Well, we've actually
11 done that, and it's actually a requirement on
12 the submission is that they look to see what
13 other measures may be similar. I think it
14 would be beneficial to be able to make it so
15 obvious about what measures exist so that
16 people don't even bother investing in
17 development of similar measures going forward.
18 That becomes a communication issue. But
19 you're absolutely right, Andrea, that that is
20 something that is, you know, highly desirable.
21 And in our communications with measure
22 developers, which we do on a regular basis,

1 these are the issues that get discussed,
2 because there isn't a point in committing more
3 resources to redevelop the same measure.

4 MEMBER KING: I am a proponent of
5 the BBT, the big basket theory. And 0068
6 appears to be the big basket and it include
7 67. In fact, if I read it right, I think it
8 includes 0142 and 1493. It includes people
9 with a PCI, people with an AMI, people with a
10 reason for aspirin. And our discussion around
11 harmonization was who needs this medicine to
12 prevent cardiovascular disease, just the same
13 kind of conversation we had about, you know,
14 who needs beta-blockers and who needs
15 ACE/ARBs? This is who needs aspirin? And 68
16 seems to be pretty close to what we've been
17 asking for all meeting long.

18 CHAIR GIBBONS: Okay. So, now
19 let's point out that 68 is in fact a component
20 of 76. So, I mean, it does get complicated,
21 but 68 is a component. It's the aspirin
22 component of 76 with slight differences in the

1 denominator because 76 is capped at 875.

2 DR. WINKLER: Right. Although we
3 are -- once we kind of figure out which ones
4 we need to work on the harmonization, those
5 issues become very serious.

6 CHAIR GIBBONS: Moot. Yes. So,
7 and then, Dana, I think the one thing
8 everybody should look at, because this
9 certainly came to mind as we were considering
10 these the last time, are the exclusions.
11 Because both 67 and 76 allow for clinically-
12 important exclusions and 68 does not allow any
13 exclusions. So, everybody should scroll down
14 and look at exclusions because that is really
15 -- aside from the denominator, overall broadly
16 cast, is in defining compliance are there
17 exclusions?

18 DR. WINKLER: Just keep going.
19 Scroll down.

20 CHAIR GIBBONS: They're on there.
21 You just got to keep scrolling on this form.

22 MEMBER JEWELL: Is it listed in

1 the exclusions or just on numerator
2 description?

3 DR. WINKLER: It's a long scroll.
4 It's on page 18 of the -- there it is.

5 Yes, these are complicated
6 analyses to try and present.

7 CHAIR GIBBONS: Okay. So, you
8 have to use the microphone, but I think if you
9 scroll down to the exclusions, you'll see that
10 there's another fundamental concern here.

11 MEMBER MAGID: Yes, so in terms of
12 the exclusions, you know, because one's a
13 hospital-based measure, it has sort of
14 hospital-based-type exclusions. One's an
15 ambulatory measure. It has ambulatory-type
16 exclusions, right? So --

17 CHAIR GIBBONS: Well, whoa. I'm
18 not sure which one you're looking at for
19 hospital-based. Which one are you --

20 MEMBER MAGID: Oh, I'm sorry.
21 Wait a second. I'm looking at the blue ones.
22 Never mind. But I'm looking on the right

1 page.

2 CHAIR GIBBONS: You got to be on
3 the right --

4 MEMBER MAGID: I'm on the right
5 page.

6 CHAIR GIBBONS: Now you got to
7 look for the right column.

8 MEMBER KOPLAN: I think one thing
9 is you do have -- when you talked about, you
10 know, lumping 67, 68, 142 and maybe 76, that
11 you have to be a little careful about over
12 lumping because it's very -- I think one of
13 the things maybe we haven't done that needs to
14 be done more is more outpatient kinds of
15 quality things. A lot of the hospital stuff
16 gets tracked a little bit more it seems like.
17 And so, you know, looking at a measure that's
18 after QMI at discharge is very different in my
19 mind than in an ambulatory setting. And I
20 don't know if I'd want to lump those two
21 because there are so many different issues
22 that come into play there.

1 I would agree that it does seem
2 like 67 and 68, at least the first block that
3 describes them, you can put them together, but
4 then there's the issue also one of them has
5 clopidogrel incorporated and one just has
6 aspirin.

7 DR. WINKLER: That's the next
8 harmonization question I was going to pose to
9 you. If you notice all six, the actual
10 inclusions for the medications are all
11 different. There are six different unique
12 inclusion criteria.

13 MEMBER RUSSO: I think it may be
14 hard to eliminate these up front now, I hate
15 to say. But as moving forward again, when
16 developers come up with the measures, they
17 need to say that they looked, but what are the
18 differences and outline the differences for us
19 why their measure should be approved in the
20 future, because I think we're going to
21 continue to see this if we don't.

22 CHAIR GIBBONS: Well, I would

1 predict; and NQF staff can help, that they
2 will all have a case for their measure going
3 forward. So, that will be it. They'll make
4 the case and you'll have a grid with six
5 measures unless we, you know, swing into
6 action here. Suma?

7 MEMBER THOMAS: Could in the
8 future -- just throwing this out there. Could
9 they send a measure to you just with like
10 their title and purpose and then you guys sort
11 of pose the question to the staff in the
12 future rather than the whole -- you know, just
13 their purpose and then you could pose those
14 questions to them?

15 DR. WINKLER: Well, I mean, I
16 think the purpose -- one of the things we hope
17 to do to have our enhanced database is expect
18 measure developers to go check and see. I
19 mean, you can just do the search, find the
20 measures and then, hello, do you need to add
21 to this?

22 But, yes, that dialogue is

1 something we would encourage and be happy to
2 participate in if indeed folks, you know,
3 contacted us.

4 MEMBER RUSSO: Is there any way we
5 could put this back? It's hard to say one is
6 better than the other. You know, is there any
7 way we could say, hey, you two look at it
8 together and, you know, harmonize, or is that
9 not going to work?

10 CHAIR GIBBONS: Well, how do I
11 politely put this? Something came up in
12 imaging last year -- Helen's not here, so --
13 which was -- at least from Committee's
14 standpoint looked like it was straightforward
15 harmonization. I would defer to Helen to try
16 to describe to you how difficult this became
17 in the negotiating process. And it took six
18 months?

19 At least six months. And that,
20 believe me, on the surface was -- I mean, the
21 Committee thought it was straightforward.
22 This is not nearly as straightforward. So, I

1 mean, I can imagine that one of these
2 negotiations might well take two to three
3 years. Mark?

4 MEMBER SANZ: Looking through
5 this, I just don't see why we can't vote. As
6 you look at the numerator for 0076, it lists
7 pretty much everything you would want as far
8 -- there are other exclusions in the numerator
9 separate from the exclusions on page 18, if
10 you go to page 12 and 13.

11 CHAIR GIBBONS: Right.

12 MEMBER SANZ: But I personally
13 would be ready to vote today. I don't really
14 want to do this again in one month, three
15 months, six months as these people go back and
16 forth and resubmit their versions of how they
17 want to -- you know, one side says I want this
18 or that. I'm pretty comfortable with 0076.

19 DR. WINKLER: Just a
20 differentiation between what we would call
21 competing measures, and that's the
22 multiplicity; do we need them all, that's

1 really a competing measures discussion. That
2 really is a steering committee decision.

3 The harmonization of the measures
4 that are left with a similar topic is
5 something we get into with the developers.

6 DR. PACE: But it's something that
7 you have the ability to only recommend
8 measures on the condition that they harmonize
9 on a particular --

10 MEMBER KOPLAN: So, were you then
11 proposing to take 67, 68 and 631 and just roll
12 them all into 76?

13 MEMBER SANZ: That would be my
14 proposal.

15 MEMBER RUSSO: And then how would
16 you handle --

17 MEMBER SANZ: I don't see the down
18 side, so --

19 MEMBER RUSSO: -- the exclusions?
20 Would we say -- how are you -- well, because
21 they're different.

22 MEMBER SANZ: Look at the

1 exclusions in the -- the exclusions in 0076
2 are not complete in the exclusion section.
3 There's actually several in the numerator
4 section. You got to look up above on page 12
5 and 13.

6 CHAIR GIBBONS: And that's
7 historical reflecting the experience with the
8 measure over time as a composite. There were
9 adjustments in both numerator and denominator.
10 And that was all spelled out in the original
11 application.

12 MEMBER KING: I would agree with
13 Mark. The question, we can't make all the 65s
14 and the 75 and the 18 and overs and the --
15 they mention six drugs. They only mention
16 five. We can't wave a magic wand and make
17 those equal, but what we can say is that it's
18 doesn't supply us with meaningful additional
19 information to justify another measure.

20 And so, if I understand Mark
21 correctly, he's saying that 67, 68 and 631
22 don't really supply anything meaningful added

1 to 0076, and actually I would agree.

2 CHAIR GIBBONS: Okay. So, we have
3 two bold statements in favor of 0076. Others
4 want to comment?

5 I'd point out we have several
6 different options. One is we could actually
7 vote today. Mark has expressed a clear
8 preference in doing that. We could as a group
9 say everybody wants to ponder this grid a bit
10 more carefully, and we'll then take a
11 subsequent vote.

12 Bruce?

13 MEMBER KOPLAN: Rather than vote
14 right now, I would -- because the only thing
15 we have all these bold statements, which I'm
16 not sure if I agree or disagree, but it would
17 be nice to just hear someone's opinion about
18 maybe like the dangers of over-lumping or some
19 -- one of the educated members of the group or
20 -- like what -- there must be some downside to
21 doing this.

22 MEMBER RUSSO: And the only other

1 question too is what do you do with the age?
2 Do we just arbitrarily say there's no age
3 cutoff now? And then what do we say about the
4 tobacco-free status, that we don't have that
5 one anymore? Like do we have to modify the
6 measure?

7 DR. WINKLER: No, you don't need
8 to do anything with the measures. If you weed
9 out and make the group smaller, then we'll
10 really hammer hard on the harmonization issues
11 around ages and things like that.

12 In terms of the smoking measure,
13 NQF has specifically gone away from having
14 disease-specific smoking measures. What we
15 have is a measure of smoking cessation for
16 everybody, and that is sort of your component
17 here that has been subsetted for this
18 population.

19 CHAIR GIBBONS: Tom?

20 MEMBER KOTTKE: Yes, and the
21 tobacco measure we declared -- or that was
22 declared invalid was advice to quit smoking,

1 not smoking status. This is smoking status.

2 CHAIR GIBBONS: This is smoking
3 status. This is the outcome. This is the
4 outcome. It's a component. And so, that's
5 why as multiple clinicians who in the State of
6 Minnesota quickly realized they'd never get to
7 100 percent because they'll always have
8 smokers in their practice and just points out
9 that we always still have a ways to go.

10 Suma?

11 MEMBER THOMAS: This measure also
12 includes that blood pressure goal of 130/80.
13 Does -- or --

14 CHAIR GIBBONS: Oh, no, no. No,
15 no. This is the revised measure that they
16 came back and changed. That's what we just
17 alerted everybody to. It's 140/90 and they
18 have agreed to change the blood pressure when
19 JNC comes out.

20 MEMBER THOMAS: If needed, right.

21 CHAIR GIBBONS: If it's needed.

22 MEMBER RASMUSSEN: So, Mark, is

1 what you're proposing lumping or a death match
2 for 76?

3 MEMBER SANZ: You're talking to an
4 interventional cardiologist, so --

5 MEMBER RASMUSSEN: Yes.

6 MEMBER SANZ: Typically I would
7 approach it with a death match.

8 MEMBER RASMUSSEN: Okay.

9 MEMBER SANZ: But why don't you
10 explain? I don't understand the difference.

11 MEMBER RASMUSSEN: So, is it
12 combining pieces of the other measures into
13 76, or just saying we like 76 enough that we
14 would vote on that? All the other ones yes?

15 DR. WINKLER: Yes, let me just
16 make it real clear --

17 MEMBER SANZ: I don't know what
18 the real difference --

19 DR. WINKLER: Yes.

20 MEMBER SANZ: I mean, seems like
21 it's --

22 DR. WINKLER: Let me just make it

1 real clear: What you need to pick from is
2 what's available up there. You're not making
3 new measures.

4 MEMBER SANZ: Seventy-six seems
5 more detailed than the other ones as far as I
6 can tell.

7 MEMBER RUSSO: I guess I'd just
8 have to look at the particular -- are all the
9 drugs included? I mean, it just takes a
10 little, you know, extra looking here because
11 --

12 MEMBER KOPLAN: Well, clopidogrel
13 or -- those types of things are not included
14 in 76, right?

15 DR. WINKLER: Well, here it is.
16 There it is, yes.

17 CHAIR GIBBONS: Yes, they actually
18 are. They're folded into the definitions.
19 It's very --

20 MEMBER KOPLAN: Okay.

21 CHAIR GIBBONS: You really have to
22 go through --

1 DR. WINKLER: It's on a different
2 page.

3 CHAIR GIBBONS: Yes, it's on a
4 different page.

5 MEMBER KOPLAN: Okay.

6 DR. WINKLER: Page 11 versus page
7 10, so it's just hard to see side-by-side.

8 MEMBER KOPLAN: They came up with
9 Pravigard, which is good, because I'd never
10 even heard of that before.

11 CHAIR GIBBONS: This side of the
12 table's getting a little punchy here. They're
13 getting hungry. We're going to have to break
14 for lunch shortly. Their glucose levels are
15 starting to fall.

16 MEMBER AYALA: I just wanted to
17 remind everyone, we need to also look at the
18 level and the setting. I don't know if that
19 makes a difference here.

20 CHAIR GIBBONS: Say that again.

21 MEMBER AYALA: The level and
22 setting. Has everybody considered those

1 differences?

2 DR. WINKLER: Just to summarize,
3 67 and 68 and 76 are really clinician level,
4 group level kinds of measures, so they're
5 similar. The 631 is a measure that can be
6 measured at the clinician level. It can also
7 be measured at higher levels of system or
8 plan, or whatever. So, they are comparable in
9 that respect.

10 MEMBER RASMUSSEN: On page 12 for
11 76 under contraindications, anticoagulant use,
12 Lovenox, Coumadin, we would need to add
13 dabigatran presumably.

14 DR. WINKLER: Right.

15 CHAIR GIBBONS: I suspect that
16 anything of that sort; a friendly amendment,
17 we can bounce back to the developers. I don't
18 know this for a fact, Jon, but I suspect that
19 internal discussion is already ongoing in the
20 State of Minnesota because there's a fairly
21 good process to try to update these whenever
22 individual clinicians call up. I mean,

1 really, it's pretty -- tries to be responsive.

2 VICE CHAIR GEORGE: Since this
3 relates to the entire population of ischemic
4 vascular disease, do they also note for
5 individual populations where certain drugs are
6 contraindicated as opposed to the rest of the
7 population considered?

8 CHAIR GIBBONS: I'm sorry, I'm not
9 following. Which group?

10 DR. WINKLER: For instance, if
11 Proxigel were added to this list, it's
12 contraindicated in stroke. And would that
13 just be noted with an asterisk?

14 (Simultaneous speaking.)

15 CHAIR GIBBONS: That I think we'd
16 have to ask the developer. I don't know how
17 they're handling that. We could easily ask.

18 All right. Before we go to lunch,
19 I need a sense. Do people want to vote on
20 this now, or do they want to postpone it under
21 further consideration?

22 Dana and Mark have already said

1 they want to vote on this. Now I need to sort
2 of get a sense from people.

3 I have questioned their glucose
4 level, on least on this side of the table,
5 given some of the comments that are going on
6 off line. There's a serious blood glucose
7 issue.

8 I don't sense a wave of enthusiasm
9 for voting now, so I think what I'm going to
10 suggest that we do moving forward is that
11 everybody ponder the basically choosing 76 as
12 in essence best in class. It's a composite.
13 It rolls the other things in. And if that is
14 our perspective, then we can have a vote on it
15 subsequently. But in the meantime, if people
16 have any questions or concerns, we can
17 certainly reflect them back to the developer,
18 just the one that Mary just asked, for
19 example. We can easily ask. And dabigatran
20 we can easily ask so that we're making certain
21 that we do due diligence on this before we
22 vote.

1 Does that sound like a reasonable
2 plan to everybody? We're going to have to put
3 a time frame on that. Any comments from those
4 on the phone?

5 MEMBER JEWELL: No, that works for
6 me.

7 MEMBER RICH: Sounds fine.

8 CHAIR GIBBONS: So, I think that's
9 how we will approach this. Right now we're
10 going to break for lunch. And then realize,
11 we've only looked at the first example of
12 competing measures.

13 MEMBER JEWELL: So, Ray and the
14 group, I'm actually going to be saying goodbye
15 to you now.

16 CHAIR GIBBONS: Okay.

17 MEMBER JEWELL: I've got another
18 meeting which is commencing shortly, so I need
19 to go attend to that. But thank you for --

20 CHAIR GIBBONS: Okay. Thank you
21 and we --

22 MEMBER JEWELL: -- so attentive to

1 me on the phone out here in the virtual world.

2 CHAIR GIBBONS: Okay. All right.

3 Take care.

4 MEMBER JEWELL: Thanks. You, too.

5 Bye-bye.

6 CHAIR GIBBONS: Bye-bye.

7 All right. We're going to break

8 for lunch, and we will reconvene at 1:00.

9 (Whereupon, the above-entitled
10 matter went off the record at 12:20 p.m. and
11 resumed at 1:00 p.m.)

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

1:01 p.m.

CHAIR GIBBONS: So, my sense is that we have gone as far as we can go today on the anti-platelet agent issue.

We will plan moving forward to redistribute the Minnesota Community Measurement Project application to everybody so that everybody can see that and all the details.

We can then entertain questions for the developer before we subsequently take a vote. Now, I think you're going to realize how important that vote is in the context of the next discussion, because if you'll keep scrolling down that same document regarding competing measures you will come to this page on lipid control. And we now have a very similar paradigm. We don't have six; we have five. But we have 0074, chronic stable CAD from the AMA and PCPI. We have 0075 on vascular disease and LDL control less than 100

1 from the National Committee for Quality
2 Insurance. And we have our newly-endorsed
3 measure, 0076, on optimal vascular care.

4 And I think you can quickly
5 appreciate that there are a lot of
6 similarities, and some of the differences are
7 actually along the same line as the last
8 discussion of anti-platelet therapy. They all
9 have the same target, LDL of less than 100.
10 All three of these have undergone review by
11 this Committee.

12 If you look carefully, there will
13 be minor differences I think in the numerator
14 for sure. The universe of 0058 and 0631 being
15 pretty similar, but 0067 being in a narrower
16 population. But then I would sort of remind
17 you, if you page down far enough, you're going
18 to get to the exclusions and you'll discover
19 in the first column and the third column there
20 are going to be exclusions. There aren't
21 going to be any exclusions in the second
22 column. So, in part, some of our discussion

1 of the anti-platelet issue is also going to
2 apply here.

3 So, I'll open it up at this point
4 for additional comments from anyone who has
5 looked over these and wants to comment or make
6 a suggestion. Leslie?

7 MEMBER CHO: Can we take 0611 out
8 of there, only because it's a primary
9 prevention and all the other ones are
10 secondary prevention?

11 DR. WINKLER: Okay.

12 MEMBER CHO: So just to make one
13 thing easier?

14 DR. WINKLER: Sure. Again, I was
15 looking for things that might be related. You
16 may not consider it a competing measure and
17 drop that out. So, fine. Can certainly do
18 that.

19 MEMBER KOTTKE: Ray?

20 CHAIR GIBBONS: I see a lot of
21 nods around the table, so I think there's a
22 consensus we should do that.

1 Tom?

2 MEMBER KOTTKE: So, going back to
3 Mark's question of -- is this what, near death
4 experience or something, so --

5 CHAIR GIBBONS: No, I think it was
6 Jon's question.

7 MEMBER KOTTKE: So, would we be
8 saying that if you're going to have some sort
9 of measure for risk factor -- secondary
10 prevention, you do this bundled measure or you
11 don't get anything from NQF? Is that what
12 sort of is on the table?

13 CHAIR GIBBONS: Well, remember the
14 votes we took yesterday where we could endorse
15 individual measures. We could endorse the
16 composite or we could endorse both.

17 Helen?

18 DR. BURSTIN: Hi, everybody. The
19 only difference here would be that we actually
20 don't have the individual measures from
21 Minnesota Community Measurement. We actually
22 have only ever endorsed the composite. So you

1 would be left without individual level --

2 MEMBER KOTTKE: No, but I'm
3 talking about 0074, 0075 and 636. But we do
4 have 74 and 75.

5 DR. BURSTIN: Yes, we have 74 and
6 75.

7 MEMBER KOTTKE: But would we be
8 dis-endorsing those?

9 DR. BURSTIN: Yes.

10 MEMBER KOTTKE: And we'd basically
11 say if you want -- an organization that wants
12 to claim that they are using an endorsed
13 measure would have to include all of the
14 components, which -- in 76? Is that --

15 DR. WINKLER: Tom, I think what
16 you're saying is if you do for a lipid control
17 what you are thinking you might do for the
18 aspirin measure and focus everything in on 76,
19 then that's effectively what you're saying.

20 MEMBER KOTTKE: Right.

21 DR. WINKLER: If you're picking 76
22 and saying the others should go away from an

1 ambulatory care measure.

2 MEMBER KOTTKE: Which may be -- I
3 mean, it's quite reasonable that outside of
4 exclusions, I mean, anybody who has vascular
5 disease and needs lipid control also needs
6 aspirin and they need, you know --

7 CHAIR GIBBONS: Need to stop
8 smoking and they need their blood pressure
9 controlled.

10 MEMBER KOTTKE: Yes. Yes, they
11 need that. Then you have interventions.

12 VICE CHAIR GEORGE: So, and I
13 don't know whether you can answer this: On
14 76, looking at the exclusion, since we don't
15 have the individual measures, is there
16 anything in there that would allow for
17 documented reasons for not prescribing --

18 CHAIR GIBBONS: Yes.

19 VICE CHAIR GEORGE: Okay.

20 CHAIR GIBBONS: Since I was the
21 primary reviewer, yes. That's part of their
22 constellation of exclusions. Physician

1 judgment. That's document.

2 Yes, Helen?

3 DR. BURSTIN: Just to follow up
4 one more time, there are multiple -- somebody
5 had asked -- I guess I was told by staff, one
6 of the questions was are there any down sides
7 to not having the individual measures? And I
8 think it's just at least important to consider
9 the fact that there are multiple uses of NQF
10 endorsed measures. Some are for payment.
11 Some are in PQRS. Some are public reporting.
12 And the question would be at the end of the
13 day would this one all-or-none composite be
14 one-size-fits-all for all potential uses?
15 Because you would essentially be saying none
16 of the other measures on their own can stand
17 alone. And as I mentioned, we don't have the
18 individual components submitted, reviewed or
19 endorsed from Minnesota, so it's not as if we
20 have that option.

21 MEMBER KOPLAN: Also, is there --

22 CHAIR GIBBONS: Yes, Bruce?

1 MEMBER KOPLAN: This kind of
2 alludes to something that was said before, but
3 the fact that one of them deals with discharge
4 after MI and the other one is more -- it
5 sounds like an ambulatory thing, is there some
6 difference in how these things -- am I wrong?

7 DR. WINKLER: No, it's just the
8 way they are identifying the denominator.
9 Seventy-five is an outpatient measure, but one
10 of the ways you could get included is if on
11 claims you have had a hospitalization --

12 MEMBER KOPLAN: Oh, yes. Okay.

13 DR. WINKLER: -- for something,
14 you know, CABG, AMI, something.

15 CHAIR GIBBONS: So, all three are
16 meant to be outpatient measures.

17 DR. WINKLER: They're all
18 outpatient measures.

19 MEMBER PHILIPPIDES: And in both
20 cases with a composite you have to hit all
21 four targets to get -- credit the numerator.
22 So, for better or for worse, it seems to me;

1 at least the way this one's written, tobacco-
2 free status for many folks will be the killer.
3 And it almost becomes what is your tobacco-
4 free status rate? Because if you have one of
5 the composites that's so much lower than the
6 other ones, that's what it sort of devolves
7 to.

8 CHAIR GIBBONS: So, Tom, might
9 want to comment because I think his
10 organization is the highest rated in the State
11 of Minnesota right now on this composite. And
12 as I recall about half of your non-100 percent
13 values is due to tobacco. Is that pretty much
14 it?

15 MEMBER KOTTKE: Yes, that's
16 probably not too inaccurate. There are very
17 considerable discussions going on about this;
18 certainly around the diabetes composite
19 measure, and I think around here of, you know,
20 if you -- I mean, if you have something where
21 patients will not move, do you discourage
22 physicians from -- and are they punished for

1 -- you know, they're doing everything they
2 can, but they feel that the measure is unfair
3 because it's out of their control.

4 MEMBER SNOW: Well, it's also
5 really not a composite anymore because the
6 rate-limiting step is tobacco so it's, as you
7 said, I mean, just --

8 MEMBER PHILIPPIDES: Well, that's
9 my concern. And if you wanted to actually get
10 a glimpse at one of the other three things,
11 this might be --

12 CHAIR GIBBONS: So, let me just
13 chime in and point out that although you might
14 think that, when the data on these composites
15 were first compiled the rate of compliance
16 with both the blood pressure and the lipid
17 control were less than with tobacco. Yes,
18 they were less than 85 percent. Each one of
19 those was less than 85 percent. Tobacco is
20 going to be about 85 percent because you got
21 about 15 percent smokers. And those other
22 components were less. So, don't misunderstand

1 from what we're saying. We could show you the
2 data, and I don't have it currently, but
3 they're still less. They are less at the Mayo
4 Clinic for sure. I can tell you that one.
5 We're not doing as well with getting LDLs less
6 than 100 as 85 percent; we're not there, in
7 people with known vascular disease. Think
8 about it. I mean, it's pretty amazing when
9 you look at the actual data.

10 So, other comments or questions
11 about lipid control? I think we're going to
12 have the same potential dilemma here, and we
13 may want to have the same process of looking
14 carefully at the specifications of 0076 before
15 we vote. And in the meantime, getting some
16 sense I think of the downside; again, as
17 stated by Helen, of doing away with the
18 others. But, you know, we propose something.
19 It goes out for public comment. And this will
20 inspire a lot of comments.

21 And Tom has suggested I need to
22 change my phone number. I'm not sure of that

1 yet, but --

2 MEMBER KOTTKE: You know, you
3 could just go to minnesotahealthscores.org.
4 And in fact, they report the composite for
5 vascular disease, but then also independently
6 report performance for blood pressure, bad
7 cholesterol and LDL for tobacco-free and
8 aspirin use daily. And so, it's not as if
9 it's bundled and opaque. And so, there is
10 that composite, but also there's ranking. And
11 so, we're not saying that you can't see behind
12 the curtain of the composite.

13 DR. WINKLER: Tom, just to
14 clarify, this is a question that comes up a
15 lot about composites -- is one of NQF's
16 guidance in the framework for composites is
17 that the measure can be deconstructed into its
18 component parts, certainly for feedback to
19 providers on the QI side. But, you know, I
20 think it becomes ambiguous if the
21 specifications don't say that they will report
22 out the sub-components if it's not specified.

1 So, and it's not in this evaluation form that
2 it would be. So, if indeed that were the
3 expectation, I think we would want to be sure
4 that Minnesota would want to specify it that
5 way, because that would be an important
6 aspect.

7 MEMBER KOTTKE: Yes, I would
8 agree.

9 DR. BURSTIN: And the other issue
10 is that at least for some of the programs like
11 PQRI, soon to be PQRS, the payment -- you
12 know, the programs for physicians to report on
13 performance, they would lose the ability to
14 use the individual measures as measures to
15 assess performance.

16 CHAIR GIBBONS: So, I can't easily
17 show it, but on my computer in front of me
18 right now is the slide from the 2007 data of
19 the composite. Of course now I've lost it.
20 I'm going to bring it up again.

21 MEMBER KOTTKE: While Ray's
22 chatting, in fact many of the clinics have

1 reporting 96 percent to 90 percent tobacco
2 free and lipid control is down around 80 in
3 others, so --

4 CHAIR GIBBONS: Right. Yes, I'm
5 looking at 2007. So you've got the current
6 one up?

7 MEMBER KOTTKE: Yes, I'm on the
8 live Web site.

9 CHAIR GIBBONS: Yes, okay.

10 MEMBER KOTTKE: And the 96 percent
11 is Edina Sports Health and Wellness. I mean,
12 you know, like what do you expect?

13 CHAIR GIBBONS: So, blood pressure
14 less than 140/90 is what?

15 MEMBER KOTTKE: Best clinic is 80
16 percent. Best clinic for LDL is 83 percent.
17 Aspirin use daily, best clinic -- well,
18 there's a bunch that are -- you know, you got
19 to scroll way down to get down as low as 95
20 percent, but there's some 100 percents.

21 CHAIR GIBBONS: So at least in
22 2007 the mean data for both blood pressure and

1 LDL cholesterol was less than the mean data
2 for tobacco-free. So, the drivers were in
3 fact those two in terms of the composite for
4 many, many more places than the tobacco-free.
5 But obviously you'll never get to 100 overall
6 because you're going to have a certain
7 percentage.

8 And do you have the state average
9 there for the composite? You know it for your
10 place. It's 70 isn't it, for your place?

11 (Off-mic comments.)

12 CHAIR GIBBONS: What's that? I
13 ask you these embarrassing questions?

14 MEMBER KOTTKE: Yes, I actually
15 don't know that. And I -- let me --

16 CHAIR GIBBONS: This is for the
17 public record. Maybe you should turn your
18 microphone off.

19 MEMBER KOTTKE: Yes, right.

20 CHAIR GIBBONS: So the statewide
21 average in 2007 for the composite was 40
22 percent. Think about what that means. Less

1 than half of the people, less than a flip of
2 the coin that the people with vascular disease
3 get those four things.

4 MEMBER KOTTKE: Well, Mayo Clinic
5 and HealthPartners Clinics were tied at 44
6 percent.

7 CHAIR GIBBONS: In what year?

8 MEMBER KOTTKE: This is current
9 posted year, whatever that is. Must have been
10 last year.

11 CHAIR GIBBONS: So, there's
12 clearly more room for improvement than tobacco
13 cessation?

14 Okay. I think we've got a path
15 moving forward at least for lipid control.
16 And then we need to keep scrolling, right?
17 There's another one on here, isn't there? Got
18 to get to it.

19 DR. WINKLER: Okay. Page 39 is
20 the beginning of the side-by-side for beta-
21 blockers. I'll point out that the third,
22 measure 160, is again this hospital measure

1 that you all still need to act on in terms of
2 the fact that it's one of those topped out
3 measures. Great measure, topped out.

4 MEMBER RUSSO: And it seems like
5 there are some differences, too. I mean, 71
6 looks at persistence of beta-blocker treatment
7 six months after discharge. Do we really want
8 to eliminate -- well, other -- because that's
9 persistence. And the first one includes an
10 ejection fraction with a low EF. The fourth
11 one looks redundant. I don't see what -- but
12 that's actually not under review anyway. I
13 don't know we can eliminate something not
14 under review.

15 DR. WINKLER: Well, what we'll do
16 is just take your input in terms of those.
17 The issue with that measure is actually that
18 it's a purely claims-based measure and there
19 is a constituency that does want and demand
20 clinics-based measures.

21 MEMBER RUSSO: Well, that would
22 mean to at least to eliminate it, but --

1 MEMBER RICH: Regarding 71 and
2 160, I mean, doesn't 160 -- it's sort of an
3 implied subset of 71, although it could happen
4 that maybe it wasn't prescribed but the person
5 is taking it. You know, it just seems that 71
6 is the more outcomes-based measure.

7 CHAIR GIBBONS: Certainly 71
8 requires, as I recall, persistence for six
9 months, right?

10 MEMBER RASMUSSEN: Seventy-five
11 percent compliance over 180 days post MI.

12 MEMBER KOTTKE: Ray, can I make a
13 --

14 MEMBER RICH: I mean, 160 is
15 really just a process measure, did they get
16 the prescription? But 71 is are they actually
17 following through?

18 CHAIR GIBBONS: Okay. Tom?

19 MEMBER KOTTKE: Oh, no, I was just
20 thinking sort of a stray thought about
21 composite measures again. We did a very large
22 randomized trial of 44 clinics for

1 preventative services and found that docs tend
2 to -- they'll start on one thing and want to
3 perfect it before they go onto the second.
4 And so, they get -- like they'll work their
5 entire lives on hypertension alone or smoking
6 alone. And we found that getting them to
7 bundle the idea of preventive services, this
8 package of preventive services. And so, I
9 think there's value in a composite measure so
10 they don't get stuck on, well, I'll work on
11 hypertension after I get all my smokers to
12 quit, you know? And because, you know -- so
13 they think of it as a group of behaviors or
14 interventions.

15 CHAIR GIBBONS: So, other thoughts
16 on the beta-blocker issue, because this is
17 much more in the category of competing
18 measures? They're all in the same sphere. I
19 mean, three of them have a denominator that's
20 based on an MI. The first one has a broader
21 denominator that's based on prior MI or LV
22 systolic dysfunction.

1 And remember, we can't redesign a
2 measure, but our challenge here is to look and
3 say, okay, has one of these trumped the
4 others? Do we want to attempt to harmonize
5 some of the criteria if we're going to have
6 four beta-blocker measures out there? And
7 obviously you've got four different
8 developers. So, you know, we can calculate
9 out her remaining life span and see whether
10 this is feasible, that she attempt to get the
11 four of them to harmonize. She's young
12 enough. I think it's still feasible. In my
13 case, maybe not. Tom's definitely not. So,
14 I --

15 DR. WINKLER: You know, doing the
16 harmonizational always sort of lands in my
17 lap. And I'm just going to say that there
18 isn't harmonization to be had among measures.
19 Like for instance, in 71 and 613, which is,
20 you know, beta-blocker after heart attack, use
21 of -- I mean, there isn't harmonization at the
22 same measure. So, pick one. That's really

1 the tough stuff we're asking you to do,
2 because harmonization can occur afterwards.
3 On the measures you think that the measure
4 concepts are unique and important. And if
5 there are little variations in how the
6 definitions that will make the whole thing
7 line up better, great, we'll work on that.
8 But what's the point of making three measures
9 that say the same thing say the same thing?

10 CHAIR GIBBONS: So, let me take a
11 stab at it and sort of point out that, as I've
12 said already, 70 is a broader measure. It
13 actually includes people -- 70. It includes
14 people with LV dysfunction. So, you don't
15 have to have a prior heart attack. You just
16 have to have LV dysfunction and you're in that
17 one as well. And it's chronic, so that it
18 will capture people whose heart attack was
19 three years ago. Are they still taking a
20 beta-blocker at this time? If they have LV
21 dysfunction, are they still taking a beta-
22 blocker at this time?

1 So, it seemed to be a broader
2 measure that is going to capture over time
3 most of the patients who enter the other
4 things.

5 Jon?

6 MEMBER RASMUSSEN: So, a thought
7 about that measure: One of the measures that
8 we discussed today will get those patients
9 with LVSD. This is one of the measures, when
10 we're looking at beta-blockers, any beta-
11 blocker will do because it combines MI
12 patients who really any beta-blocker has been
13 shown to help. LVSD, it's a more narrow
14 group. So, I think there's other measures
15 that will touch on that LVSD portion. If you
16 look at 160, that's our inactive/hall of fame
17 measure that we were talking about earlier
18 today that is already pretty high. Seventy-
19 one then takes the piece of 70 that takes the
20 MI piece and it's also a medication
21 persistent-measure, which we've talked about
22 being the goal long term.

1 MEMBER RUSSO: The only other
2 comment, although that's -- I agree with
3 everything said, is just that there were
4 specific beta-blockers that might be
5 appropriate according to the guidelines for
6 those with heart failure and systolic
7 dysfunction. Although this doesn't say heart
8 failure, it says LV systolic dysfunction. So
9 there's a little disconnect there because we
10 want to use the ones that are in the
11 guidelines, I think. So, we want long-acting,
12 you know, metoprolol or carvedilol. So, it's
13 the specification for the type of beta-blocker
14 that might be in question with that.

15 MEMBER RASMUSSEN: But the way 70
16 is written I believe that any beta-blocker
17 will meet that measure because they combined
18 the MI, in which case, you know, really any
19 beta-blocker would be okay, but that would
20 also be okay for the patient with LVSD. The
21 standalone measure for LVSD requires one of
22 the three specific beta-blockers.

1 MEMBER RUSSO: But it says "or,"
2 right, "or left ventricular?" So, prior MI or
3 left ventricular systolic dysfunction.

4 MEMBER RASMUSSEN: Yes, so that
5 creates the denominator. The numerator allows
6 for any beta-blocker, I believe.

7 MEMBER KING: No, the numerator
8 says bisoprolol, carvedilol or sustained-
9 release metoprolol.

10 MEMBER RASMUSSEN: Okay.

11 MEMBER KING: So, it does --

12 MEMBER RASMUSSEN: My mistake.

13 MEMBER KING: -- restrict it to --

14 MEMBER RUSSO: But is that
15 appropriate.

16 MEMBER RASMUSSEN: Yes, I had the
17 measures mixed up.

18 MEMBER RUSSO: So, let me think
19 now. So, for the prior MI that doesn't have
20 -- is it appropriate to restrict that? I
21 don't know. It's not.

22 CHAIR GIBBONS: Well, Dana can

1 comment. I think that one of the things you
2 run into here is again if you've got to parse
3 out multiple measures, then you have different
4 beta-blockers that qualify in each one. And
5 is that helpful to practicing physicians?
6 Isn't it better that they actually get in the
7 habit of using the more restrictive beta-
8 blockers and then they can not have to -- they
9 don't have to think about it. They just know
10 I'll use one of these three and it's going to
11 be okay no matter what the patient's problem
12 is.

13 And cost, now TOPROL-XL is -- or
14 metoprolol succinate is available on most of
15 the drug programs, so cost is no longer an
16 issue. And so is carvedilol. It's available
17 on a couple of them for 10 bucks a quarter.
18 So, cost for those three is no longer an
19 issue.

20 MEMBER RUSSO: The only one that
21 stands out are these four that doesn't seem to
22 add anything without all these questions in

1 mind is the 613, I think. Or what does that
2 add except the claims data.

3 DR. WINKLER: Yes, it added the
4 data platform, which was the original issue,
5 you know, several years ago.

6 MEMBER RUSSO: But we should be
7 shifting towards, you know, clinical data to
8 -- I think, right? Or do we want to -- why do
9 we want that in there? I know someone wants
10 it in there, but I don't even know who. So,
11 but I'm just being naive about this. I don't
12 think that's valuable, as valuable as the
13 other ones.

14 DR. WINKLER: Well, certainly a
15 lot of our audience members and stakeholders
16 who do a lot of data crunching using claims
17 data are really constantly asking for data or
18 measures based on claims data. So, there is
19 a huge audience out there.

20 Now, I think that as we transition
21 into electronic health records, that is likely
22 to change; may not totally go away. But there

1 is a significant stakeholder group who very
2 specifically is always asking us, always
3 asking us for which of your measures can be
4 done with claims.

5 MEMBER RUSSO: Okay. Sorry, I
6 didn't mean to insult anyone in the room. I'm
7 just asking the question.

8 MEMBER SNOW: No, but that's
9 important transition and it's probably
10 valuable for them to hear that they need to be
11 getting ready to think about something else
12 rather than just embed that backward thinking.

13 MEMBER KING: Well, excuse me, but
14 I'm not so sure in this particular case. In
15 other words, when you're talking about lipid
16 control or blood pressure, you have to have a
17 clinical measurement. And so, someone needs
18 to take their blood pressure or measure their
19 cholesterol. If you want to know if someone
20 had a heart attack and if someone got a drug,
21 an extremely reliable way of doing that is
22 looking at diagnosis codes from hospitals and

1 offices and pharmacy codes, because that means
2 they really went to the pharmacy and picked it
3 up. That is not an irrelevant -- that is an
4 extremely relevant and perhaps superior way,
5 looking at data and say I gave it to them or
6 I meant to, or I said it in my note but they
7 didn't get the prescription is another way of
8 measuring that. But I wouldn't call it
9 superior for this particular measure. If you
10 want to know if they got it, claims data is
11 actually superior in this particular case
12 because there's no clinical thing that you
13 have to measure.

14 MEMBER RUSSO: And to add to that,
15 too, I think and to clarify, certainly things
16 like claims data for mortality post-discharge
17 is invaluable. There's no other way to get at
18 that data. But the clinical data clearly is
19 better for this kind of measurement; at least
20 for us clinically.

21 MEMBER PHILIPPIDES: Can I circle
22 back to 70 for a second?

1 CHAIR GIBBONS: Absolutely.

2 MEMBER PHILIPPIDES: So, I'm going
3 to express some angst. I don't think it's
4 existential angst; it's just plain angst. And
5 in the composites that we looked at before, we
6 had a disease process that affected a patient
7 and then we said what are the treatments that
8 have been shown to give them benefit? And
9 that's how a clinician thinks, I think, and
10 that's what we should be ranking. That's what
11 you guys did in Minnesota so well.

12 This is slightly different. This
13 basically looks at several different
14 conditions; two in this case, and says when
15 should give beta-blocker? You know, it's not
16 exactly like clinicians think. You know, it
17 would be strange to just list all of the
18 conditions that required beta-blocker and then
19 ranked on that.

20 So, it doesn't sort of feel like
21 the way the clinician would think of it.

22 CHAIR GIBBONS: We're retiring

1 160, or at least that -- so we have three
2 other measures. So, you know, the rubber hits
3 the road here. We've got three measures
4 dealing with the use of beta-blockers post-MI.
5 And do we want three different measures out
6 there to contribute to the confusion, or do we
7 want to make a case for one of these as best
8 in class and trumps the others? We cannot sit
9 and fiddle with them. We have to either say,
10 okay, all of these go out and people look and
11 say, well, why in the world didn't the
12 Committee pick one? Or we pick one and then
13 they'll say why in the world did they pick
14 that one?

15 Bruce?

16 MEMBER RICH: I think we should
17 definitely pick best in class, otherwise I
18 think that we're not really being responsible
19 as a committee.

20 MEMBER KOPLAN: Can you put two
21 together? And then you'd have two instead of
22 three, you know what I mean?

1 CHAIR GIBBONS: You can pick two
2 out of three and make one go away; I think
3 that's feasible, but you'll have two different
4 platforms.

5 MEMBER KOPLAN: Are 71 and 613
6 more alike than -- because the other one's
7 chronic stable --

8 MEMBER SNOW: No.

9 MEMBER KOPLAN: No?

10 MEMBER SNOW: I don't think so.

11 CHAIR GIBBONS: Doesn't sound like
12 you have a ground support for that particular
13 combination of two. All right.

14 MEMBER SNOW: Does 70 have the key
15 features of 71 in fact? I mean, there's this
16 issue about disease process, but the thing
17 about 71 is that it's about persistence
18 adherence. Because I'll tell you, there's
19 plenty of data out there that show that people
20 get a prescription for a beta-blocker and then
21 they don't fill the second one. And knowing
22 about that is very important. And that's a

1 key care issue. And that's what 71 is about.

2 And my question really is whether
3 70 can take care of that, because it's partly
4 about the wording. It says they may have had
5 an MI in the remote past. Are they still on
6 the beta-blocker? That's an argument for
7 persistence. And so, maybe it's going to take
8 care of 71.

9 Now, what it won't do is if they
10 just had the MI -- because -- but in time --

11 CHAIR GIBBONS: Well, Jon can
12 comment. I think the difference here is 70 is
13 based on prescriptions -- prescribing. So in
14 essence, it just says two years later, after
15 their infarc, did the physician prescribe the
16 beta-blocker? Now, does that mean they ever
17 got it filled? That's the point that Dana
18 raised earlier; we really don't know. So it's
19 not a perfect measure from that standpoint,
20 but it will capture over time whether the doc
21 thinks they're persistent.

22 Now as a doc, I was recently

1 chagrined to find that somebody I'd dutifully
2 written, you know, statin prescriptions for
3 for the last eight years had never gotten any
4 of them filled. I mean, any of them. And sat
5 there and sort of smiled and said, well, I
6 didn't have the heart to tell you.

7 And unless you think this was
8 somebody who wasn't pretty sophisticated, they
9 have Ph.D. after their name.

10 MEMBER SNOW: Right. So, you
11 wrote for 10, then went for 20, then went for
12 40.

13 MEMBER KOTTKE: Seventy-one is
14 just for six months. I mean, do we believe
15 that? I mean, I think --

16 CHAIR GIBBONS: And that's the
17 point I think Jon made when he reviewed it.

18 MEMBER RASMUSSEN: And to Roger's
19 point, we sort of run out of evidence-base
20 after a couple of years with beta-blocker
21 post-MI. So, we get it the first six months,
22 which is a pretty acute period, or we

1 potentially run out of data on the back end
2 with the 70.

3 MEMBER SNOW: We don't know what
4 they're doing at a year.

5 CHAIR GIBBONS: Come on, group.
6 We got to be bold here.

7 MEMBER RUSSO: The harder part --
8 I think what we're -- maybe not just me, but
9 it's hard because when we reviewed them and
10 we're looking at the voting, you could see
11 here that, you know, everyone wasn't uniform;
12 maybe more uniform for some than others, but
13 there must have been something in the original
14 performance of the measure that we had some
15 differences in opinion. So, we're looking at
16 this and trying to remember all the details of
17 how it performed. So, which is better? You
18 know, there may be pluses and minuses of both,
19 but are we assuming they both -- they
20 obviously must have had a good gap, otherwise
21 we wouldn't have approved it. It's hard to
22 make the decision between the two.

1 MEMBER AYALA: Can we just say 70
2 and 71 together? I mean, two separate ones,
3 but just say just choose those two out of the
4 four?

5 CHAIR GIBBONS: Well, we've
6 already -- remember there's three, because
7 we've already rotated 160. So, it really is
8 three: 70, 71 and 613.

9 DR. KING: I'm not so sure I would
10 have voted for 70 or 71 if I'd realized that
11 613 existed.

12 DR. WINKLER: See, this is the
13 opportunity. You looked at each of those as
14 individual. That was the reason we did it in
15 a step-wise approach. So, now that's why your
16 final vote was whether it met criteria. And
17 we still have yet to make your final
18 recommendations for endorsement, and that's
19 because we have all of these secondary
20 questions to approve.

21 Now, just to be clear, 613 is
22 really not on the table, but your feedback and

1 your discussion certainly is going to
2 influence where we go with it in the future.

3 DR. PACE: So as Reva's saying,
4 your prior vote was preliminary because you
5 still had to look at the comparison to see if
6 any of these are superior. And as you were
7 talking about, you can recommend more than
8 one. I mean, our ideal situation is that one
9 is clearly best. If you recommend more than
10 one, we're going to want the steering
11 committee's justification for that. What
12 added value does it have? What additional
13 group of entities will actually be included in
14 performance measurement? What is the value of
15 having the more than one measure?

16 DR. KOTTKE: That raises the
17 stakes, if we have to justify ourselves. I
18 mean, the conflict bit is about how much do we
19 want to be purely data-driven, sort of USPSTF
20 level, you know, like going beyond a year. I
21 mean, my personal feeling is 613 is the -- you
22 know, the probably the EF can be subsumed

1 under a heart failure composite. And 613
2 otherwise, it's simple. You know, you had a
3 heart attack, a myocardial infarction, you
4 ought to be on a beta-blocker.

5 CHAIR GIBBONS: Okay. So there's
6 an argument for 613. And Dana, I think, was
7 arguing for 613. So I consider the straw vote
8 has already been taken, that there are two
9 votes for 613. Are there others who want to
10 stand up for 613?

11 Yes. Sorry. Sorry. Yes.
12 George, 613. Three. There's a growing
13 groundswell. Bruce, 613. Four.

14 MEMBER MAGID: Is the difference
15 between 613 and 71 the point that Roger
16 brought up about the fact that with 613, you
17 could have filled your prescription once and
18 then we have no information about --

19 MEMBER KING: On the measurement
20 date. When they're measuring it that year,
21 you had to be on it then.

22 CHAIR GIBBONS: Right.

1 MEMBER SNOW: It says prescribe.

2 I don't know if it was prescription --

3 MEMBER KING: No, at the pharmacy.

4 MEMBER SNOW: Is that --

5 MEMBER KING: It's pharmacy data.

6 MEMBER SNOW: Okay.

7 MEMBER KING: So you're on it when
8 they do this thing.

9 MEMBER MAGID: And it's not tied
10 to any time period then. So, anyone who's had
11 an MI, this is for the rest of their life.

12 Whereas 71 is tied to an event.
13 And so, I see sort of two advantages of 71.
14 One is it looks at therapy over a longer
15 period of time. But the other thing is is
16 that it's focused on the time that's most
17 evidence-based, right? I mean, the first year
18 after an MI is where we have the evidence. We
19 don't have any evidence to say that if you had
20 an MI 10 years ago you should be on a beta-
21 blocker. We don't have any evidence to say
22 five years ago if you had an MI you should be

1 on a beta-blocker. I don't even think we have
2 evidence to say if you were on MI two years
3 ago you should be on a beta-blocker. So, the
4 problem with 613 is it's certainly a lot less
5 evidence-based than 71.

6 MEMBER KOTTKE: Of course we do
7 have evidence that people who have a second MI
8 and are on a beta-blocker have higher survival
9 rates.

10 MEMBER MAGID: Right, but we're
11 talking about -- you know, right? I mean, if
12 you've had MI -- my dad had an MI --

13 CHAIR GIBBONS: We want to get
14 comments from the public.

15 MEMBER MAGID: Okay.

16 DR. BONOW: Well, sorry, but Mr.
17 Public was wondering if Dr. Smith is coming
18 back, because he and I have been dealing with
19 this in the secondary prevention guidelines
20 update, and we did look at what the evidence
21 was for beta-blockers after an MI, after the
22 first year. And that's why some of the other

1 -- besides 613, some of the other measures
2 might be more pertinent to the fact that -- I
3 agree with David that the evidence after a
4 year, it gets pretty weak, and maybe you can
5 out to three years and find some data, but
6 it's not very strong. Whereas if you have a
7 low ejection fraction, then you want to be on
8 it forever, which is I think what the left
9 column is about.

10 CHAIR GIBBONS: I'm going to try
11 to move this along. Okay. So, here's what
12 we're going to do. We're going to have a vote
13 where there are four options.

14 MEMBER RUSSO: Could I ask one
15 quick question --

16 CHAIR GIBBONS: Yes.

17 MEMBER RUSSO: -- because I want
18 to make sure? So, the last column, is there
19 -- so, we're holding the practice or the
20 physician responsible. So, is there something
21 in there for adjustment for -- because it's
22 the prescription for the beta-blocker, so low

1 SES. Is there an adjustment in there, too?
2 So, the patient not filling the prescription,
3 how is that dealt with? So, are we going to
4 have adverse -- so, people who take care of
5 patients in an indigent area might look worse
6 because of that, because there's no
7 adjustment, is that right? Because this is
8 filling a prescription.

9 CHAIR GIBBONS: Six-thirteen.

10 MEMBER RUSSO: Six-thirteen is the
11 claims data one.

12 DR. WINKLER: I was going to say,
13 typically --

14 MEMBER RUSSO: Good point.

15 DR. WINKLER: -- these are when
16 they have to --

17 MEMBER RUSSO: Yes, have the
18 benefit. Yes, but there's still no
19 adjustment, I guess. Those are any other --
20 okay.

21 CHAIR GIBBONS: There are
22 exclusions for contraindications, which you

1 can find on the form.

2 Okay. So, here's going to -- I'm
3 going to try to force some sense of where
4 everybody is. All right?

5 So, you get to vote once and you
6 can vote for preserving all three measures.
7 Okay? Preserve all three measures. That's
8 option No. 1. Option No. 2 is you got to
9 preserve a single measure, which is going to
10 be 0070. Option No. 3 is 0071. And option
11 No. 4 is 0613.

12 And I need everybody to vote.
13 There can be no abstentions. This is not like
14 the U.N. So, I need everybody to vote to find
15 out where everybody stands. So, option No. 1
16 is to hold them all; and then option No. 2 is
17 0070 alone; option No. 3 is 0071 alone; and
18 option No. 4 is 0613 alone. And we're going
19 to have to do this by show of hands. We
20 couldn't have possibly foreseen how
21 complicated this discussion would get, so --

22 PARTICIPANT: (Off microphone.)

1 CHAIR GIBBONS: Oh, we did? Okay.
2 We did, but we didn't anticipate this chairman
3 trying to force the issue with this vote.

4 All right. So, option No. 1,
5 preserve all three measures. Show of hands?

6 There's a groundswell of opinion
7 for that one.

8 Okay.

9 DR. WINKLER: Devorah? Are you
10 still with us, Devorah?

11 MEMBER RICH: I'm still here.
12 (Telephonic interference.)

13 DR. WINKLER: We lost you a bit.

14 MEMBER RICH: What?

15 DR. WINKLER: We can hardly hear
16 you.

17 MEMBER RICH: Okay. My vote is
18 for the third option, 0071.

19 DR. WINKLER: Okay. We'll record
20 it.

21 CHAIR GIBBONS: Okay. All right.
22 Option No. 2, 0070. Show of hands?

1 (A show of hands.)

2 Two.

3 (A show of hands.)

4 Option No. 3: 0071?

5 (A show of hands.)

6 And option No. 4 is 0613.

7 (A show of hands.)

8 CHAIR GIBBONS: Okay. So, I think
9 that's pretty clear. What was the final tally
10 for 0071?

11 DR. WINKLER: 0071 was 13.

12 CHAIR GIBBONS: There it is.

13 Okay. So, operationally, staff, what does
14 this mean?

15 DR. WINKLER: Well, what it means
16 is going forward, if indeed you all feel
17 comfortable that is your final vote among the
18 beta-blocker measures, is that 70 will not be
19 endorsed, 71 -- or recommended for -- not be
20 endorsed. Seventy-one is recommended for
21 endorsement. One-sixty is the one that's
22 still in the hall of fame. And 613, even

1 though it's not on the table, the
2 recommendation we will carry forward
3 associated with this is this committee doesn't
4 feel it's needed in view of the other measure.
5 Does that summarize what we did? Is everybody
6 comfortable with that?

7 MEMBER RICH: Could you just
8 explain, where does that leave us at this
9 point with 160? I mean, what --

10 CHAIR GIBBONS: We got -- 160
11 we're still going to have a separate review as
12 we indicated earlier with respect to its
13 installation in the hall of fame.

14 DR. WINKLER: Right.

15 MEMBER RICH: Okay. Thanks.

16 MEMBER SANZ: Mr. Chairman?

17 CHAIR GIBBONS: Baseball analogies
18 work. I mean, baseball analogies work. Mark?

19 MEMBER SANZ: Mr. Chairman, I
20 believe your glucose levels are risen highly.

21 (Laughter.)

22 Prior to lunch, I can't see a

1 whole of difference between forcing through
2 this vote and one on the vascular disease
3 vote. Could you explain to me why we did this
4 and not that?

5 CHAIR GIBBONS: I think these are
6 more clearly competing measures rather than
7 the composite versus individual measure. That
8 would be one sense.

9 And secondly, 0076 is really a sea
10 change and I didn't sense that everybody was
11 comfortable yet voting for the sea change. I
12 want everybody to think that through, because
13 we're voting for a sea change with that one.
14 It will change the playing field. It might
15 not change it right away, but it will change
16 the playing field.

17 So, let us move forward, now that
18 we're making such intense progress, to the
19 next -- we have to keep scrolling down.

20 ACE/ARB.

21 DR. WINKLER: Now, one of the
22 things that -- these are only the measures

1 that are ACE/ARB associated more with the
2 coronary artery disease realm and don't
3 include the ones we were talking about today
4 that include those in the heart failure realm.

5 CHAIR GIBBONS: So these are only
6 from phase I?

7 DR. WINKLER: Yes.

8 CHAIR GIBBONS: So, we again have
9 four measures.

10 DR. RASMUSSEN: Only two of these
11 were on phase I.

12 CHAIR GIBBONS: Two of them are
13 phase I. One is endorsed and not under review
14 and I don't know what --

15 DR. WINKLER: Yes, the --

16 CHAIR GIBBONS: Tell me about the
17 last column.

18 DR. WINKLER: Same thing. It
19 should say endorsed, not under review.
20 They're the same kind of measures we've been
21 talking about, these clins-based measures, for
22 the most part.

1 One-thirty-seven is the hospital
2 measure you've already evaluated in the first
3 phase, but it doesn't fall into the legacy
4 hall of fame inactive bucket.

5 MEMBER SANZ: Given our votes in
6 the last two days, what is not subsumed under
7 the votes we've already done since most of
8 these involve -- in fact, not all of them
9 involve LV dysfunction?

10 DR. WINKLER: Well --

11 MEMBER SANZ: Have we already
12 subsumed these?

13 DR. WINKLER: Well, I think one of
14 the issues that I think demands a little more
15 thinking is for the hospital measures what
16 gets you into the denominator is your primary
17 discharge diagnosis. And if it's AMI, you're
18 in the AMI measure. If it's heart failure,
19 you're in the heart failure measure.

20 MEMBER SANZ: Is that a choice of
21 the developer, or does it have to be that way?

22 DR. WINKLER: Well, I think that's

1 the way that CMS has developed those measures
2 because they're groups. There's the group of
3 AMI measures that will apply to all patients
4 with a primary discharge diagnosis of AMI.
5 They did a similar set of measures for heart
6 failure.

7 CHAIR GIBBONS: They're a
8 different section of Hospital Compare. If you
9 go on Hospital Compare, they're in different
10 places.

11 All right. So, we're in the same
12 --

13 DR. KOPLAN: Does it look like
14 everything goes in the 51?

15 CHAIR GIBBONS: I'm trying to find
16 the numerator statement. It's here. I'm just
17 scrolling down and seeing.

18 DR. RICH: For 551 the numerator
19 details are blank. Why is that?

20 DR. WINKLER: Well, the way we
21 make these is based on what's input into those
22 fields in that submission form. And depending

1 on how -- Yes, I think they're there, but --
2 yes, sometimes they end up in the wrong
3 fields. But the measure developers, when they
4 make their submissions are actually doing the
5 data entry into our database. So we end up
6 with things being --

7 DR. RICH: It's under the
8 numerator statement? Okay.

9 DR. WINKLER: Yes.

10 DR. RICH: I'm sorry. My apology.

11 DR. WINKLER: Yes, it's under the
12 numerator statement.

13 CHAIR GIBBONS: So, at least I
14 don't see a mention here of ejection fraction.
15 Have I missed something? On 51 Bruce raised
16 the question, did that encompass everything.
17 So, that encompasses quote high-risk co-
18 morbidities: heart failure, hypertension,
19 diabetes or chronic kidney disease, but I
20 don't see any mention of LV systolic
21 dysfunction.

22 MEMBER SANZ: Could I ask what is

1 the --

2 CHAIR GIBBONS: Sorry. It's
3 claims-based, so they don't have it.

4 MEMBER SANZ: Could I ask; you
5 probably know, Ray, what is the data on ACE
6 inhibitors for things like carotid artery
7 disease, without LV dysfunction of MI or -- I
8 just don't remember seeing it, but you may be
9 able to point to it.

10 CHAIR GIBBONS: Yes, I think we
11 would have to look at the AHRQ Evidence-Based
12 Practice Center Meta-Analysis that was
13 published in Annals, November of 2009. And
14 it's on the AHRQ web site, but of course it's
15 impossible to find. Because they go through
16 the inclusion criteria for all the trials and
17 I don't honestly remember whether cerebral
18 vascular disease was included. Peripheral
19 vascular disease was because the HOPE trial
20 enrolled a lot of patients whose sole
21 manifestation of presumed vascular disease was
22 peripheral.

1 Does anybody else in the room want
2 to take a stab at that, or know whether
3 cerebral vascular disease was included? I
4 don't remember.

5 I'm pretty sure it was November
6 2009 Annals of Internal Medicine. I can't
7 remember the authors, but it's from the AHRQ
8 Evidence-Based Practice Center review of ACE
9 inhibitors that concluded that for coronary
10 disease or coronary disease equivalents that
11 ACE inhibitors reduced total mortality.

12 MEMBER RUSSO: Can I make just a
13 general statement about the four? The two
14 that do not include an ejection fraction to me
15 have much less value, or little value, because
16 really the limitations of claims data and
17 guideline compliance is really the EF number
18 on those. So, I would say that out of the
19 four, two of them are easy to say are much
20 less valuable. But I think actually they're
21 not under review anyway.

22 CHAIR GIBBONS: But we can provide

1 guidance. Helen?

2 DR. BURSTIN: (Off microphone)
3 added complexity of these as well as the data
4 source. We talked about the fact that 0551 is
5 completely claims-based, so of course it
6 doesn't have EF, at least at this point. But
7 0066 is currently specified for multiple
8 platforms including its been re-tooled for
9 EHRs, which is how the LVEF could be brought
10 to bear.

11 So one other consideration for the
12 Committee is if you think they're equivalent,
13 is that something you want to consider as well
14 to have the option of having an EHR-based
15 measure in addition to a pure claims-based
16 measure, which you're right, could not get an
17 EF.

18 CHAIR GIBBONS: Does 0066
19 encompass 0137?

20 MEMBER RUSSO: I think the
21 hospital -- the level -- let me think here.
22 So, the 0137 is at hospital --

1 CHAIR GIBBONS: Discharge.

2 MEMBER RUSSO: -- discharge.

3 CHAIR GIBBONS: But that person's
4 got to have a diagnosis of coronary disease,
5 so they're going to fall in 0066. Well, their
6 MI will give them a diagnosis of coronary
7 disease and their systolic dysfunction will
8 qualify under 0066.

9 DR. WINKLER: Yes, from a patient
10 level, you're right, they'll overlap. But the
11 0137 is a hospital-level measure of hospital
12 performance and it's measured and reported
13 that way, whereas 66 is a clinician-level
14 measure and it's measured and reported that
15 way.

16 MEMBER MAGID: So, I've been
17 wondering about that, Reva. Can we ever
18 really combine a hospital measure and an
19 ambulatory measure, because they're really
20 targeting different organizations.

21 MEMBER SNOW: And if so, maybe it
22 would be better not to put them -- it would be

1 a little easier if we didn't --

2 DR. WINKLER: Well, I think since
3 you mentioned -- this is sort of the first
4 time we've ever actually had to do this as
5 explicitly as we're asking you to do today.
6 These are the questions, is do we include, do
7 we not include, you know?

8 MEMBER MAGID: So I would suggest
9 for the Committee's consideration that when
10 you do this in the future that you set up
11 tables that compare hospital measures and you
12 set up tables that compare ambulatory measures
13 because they're really targeting different
14 organizations.

15 DR. WINKLER: But we still will
16 have the harmonization issues.

17 MEMBER MAGID: That may be, but in
18 terms of saying we're going to get rid of
19 something or not, I'm not sure we can --

20 DR. WINKLER: That's a fair
21 comment.

22 MEMBER MAGID: Yes.

1 DR. PACE: But that's for
2 discussion. I mean, it depends again on the
3 data. I mean, at this point in time that's a
4 realistic issue because of the different data
5 platforms. In the future that may not be as
6 much of an issue, but definitely, you know, we
7 can put them together that way.

8 CHAIR GIBBONS: I'm going to try
9 to move this along because I think I've heard
10 some worthwhile comments that can drive votes.

11 So, the point's already been made
12 that 551 and 594, because they use
13 administrative data, do not have LVEF and we
14 therefore consider them inferior to the other
15 two.

16 So, I'm going to ask you to vote
17 yes or no and whether you agree with that
18 statement; are 551 and 594 inferior to the
19 other two? Yes, raise your hand?

20 MEMBER RICH: Yes.

21 DR. WINKLER: Okay. Thanks.

22 CHAIR GIBBONS: No?

1 DR. WINKLER: Thanks, Devorah.

2 CHAIR GIBBONS: No?

3 DR. WINKLER: Are there any note
4 votes?

5 DR. WINKLER: Okay. So it was --

6 CHAIR GIBBONS: There are no
7 votes? So, that was a unanimous vote.

8 So, now let's attack 0066 and
9 0137, both of which were reviewed here. And
10 I think David has already made the point: one
11 is an inpatient measure reported as a measure
12 of hospital performance; the other is an
13 outpatient measure reporting on clinician
14 behavior.

15 Do we believe -- I mean, do we --
16 I think there's a fair argument just from that
17 that both of them should be preserved. If
18 you're in favor of preserving both of them,
19 please vote yes at this time.

20 MEMBER RICH: Yes.

21 DR. WINKLER: Thank you, Devorah.

22 CHAIR GIBBONS: Is anybody

1 opposed?

2 Okay. Now, I think the only
3 remaining issue is is there any harmonization
4 to be done across these two?

5 DR. WINKLER: I think if you guys
6 can point anything out, it would be helpful.
7 What we will do is a much more careful look at
8 them. But if you can point anything out, it
9 would be useful.

10 MEMBER PHILIPPIDES: Do both look
11 at diabetes or just the one?

12 CHAIR GIBBONS: Just the one.
13 Just the one. The outpatient measure uses
14 some other parameter, LV systolic dysfunction
15 or diabetes, to make the case for using an ACE
16 inhibitor. So that's gotten on base. That
17 goes back to stable angina or the MI
18 guidelines.

19 MEMBER KOTTKE: Ray.

20 CHAIR GIBBONS: Yes, did you find
21 the paper?

22 MEMBER KOTTKE: Yes, and basically

1 it -- I mean, I just only have the abstract,
2 but it's in patients. It appears to be just
3 patients with ischemic heart disease and they
4 don't talk -- the title doesn't say ischemic
5 heart disease or equivalents. It says
6 ischemic heart disease.

7 CHAIR GIBBONS: Okay. So, we'll
8 have to actually pull the full paper and the
9 AHRQ to answer the question about cerebral
10 vascular disease, because HOPE certainly had
11 people with peripheral heart artery disease
12 and that's a major component with a meta-
13 analysis.

14 Okay. Well, we at least tried on
15 that front. Harmonization issues. Any other
16 harmonization issues that people can see?

17 DR. WINKLER: Just as information
18 for me, when we use the term ACE/ARBs, we're
19 talking about the class of drugs, correct? We
20 don't need to parse out individual drugs?

21 CHAIR GIBBONS: Correct.

22 DR. WINKLER: I didn't think so.

1 Just checking.

2 MEMBER KOTTKE: Well, that's --
3 there's some debate about that in the
4 literature, but I think most people would say
5 there are ARB for people who can't take an
6 ACE.

7 DR. BURSTIN: Any issue with the
8 fact that one has AMI in it and one doesn't?
9 I mean, they both have LVSD based on EF, but
10 one is specific to having been post-MI.

11 CHAIR GIBBONS: Well, that's the
12 hospital part. Once that person leaves the
13 hospital, they're in the purview of the second
14 measure.

15 DR. BURSTIN: Although wouldn't it
16 make sense potentially -- I mean, again, it's
17 not all about the first measure; it's also
18 about the hospital measure. One potential
19 thing would be, shouldn't the hospital measure
20 be potentially broader to be ischemic vascular
21 disease or LVSD without a specific focus on
22 AMI? Just a consideration.

1 CHAIR GIBBONS: Well, it would
2 require certainly a rethinking on CMS' part,
3 because that would cover about six different
4 DRGs.

5 Tom?

6 MEMBER KOTTKE: So, I have the
7 article here and on the table it's baseline
8 risk, quality of the evidence as -- I think
9 that's what it says. Strength of evidence is
10 low. ACE inhibitors; perindopril, ramipril,
11 reduced composite efficacy and endpoint
12 cardiovascular death, non-fatal, da-da-da-da,
13 for the -- or one of the following depending
14 on the trial. Stroke -- oh, maybe non-fatal
15 stroke -- sorry. I'm reading the wrong thing.
16 So, that wasn't about entrance criteria, but
17 was about outcome.

18 CHAIR GIBBONS: Yes, that's the
19 endpoints. Yes, the actual meta-analysis
20 covered just every endpoint in excruciating
21 detail. It was a very hard go at reading. It
22 was a table with 18 or 20 entries. It

1 required endurance.

2 I don't see any other issues for
3 harmonization. Unless somebody else does, I
4 think we may have done all we could with this
5 issue.

6 It hasn't been a big deal. Okay.
7 So --

8 DR. BURSTIN: But just in terms of
9 the evidence, I guess just one question back
10 to CMS; maybe not for this moment, but perhaps
11 for the next iteration these measures are
12 obviously undergoing change. It may be a
13 whole lot of DRGs, but if the evidence
14 suggests somebody's in there with unstable
15 angina and they had LVSD, wouldn't you kind of
16 want to do the same thing even if they're not
17 there for an AMI? I'm just trying to think.
18 Again, you guys are the smart evidence-based
19 guys, but they're in the AMI bucket because
20 that's how they've done it. And I guess the
21 question would be going forward should they
22 consider a broader bucket?

1 CHAIR GIBBONS: Thoughts about
2 that? It's a good question. Personally I
3 think they should. How in the world they
4 would ever report it I think defies
5 imagination, but the evidence will certainly
6 -- because there are seven different -- all
7 these different DRGs. So what are they going
8 to put down on Hospital Compare?

9 DR. BURSTIN: Call it, you know,
10 unstable coronary, you know --

11 CHAIR GIBBONS: Ah, it's not
12 necessarily even unstable.

13 MEMBER RASMUSSEN: Do we just
14 leave it as LVSD, make that the overriding
15 criteria and then let everything else fall
16 beneath an MI, if they had ICD?

17 DR. BURSTIN: It's not urgent for
18 today. Just as you talk about recommendations
19 for their future consideration, it would be
20 nice if they kind of tracked with the
21 evidence.

22 CHAIR GIBBONS: So, have we

1 finished off the competing measures table from
2 phase 1?

3 DR. WINKLER: Yes, and given the
4 discussions we've had and the fact that we've
5 talked about measures, I think we need to redo
6 the side-by-sides for phase 2 and save that
7 for another day.

8 But I think that we've learned a
9 lot from listening to you struggle with this.
10 This discussion is not over. I think that
11 Ray's asked you something fairly considerable,
12 and that's to think of the ramifications and
13 think about, you know, the support for just
14 doing the composite measure versus any
15 component measures and we will get your
16 feedback off -- you know, down the road when
17 you've had a chance to really review and look
18 at those more carefully.

19 At this point, I mean, you've done
20 an enormous amount of work for us, you know,
21 over the last two days.

22 We need to kind of regroup a lot

1 of what it is you've brought us to. We do
2 need to do some follow up with you.

3 As I mentioned at the beginning,
4 we're going to be putting these
5 recommendations and reports out for public
6 comment. And so, phase 1 goes before phase 2.
7 They're going separately. So, we are going to
8 be, you know, wanting to wrap up and focus on
9 phase 1. So, we need to wrap back with you
10 with these final decisions.

11 Also, if you noticed, as we were
12 going through the evaluation, your last vote
13 was on, does the measure meet criteria. And
14 that's because of all these subsequent
15 decisions about competing measures and the
16 hall and fame, and all these other things that
17 are potential caveats. So, what we're going
18 to ultimately want to do is a final tally of
19 what you thought met criteria, but what may
20 fall out from recommendation for final
21 endorsement because of all of these other
22 issues, secondary issues that we've talked

1 about. And then end up with a list of final
2 recommendations for you to approve before we
3 take this out for public comment.

4 So, we do need to do some ongoing
5 work. I think it can be done a great deal by
6 email. I do envision we're going to need at
7 least one conference call to be able just to
8 talk through it so that everybody's
9 comfortable.

10 These are thorny issues. You are
11 the first group that we've posed a lot of
12 these questions to. You're helping us learn.
13 You're the pilot test. If it's felt a little
14 uncomfortable and messy, I think that's
15 somewhat the nature of the beast. It's your
16 expertise we're really drawing on to help us
17 figure out the best way to approach this.

18 This is the first of 25
19 endorsement maintenance committees -- 22,
20 sorry -- going forward and approaching our
21 work in this way is different than the way
22 we've done it before. Clearly you've brought

1 up issues we had not anticipated. We're
2 having to regroup a few things. That's the
3 nature of continuous learning, which we cannot
4 thank you enough for helping us do. So, I
5 think that -- I'm not going to ask you to do
6 anything more today.

7 CHAIR GIBBONS: I am.

8 DR. WINKLER: Okay.

9 CHAIR GIBBONS: So, we're not done
10 yet. I want to just remind people of what's
11 going to happen, okay, so that no one's
12 terribly shocked. One is, for retirement in
13 the hall of fame, we're going to ask the
14 original reviewers of three different
15 measures; aspirin, beta-blockers; and,
16 Kathleen, you've already identified for LVEF,
17 to revisit that measure in light of our
18 discussion, provide a score for all four
19 criteria. And overall that will then be
20 distributed to everybody prior to the
21 conference call for their review and
22 consideration. And we will then take a final

1 vote on the conference call following a brief
2 presentation by each of those three people.

3 We are going to redistribute to
4 everybody 0076, given the magnitude of the
5 discussion we've had about that measure as a
6 composite. And we've already voted on that
7 with the only concern being the blood
8 pressure. But now that we're looking at it as
9 a possible at least replacement of individual
10 measures, I think everybody has expressed
11 appropriate concern about proceeding too
12 hastily.

13 So, we need everybody to review
14 that and we need them to review that, not just
15 for the conference call, well in advance,
16 because we would like to flush out any
17 questions that are relevant with the
18 developers. And we could conceivably try to
19 have them on the call.

20 DR. WINKLER: Yes, definitely.

21 CHAIR GIBBONS: Okay. But I think
22 it would be nice if we tried to flush out as

1 many of those things beforehand as we could so
2 that we can then basically -- and we'll ask
3 the staff to present a grid of pros and cons.
4 I think Helen has already done that verbally,
5 but we want a grid of pros and cons, because
6 in essence we're going to be voting on the
7 same sort of issues: preserving these
8 individuals versus the composite. It's not
9 quite the same as the previous vote because
10 the individuals are from different groups, but
11 I think we want to have that well flushed out
12 for everybody in advance.
13 So, that's going to take place.

14 And then lastly, we're going to
15 have a grid of competing measures from phase
16 2, which some of you highlighted already as we
17 were going through that process. And as Reva
18 said, I think staff will have the guidance
19 from this exercise today to create a grid that
20 will basically hopefully facilitate the
21 discussion. And that for sure we will need
22 people to take a look at prior to the call

1 because just from the discussion we've had
2 today, that would totally consume a conference
3 call unless we are more efficient.

4 So now, lastly, I would like to
5 suggest to the NQF staff and to all of you
6 that it would be best if this conference call
7 takes place when the constructive dialogue
8 we've had here is still fresh in everybody's
9 minds. And I know it seems like a long way
10 away, but summer is coming. So we need to do
11 it before everybody departs for parts unknown
12 for their summer vacation.

13 So, I'm now going to just do a
14 little informal ballot. Okay? How many of
15 you have planned summer vacation -- and I sort
16 of tend to define that as a week away --
17 planned summer vacation before June 1? Two.

18 How many have planned summer
19 vacation during the month of June? Two more.
20 Okay.

21 So, as a target we certainly want
22 to have it before June 30th, and it would be

1 nice the sooner the better since we have
2 people departing. We'll distribute a grid to
3 try to figure out when the most people are
4 available, but I think as a target, unless I
5 hear otherwise, certainly before the end of
6 June.

7 DR. WINKLER: In fact for phase 1
8 we really need to have it done by the middle
9 of May, which kind of goes along with you. We
10 may need to do like the phase 2 competing
11 measures later, but we need to get the phase
12 1 stuff finalized for going out for public
13 comment in June. So, it kind of dovetails
14 with that timeline you talked about.

15 MEMBER RUSSO: Just a quick
16 question. When things go out for public
17 comment on the things we discussed today, does
18 the measure developer have a heads-up before
19 the -- that they know that this is something
20 that might be retired, or how do you deal with
21 that?

22 DR. WINKLER: Remember, they've

1 all been here.

2 MEMBER RUSSO: That's true. Good
3 point.

4 DR. WINKLER: They definitely are
5 quite interested in the discussion and your
6 recommendations. But as a caveat to everyone,
7 we're continuing to, you know, progress
8 towards your final recommendations as we're
9 going through these subsequent steps. And the
10 measure developers will be invited to join
11 your conference call. Your conference call
12 actually will be the equivalent of a meeting.
13 Anybody can listen in. It will be a public
14 call.

15 CHAIR GIBBONS: So, and we will be
16 happy to give them your phone number and email
17 if you wish.

18 MEMBER RUSSO. No, I don't. Well,
19 we're from phase 1, so I'd have to look if
20 they were all here today hearing this, I
21 guess. Okay.

22 CHAIR GIBBONS: Is there any other

1 business, staff? We never did solicit public
2 comment today.

3 MEMBER ALLRED: I have one
4 question before we --

5 CHAIR GIBBONS: Yes. Please, Carol?

6 MEMBER ALLRED: Before we do 0076,
7 don't we have to vote on the blood pressure
8 portion of that?

9 CHAIR GIBBONS: We voted
10 conditionally the last time that if they made
11 that blood pressure change, we would approve
12 it. So, that's why I just registered for
13 everybody.

14 MEMBER ALLRED: Okay. So, we're
15 okay on that?

16 CHAIR GIBBONS: Yes, we're okay
17 from a process standpoint. For transparency,
18 I pointed out that they had responded and met
19 our request. So, we've had that vote and, you
20 know, we actually scored -- I was the primary
21 reviewer. It was scored reflecting the old
22 blood pressure criteria, but that was the

1 single deficiency that everybody identified.

2 So, we have had that vote.

3 Public comments from the room?

4 Look forward to the conference

5 call. Okay.

6 Any on the phone, are there any

7 public comments or questions?

8 DR. WINKLER: Operator?

9 OPERATOR: Star 1 for a comment or
10 question.

11 (No response.)

12 OPERATOR: There are not, sir.

13 DR. WINKLER: Okay.

14 CHAIR GIBBONS: Thank you very
15 much, operator.

16 OPERATOR: You're welcome.

17 CHAIR GIBBONS: I hesitate to say
18 this, but I think we're actually done for this
19 meeting. Thank you, everybody, as always for
20 your cooperation.

21 (Applause.)

22 MEMBER RICH: I just want to say

1 that I really have enjoyed participating in
2 this. I look forward to having more of those
3 measures that I have to present to you again.
4 But I've really enjoyed working with all of
5 you. It's really been a fabulous learning
6 experience and very rewarding. So thank you,
7 and thank you for including me.

8 CHAIR GIBBONS: Thank you,
9 Devorah. And I will just reflect as the chair
10 my thanks to all of you for your diligence.
11 This is hard work. As you slough through 10
12 or 15 or 20 of these in a day, it gets pretty
13 demanding. I do think that this group
14 excelled from the standpoint of treating each
15 other with mutual respect and of trying to
16 mold together different viewpoints, different
17 backgrounds in the cause of advancing this
18 particular effort and quality overall. And
19 obviously we had some jokes along the way and
20 a lot of good interaction, but I personally
21 had the feeling that everybody was trying to
22 work together towards the goal and not

1 pursuing any particular personal or
2 professional agenda, and that's why I think
3 the work went well. And I thank you all for
4 your cooperation and the effort.

5 MEMBER SNOW: Well, I know that I
6 speak for many others in saying that you and
7 Mary have given us great leadership, and we
8 thank you for that. It kept us going, kept us
9 honest, and frequently kept us laughing.

10 DR. WINKLER: Thank you, all. You
11 will definitely be hearing from us.

12 CHAIR GIBBONS: Travel safely.

13 DR. WINKLER: Our work is not
14 done. Although we're unlikely to meet face-
15 to-face again, I think we can anticipate at
16 least one if not two conference calls and
17 emails. So, we'll see you in virtual space.
18 Travel safely.

19 (Whereupon, the above-entitled
20 matter went off the record at 2:19 p.m.)

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22

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This is to certify that the foregoing transcript

In the matter of: Cardiovascular Steering Committee

Before: NQF

Date: 04-08-11

Place: Washington, DC

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